

**Oracle® Process Manufacturing**  
Quality Management User's Guide  
Release 12.1  
**Part No. E13689-02**

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# Contents

## Send Us Your Comments

## Preface

### 1 Understanding Quality Management

About This Guide.....	1-1
About Quality Management.....	1-3
Tasks and Responsibilities.....	1-4
Process Flow.....	1-7
Understanding the Interface to Other Applications.....	1-11
Understanding Navigation.....	1-13
Using the Navigator Find Window.....	1-20

### 2 Setting Up

Setting Up in Other Applications.....	2-1
Setting Up Quality Tests.....	2-4
Setting Up Test Classes.....	2-4
Finding Test Classes.....	2-5
Setting Up Test Groups.....	2-6
Setting Up Test Units.....	2-7
Finding Test Units.....	2-8
Setting Up Sampling Plans.....	2-9
Finding Sampling Plans.....	2-12
Setting Up Parameters.....	2-13

### **3 Tests**

Requirements.....	3-1
Entering Test Methods.....	3-3
Finding Test Methods.....	3-5
Understanding Tests.....	3-6
Entering Tests.....	3-10
Entering Customer Display Information.....	3-14
Entering Experimental Error.....	3-15
Finding Tests.....	3-19

### **4 Specifications**

Requirements.....	4-2
Understanding Specifications.....	4-4
Using Lot UOM Conversions Based on Quality Results.....	4-9
Understanding the Status Approval Workflow.....	4-12
Adding and Editing Status Codes.....	4-15
Entering Status Details.....	4-19
Finding a Status Code.....	4-20
Understanding Specification Version Control.....	4-21
Understanding License Plate Numbers for Containerization.....	4-22
Entering a Specification.....	4-23
Copying a Specification.....	4-33
Finding an Item Specification.....	4-34
Entering an Item Specification Validity Rule.....	4-35
Displaying the Item Specification Validity Rules Summary.....	4-46
Entering a Monitoring Specification Validity Rule.....	4-50
Displaying the Monitoring Specification Validity Rules Summary.....	4-53
Displaying Specification Summaries from the Navigator.....	4-54

### **5 Samples**

Requirements.....	5-1
Understanding Sampling.....	5-3
Entering Item Samples.....	5-15
Entering Monitoring Samples.....	5-35
Finding Samples.....	5-41
Displaying Sample Groups.....	5-45
Displaying Sample Summaries from the Navigator.....	5-49
Displaying the Samples Summary Window.....	5-53

## 6 Results

Requirements.....	6-1
Understanding Results.....	6-4
Entering Results.....	6-14
Selecting Samples and Tests for Mass Results Entry.....	6-27
Using the Mass Results Entry Window.....	6-29
Displaying Test Details from Mass Results Entry.....	6-31
Displaying Experimental Errors from Mass Results Entry.....	6-32
Finding Samples from the Results Window.....	6-33
Compositing Test Results.....	6-34
Viewing Samples for Composed Results.....	6-37
Adding Tests to Composed Results.....	6-39
Comparing Specifications.....	6-41
Finding Samples for Specification Comparison.....	6-46
Changing Quality Disposition.....	6-47
Associating Results to Another Sample.....	6-54

## 7 Reports and Inquiries

Requirements.....	7-2
Running the Item/Location Required Analysis Report.....	7-2
Item/Location Required Analysis Report Description.....	7-4
Running the Item/Location Test Results Report.....	7-4
Item/Location Test Results Report Description.....	7-6
Running the Customer/Supplier Test Results Report.....	7-7
Customer/Supplier Test Results Report Description.....	7-9
Running the Production Test Results Report.....	7-10
Production Test Results Report Description.....	7-12
Running the Certificate of Analysis or Conformance Report.....	7-14
Certificate of Analysis or Conformance Report Description.....	7-17
Making a Sample Storage Summary Inquiry.....	7-19
Finding a Sample Storage Summary.....	7-20
Generating Sample Labels.....	7-20

## 8 Stability Studies

Requirements.....	8-2
Understanding Stability Studies.....	8-4
Example of a Stability Program for Product X.....	8-6
Managing the Stability Study Lifecycle.....	8-7
Setting Up for a Stability Study.....	8-8

Planning a Stability Study.....	8-9
Performing Initial Sampling and Testing.....	8-10
Approving a Stability Study Plan.....	8-11
Launching a Stability Study.....	8-13
Performing Stability Study Testing.....	8-13
Evaluating a Stability Study.....	8-13
<b>Understanding the Stability Study Change Status Workflow.....</b>	<b>8-14</b>
Creating Test Interval Plans.....	8-16
Generating a Series of Testing Periods.....	8-20
Finding Test Interval Plans.....	8-21
Creating a Storage Condition Plan.....	8-22
Finding Storage Condition Plans.....	8-24
Defining Storage Packages.....	8-24
Finding Storage Packages.....	8-25
Creating and Managing a Stability Study.....	8-26
Finding Stability Studies.....	8-31
Assigning Stability Study Material Sources.....	8-33
Editing Stability Study Variants.....	8-35
Finding Stability Study Variants.....	8-42
Editing Variant Time Points.....	8-43

## **A Quality Management Navigator Paths**

Quality Management Navigator Paths.....	A-1
-----------------------------------------	-----

## **B Quality Management Responsibilities**

Quality Management Responsibilities.....	B-1
------------------------------------------	-----

## **C Quality Management Business Rules**

Specification Matching Business Rules.....	C-1
--------------------------------------------	-----

## **D Quality Management Workflows**

Basic Business Needs.....	D-2
Technical Overview.....	D-3
Understanding Workflow Processes.....	D-3
Understanding OPM Quality Management Workflows.....	D-4
Setting Up OPM Quality Management Workflows.....	D-7
Using OPM Quality Management Workflows.....	D-9
OPM Quality Sample Creation Workflow.....	D-10
OPM Quality Test Workflow.....	D-23

OPM Quality Sample Disposition Workflow.....	D-25
OPM Quality Composite Results Workflow.....	D-27
OPM Quality Sample Group Disposition Workflow.....	D-29
OPM Quality Spec Status Change Approval Workflow.....	D-30
OPM Quality Spec Customer Validity Rule Status Change Approval Workflow.....	D-32
OPM Quality Spec Inventory Validity Rule Status Change Approval Workflow.....	D-34
OPM Quality Spec Supplier Validity Rule Status Change Approval Workflow.....	D-35
OPM Quality Spec WIP Validity Rule Status Change Approval Workflow.....	D-37
OPM Quality Spec Monitoring Validity Rule Status Change Approval Workflow.....	D-39
OPM Quality Sample Group Rejection Workflow.....	D-40
OPM Quality Stability Study Change Status Workflow.....	D-42
OPM Quality Stability Study Lot Sample Workflow.....	D-45
OPM Quality Stability Study Batch Creation Workflow.....	D-47
OPM Quality Stability Study Testing Workflow.....	D-49
OPM Quality Stability Study Time Point Test Workflow.....	D-50
OPM Quality UOM Conversion Workflow.....	D-54
Approval Management Engine (AME) Approval Matrix.....	D-56

## **E Oracle E-Record Events in Quality Management**

Events.....	E-1
Subscriptions.....	E-6
Approval Matrix.....	E-8
Approval of Quality Specification.....	E-12
Samples Creation.....	E-15
Results.....	E-15
Sample and Sample Group Disposition.....	E-16
Stability Study Change Status.....	E-19

## **Glossary**

## **Index**



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# Send Us Your Comments

**Oracle Process Manufacturing Quality Management User's Guide, Release 12.1**

**Part No. E13689-02**

Oracle welcomes customers' comments and suggestions on the quality and usefulness of this document. Your feedback is important, and helps us to best meet your needs as a user of our products. For example:

- Are the implementation steps correct and complete?
- Did you understand the context of the procedures?
- Did you find any errors in the information?
- Does the structure of the information help you with your tasks?
- Do you need different information or graphics? If so, where, and in what format?
- Are the examples correct? Do you need more examples?

If you find any errors or have any other suggestions for improvement, then please tell us your name, the name of the company who has licensed our products, the title and part number of the documentation and the chapter, section, and page number (if available).

Note: Before sending us your comments, you might like to check that you have the latest version of the document and if any concerns are already addressed. To do this, access the new Applications Release Online Documentation CD available on My Oracle Support and [www.oracle.com](http://www.oracle.com). It contains the most current Documentation Library plus all documents revised or released recently.

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Please give your name, address, electronic mail address, and telephone number (optional).

If you need assistance with Oracle software, then please contact your support representative or Oracle Support Services.

If you require training or instruction in using Oracle software, then please contact your Oracle local office and inquire about our Oracle University offerings. A list of Oracle offices is available on our Web site at [www.oracle.com](http://www.oracle.com).



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# Preface

## Intended Audience

Welcome to Release 12.1 of the *Oracle Process Manufacturing Quality Management User's Guide*.

This guide assumes that you have working knowledge of your business area's processes, tools, principles, and customary practices. It also assumes that you are familiar with Oracle Process Manufacturing. If you have never used Oracle Process Manufacturing, we suggest you attend one or more of the Oracle Process Manufacturing training classes available through Oracle University.

See Related Information Sources on page xiii for more Oracle Applications product information.

## TTY Relay Access to Oracle Support Services

To reach AT&T Customer Assistants, dial 711 or 1.800.855.2880. An AT&T Customer Assistant will relay information between the customer and Oracle Support Services at 1.800.223.1711. Complete instructions for using the AT&T relay services are available at <http://www.consumer.att.com/relay/tty/standard2.html>. After the AT&T Customer Assistant contacts Oracle Support Services, an Oracle Support Services engineer will handle technical issues and provide customer support according to the Oracle service request process.

## Documentation Accessibility

Our goal is to make Oracle products, services, and supporting documentation accessible to all users, including users that are disabled. To that end, our documentation includes features that make information available to users of assistive technology. This documentation is available in HTML format, and contains markup to facilitate access by the disabled community. Accessibility standards will continue to evolve over time, and

Oracle is actively engaged with other market-leading technology vendors to address technical obstacles so that our documentation can be accessible to all of our customers. For more information, visit the Oracle Accessibility Program Web site at <http://www.oracle.com/accessibility/>.

## **Accessibility of Code Examples in Documentation**

Screen readers may not always correctly read the code examples in this document. The conventions for writing code require that closing braces should appear on an otherwise empty line; however, some screen readers may not always read a line of text that consists solely of a bracket or brace.

## **Accessibility of Links to External Web Sites in Documentation**

This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

## **Structure**

### **1 Understanding Quality Management**

This topic provides the fundamentals of Quality Management. It presents the basic tasks, responsibilities, and process flow required to manage the quality of a product. An introduction to process quality management concepts, and the impact that quality has on other applications is provided.

### **2 Setting Up**

This topic explains how to set up quality responsibilities, action codes, grades, test classes, test units, sampling plans, and process quality parameters.

### **3 Tests**

This topic explains the fundamentals of quality tests. It provides the processes to enter or find test methods, gives a concise explanation of test data types, and explains how to enter tests, customized customer display information, and experimental error.

### **4 Specifications**

This topic explains the basic concepts of quality specifications. You are shown how to enter and find specifications and their associated specification validity rules for both item and monitoring specifications. Specification summaries available from the Quality Workbench navigator are described.

### **5 Samples**

This topic includes procedures for entering and finding item samples and monitoring samples. Procedures for displaying sample groups and displaying sample summaries on the navigator are also provided.

### **6 Results**

This topic provides an overview of quality results, including the process for entering them. You are shown how to composite test results, compare specifications, change

quality disposition, and manage expired lots.

## **7 Reports and Inquiries**

This topic explains several preformatted reports that assist you in identifying items that need quality attention. Reports display results obtained from quality test samples taken from inventory, customers, suppliers, and production. A Certificate of Analysis or Certificate of Conformance report provides documentation that the items produced or shipped comply with test procedures and quality specifications prescribed by the customer. A sample storage inquiry helps you determine the physical storage subinventory and locator for each sample.

## **8 Stability Studies**

This topic provides procedures for creating and managing stability studies including when they are performed, and what essential guidelines exist for stability testing programs. The topic also provides an overview of the stability study lifecycle management, including the creation of test interval plans and the creation of a storage condition plan. You are given guidance on the creation and management of a stability study, including the assignment of its material sources, editing stability study variants and time points, and defining its storage packages.

### **A Quality Management Navigator Paths**

### **B Quality Management Responsibilities**

### **C Quality Management Business Rules**

### **D Quality Management Workflows**

This topic introduces you to the concept of a workflow process and refers you to the documentation that fully explains Oracle workflows. It presents an understanding of the OPM Quality Management workflows, how to set them up, how to start them, and how to use the Quality windows.

### **E Oracle E-Record Events in Quality Management**

OPM Quality Management supports the acquisition of electronic signatures on electronic records. Electronic documentation replaces paper with a seamless interface of business activities that improves manufacturing throughput and enhances the overall quality of operations in the supply chain. The following provides information for online and deferred events that are e-record and e-signature enabled in the OPM Quality Management application. A brief discussion of each event is provided. Refer to the Oracle E-Records Implementation Guide for details on setting up the events and approvals

## **Glossary**

# **Related Information Sources**

## **Related Guides**

Oracle Process Manufacturing shares business and setup information with other Oracle Applications products. Therefore, you may want to refer to other guides when you set up and use Oracle Process Manufacturing. You can read the guides online from the Oracle Applications Document Library CD included in your media pack, or by using a Web browser with a URL that your system administrator provides. If you require

printed guides, then you can purchase them from the Oracle Store at <http://oraclestore.oracle.com>

## **Guides Related to All Products**

### *Oracle Alert User's Guide*

This guide explains how to define periodic and event alerts to monitor the status of your Oracle Applications data.

### *Oracle Applications Concepts*

This book is intended for all those planning to deploy Oracle E-Business Suite Release 12, or contemplating significant changes to a configuration. After describing the Oracle Applications architecture and technology stack, it focuses on strategic topics, giving a broad outline of the actions needed to achieve a particular goal, plus the installation and configuration choices that may be available.

### *Oracle Applications Flexfields Guide*

This guide provides flexfields planning, setup, and reference information for the Oracle Applications implementation team, as well as for users responsible for the ongoing maintenance of Oracle Applications product data. This guide also provides information on creating custom reports on flexfields data.

### *Oracle Application Framework Personalization Guide*

This guide covers the design-time and run-time aspects of personalizing applications built with Oracle Application Framework.

### *Oracle Applications Installation Guide: Using Rapid Install*

This book is intended for use by anyone who is responsible for installing or upgrading Oracle Applications. It provides instructions for running Rapid Install either to carry out a fresh installation of Oracle Applications Release 12, or as part of an upgrade from Release 11*i* to Release 12. The book also describes the steps needed to install the technology stack components only, for the special situations where this is applicable.

### *Oracle Application Server Adapter for Oracle Applications User's Guide*

This guide covers the use of OracleAS Adapter in developing integrations between Oracle applications and trading partners.

Please note that this guide is in the Oracle Application Server 10*g* (10.1.3.1) Documentation Library.

### *Oracle Applications System Administrator's Guide Documentation Set*

This documentation set provides planning and reference information for the Oracle Applications System Administrator. *Oracle Applications System Administrator's Guide - Configuration* contains information on system configuration steps, including defining concurrent programs and managers, enabling Oracle Applications Manager features, and setting up printers and online help. *Oracle Applications System Administrator's Guide - Maintenance* provides information for frequent tasks such as monitoring your system with Oracle Applications Manager, managing concurrent managers and reports, using

diagnostic utilities, managing profile options, and using alerts. *Oracle Applications System Administrator's Guide - Security* describes User Management, data security, function security, auditing, and security configurations.

*Oracle Applications User's Guide*

This guide explains how to navigate, enter data, query, and run reports using the user interface (UI) of Oracle Applications. This guide also includes information on setting user profiles, as well as running and reviewing concurrent requests.

*Oracle e-Commerce Gateway User's Guide*

This guide describes the functionality of Oracle e-Commerce Gateway and the necessary setup steps in order for Oracle Applications to conduct business with trading partners through Electronic Data Interchange (EDI). It also contains how to run extract programs for outbound transactions, import programs for inbound transactions, and the relevant reports.

*Oracle e-Commerce Gateway Implementation Guide*

This guide describes implementation details, highlights additional setups for trading partner, code conversion, and Oracle Applications as well as provides the architecture guidelines for transaction interface files. This guide also contains troubleshooting information and how to customize EDI transactions.

*Oracle Report Manager User's Guide*

Oracle Report Manager is an online report distribution system that provides a secure and centralized location to produce and manage point-in-time reports. Oracle Report Manager users can be either report producers or report consumers. Use this guide for information on setting up and using Oracle Report Manager.

*Oracle iSetup User Guide*

This guide describes how to use Oracle iSetup to migrate data between different instances of the Oracle E-Business Suite and generate reports. It also includes configuration information, instance mapping, and seeded templates used for data migration.

*Oracle Workflow Administrator's Guide*

This guide explains how to complete the setup steps necessary for any product that includes workflow-enabled processes. It also describes how to manage workflow processes and business events using Oracle Applications Manager, how to monitor the progress of runtime workflow processes, and how to administer notifications sent to workflow users.

*Oracle Workflow Developer's Guide*

This guide explains how to define new workflow business processes and customize existing Oracle Applications-embedded workflow processes. It also describes how to define and customize business events and event subscriptions.

*Oracle Workflow User's Guide*

This guide describes how users can view and respond to workflow notifications and monitor the progress of their workflow processes.

*Oracle Workflow API Reference*

This guide describes the APIs provided for developers and administrators to access Oracle Workflow.

*Oracle XML Gateway User's Guide*

This guide describes Oracle XML Gateway functionality and each component of the Oracle XML Gateway architecture, including Message Designer, Oracle XML Gateway Setup, Execution Engine, Message Queues, and Oracle Transport Agent. The integrations with Oracle Workflow Business Event System and the Business-to-Business transactions are also addressed in this guide.

*Oracle XML Publisher Report Designer's Guide*

Oracle XML Publisher is a template-based reporting solution that merges XML data with templates in RTF or PDF format to produce a variety of outputs to meet a variety of business needs. Using Microsoft Word or Adobe Acrobat as the design tool, you can create pixel-perfect reports from the Oracle E-Business Suite. Use this guide to design your report layouts.

*Oracle XML Publisher Administration and Developer's Guide*

Oracle XML Publisher is a template-based reporting solution that merges XML data with templates in RTF or PDF format to produce a variety of outputs to meet a variety of business needs. Outputs include: PDF, HTML, Excel, RTF, and eText (for EDI and EFT transactions). Oracle XML Publisher can be used to generate reports based on existing E-Business Suite report data, or you can use Oracle XML Publisher's data extraction engine to build your own queries. Oracle XML Publisher also provides a robust set of APIs to manage delivery of your reports via e-mail, fax, secure FTP, printer, WebDav, and more. This guide describes how to set up and administer Oracle XML Publisher as well as how to use the Application Programming Interface to build custom solutions.

**Guides Related to This Product**

*Oracle Process Manufacturing Cost Management User's Guide*

The Oracle Process Manufacturing Cost Management application is used by cost accountants to capture and review the manufacturing costs incurred in their process manufacturing businesses. The guide describes how to set up and use this application.

*Oracle Process Manufacturing Process Execution User's Guide*

The Oracle Process Manufacturing Process Execution application lets you track firm planned orders and production batches from incoming materials through finished goods. Seamlessly integrated to the Product Development application, Process Execution lets you convert firm planned orders to single or multiple production batches, allocate ingredients, record actual ingredient usage, and then complete and close production batches. Production inquiries and preformatted reports help you

optimize inventory costs while maintaining a high level of customer satisfaction with on-time delivery of high quality products. The *Oracle Process Manufacturing Process Execution User's Guide* presents overviews of the tasks and responsibilities for the Production Supervisor and the Production Operator. It provides prerequisite setup in other applications, and details the windows, features, and functionality of the application.

*Oracle Process Manufacturing Product Development User's Guide*

The Oracle Process Manufacturing Product Development application provides features to manage formula, routing, recipe, and validity rule development within process manufacturing operations. Use it to manage multiple laboratory organizations and support varying product lines throughout the enterprise. Characterize and simulate the technical properties of ingredients and their effects on formula performance and cost. Simulate and optimize formulations before beginning expensive laboratory test batches. Product Development coordinates each development function to provide a rapid, enterprise-wide implementation of new products in your plants. The guide describes how to set up and use this application.

*Oracle Process Manufacturing Quality Management User's Guide*

The Oracle Process Manufacturing Quality Management application provides features to test material sampled from inventory, production, or receipts from external suppliers. The application lets you enter specifications and control their use throughout the enterprise. Customized workflows and electronic recordkeeping automate plans for sampling, testing, and result processing. Compare specifications to assist in regrading items, and match customer specifications. Aggregate test results and print statistical assessments on quality certificates. Run stability testing with unrivaled ease. Several preformatted reports and inquiries help manage quality testing and reporting. The guide describes how to set up and use this application.

*System Administration User's Guide*

Much of the System Administration duties are performed at the Oracle Applications level, and are therefore described in the Oracle Applications System Administrator's Guide. The *Oracle Process Manufacturing System Administration User's Guide* provides information on the few tasks that are specific to Oracle Process Manufacturing. It offers information on performing Oracle Process Manufacturing file purge and archive, and maintaining such things as responsibilities, units of measure, and organizations.

*Regulatory Management User's Guide*

Oracle Process Manufacturing Regulatory Management provides solutions for document management that help meet the FDA 21 CFR Part 11 and other international regulatory compliance requirements. Regulatory information management is facilitated by use of electronic signatures. Manage hazard communications by collaborating with Oracle partners to dispatch safety documents, attached printed documentation sets such as the MSDS to shipments, and set up workflows to manage documentation revisions, approvals, and transmittals. The *Oracle Process Manufacturing Regulatory Management User's Guide* provides the information to set up and use the application.

### *Oracle Manufacturing Execution System for Process Manufacturing*

Oracle Manufacturing Execution System (MES) for Process Manufacturing provides a seamless integration to product development and process execution applications for rapid deployment and tracking of procedures, work instruction tasks, and batch records. Set up and manage material dispensing operations and produce electronic batch records interactively with full electronic signature control, nonconformance management, and label printing routines. The *Oracle Manufacturing Execution System for Process Manufacturing User's Guide* delivers the information to set up and use the application.

### *API User's Guides*

Public Application Programming Interfaces (APIs) are available for use with different Oracle Process Manufacturing applications. APIs pass information into and out of the application tables, thereby bypassing the user interface. Use of these APIs is documented in separately available documentation.

### *Oracle Engineering User's Guide*

This guide enables your engineers to utilize the features of Oracle Engineering to quickly introduce and manage new designs into production. Specifically, this guide details how to quickly and accurately define the resources, materials and processes necessary to implement changes in product design.

### *Oracle Inventory User's Guide*

This guide describes how to define items and item information, perform receiving and inventory transactions, maintain cost control, plan items, perform cycle counting and physical inventories, and set up Oracle Inventory.

### *Oracle Bills of Material User's Guide*

This guide describes how to create various bills of material to maximize efficiency, improve quality and lower cost for the most sophisticated manufacturing environments. By detailing integrated product structures and processes, flexible product and process definition, and configuration management, this guide enables you to manage product details within and across multiple manufacturing sites.

### *Oracle Work in Process User's Guide*

This guide describes how Oracle Work in Process provides a complete production management system. Specifically this guide describes how discrete, repetitive, assemble-to-order, project, flow, and mixed manufacturing environments are supported.

### *Oracle Quality User's Guide*

This guide describes how Oracle Quality can be used to meet your quality data collection and analysis needs. This guide also explains how Oracle Quality interfaces with other Oracle Manufacturing applications to provide a closed loop quality control system.

### *Oracle Shipping Execution User's Guide*

This guide describes how to set up Oracle Shipping to process and plan your trips,

stops and deliveries, ship confirmation, query shipments, determine freight cost and charges to meet your business needs.

#### *Oracle Purchasing User's Guide*

This guide describes how to create and approve purchasing documents, including requisitions, different types of purchase orders, quotations, RFQs, and receipts. This guide also describes how to manage your supply base through agreements, sourcing rules and approved supplier lists. In addition, this guide explains how you can automatically create purchasing documents based on business rules through integration with Oracle Workflow technology, which automates many of the key procurement processes.

#### *Oracle interMedia User's Guide and Reference*

This user guide and reference provides information about Oracle interMedia. This product enables Oracle9i to store, manage, and retrieve geographic location information, images, audio, video, or other heterogeneous media data in an integrated fashion with other enterprise information. Oracle Trading Community Architecture Data Quality Management uses interMedia indexes to facilitate search and matching.

#### *Oracle Self-Service Web Applications Implementation Guide*

This manual contains detailed information about the overview and architecture and setup of Oracle Self-Service Web Applications. It also contains an overview of and procedures for using the Web Applications Dictionary.

### **Installation and System Administration**

#### *Oracle Applications Concepts*

This guide provides an introduction to the concepts, features, technology stack, architecture, and terminology for Oracle Applications Release 11i. It provides a useful first book to read before an installation of Oracle Applications. This guide also introduces the concepts behind Applications-wide features such as Business Intelligence (BIS), languages and character sets, and Self-Service Web Applications.

#### *Installing Oracle Applications*

This guide provides instructions for managing the installation of Oracle Applications products. In Release 11i, much of the installation process is handled using Oracle Rapid Install, which minimizes the time to install Oracle Applications and the Oracle technology stack by automating many of the required steps. This guide contains instructions for using Oracle Rapid Install and lists the tasks you need to perform to finish your installation. You should use this guide in conjunction with individual product user guides and implementation guides.

#### *Upgrading Oracle Applications*

Refer to this guide if you are upgrading your Oracle Applications Release 10.7 or Release 11.0 products to Release 11i. This guide describes the upgrade process and lists database and product-specific upgrade tasks. You must be either at Release 10.7 (NCA, SmartClient, or character mode) or Release 11.0, to upgrade to Release 11i. You cannot

upgrade to Release 11*i* directly from releases prior to 10.7.

#### *"About" Document*

For information about implementation and user documentation, instructions for applying patches, new and changed setup steps, and descriptions of software updates, refer to the "About" document for your product. "About" documents are available on OracleMetaLink for most products beginning with Release 11.5.8.

#### *Maintaining Oracle Applications*

Use this guide to help you run the various AD utilities, such as AutoUpgrade, AutoPatch, AD Administration, AD Controller, AD Relink, License Manager, and others. It contains how-to steps, screenshots, and other information that you need to run the AD utilities. This guide also provides information on maintaining the Oracle applications file system and database.

#### *Oracle Applications System Administrator's Guide*

This guide provides planning and reference information for the Oracle Applications System Administrator. It contains information on how to define security, customize menus and online help, and manage concurrent processing.

#### *Oracle Alert User's Guide*

This guide explains how to define periodic and event alerts to monitor the status of your Oracle Applications data.

#### *Oracle Applications Developer's Guide*

This guide contains the coding standards followed by the Oracle Applications development staff and describes the Oracle Application Object Library components that are needed to implement the Oracle Applications user interface described in the Oracle Applications User Interface Standards for Forms-Based Products. This manual also provides information to help you build your custom Oracle Forms Developer forms so that the forms integrate with Oracle Applications.

#### *Oracle Applications User Interface Standards for Forms-Based Products*

This guide contains the user interface (UI) standards followed by the Oracle Applications development staff. It describes the UI for the Oracle Applications products and how to apply this UI to the design of an application built by using Oracle Forms.

### **Other Implementation Documentation**

#### *Oracle Applications Product Update Notes*

Use this guide as a reference for upgrading an installation of Oracle Applications. It provides a history of the changes to individual Oracle Applications products between Release 11.0 and Release 11*i*. It includes new features, enhancements, and changes made to database objects, profile options, and seed data for this interval.

#### *Oracle Workflow Administrator's Guide*

This guide explains how to complete the setup steps necessary for any Oracle Applications product that includes workflow-enabled processes, as well as how to

monitor the progress of runtime workflow processes.

*Oracle Workflow Developer's Guide*

This guide explains how to define new workflow business processes and customize existing Oracle Applications-embedded workflow processes. It also describes how to define and customize business events and event subscriptions.

*Oracle Workflow User's Guide*

This guide describes how Oracle Applications users can view and respond to workflow notifications and monitor the progress of their workflow processes. Oracle Workflow API Reference This guide describes the APIs provided for developers and administrators to access Oracle Workflow.

*Oracle Applications Flexfields Guide*

This guide provides flexfields planning, setup and reference information for the Oracle E-Records implementation team, as well as for users responsible for the ongoing maintenance of Oracle Applications product data. This guide also provides information on creating custom reports on flexfields data.

*Oracle eTechnical Reference Manuals*

Each eTechnical Reference Manual (eTRM) contains database diagrams and a detailed description of database tables, forms, reports, and programs for a specific Oracle Applications product. This information helps you convert data from your existing applications, integrate Oracle Applications data with non-Oracle applications, and write custom reports for Oracle Applications products. Oracle eTRM is available on Oracle Metalink.

*Oracle Applications Message Manual*

This manual describes all Oracle Applications messages. This manual is available in HTML format on the documentation CD-ROM for Release 11*i*.

## Integration Repository

The Oracle Integration Repository is a compilation of information about the service endpoints exposed by the Oracle E-Business Suite of applications. It provides a complete catalog of Oracle E-Business Suite's business service interfaces. The tool lets users easily discover and deploy the appropriate business service interface for integration with any system, application, or business partner.

The Oracle Integration Repository is shipped as part of the E-Business Suite. As your instance is patched, the repository is automatically updated with content appropriate for the precise revisions of interfaces in your environment.

## Do Not Use Database Tools to Modify Oracle Applications Data

Oracle STRONGLY RECOMMENDS that you never use SQL\*Plus, Oracle Data Browser, database triggers, or any other tool to modify Oracle Applications data unless

otherwise instructed.

Oracle provides powerful tools you can use to create, store, change, retrieve, and maintain information in an Oracle database. But if you use Oracle tools such as SQL\*Plus to modify Oracle Applications data, you risk destroying the integrity of your data and you lose the ability to audit changes to your data.

Because Oracle Applications tables are interrelated, any change you make using an Oracle Applications form can update many tables at once. But when you modify Oracle Applications data using anything other than Oracle Applications, you may change a row in one table without making corresponding changes in related tables. If your tables get out of synchronization with each other, you risk retrieving erroneous information and you risk unpredictable results throughout Oracle Applications.

When you use Oracle Applications to modify your data, Oracle Applications automatically checks that your changes are valid. Oracle Applications also keeps track of who changes information. If you enter information into database tables using database tools, you may store invalid information. You also lose the ability to track who has changed your information because SQL\*Plus and other database tools do not keep a record of changes.

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# Understanding Quality Management

This topic provides the fundamentals of Quality Management. It presents the basic tasks, responsibilities, and process flow required to manage the quality of a product. An introduction to process quality management concepts, and the impact that quality has on other applications is provided.

This chapter covers the following topics:

- About This Guide
- About Quality Management
- Tasks and Responsibilities
- Process Flow
- Understanding the Interface to Other Applications
- Understanding Navigation
- Using the Navigator Find Window

## About This Guide

The purpose of this guide is to provide reference information for end-level users of the Oracle Process Manufacturing (OPM) Quality Management application. It presents:

- Overviews of tasks and responsibilities accountable for managing quality within the supply chain.
- Process flows presented in the OPM Quality Management application.
- Navigating the Quality Workbench. This includes a discussion of using the Navigator Find window.
- Interfacing of OPM Quality Management with other Oracle applications.
- Prerequisite setup in other applications, including Oracle Inventory, Oracle Quality,

OPM Product Development, OPM Process Execution, Oracle Receivables, Oracle Order Management, OPM Order Fulfillment, and Oracle Purchasing.

- Prerequisite setup of actions, grades, reasons, and material status in Oracle Inventory.
- Setup of test classes, test units, sampling plans, and process quality parameters.
- Discussions of test methods and tests. This includes entering test methods, understanding tests, and entering test data. Additional discussions include customizing customer-specific quality certificate information, and defining experimental error action zones for tests.
- Discussions of item specifications, monitoring specifications, and their validity rules. This includes procedures for entry of base and overlay item specifications and monitoring specifications, the status approval process, editing and adding status codes, copying a specification, implementing specification version control, managing optional tests, creating samples automatically, and entry of item specification validity rules and monitoring specification validity rules.
- Discussions of samples. This includes information on the sampling process, entering item samples and monitoring samples, displaying sample groups, and displaying sample summaries from the Navigator. Procedures for retaining, archiving, and reserving samples are presented with business rules governing them.
- Discussions of results. This includes information on entering results, editing results, completing receiving inspection based on sample results, and how to prevent the completion of a batch step until acceptable results are recorded and approved. The process for selecting samples and tests for mass results entry is described. The procedures for compositing tests results and adding tests to composited results are presented. The procedures for viewing UOM conversions history and recommending interim lot UOM conversions are discussed. The specification comparison feature determines how closely a set of results meets the requirements of the comparison specification. Procedures for changing quality disposition and managing expired lots are presented. Requirements and procedures for associating results to other sample are presented.
- Several preformatted reports and inquiries help manage quality testing, analysis, and reporting.
- Appendixes provide navigator paths, specification matching business rules, workflows, and e-signature and e-record information.

Depending on your system security profile, it is possible that you do not have access to all of the windows and functions described in this guide. If you do not see a menu option described, and you need to access it, then contact your system administrator.

## About Quality Management

To maintain productivity and a high level of customer satisfaction, the inherent variability of materials and methods used in a process manufacturing environment must be controlled. Most process companies use quality inspection to determine the capabilities of their manufacturing procedures. By understanding process and material variability, process manufacturers optimize throughput without sacrificing product quality.

## Understanding Quality Improvement

Quality improvement is a continuous process that controls component variability by monitoring the sources of material instability. Quality responsibilities in the supply chain assist in this process by:

- Monitoring process behavior, and assigning reasons for process failures.
- Understanding the source of a nonconforming material, and taking action to minimize, or virtually eliminate it.

The aim is to identify methods to turn unpredictable manufacturing events into well characterized manufacturing capabilities.

Process control begins with understanding process capability. Knowing how to improve the manufacturing process helps everyone in the supply chain. One of the aims of total quality management is to design quality into products. The overall aim of quality inspection is to ensure material conformance to specification in inventory, production, shipping, and receiving operations.

## Designing Quality into Products

Consistent testing of products and materials reduces waste by detecting potential problems before they become major issues. A total quality approach designs the manufacturing process in parallel with the quality testing process. Oracle Process Manufacturing (OPM) Quality Management interfaces quality testing into all aspects of research, development, commercialization, production, purchasing, and shipping operations. This seamless interfacing across the supply chain assists in the consistent development and application of quality standards.

## Communicating Quality Throughout the Supply Chain

The most important part of quality management is the successful communication of quality requirements from receipt of incoming materials to the shipment of finished goods. OPM Quality Management provides notification and approval workflows to control quality throughout the supply chain.

### **Communicating Quality Consistently**

Consistency is essential to uniform quality communications. By using common test methods, sampling plans, and decimal precision for reports, the supply chain benefits from a standardized approach to quality testing.

### **Agreeing to Quality Capabilities**

The specification serves as a written agreement on the conformance of a material to a predefined level of acceptance. OPM Quality Management uses the specification and the specification validity rule to manage the inspection sampling. From the laboratory batch to the full production run, the specification validity rule controls the use of the specification in the supply chain. Workflows reduce the specification and validity rule approval process to a series of defined steps that are managed by the application.

### **Ensuring Proper Sample Collection and Processing**

The coordination of sampling throughout the supply chain is often complex and error prone. OPM Quality Management controls the sampling process through workflow notifications to create and process samples. The application monitors business events that require sampling, and optionally updates inventory to reflect material sampled. Using this transaction event-based approach, each of the quality inspection points are coordinated. From material receipt, through batch step release, the sample is traced by source, priority, and disposition.

### **Ensuring Proper Result Reporting**

From result entry to result evaluation, OPM Quality Management coordinates the appropriate capture of electronic signatures for electronic results records. The application composites results and compares specifications on analyzed samples for efficient quality grade assignment and customer specification matching.

## **Tasks and Responsibilities**

Each role in the organization must collaborate throughout the supply chain to ensure effective quality management and information sharing.

The following is representative of the work breakdown structure for managing quality within the supply chain. It lists most of the key tasks and job titles responsible for those tasks:

- Set up process quality parameters.
  - Quality Manager
- Set up test methods.
  - Quality Manager

- Set up individual tests.
  - Quality Manager
- Create sampling plans for quality inspection.
  - Quality Manager
- Create certificate requirements.
  - Formulator
  - Quality Manager
- Create specifications.
  - Formulator
  - Process Engineer
  - Quality Manager
- View specifications throughout the supply chain.
  - Formulator
  - Process Engineer
  - Production Operator
  - Production Supervisor
  - Quality Manager
  - Quality Technician
  - Inventory application
  - Order Management application
  - Process Operations Administrator
- Create specification validity rules for inventory, work in process, customer, or supplier use.
  - Formulator
  - Process Engineer

- Quality Manager
- Sample materials.
  - Formulator
  - Process Engineer
  - Quality Technician
  - Quality Manager
  - Production Supervisor
  - Production Operator
  - Process Operations Administrator
- Perform tests.
  - Quality Technician
  - Quality Manager
  - Process Operations Administrator
- Report results.
  - Quality Technician
  - Quality Manager
  - Formulator
  - Process Engineer
  - Production Supervisor
  - Production Operator
  - Process Operations Administrator
- Approve results.
  - Quality Manager
- Perform additional tests, if required.

- Quality Technician
- Quality Manager
- Formulator
- Process Engineer
- Production Supervisor
- Production Operator
- Publish certificates.
  - Quality Manager
- Run reports and inquiries.
  - Quality Technician
  - Quality Manager
  - Formulator
  - Process Engineer
  - Production Supervisor
  - Production Operator
  - Process Operations Administrator

## Process Flow

The following provides a suggested process flow for setting up and running Oracle Process Manufacturing (OPM) Quality Management.

### Set Up Other Applications

Set up each of the following applications:

- System Administration
- Set up required profile options and setups as described in the *Oracle Applications System Administrator's Guide*, *Oracle Approvals Management (OAM) Implementation Guide*, *Oracle Workflow User's Guide*, and this document.  
Required.

- Set up responsibilities for Quality Manager, Quality Technician, Workflow Administrator Event Manager, Workflow, Approvals Management Business Analyst, and ERES Adminstrator. Required.
- Oracle Inventory
  - Set up process quality-enabled items, test kits, lots, item attributes, unit of measure conversions, and item lot conversions. Required.
  - Set up subinventories and locators.
  - Set up actions, grades, reasons, and material status
  - Configure the allowed transactions for the Quality Sample Issue transaction type
  - Set up item retest and expiration dates and notifications
  - Set up lot retest and expiration dates and notifications
  - Set up organizations including quality laboratories
- Oracle Process Manufacturing (OPM) Product Development
  - Set up formulas, routings, operations, and recipes.
  - Set up quality laboratory equipment or instruments as plant resources.
  - Set up a sample as a formula byproduct. Required if controlling batch step completion based on results.
  - Set up organizations as plants or research and development laboratories as required.
- OPM Process Execution
  - Create batches to define spec validity rules and manually create samples. Optional. Batch creation automatically triggers automatic sample creation.
  - Verify sample byproduct on batches for sampling WIP steps.
- Oracle Receivables
  - Set up customers.
  - Set up ship to locations.
  - Set up bill locations.

- Oracle Order Management
  - Set up sales orders.
- Oracle Purchasing
  - Set up suppliers.
  - Set up test providers as suppliers, supplier sites, and purchase orders.
  - Set up purchase orders having an inspection receipt routing.
- Oracle Quality
  - Set up collection elements.
  - Set up collection plans.
  - Set up collection triggers.

## **Set Up OPM Quality Management**

Set up OPM Quality Management in the Quality Manager responsibility:

- Define Test Classes. Optional.
- Define Test Units. Required.
- Define Sampling Plans. Optional.
- Configure Process Quality Parameters for a particular organization. Optional.
- Define specification Version Control in the Process Quality Parameters window. Optional.
- Define Test Methods. Optional.
- Define Tests. Required.
- With Oracle E-Records enabled:
  - Set up specification approval.
  - Set up specification validity rule approval for Inventory, WIP, Customer, and Supplier types.
  - Set up specification validity rule approval for monitoring type specifications.

- Set up sample creation approval.
- Set up results entry approval.
- Set up results evaluation approval.
- Set up sample disposition approval.
- Set up sample group approval based on the last sample and composite results or both.
- Set up appropriate workflow notifications. Refer to the "Understanding OPM Quality Management Workflows" topic in "Appendix C" for additional information.

## **Set Up and Create Specifications**

Set up and create specifications in the Quality Manager responsibility:

- Create and approve new item specifications. Required.
- Create and approve new item specification validity rules. Required.

## **Set Up and Create Item Samples**

Set up and create samples in the Quality Manager or Quality Technician responsibilities:

- Define samples manually or automatically. Required.
- Associate a sample to a specification version. Optional.

## **Enter Test Results**

Enter results in the Quality Manager or Quality Technician responsibility:

- Enter results against a sample. Required.
- Use mass entry of results option. Optional.
- Associate results to new item and lot. Optional.
- Add tests to the result set. Optional.

## **Evaluate Test Results**

Results are evaluated in the Quality Manager responsibility:

- Review results. Optional.
- Change the sample disposition. Required.
- Change the sample group disposition. Required.
- Change material status and grade. Optional.

## Composite Test Results

Composite results in the Quality Manager responsibility:

- Find the sample group to composite results. Optional.
- Create or view composite results. Optional.
- View the samples that comprise the composite result set. Optional.
- Add a test to all samples in the sample group. Optional.
- Save the composite results. Optional.

## Compare Specifications

Specifications comparison for results is performed in the Quality Manager responsibility:

- Retrieve sample results and find a specification for comparison. Optional.
- Add tests from the comparison specification to the results set. Optional.
- Change the comparison specification to the current specification. Optional.

## Set Up, Run, and Evaluate a Stability Study

Refer to the "Stability Testing" topic for a complete discussion of how to set up, run, and evaluate a stability study.

## Understanding the Interface to Other Applications

Quality Management interfaces with Oracle Process Manufacturing (OPM) Process Execution, Oracle Inventory, Oracle Quality, and Oracle Purchasing applications to allow the following optional functionality:

## Batch Updated by Sample Quantity

When sampling is performed on work in process material, the batch must account for the sample quantity drawn from it. This quantity is either consumed for destructive testing purposes, or it is retained in inventory for possible future testing. The application lets you trace this material by yielding the sample as a byproduct of the batch. In cases where the sample quantity drawn is negligible, the WIP sample quantity can be configured as part of the overall process loss, and does not need to be accounted for in the batch.

## Batch Step Release Notifies Sampler

Configure the validity rule for a WIP specification to notify appropriate individuals to draw the number of samples required by the sampling plan. The release of a batch step sends a summary notification of all the samples required for the batch. By notifying samplers at the beginning of a batch step, they can prepare for the sample drawing process. This also serves to constrain batch step completion based on the results of quality testing.

## Batch Step Completion Controlled by Quality Testing Requirements

The validity rule for a WIP specification prevents a batch step from completing once a sample is taken and quality testing results are pending. Once testing is complete, the application allows the batch step to complete if quality results and the sample disposition are acceptable. Completion of the batch step is not permitted if a sample is rejected, or if adjustments must be made.

## Inventory Adjusted for Sample Quantity

The sample quantity can be deducted from the on-hand balance of an item when a sample is drawn from inventory. This inventory adjustment option is configurable at the process quality parameter level, which defaults and can be overridden at the specification validity rule and sample levels.

## Material Status and Grade Updates Based on a Final Results Set

The application updates material status and grade based on the final results for the item lot sampled from inventory or production. It ensures that each required sample and the sample group has a final disposition that is acceptable or unacceptable before updating the material status and grade of the material sampled.

## Receipts Sampled Prior to Being Inventoried

Receiving inspection in Oracle Purchasing is enforced through an inline inspection step using Oracle Quality collection plans before the material is delivered into inventory. A

workflow notification is sent for taking lab samples based on an OPM Quality Management supplier specification validity rule. Create a sample against the receipt and receipt line without specifying a lot number. The acceptability of the supplier sample results displays in context with the collection plan results and the accepted and rejected quantities are either delivered into inventory or put on hold for further action.

## Inspection Lead Time for Planning

Material that is received or manufactured often requires quality testing before it is used for production or shipping. The duration of quality test can be defined as a post-processing lead time for an item in Oracle Inventory, so that Oracle Advanced Supply Chain Planning recognizes the future availability of the lot without suggesting another planned order. After quality assurance completes inspection and assigns a final disposition, the lot is released according to this hold date or updated to another date in the future.

## Changing the Status of Expired Lots

You can access the Inventory Quantities - Mass window to change the status of expired lots.

Refer to the *Oracle Inventory User's Guide* for a complete discussion of the Inventory Quantities - Mass window.

## Understanding Navigation

The following information is a summary of more detailed discussions found in the *Oracle Applications User's Guide*.

### Navigating the Application

In addition to the standard menu and tool palette, a hierarchical navigator provides a display of the objects in a treelike framework known as a workbench.

#### Node and Leaf

The top-level nodes in the navigator are expanded to display groups of individual database objects. Lower level nodes, and the objects they contain, are indented to indicate that they belong to these higher level nodes. The terminal node in a branch is called a leaf node.

#### Menu and Tools

Menu and tools let you access all globally available functions.

#### Data Organizer

The Data Organizer groups objects on separate tabs. Each has a unique icon and its own

hierarchy. The Oracle Process Manufacturing (OPM) Quality Management application uses Data Organizer tabs to group specifications and samples. Refer to the "Identifying Nodes and Tabs on the Navigator" topic for specific nodes and tabs used in OPM Quality Management.

### Summary Views

Summary views provide the highest level of business information and only display information. When you select an unexpanded, higher level node on the Data Organizer, the summary view also lists the contents of the container in a multirecord block.

### Detail Views

Detail views let you display and edit information.

### To navigate the application from the workbench:

The following is a typical flow through the Quality Management application:

1. Log on to your assigned responsibility.
2. Choose **Quality Workbench** from the **Navigator** menu.
3. Select the tab that contains the object type of interest.
  - Click **Specifications**, and select the **Show Active Specs** indicator to display only approved specifications and specification validity rules. Deselect the indicator to show all specifications and specification validity rules.
  - Click **Samples**, and select the **Show Active Samples** indicator to display only pending or in-progress samples. Deselect the indicator to show all samples, regardless of their disposition.
4. Select the appropriate **View By** field. This field presents records sorted and grouped by the selection you make.
5. Use one of the following methods to find the appropriate folder:
  - Expand or collapse entries in the hierarchical Data Organizer.
  - Use the Find feature to retrieve the appropriate object from the results. Save the objects in a Personal or Public folder for future reference in the Data Organizer.
6. Use one of the following methods to show the detailed view of a selected object:
  - Select the object in the Summary View and click the desired button.
  - Double-click the object in the Data Organizer until you reach the terminal or leaf object.

7. Perform actions on selected objects that you have permission to edit.
8. Navigate from detailed view to other related windows.

## Identifying Nodes and Tabs on the Navigator

The navigator has these two tabs:

- Specifications
- Samples

### Selecting the Specifications Tab

The following lists some of the typical elements displayed on the navigator when you display active specifications on the Quality Workbench in the View By Specification mode.

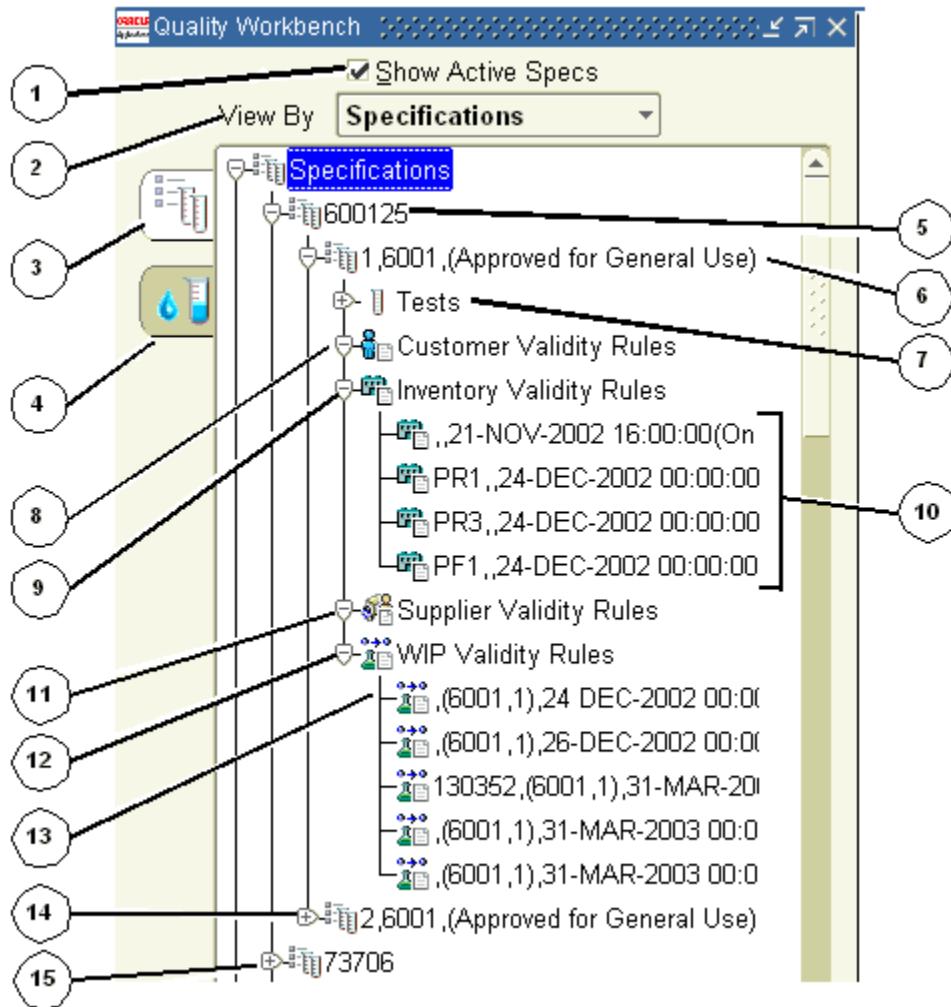
The numbers reference each of the nodes and tabs depicted in the graphic that follows this discussion. Click nodes that are marked with a plus (+) sign to expand them.

- **1** is the Show Active Specs indicator. When you select Show Active Specs, the navigator only displays those specifications that are active. Active specifications have a status of Approved for Laboratory Use or Approved for General Use.
- **2** is the View By box. You can display the list by Specifications, Customer, Supplier, Item, Owner Organization, or Status.
- **3** is the Specifications tab. Select it to display all available quality specifications for the organizations you can access.
- **4** is the Samples tab. Select it to display available quality samples.
- **5** is the specification name. Click it to display the Specification Summary window. This window is discussed in the "Displaying Specifications Summaries from the Navigator" topic.
- **6** is the specification version, owner organization, item, revision, and status. Click it to display the Specifications window. This window is discussed in the "Entering a Specification" topic.
- **7** is the Tests node. Select it to display the Specifications window. This window is discussed in the "Entering a Specification" topic. Expand this node to view the list of tests on the specification.
- **8** is the Customer Validity Rules node. Select it to display the Validity Rules Summary for Item Spec window. Information displayed includes the Customer, Order, effective date From, and Specification Validity Rule Status. This window is

discussed in the "Displaying the Item Specification Validity Rules Summary" topic.

- **9** is the Inventory Validity Rules node. Select it to display the Validity Rules Summary for Item Spec window. This expanded node displays the list of inventory specification validity rules. This window is discussed in the "Displaying the Item Specification Validity Rules Summary" topic.
- **10** is the list of each of the inventory specification validity rules. The information displayed after each validity rule is comma-delimited, and corresponds to each row of information displayed on the Validity Rules Summary for Item Spec window. For example, Organization, Subinventory, Locator, Lot, effective date From, and Validity Rule Status.
- **11** is the Supplier Validity Rules node. Select it to display the Validity Rules Summary for Item Spec window. Information displayed includes the Supplier, effective date From, and Validity Rule Status. This window is discussed in the "Displaying the Item Specification Validity Rules Summary" topic.
- **12** is the WIP Validity Rules node. Select it to display the Validity Rules Summary for Item Spec window. This window is discussed in the "Displaying the Item Specification Validity Rules Summary" topic.
- **13** is the list of each of the WIP validity rules. The information displayed after each validity rule is comma-delimited, and corresponds to each row of information displayed on the Validity Rules Summary for Item Spec window. This information displayed includes the Organization, Batch, (Recipe, Version), effective date From, and Validity Rule Status.
- **14** is the next active version of the specification version, owner organization, item, revision, and status.
- **15** is the next active specification.

The following graphic illustrates the previously described nodes and tabs in the navigator window when the Specifications tab is selected:



### Selecting the Samples Tab

The following lists some of the typical elements displayed on the navigator when you display active samples on the Quality Workbench in the View By Organization mode. You can view the samples for organizations that your responsibility can access. The numbers reference each of the nodes and tabs depicted in the graphic that follows this discussion.

- 1 is the Show Active Samples indicator. When you select Show Active Samples, the navigator only displays those samples that are active. Active samples have a disposition of Pending or In Progress.
- 2 is the View By box. You can display the list by Organization, Item, Disposition, Test, Test Class, Test Method, or Laboratory.
- 3 is the Specifications tab. Select it to display all available quality specifications.

- **4** is the Samples tab. Select it to display available quality samples for those organizations that your responsibility can access.
- **5** is the Samples By Organization node. Expand it to display all the organizations that your responsibility can access.
- **6** is an Organization node. Expand it to display all samples in the organization. If you select Show Active Samples, then only the active samples are displayed.
- **7** is a Sample node. Information displayed includes Sample, Item, Revision, Lot, and Disposition. Select it to display the sample in the Item Samples window.
- **8** is the Results node. Select it to display the Results window for the sample. Expand it to display all tests assigned to the sample.
- **9** is the results set for the sample. Select it to display the Results window. You must be a valid user in the laboratory associated to a test in order to enter test results, or to add tests to a sample with a disposition of Pending or In Progress.
- **10** is the next Organization node.

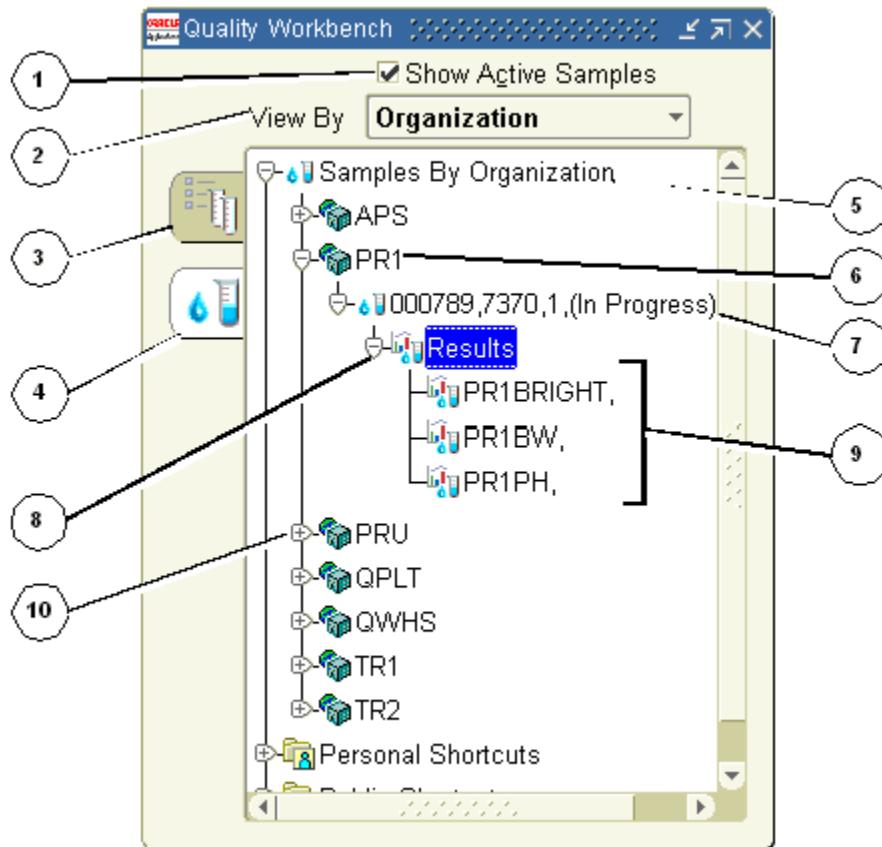
**Displaying the Samples Summary window:**

Display the Samples Summary window for an item by selecting View By Item, and then select the item. Refer to the "Displaying the Samples Summary from the Navigator" topic for a complete discussion of this feature.

**Displaying the Item Samples window:**

Display the Item Samples window for each sample by expanding the node and selecting an individual sample.

The following graphic illustrates the previously described nodes and tabs in the Quality Management workbench window when the Samples tab display:



## Standard Custom View

A standard custom view lets you query the database for:

- Specifications based on:
  - Specification, to view a list of specifications based on specification name displayed in ascending alphanumeric order
  - Customer, to view a list of specifications based on customer displayed in ascending alphanumeric order
  - Supplier, to view a list of specifications based on supplier displayed in ascending alphanumeric order
  - Item, to view a list of specifications based on item displayed in ascending alphanumeric order
  - Owner Organization, to view a list of specifications based on owner organization displayed in ascending alphanumeric order

- Status, to view a list of specifications based on specification status
- Samples based on:
  - Item, to view a list of samples based on item displayed in ascending alphanumeric order
  - Disposition, to view a list of samples based on sample disposition displayed in ascending alphanumeric order
  - Test, to view a list of samples based on test displayed in ascending alphanumeric order
  - Test Class, to view a list of samples based on test class displayed in ascending alphanumeric order
  - Test Method, to view a list of samples based on test method displayed in ascending alphanumeric order
  - Laboratory, to view a list of samples based on laboratory displayed in ascending alphanumeric order

Once a view is generated, the criteria or output can be saved for future use in the Personal or Public Shortcuts. Click a node to display a summary window.

## Using the Navigator Find Window

Use the Quality Workbench Find Samples or Find Specifications window to find one or a series of specifications and samples.

- To display the Find Samples window, select the Quality Workbench navigator, select the Samples tab, and choose Find from the View menu, or right-click then choose Find.
- To display the Find Specifications window, select the Quality Workbench navigator, select the Specifications tab, and choose Find from the View menu, or right-click then choose Find.

See: *Oracle Applications User's Guide*

## To display the Find Samples window from the Quality Workbench:

1. Navigate to the **Find Samples** window on the navigator.
2. Enter one or more search criteria on the **Standard**, **Source**, or **Advanced** tabs.

### **Standard**

3. Enter the **Sample** organization and sample number.
4. Select sample **Disposition** as:
  - **Retain** when the sample is reserved and put in storage. Typically, results do not exist for a sample with this disposition.
  - **Pending** when the sample is saved, and results are expected, but not yet recorded.
  - **In Progress** when at least one result exists for the sample, but testing is not yet complete.
  - **Complete** when testing of all required tests and all additional tests is complete.
  - **Accept** when sample testing is complete, and results are in-specification.
  - **Accept With Variance** when sample testing is complete, and at least one result is in the experimental error region or out-of-specification. However, the sample approver has accepted this with variance.
  - **Reject** when sample testing is complete, and results are not acceptable, or out-of-specification.
  - **Cancel** when the sample is canceled.
5. Enter **Item** as the item sampled.
6. Select the sample **Source** as:
  - Customer
  - Inventory
  - Supplier
  - Stability Study
7. Enter **Parent Lot** as the item parent lot number.
8. Enter **Lot** as the item lot number.
9. Enter **LPN** as the License Plate Number of the sample. You can select the LPN number from the LOV.

**Note:** This field is enabled only for WMS enabled organizations.

10. Enter **Laboratory** as the laboratory where the sample is sent for analysis.
11. Enter **Date Drawn** as the date the sample was taken. This must be entered in the format DD-MMM-YYYY.
12. Select **Priority** as:
  - **Normal** to indicate that the sample has the usual processing requirements.
  - **Low** to indicate that the sample has minimal urgency for processing.
  - **High** to indicate that the sample has urgent processing requirements.
13. Enter **Specification** as the specification name and version associated to the sample entered.

#### **Source**

14. Enter any of these additional criteria when Source is selected as Customer, Supplier, Inventory, or WIP:
  - Customer Name
  - Operating Unit
  - Ship To
  - Order
  - Line
  - Subinventory
  - Locator
  - Supplier
  - Supplier Site
  - Purchase Order
  - Line
  - Receipt

- Line
- Batch
- Recipe
- Formula
- Line
- Routing
- Step
- Operation
- Charge

### **Advanced**

15. In an advanced search of samples, select **Item** as:

- Sample
- Date Drawn
- Disposition
- Organization
- Laboratory

This selection functions with the **Condition** field and the **Value** field to define a custom search. You can enter any number of individual criteria to narrow your search.

16. Select **Condition** as:

- **Equals** to find targets equal to the specified Value entered.
- **Greater than** to find targets greater than the specified Value entered.
- **Less than** to find targets less than the specified Value entered.
- **Greater than or equal to** to find targets greater than or equal to the specified Value entered.
- **Less than or equal to** to find targets less than or equal to the specified Value

entered.

- **Like** to find targets similar to the information specified using the wildcard %.

For example, if you specify the Item as Sample, select the Condition Like and enter FORM%, then you find each target product that contains entries with the letters FORM.

17. Enter the **Value** for the appropriate condition selected.
18. Click **Find**. The window displays the results of the search.
19. Select the drill-down indicator next to the row you want to display the details of the search.

## To display the Find Specifications window from the Quality Workbench:

1. Navigate to the **Find Specifications** window on the navigator.
2. Enter one or more search criteria on the Standard, Validity Rule Type, or Advanced tabs.

### Standard

3. Enter **Specification** as the name for the specification.
4. Enter **Version** as the version for the specification.
5. Select **Specification Status** for the specification to find as:
  - **New** to indicate that the specification is new.
  - **Request Approval for Laboratory Use** to indicate that an approval is requested for using the laboratory specification.
  - **Revise for Laboratory Use** to indicate that a revision is requested for using the laboratory specification.
  - **Approved for Laboratory Use** to indicate that the specification is approved for laboratory use.
  - **Request Approval for General Use** to indicate that a request was made to approve the specification for general use.
  - **Revise for General Use** to indicate that a request was made to revise the specification for general use.

- **Approved for General Use** to indicate that the specification is approved for general use.
- **On Hold** to indicate that the specification is on hold.
- **Frozen** to indicate the specification is frozen.
- **Obsolete/Archived** to indicate that the specification is no longer approved for use and is obsoleted, archived, or both.

6. Enter **Item** as the item code for the material being specified as it is listed on the Item Master. The item must be set up as process quality-enabled in the Item Master. Refer to the *Oracle Inventory User's Guide* for detailed information.
7. Enter **Grade** as the grade for the item lot.
8. Enter **Owner Organization** as the owner organization of the specification.
9. Enter **Owner** as the owner of the specification.
10. Enter **Validity Rule Type** as:
  - Customer
  - Inventory
  - Supplier
  - Production

#### **Validity Rule Type**

11. Enter any of these additional criteria when a Validity Rule Type is selected as Customer, Supplier, Inventory, or Production:
  - Organization
  - Status
  - Customer Name
  - Operating Unit
  - Ship To
  - Order
  - Line

- Parent Lot
- Lot
- Subinventory
- Locator
- Supplier
- Supplier Site
- Purchase Order
- Line
- Batch
- Recipe
- Formula
- Line
- Routing
- Step
- Operation
- Charge

### **Advanced**

12. In an advanced search of specifications, select **Item** as:

- Specification
- Item
- Status
- Owner Organization
- Owner

13. Select **Condition** as:

- **Equals** to find targets equal to the specified Value entered.
- **Greater than** to find targets greater than the specified Value entered.
- **Less than** to find targets less than the specified Value entered.
- **Greater than or equal to** to find targets greater than or equal to the specified Value entered.
- **Less than or equal to** to find targets less than or equal to the specified Value entered.
- **Like** to find targets similar to the information specified using the wildcard %.  
For example, if you specify the Item as Sample, select the Condition Like, and enter FORM%, then you find each target product that contains entries with the letters FORM.

This selection functions with the **Condition** field and the **Value** field to define a custom search. You can enter any number of individual criteria to narrow your search.

14. Enter the **Value** for the appropriate condition selected.
15. Click **Find**. The window displays the results of the search.
16. Select the drill-down indicator next to the row you want to display the details of the search.



# 2

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## Setting Up

This topic explains how to set up quality responsibilities, action codes, grades, test classes, test units, sampling plans, and process quality parameters.

This chapter covers the following topics:

- Setting Up in Other Applications
- Setting Up Quality Tests
- Setting Up Test Classes
- Finding Test Classes
- Setting Up Test Groups
- Setting Up Test Units
- Finding Test Units
- Setting Up Sampling Plans
- Finding Sampling Plans
- Setting Up Parameters

### Setting Up in Other Applications

#### Setting Up in Oracle Inventory

If you plan to set up inventory quality attributes, then set up the following in the Oracle Inventory application:

- Items and item attributes for every raw material, intermediate, and end item. Items must be set up as process quality-enabled in the Item Master
- Unit of measure conversions for each item, between the primary inventory unit of measure and the unit of measure you use, if these are different

- Status and Grade control on the Item Master
- Expiration date, retest date, and retest interval
- Action and reason codes

Refer to the *Oracle Inventory User's Guide* for detailed information.

## Setting Up Action Codes

The Maintain Actions window lets you set up action codes in Oracle Inventory, and view all existing action codes. Action codes represent user actions to perform when quality testing yields out-of-specification exception cases, such as out-of-specification conditions, or experimental error results. You can associate an action to a result disposition when you evaluate the result. Action codes are assigned for experimental error at the test and specification levels. They are also assigned in individual specification tests for out-of-specification results. Action codes display for items on appropriate quality reports.

The Find Actions dialog box lets you search for actions by action code, description, or marked for deletion.

Refer to the *Oracle Inventory User's Guide* for detailed information on setting up and finding action codes.

## Setting Up Grades

The Maintain Grades window lets you set up grades and view all existing grades in Oracle Inventory. Grade is a characteristic of an item lot and is usually a combination of inventory and quality attributes. Items must be lot and grade-controlled to enter grades for them. The process of assigning a grade to a lot provides a standardized means of describing its marketability. Grades are often based on criteria such as color, physical size, weight, or appearance. If a lot grade changes on a locator-controlled item, then assign the item to a new locator manually.

The Find Grades dialog box lets you search for grades by grade code, description, or marked for deletion.

Refer to the *Oracle Inventory User's Guide* for detailed information on setting up and finding grades.

## Setting Up Quality Attributes for Items

Once you enter action codes, grades, and reasons in Oracle Inventory, use them to set default attributes for inventory items. Quality attributes include grade and material status control.

## Setting Up Material

With material status, Oracle Inventory lets you identify the use of lot-controlled material in production, order processing, or shipping. Once it is determined that a sample does not meet quality specifications or has failed quality tests, change the status of the sample lot for certain purposes in production or shipping.

The first step is to define each Material Status and its associated permissions. After you perform quality tests, change the status of lots that do not meet quality specifications in order to prevent them from being sold or used for production.

Refer to the *Oracle Inventory User's Guide* for a complete description of setting up material status.

## Setting Up Reason Code Access

When you select an inventory transaction reason code on the Process Quality Parameters window or the Quality Change Disposition dialog box, only those reason codes that you were granted permission to access display. Refer to the *Oracle Inventory User's Guide* for detailed information.

## Setting Up Security Profile

Depending on your security profile, some of the information on certain windows may not be available to you. Contact your Product Development Security Manager or Product Development Security Profile Manager if you require access to this information.

## Setting Up Specification Matching for Use In Oracle Order Management

Oracle Order Management users define specifications, create samples, and record results for customers, ship-to locations, sales orders, and order lines. Defining a customer order specification requires entry of the operating unit and order information. Customer quality data and Query Find functions display optional fields for customer ship-to location, operating unit, order number, order type, and order line number. To select available inventory based on whether quality results match the customer specification, a sample and a set of results must exist for the order line item and one lot must display in the Oracle Inventory Transact Move Orders window using the Manual Allocate option. Available lots display in addition to information whether an acceptable quality match exists. The Order Management user can view the specification and results for each lot.

In order for specification matching to find results, a sample and set of results must exist for the order line item and one lot must display in the Select Available Inventory window or Transact Move Orders window in Oracle Inventory using the Manual Allocate option.

The Customer Test Results report displays customer number, operating unit, ship-to,

order number, type, and line when this information is entered.

## Setting Up Action Codes

The Maintain Actions window lets you set up action codes in Oracle Inventory, and view all existing action codes. Action codes represent user actions to perform when quality testing yields out-of-specification exception cases, such as out-of-specification conditions, or experimental error results. You can associate an action to a result disposition when you evaluate the result. Action codes are assigned for experimental error at the test and specification levels. They are also assigned in individual specification tests for out-of-specification results. Action codes are displayed for items on appropriate quality reports. Refer to the *Oracle Inventory User's Guide* for detailed information on setting up action codes.

The Find Actions dialog box lets you search for actions by action code, description, or marked for deletion. Refer to the *Oracle Inventory User's Guide* for detailed information on finding action codes.

## Setting Up Grades

The Maintain Grades window lets you set up grades and view all existing grades in Oracle Inventory. Grade is a characteristic of an item lot and is usually a combination of inventory and quality attributes. Items must be lot and grade-controlled in order to enter grades for them. The process of assigning a grade to a lot provides a standardized means of describing its marketability. Grades are often based on criteria such as color, physical size, weight, or appearance. If a lot grade changes on a locator-controlled item, then you need to assign the item to a new locator manually. Refer to the *Oracle Inventory User's Guide* for detailed information on setting up grades.

The Find Grades dialog box lets you search for grades by grade code, description, or marked for deletion. Refer to the *Oracle Inventory User's Guide* for detailed information on finding grades.

## Setting Up Quality Tests

A test helps determine a quality characteristic or attribute of an item or lot. A test method describes how a test is performed. A test method can refer to a test protocol or standard operating procedure. Set up tests and test methods using information provided in "Tests."

## Setting Up Test Classes

The Test Classes window lets you group specific tests into meaningful sets for purposes of evaluating them or managing them in workflows, or managing results. You set up basic classes for each test data type.

Here are some examples of test classes:

- CHEMICAL, a test class containing test measurements of pH, sugar content, or water content
- PROTEIN, a test class containing test measurements of total protein, albumin, and globulin.
- MICROBIO, a test class containing test measurements of bacterial, fungal, or viral components
- ENTERICS, a test class containing tests for enteropathogens
- PHYSICAL, a test class containing test measurements of specific gravity, hardness, or visual opacity
- DISSOLVE, a test class containing measurements for various materials to dissolve

## Prerequisites

- Analyze all tests performed and group them into meaningful classes.
- Develop a list of test classes and descriptions.

## To set up test classes:

1. Navigate to the **Test Classes** window.
2. Enter a code for the test **Class**. Required.
3. Enter a **Description** for the test class. Required.
4. Save the window.

Refer to "Setting Up Test Groups" for detailed information on test grouping.

## Finding Test Classes

The Find Test Classes dialog box lets you search for test classes by class, description, or marked for deletion.

## Prerequisites

- Enter a test class.

## To find a test class:

1. Navigate to the Find Test Classes dialog box.
2. Enter any of the following to narrow your search:
  - **Class code**
  - **Description** of the class
3. Select **Marked for Deletion** as:
  - **Yes** to find test classes that are marked for deletion.
  - **No** to find test classes that are not marked for deletion.
  - Leave this field blank if you do not want to limit your search based on whether a test class is marked for deletion.
4. Click **Find**. The **Test Classes** window displays the results of the search.

## To create a new test class from the Find Test Classes dialog box:

1. Click **New**. The **Test Classes** window displays.
2. Create a new test class as described in "Setting Up Test Classes."

## Setting Up Test Groups

A test group organizes tests into a meaningful set for collaborative analysis. Test grouping facilitates the rapid creation of specifications and addition of tests during sample analysis. After tests are grouped and sequenced into a test class, you can add a test group to a specification or results record using the Test Group window. You can add individual tests or all tests in the group before the specification is approved or results have a final sample disposition. A test can belong to only one test class or test group.

See: *Oracle Applications Flexfields Guide*

## Prerequisites

- Perform all required setup procedures.
- Enter tests.

- Optionally, enter specifications for test group assignment.

### To define a test group:

1. Navigate to the **Test Classes** window.
2. Enter a **Test Class**.
3. Enter a **Description** for the test class.
4. Select the **Test Group** indicator to treat the test class as a test group.

### To sequence tests in a test group:

1. Navigate to the **Tests** window.
2. Enter a test as described in "Entering Tests."
3. Select the desired test class with a previously defined **Test Group** indicator.
4. Enter **Ordering** as the sequence number for the test to appear in the list of tests in the test group. Tests are listed in ascending order. If you plan to add tests before 10, then sequence the list beginning at 10.

## Setting Up Test Units

The Test Units window lets you set up quality test units and view all existing quality test units. Set up standard or custom test units such as %T for percent optical transmittance, or A for spectral absorbance. Test units are used for recording results.

If you want to convert test units, then set up an expression test for the conversion. For example, to convert a Celsius temperature of 100 degrees into degrees Fahrenheit, multiply the Celsius temperature reading by nine-fifths, or the decimal 1.8, to get 180. Then, add 32 to 180 to get 212 degrees Fahrenheit. The expression is:

"CELSIUS" test result

"FAHRENHEIT" expression is:  $(1.8 * "CELSIUS") + 32$

See: *Oracle Applications Flexfields Guide*

## Prerequisites

- Analyze all tests performed and identify their reporting units.
- Develop a list of units and a description for each one.

## To set up test units:

1. Navigate to the **Test Units** window.
2. Enter a code for the test **Unit**. Required.
3. Enter a **Description** of the test unit. Required.
4. Save the window.

## Finding Test Units

The Find Test Units dialog box lets you search for test units by unit, description, or marked for deletion.

### Prerequisites

- Enter a test unit.

## To find a test unit:

1. Navigate to the Find Test Units dialog box.
2. Enter any of the following to narrow your search:
  - **Unit** code
  - **Description** of the unit
3. Select **Marked for Deletion** as:
  - **Yes** to find test units that are marked for deletion.
  - **No** to find test units that are not marked for deletion.
  - Leave this field blank if you do not want to limit your search based on whether a test unit is marked for deletion.
4. Click **Find**. The **TestUnits** window displays the results of the search.

## To create a new test unit from the Find Test Units dialog box:

1. Click **New**. The **TestUnits** window displays.

2. Create a new test unit as described in "Setting Up Test Units."

## Setting Up Sampling Plans

The Sampling Plan window lets you define how much and how often to sample. By entering the number, size, and frequency of samples to take, the sampling plan lets you prescribe sample groups. Used in conjunction with the Sample Creation Notification workflow, individuals responsible for sampling are notified when and where to sample materials that require quality testing. Sampling plans are an optional setup. They are associated to a specification validity rule on the Validity Rules for Item Spec window.

### Understanding Count, Frequency Type, and Frequency Period

The Count, Frequency Type, and Frequency Period, or Per fields, work together to define the number of repetitions for sampling.

For example, to indicate ten samples that each contain 5 milliliters every hour, you would enter:

Count = 10

Quantity = 5 mL

Per = 1 hour

The following are examples of each sampling plan type:

#### Time-based Sampling Rate

Time-based sampling is entered in hours, minutes, days, weeks, months, or years. To take one sample every five minutes, enter:

- Count = 1
- Per = 5 Minutes

#### Quantity-based Sampling Rate

Quantity-based sampling is entered in a valid inventory UOM. To take one sample every 1,000 kilograms produced, enter:

- Count = 1
- Per = 1000 kg

#### Fixed Number of Samples to Take

Fixed number sampling is entered for a batch, batch step, or receipt. To take three samples per receipt, enter:

- Count = 3

- Per = 1 Receipt

To take two samples of 10.0 grams for every five batches produced, the sampling plan is entered as:

- Count = 2
- Quantity = 10.0000000000
- UOM = GRAM
- Frequency Type = Fixed Number
- Per = 5 Batch

### **Percentage of Samples to Take**

Percentage-based sampling frequency applies to the amount of product produced, or the amount of item delivered. To sample 20% of a delivery, enter:

- Count = 1
- Per = 20 Percent Amount of Product Produced

## **Sampling Plan Definition is Optional**

Defining a sampling plan is optional. Setup a sampling plan before you create specifications and samples in which you intend to use it. A sampling plan becomes effective for a process quality-enabled item and optionally, for a grade when it is associated with a specification validity rule. The Validity Rules for Item Spec window displays all applicable details of a sampling plan if one is selected for use. You can have required, reserved, or archived samples associated with a sampling plan. As long as one of these sample types is specified, the sampling plan is valid.

You can use flexfields and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## **Prerequisites**

- Set up inventory item units of measure for the material requiring sampling inspection.

## **To set up a sampling plan:**

1. Navigate to the **Sampling Plan** window.
2. Enter the **Name** for the sampling plan. Required.

3. Enter a **Description** for the sampling plan. Required.

### **Required Samples**

4. Enter the **Count** as the number of samples to take at each instance of the frequency entered. You do not have to enter this field. You can specify the sampling plan in terms of reserved or archived samples to be taken.
5. Enter **Quantity** and **UOM** as the sample size, or the amount of material needed to take a sample from the material requiring inspection. This is expressed in the primary inventory unit of measure as defined in Oracle Inventory. Required.
6. Enter the **Frequency Type** as previously described:
  - **Time Based** to indicate time-based sampling in hours, minutes, days, weeks, months, or years.
  - **Quantity Based** to indicate quantity-based sampling in a valid inventory UOM. Enter the sample UOM.
  - **Fixed Number** to indicate fixed number sampling for a batch, batch step, or receipt.
  - **Percent** to indicate sampling by percentage of product produced, or percentage of item delivered.
7. Enter **Per** as the frequency period. Count, Frequency Type, and Frequency Period or Per fields work together to define the number of repetitions for sampling.
8. Depending on the entry you make in the **Frequency Type** field, do one of the following:
  - For time based sampling, select **Hours**, **Minutes**, **Days**, **Weeks**, **Months**, or **Years**.
  - For quantity based sampling, enter a valid inventory **UOM**.
  - For fixed number sampling, select **Batch**, **Batch Step**, or **Receipt**.
  - For percent sampling, select **Amount of item delivered** or **Amount of product produced**.

### **Reserved Samples**

9. Enter **Count** as the number of samples to take at each instance of the frequency entered.
10. Enter the **Quantity** of sample for the reserved sample.

11. **UOM** displays the unit of measure for the sample size. This defaults from the default UOM for required samples.

#### Archived Samples

12. Enter **Count** as the number of samples to take at each instance of the frequency entered.
13. Enter the **Quantity** of sample for the archived sample.
14. **UOM** displays the unit of measure for the sample size. This defaults from the default UOM for required samples.
15. Save the window.

## Finding Sampling Plans

The Find Sampling Plans dialog box lets you search for sampling plans by name, frequency type, or marked for deletion.

### Prerequisites

- Enter a sampling plan.

### To find a sampling plan:

1. Navigate to the Find Sampling Plans dialog box.
2. Enter any of the following to narrow your search:
  - **Name** of the sampling plan
  - **Frequency Type** of the sampling plan as Time Based, Quantity Based, Fixed, or Percent
3. Select **Marked for Deletion** as:
  - **Yes** to find sampling plans that are marked for deletion.
  - **No** to find sampling plans that are not marked for deletion.
  - Leave this field blank if you do not want to limit your search based on whether a sampling plan is marked for deletion.
4. Click **Find**. The **Sampling Plan** window displays the results of the search.

## To create a new sampling plan from the Find Sampling Plans dialog box:

1. Click New. The Sampling Plan window displays.
2. Create a new sampling plan as described in "Setting Up Sampling Plans."

## Setting Up Parameters

The Process Quality Parameters window lets you set up system defaults to enforce quality management business rules for a specific organization. This window serves as a default template that is typically defined at the time of implementation by a system administrator and may be updated later. Following are windows and options that are configurable on other Oracle Process Manufacturing (OPM) Quality Management windows:

- Validity Rules for Item Spec window
  - Control Batch Step Status
  - Control Lot Attributes
  - In-Specification Status
  - Out-of-Specification Status
  - Update Inventory Quantity
  - Lot Optional
  - Delayed Lot Entry
- Item Samples window
  - Lot Retest
  - Update Inventory Quantity

When you select an inventory transaction reason code on this window, only display those reason codes that you were granted permission to access. Refer to the *Oracle Inventory User's Guide* for detailed information on reason code.

## Prerequisites

- Set up organizations as process-enabled.
- Set up quality action codes in Oracle Inventory to assign them to retest and

resample actions.

- Set up reason codes in Oracle Inventory for the inventory transaction for samples.
- Set up material statuses in Oracle Inventory for in-specification and out-of-specification statuses.

## To set up Oracle Process Manufacturing Quality Management parameters:

1. Navigate to the **Process Quality Parameters** window.
2. Enter the desired default process-enabled inventory **Organization**.  
**Organization Type**
  3. Select **Organization Type** as **Quality Laboratory** to designate the organization as a quality laboratory where the sample is analyzed.  
**Plant** is selected if an organization is defined as a plant organization in OPM Product Development. This field is display only.  
**Laboratory** is selected if an organization is defined as a research and development laboratory organization in OPM Product Development. This field is display only.

**Note:** Quality Laboratory is used to designate the organization as a quality laboratory where the sample is analyzed. Laboratory is selected if an organization is defined as a research or lab organization in OPM Product Development.

### Spec

4. Select **Version Control** as:
  - **Yes** to activate full version control for specifications. Changes made to an unapproved specification require a new version.
  - **No** to specify that specification version control is not active for specifications. You can make changes to an existing unapproved specification without changing its version.
  - **Optional** to specify that version control is discretionary for specifications. Create a new version when you update an existing unapproved version.
5. Select **Exact Spec Match** if a specification must be an exact match based on the sample source or inventory selection criteria. Deselect to enable the application to retrieve the specification that best matches this criteria based on the specification matching hierarchy. For detailed information refer to "Specification Matching

Business Rules" in Appendix B.

#### Actions

6. Enter a **Retest Action** for samples. Retest actions are set up in Oracle Inventory.
7. Enter a **Resample Action** for samples. Resample actions are set up in Oracle Inventory.

#### Spec Validity Rule

8. Select **Create Samples Automatically** to enable automatic sample creation on the Specification Validity Rules window for an Inventory, WIP, or Supplier sample type.
9. Select **Lot Optional** to bypass the entry of a lot number while creating a sample against a lot-controlled item. Deselect to require a lot to be entered on a sample.
10. Select **Delayed Lot Entry** to require the entry of a lot number when assigning the final disposition for a supplier, inventory, or WIP sample. Deselect to make the entry of a lot optional when assigning the final sample disposition. Delayed Lot Entry is available only if Lot Optional is selected. Refer to "Delaying the Entry of Lot Numbers" for additional information.
11. Select **Control Batch Step Status** to indicate that you want quality test results to control the completion of batch steps. The batch step quality status of whether sampling and results are required is reflected at the batch step level. Only in-specification results permit a batch step to complete.

#### Inventory Updates

12. Enter an inventory **Transaction Reason** code. This previously defined reason code is used for the sample inventory transaction, when a sample record is created and **Update Inventory Quantity** is selected.
13. Select **Update Inventory Quantity** to enforce an inventory transaction for drawing the sample quantity.
14. Select **Control Lot Attributes** for the application to update lot attributes status, grade, and hold date based on the test result of samples in a sample group.
15. Enter the default **In-Spec Status** to update the material status when in-specification results are entered. The sample group has a disposition of Accept and **Control Lot Attributes** is selected.
16. Enter the default **Out-of-Spec Status** to update the material status when out-of-specification results are entered. The sample group has a disposition of Reject and **Control Lot Attributes** is selected.

## Samples

17. Select **Manual Spec Selection** to override the default specification and select an alternate specification on the Item Samples window. Select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to the most generic match. For detailed information, refer to "Specification Matching Business Rules" in Appendix B. Deselect to use the default specification only.
18. Select **Consider Optional Tests Results** for optional tests that display on the specification and results records to contribute to the final disposition of the sample. Deselect to exclude optional test results when assigning a final sample disposition. For example, a new test which is measured over time does not factor into sample dispositions until its test limits are formalized based on the results collected. The Consider Optional Tests Results option is specific to a specification validity rule organization and is enforced for all item specifications in which the test is used. If an optional test result is used, then its result evaluation is factored into the possible sample dispositions. An out-of-specification result for an optional test only permits the sample disposition to change to Accept with Variance, Reject, or Cancel.
19. Select the **Account** to use for deducting inventory for samples creation. The Account list is based on the organization you select.

## Document Numbering

20. Select **Assignment Type** as:
  - **Automatic** for the system to automatically generate the sample number when creating a sample
  - **Manual** to manually enter the sample number
21. If the Assignment Type you select is Manual, then enter **Last Assigned** as the starting number for the automatic generation of samples. This field is disabled if Assignment Type is Manual.

## Results

### Applications Programming Interface Decimal Precision

22. Select one of the following for **Applications Programming Interface Decimal Precision**:
  - **Round** to round decimals for the data imported by the Applications Programming Interface
  - **Truncate** to truncate decimals for the data imported by the Applications Programming Interface. If a test or specification is defined with a decimal precision that is less than the default of nine places and the numeric results are

imported using an Applications Program Interface (API), then the numeric results are rounded as indicated by this entry.

## **Stability Studies**

### **Document Numbering**

**23.** Select **Assignment Type** as:

- **Automatic** to automatically generate the sample number when creating a sample
- **Manual** to manually enter the sample number

**24.** Enter **Last Assigned** as the starting number for the automatic generation of samples, if the Assignment Type is Manual. This field is disabled if Assignment Type is Automatic.

**25.** Save.



---

# Tests

This topic explains the fundamentals of quality tests. It provides the processes to enter or find test methods, gives a concise explanation of test data types, and explains how to enter tests, customized customer display information, and experimental error.

This chapter covers the following topics:

- Requirements
- Entering Test Methods
- Finding Test Methods
- Understanding Tests
- Entering Tests
- Entering Customer Display Information
- Entering Experimental Error
- Finding Tests

## Requirements

Following are some requirements that customers have for tests in Oracle Process Manufacturing (OPM) Quality Management.

### Can a separate test be entered that calculates one or more tests performed on a sample?

Yes. Use the expression test data type to build a mathematical expression to reference the results of other numeric-based tests.

#### Build Mathematical Expressions in a Test Format

Enter arithmetic operators such as +, -, \*, /, (), exponents, constants, or any valid SQL operator to build an Expression test data type. Calculate the results of the Expression test after you enter results for all tests referenced in it. In case of replicated tests, the

latest result of the referenced test is used. An Expression test can be added to a result set on an as needed basis if all of the referenced tests already exist in the result set. Decimal precision and experimental error regions and actions can be defined for an Expression test.

## **Can the actual method used to generate a test result be identified?**

Yes. Test Methods let you describe how a test is performed, and help distinguish tests by their methods of execution.

### **Identify Test Methods Used to Generate Results**

Enter test methods to describe how a test is performed. A test method can refer to a test protocol or standard operating procedure. The test method is associated to the test during test definition. It facilitates the execution of quality tests by providing requirements for the quantity of test material, specific instrumentation to use for testing, number of replicates required, and the duration of the test.

## **Can testing resources be identified?**

Yes. Associate instruments to test methods to identify testing resources to monitor in your planning application.

### **Develop Quality Procedures for Laboratory Instrumentation**

The quality laboratory is an inventory organization where sample analysis is performed. It contains resources or equipment that must be scheduled, calibrated, and evaluated for cost. You can define an instrument for quality testing purposes and associate it to a test method to support quality laboratory management and scheduling. OPM supports unique combinations of instrument and test method for a particular test, and you can perform a test in various ways using different laboratory equipment. Define laboratory instruments used for quality testing as generic resources in the OPM Planning application. Instrument resources are assigned at the organization level in the OPM Product Development application.

## **Is there flexibility in displaying decimals on-screen and in reports?**

Yes. For numeric-based tests, the application saves and reports nine decimal places for each test result, specification target, minimum, maximum, and experimental error value. Specify decimal precision for displaying and saving results in the application by using the Display Decimal Precision field. Also, use the Report Decimal Precision field to specify the desired decimal precision for reporting results on a Certificate of Analysis.

### **Define Decimal Precision for Displayed and Printed Values**

Define decimal precision for Numeric Range, Numeric Range with Display, and Expression test data types. Test results are rounded based on the display precision specified at the test and specification levels. During test definition, define the reported

decimal precision for specific customers.

## Entering Test Methods

The Test Methods window lets you enter and display all previously defined test methods. A test method is associated to a single test on the Tests window so that there is a one-to-one relationship between the test and the test method. This window lets you relate test-specific attributes to ensure the referential integrity of your overall testing process. For example, a test for chloride in material can be done by several methods. Attributes of a test method include:

- Quantity of material required
- Instrument to perform the test
- Number of replicates required
- Test kit produced internally or externally
- Duration of the test
- Decimal precision

In order to interpret a test result, you need to know not only the test, but the method that was used to run it. A test method is associated to a test on the Tests window. For quality laboratory management and scheduling purposes, you need to know which instruments are scheduled for testing, and test time duration on these resources.

## Prerequisites

- List all test methods to enter.
- Set up quality testing instruments as resources.
- Identify any instrument-test dependencies. For example, a standard is only run on a specific instrument to test calibration.
- Set up test kit organizations as quality laboratories, test kit items, and inventory units of measure for the material to test in Oracle Inventory.

## To enter a test method:

1. Navigate to the **Test Methods** window.
2. Enter the test **Method** code. Required.

3. Enter a brief **Description** of the test method Required.
4. Enter the test **Qty** of material required for the test. If the test is passive, and does not require a physical sample quantity, then leave this field blank. For example, determining the color of a lot by visual methods may not require the removal of a physical sample.
5. Select the test quantity **UOM** for the test method. Required if you enter a test quantity.
6. Enter the desired **Stored Precision** for the result. You can override the stored precision using the **Tests** window.

#### **Duration**

7. Enter the test method duration as the total time to perform the test in the **Days**, **Hours**, **Minutes**, and **Seconds** fields. If the test is sent to an external laboratory, then enter the total test turnaround time.
8. Enter the required number of test replicates in the **Replicate** field. Required.
9. Select a test kit **Organization** from the list of quality laboratory organizations that your responsibility can access. The organization must be defined as a Quality Laboratory.
10. Select the **Test Kit** item. Test kit items are process quality-enabled items defined in Oracle Inventory. Test kit items display based on the test kit organization you select. If you do not select an organization, then this field is disabled.
11. Enter **Resource** as the instrument to use for the test method.
12. Save the window.

#### **To duplicate a test method:**

1. Query the test method to duplicate.
2. Choose **New** from the **File** menu.
3. Choose **Duplicate**, then choose **Record Above** from the **Edit** menu. The record in the row is copied.
4. Enter a new **Method**, and make any necessary changes to other fields.
5. Save the window.

## To mark a test method for purge:

1. Choose **Mark for Purge** from the **Actions** menu. The record is marked for deletion.
2. Save the window.

## To edit text in a test method:

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.
2. Make appropriate text changes.
3. Save the window.

# Finding Test Methods

The Find Test Methods dialog box lets you search for test methods by method, description, instrument, or marked for deletion.

## Prerequisites

- Enter a test method.

## To find a test method:

1. Navigate to the Find Test Methods dialog box.
2. Enter any of the following to narrow your search:
  - **Method** code
  - **Description** of the method
  - **Resource** used for the test method
3. Select **Marked for Purge** as:
  - **Yes** if you want find test methods that are marked for deletion.
  - **No** if you do not want to find test methods that are marked for deletion.
  - Leave this field blank if you do not want to limit your search based on whether a test method is marked for deletion.

## To create a new test method code from the Find Test Methods dialog box:

1. Click New. The Test Methods window displays.
2. Create a new test method as described in the "Entering Test Method Codes" topic.

## Understanding Tests

A test helps determine a quality characteristic or attribute of an item or lot. Test data type refers to the data type or format expected for the test result. Following are the test data types you can set up:

### Non-Validated Test

Enter a test code and description. Test results for the Non-Validated test data type are free-form text. This entry does not require validation. Results for items or lots cannot fail this test data type.

### Numeric Range Test

Enter a test code, description, test unit, and range of acceptable values for the test. If results for the item or lot fall outside this range, then the material fails this test. For example, a glucose test has a full functional test range of 20 to 300 g/dL. Results outside this test range cannot be saved.

### List of Test Values Test

Enter a test code, description, unit, and list of valid values for this test data type. For example, Clear, Slightly Cloudy, and Turbid are valid list of test values. Test results must match an entry in the list.

### Text Range Test

Enter a test code, description, unit, and ordered list of valid values for this test data type. Defining a test of this type builds a lookup table where a text value in the list maps to a sequence number. Values in this ordered list are defined in a text or alphanumeric format so that the specification minimum, target value, specification maximum, and results are recorded as text or alphanumeric formatted values.

The sequence number is a display-only field that represents the order of the values relative to each other and to a result. Enter the text range values in the order used for results evaluation. By selecting New Record and then Insert Record, you can insert new values between existing values in the list.

The following is an example of entering a sequenced set of values for a Text Range test data type:

- The test minimum is A2.
- The test maximum is D2.
- The specification minimum is A1.
- The specification maximum is D1.

Sequence	Value
1	A2
2	A1
3	D1
4	D2

A specification against a Text Range test data type refers to a subset of this list of values as acceptable results. When you enter results, the application validates the value entered by looking up the corresponding sequence number in order to evaluate whether the results are within the acceptable range of the test or the specification.

## Numeric Range with Display Text

When you define a Numeric Range with Display Text test, the application builds a lookup table so that a numeric value in the list maps to a text equivalent. The application converts a numeric result into a text results for display and reporting purposes. You can define subranges within the numeric range that have individual display values assigned.

In the following example, a numeric result greater than or equal to zero and less than or equal to ten displays LOW. A result greater than or equal to 10.0001 and less than or equal to 20 displays MEDIUM.

Open-ended ranges are permitted. The maximum field in the last row of subranges is blank. Leave the minimum field on the first row of subranges blank to allow for values less than the maximum of the first subrange.

Range Minimum	Range Maximum	Displayed Text Result
0	10	LOW

Range Minimum	Range Maximum	Displayed Text Result
10.0001	20	MEDIUM
20.0001	30	HIGH
30.0001	No Value Entered	DILUTE AND REPEAT

### Subranges Cannot Overlap

Numbers used for a minimum or a maximum cannot be repeated for a specific test code. This allows for the less than or equal to condition and the greater than or equal to condition observed at the ends of ranges. It also allows for holes in ranges. In the previous example, 10 is used for the maximum of the first subrange. It cannot, however, be used for the minimum of the next subrange. When 10 is entered in as the maximum, of a subrange, the next minimum has a default minimum of 10.001.

### Display Text Can Be Repeated

Display text does not have to be unique for each subrange. This helps in situations where results below a certain number or above a certain number display RESULT OUTSIDE THE DETECTION LIMIT.

### Enter Single Numbers or a Range of Numbers

You can enter a single number rather than a range of numbers as a result. Each number in the list is associated to display text. If the numeric result is within the minimum and maximum values, then the result is associated to the specified display text. The Results window displays both the numeric result and equivalent display text. To enter a single number, enter it as both a minimum and maximum value.

## Expression Test

The Expression test data type lets you enter a mathematical expression to calculate test results. The application uses the results from other Numeric Range tests and constants, and applies a mathematical expression to calculate a result. You can save an expression type test that is based on a combination of other numeric-based tests.

### Use Valid Arithmetic Operators and Mathematical Functions

Valid arithmetic operators are: +, -, \*, /, and any SQL operators such as SQRT("A") and ABS("B"). Define the decimal precision of an Expression test data type. Change arithmetic operators, mathematical functions, and other tests used in the expression until the time that the Expression test is used in a specification. Once it is used in the specification, you cannot update it.

### **Business Rules Followed in Expression Test Data Types**

The following summarizes the business rules for Expression test data types:

- You can define experimental error for an Expression test data type.
- Tests that are referenced in the Expression test must be either Numeric Range or Numeric Range with Display Text, and not marked for deletion.
- Test codes that are referenced in an Expression test must be enclosed within double quotation marks. For example, FAHRENHEIT is a valid test code for entry in an Expression test, if the test for Fahrenheit is a defined test.
- Referenced tests must have lower test sequence numbers than the Expression test.
- Decimal precision defaults from the test method.
- Specification target, minimum, and maximum follow the same rules as for other numeric-based tests.
- The expression is calculated at result time when all referenced tests have a result entered in the result set. In cases of replicated or repeated tests that are referenced in the Expression test, the most recent result of the referenced test is used.
- Expression tests can only be added to a result set on an as needed basis if any and all of the referenced tests already exist in the result set.
- Expression tests are calculated regardless of whether the tests they reference pass or fail their individual specifications.
- You can save an expression type test that is based on a combination of other numeric-based tests. Some expressions can be calculated before all referenced tests are complete using the SQL command NR1. Also, if referenced test results are edited, expressions can be recalculated.

### **Entering Arithmetic Operators and Mathematical Functions**

To enter arithmetic operators, put quotation marks around the names of component Numeric Range tests used in the expression. Operands in the expression are enclosed within double quotation marks.

Tests A and B are two Numeric Range test codes:

- To add the two tests, enter "A"+"B"
- To subtract the two tests, enter "A"- "B"
- To multiply the two tests, enter "A"\*\*"B"

- To divide the two tests, enter "A"/"B"

Tests C and D are two Numeric Range tests:

- To take the square root of test C, enter SQRT("C"). If you use the POWER function, then enter POWER("C", (1/2))
- To take the cube root of test D, enter POWER("D", (1/3))
- To calculate an expression without the result of test D, enter NVL("D", 0)

#### **Example of Entering an Expression Test**

To enter an Expression test data type for calculation of Density, define the mathematical expression for Density, which is by definition, Density = Mass/Volume. Define tests for Mass and Volume. Define an Expression type test for Density. Enter "Mass"/"Volume" in the Expression field. Enter other appropriate fields for the Expression test.

## **Entering Tests**

The Tests window lets you define tests that become part of a specification, or that are added on an impromptu basis for sample analysis. Refer to the "Understanding Test Data Types" topic for details on the test data types you can enter on this window.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## **Prerequisites**

- Enter test methods and test units.
- Enter test classes to group specific tests into meaningful sets.
- Enter instruments to track them as resources.
- Enter quality action codes to assign them to experimental error regions for tests.
- Enter customers in Oracle Receivables to define customer-specific test information for reporting purposes.

## **To set up test data types:**

1. Navigate to the **Tests** window.
2. Enter a **Test** code for the test. For example, CHLORIDE. Required.
3. Enter a **Description** for this test code. For example, Chloride in mEq/L. Required.

4. Enter the **Class** code for this test data type. A description of the test class displays in the unlabeled field.
5. **Ordering** is the sequence of the test as it appears in a test group. Refer to "Setting Up Test Groups" for detailed information.
6. Enter the test **Method**. For example, Ion-Specific Electrode. Test Method entry is described in the "Entering Test Methods" topic. Required.
7. Select one of the following as test **DataType**:
  - **Non-Validated** if you do not want test results to cause the item or lot to be rejected. Enter a test code and description. Test results are recorded for future evaluation against the test value. Test results from this test data type do not cause an item or lot to be rejected. Non-validated results do not prevent a step from completing.
  - **Numeric Range** if you want an item or lot falling outside a specified range to be rejected. Enter a test code, description, and range of possible values.
  - **List of Test Values** if you want an item or lot to match an entry in a specific list of values. Enter a test code, description, and a list of valid test values for the test.
  - **Text Range** if you want an item or lot to match an entry in an ordered list, and a particular specification to restrict the acceptable entries to a subset of the list by specifying the limits of the subset. Enter a test code, description, and a list of valid values. The entries you make are sequenced automatically.
  - **Numeric Range with Display Text** if you want subsets of a numeric range to display text values. Enter a test code, description, subranges, and corresponding text values. Make the range open-ended by not making an entry in the minimum of the first subrange or the maximum of the last subrange.
  - **Expression** if you want to enter a mathematical expression for calculation of test results. Only those tests with numeric data types can be referenced. These are Numeric Range and Numeric Range with Display Text. For example, to calculate density, you define tests for mass and volume, since density equals mass divided by volume.
- Required.

Depending on selection of test data type, the remaining fields on the window vary. For example, if you select Numeric Range, then the Range fields are editable. If you select List of Specifications, then the Value and Description fields are editable.
8. Enter the test **Unit** code for the test. For example, enter mEq for milliequivalents.

The description of the unit displays. Required for all test data types except Non-Validated.

9. Enter the test **Priority** as **Low**, **Normal**, or **High**. Test priority determines the order a test displays on a worklist. Test priority is defined initially at the Test level. It can be overridden at the Specification level. A System Administrator can add to the seeded list of values for test priority using the lookup functionality.
10. **Replicate** displays the number of test replicates for this test. It defaults from the value entered on the **Test Methods** window. Enter this field if you have not defined a test method for this test.

### Values

11. Enter the fields as described for the test data type selected:
  - For a **Non-Validated** test data type, you cannot enter data in this panel.
  - For a **Numeric Range** test data type, enter the lower limit of the **Range** in the first field. Enter the upper limit of the range in the next field. You define the target value in the specification. For example, pH has a test range of 0 to 14, but an item could have a pH specification range of 4.2 to 6.7. The **Seq** field displays the sequence number of each value listed.
  - For a **List of Test Values** test data type, enter each possible **Value** required for item or lot characteristic state. Define the target value in the specification. Enter one value and description per line. For example, the value list could include RED, BLUE, and CLEAR, but an item could have a value specification of RED. The **Seq** field displays the sequence number of each value listed.
  - For a **Text Range** test data type, enter a **Value** and text **Description**. Enter values in the order you want. The text description represents the text to assign to each of the sequenced values. The **Seq** field displays the sequence number of each value listed.
  - For a **Numeric Range with Display Text** test data type:

Enter the minimum value for the interval in the **Min** field. Leave the first **Min** field blank for an open-ended test range. This field is automatically entered for each interval in the range after the first subrange. Required if it is not the first subrange.

Enter the maximum value for the interval in the **Max** field. When you enter a maximum value and tab to the next field, the **Min** field automatically displays the next **Min** value. Leave the last **Max** field blank for an open-ended test range. Required if it is not the last subrange.

Enter the text to **Display** when a test value is within the interval specified by the minimum and maximum values entered for the row.

The **Seq** field displays the sequence number of each value listed.

- For **Expression** test data types:

Enter the expression in the **Expression** field. Refer to the "Understanding Test Data Types" topic for guidance on entering an expression. To enter a test to reference in the expression, click **Test** and select the test code from the LOV. The test displays with double-quotation marks around it. Enter the appropriate arithmetic and mathematical operators outside the double quotation marks. Enter any SQL-compatible expression.

For example, to take the cube root of a test named EXAMPLE, click **Test**, select "EXAMPLE". Enter the following mathematical operators:  
POWER("EXAMPLE", (1/3)).

12. Enter the **Stored Precision** as the number of decimals stored and displayed for this test. The default value is entered on the **Test Methods** window. Required if the test entered is a Numeric Range, Numeric Range with Display Text, or an Expression type test.
13. Enter the **Report Precision** as the number of decimals to report on the Certificate of Analysis for this test. Values entered on the **Customer Display** window for a particular test override this information. The precision entered must be less than or equal to the value entered in the **Display Decimal Precision** field. Required if the test entered is a Numeric Range, Numeric Range with Display Text, or an Expression type test.
14. For Numeric Range, Numeric Range with Display Text, and Expression test data types to click **Experimental Error** to display the **Experimental Error** window. Define an experimental error region that is calculated from either a percentage of the entire test range, or from a number representing the tolerance around the specification minimum or maximum. Values entered default to the test when it is added to a specification.
15. Click **Customer Display** to display the **Customer Display** window where you can enter an optional customized set of test-specific information used to run a report on this test for specific customers.
16. Save the window.

### To insert a new row in a List of Test Values, Text Range, or Numeric Range with Display Text test:

You can only insert a new row for these test data types if the test is not already used in a specification and has results entered for it.

1. Position the cursor on the row directly above where you want to insert the row. For

example, to insert a row between the second and third entries in the list, position the cursor at the second entry.

2. Choose **New** from the **File** menu. A new blank row inserts directly below the row selected.
3. Enter new values.
4. Save the window.

### **To enter a new test method:**

1. Choose **Test Methods** from the **Actions** menu. The **Test Methods** window displays.
2. Enter the new test method as described in the "Entering Test Methods" topic.

### **To mark a test for purge:**

1. Choose **Mark for Purge** from the **Actions** menu. The record is marked for deletion. Once a test is marked for deletion, you cannot edit it.
2. Save the window.

### **To edit text in a test:**

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** dialog box displays.
2. Make appropriate text changes.
3. Save.

### **To edit text in a List of Test Values, Text Range, or Numeric Range with Display Text test:**

1. Position the cursor on the record to edit in the **Values** tab.
2. Make appropriate text changes.
3. Save the window.

## **Entering Customer Display Information**

The Customer Display dialog box lets you enter an optional customized set of

test-specific information used when you run a report for specific customers. Display this dialog box from the Tests window where a specific test is entered or maintained. This information includes a test alias label that prints on customer-specific quality certificates, and the decimal precision to show for test results.

## Prerequisites

- Enter the test to customize with customer-specific information.

### To enter customer display information:

1. Navigate to the Customer Display dialog box.
2. Enter a **Customer** previously defined in Oracle Receivables.
3. **Number** displays the customer account number that corresponds to the customer entered.
4. Enter a label or customer alias name for the test to **Display** on all reports generated. This field overrides the test name when it displays on a customer-specific quality certificate.
5. Enter **Report Precision** to use for the customer. Enter the preference for decimal precision for numeric results printed on a quality certificate. The report precision defined here overrides the precision entered on the Tests window. You can only enter this field for Numeric Range, Numeric Range with Display Text, and Expression test data types for a customer-specific quality certificate.
6. Click **OK** to navigate back to the Tests window.

## Entering Experimental Error

Experimental error accounts for inaccuracy and imprecision in test results by defining action zones around the specification limits or target. User actions such as RETEST display as warnings when a test result falls inside the experimental error range.

You can define experimental error at the test level for Numeric Range, Numeric Range with Display Text, and Expression test data types. When a test is associated to a specification, the corresponding experimental error values default from the test. However, you can override these values at the specification level.

## Understanding Experimental Error Regions

The experimental error region is calculated from either a percentage of the entire test range, or from a number representing the tolerance around the specification minimum or maximum. Experimental error regions cannot overlap. If gaps are entered, then an

error displays when the specification is validated.

Experimental error is defined for any combination of regions:

- Experimental error region below the specification minimum = Specification Minimum - Number or, Specification Minimum - (Percentage \* Test Range)
- Experimental error region above the specification minimum = Specification Minimum + Number or, Specification Minimum + (Percentage \* Test Range)
- Experimental error region below the specification maximum = Specification Maximum - Number or, Specification Maximum - (Percentage \* Test Range)
- Experimental error region above the specification maximum = Specification Maximum + Number or, Specification Maximum + (Percentage \* Test Range)

The experimental error regions below the Specification Minimum and above the Specification Maximum can overlap with the out-of-specification regions.

The following is a specific example of a Numeric Range test data type:

- Test data type is Numeric Range.
- Test range C is from 0 to 14.
- Test minimum at point A is 0.
- Test maximum at point B is 14.
- Test error type is number.
- Item specification range F is from 8 to 12.
- Specification minimum at point D is 8.
- Specification maximum at point E is 12.
- When a test error of plus or minus 1 is applied:
  - Specification minimum - test error at point G is 7.
  - Specification minimum + test error at point H is 9.
  - Specification maximum - test error at point I is 11.
  - Specification maximum + test error at point J is 13.

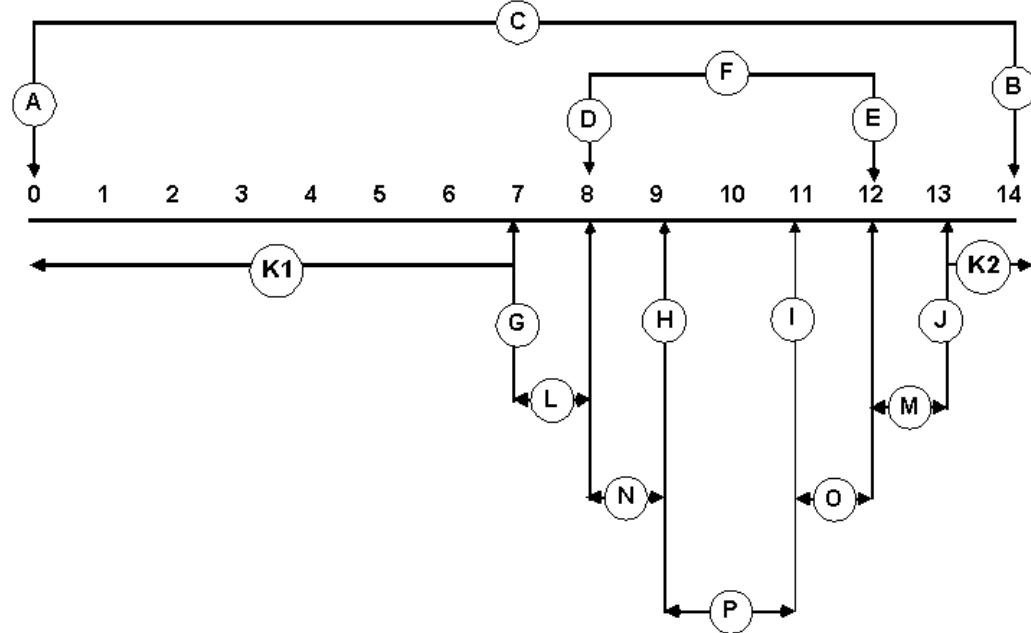
The following is an assessment of values:

- Values less than 7 and greater than 13 are outside the specification, as shown by

ranges K1 and K2.

- Values ranging from:
  - 7 to 8 are outside the specification, but within the experimental error region, as shown by range L.
  - 12 to 13 are outside the specification, but within the experimental error region, as shown by range M.
  - 8 to 9 are within the specification, but also within the experimental error region, as shown by range N.
  - 11 to 12 are within the specification, but also within the experimental error region, as shown by range O.
  - 9 to 11 are within-specification, as shown by range P.

The following graphic depicts the previously described points, ranges, and values using the specific example of a Numeric Range test data type:



## Assigning Action Codes

Associate an action code to each of the experimental error regions that you define. If an experimental error is not defined for a test, then action codes cannot be assigned.

Entering a result within the experimental error region displays a warning message with the associated out-of-specification action code. Appropriate action codes also display for results that are outside the specification limits. Refer to the *Oracle Inventory User's*

*Guide* for detailed information on setting up action codes.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Define action codes in Oracle Inventory.
- Enter a test that requires entry of experimental error.

### To enter experimental error for a test:

1. Navigate to the **Experimental Error** window.
2. Select the **Error Type**:
  - **Percent** to indicate the specification value for calculating the experimental error regions is a percent.
  - **Number** to indicate the specification value for calculating experimental error regions is a number.Required.
3. Enter one or more of the following fields:
  - **Below Specification Min** to define the percentage or number to use in calculating the experimental error region below the specification minimum. Enter the beginning of the action zone at the low end of the specification.
  - **Above Specification Min** to define the percentage or number to use in calculating the experimental error region above the specification minimum. Enter the end of the zone of the action zone at the low end of the specification.
  - **Below Specification Max** to define the percentage or number to use in calculating the experimental error region below the specification maximum. Enter the beginning of the action zone at the high end of the specification.
  - **Above Specification Max** to define the percentage or number to use in calculating the experimental error region above the specification maximum. Enter the end of the action zone at the high end of the specification.
4. Enter the appropriate **Action** code to associate with the experimental error region. The **Action Description** field displays the action associated with the code entered.
5. Optionally, press **Reset** to reset the values to those displayed when you originally

displayed the window.

6. Click **OK** to return to the **Tests** window.

#### **Example of Entering Experimental Error**

A test has a range of 0 to 200. The test has an experimental error of plus or minus two percent of the specification minimum. Two percent is four points on either side of the specification minimum. If results are inside this action zone, then the individual performing the test must repeat it, and alert the individual requesting the test or owner of the sample. The action RTAO is defined to indicate Retest and Alert Owner.

In this case, select Percent as Error Type, enter 2 in the Below Specification Min field, and enter 2 in the Above Specification Min field. Enter RTAO in the Action field to indicate that you want to retest the sample and alert the sample owner. After you click **OK** and save the window, the experimental error and action is applied to the database.

In the Specifications window, you can override the test numbers or add percentages for an action zone around the specification maximum. The specification minimum for this example is 90, the specification maximum is 170, and the test default experimental error is plus or minus two percent. Enter a result of 91. This is within the action zone which ranges from 86 to 94. The application displays a warning on the appropriate Results window with the action code and action code description.

## **Finding Tests**

The Find Tests dialog box lets you find tests by class, method, data type, test unit, priority, or if they are marked for deletion.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## **Prerequisites**

- Enter a test.

### **To find a test:**

1. Navigate to the Find Tests dialog box.
2. Enter any of the following to narrow your search:
  - **Test code**
  - **Class** code for the test data type

- **Method** for the test
- **Data Type** for the test
- **Unit** as test unit for the test
- **Priority** for the test as High, Low, or Normal

3. Select **Marked for Deletion** as:

- **Yes** to find tests that are marked for deletion.
- **No** not to find tests that are marked for deletion.
- Leave this field blank to not limit your search based on whether a test is marked for deletion.

4. Click **Find**. The **Test** window displays the results of the search.

#### To create a new test from the Find Tests dialog box:

1. Click **New**. The **Tests** window displays.
2. Create a new test as described in the "Entering Tests" topic.
3. Save the window.

# 4

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## Specifications

This topic explains the basic concepts of quality specifications. You are shown how to enter and find specifications and their associated specification validity rules for both item and monitoring specifications. Specification summaries available from the Quality Workbench navigator are described.

This chapter covers the following topics:

- Requirements
- Understanding Specifications
- Using Lot UOM Conversions Based on Quality Results
- Understanding the Status Approval Workflow
- Adding and Editing Status Codes
- Entering Status Details
- Finding a Status Code
- Understanding Specification Version Control
- Understanding License Plate Numbers for Containerization
- Entering a Specification
- Copying a Specification
- Finding an Item Specification
- Entering an Item Specification Validity Rule
- Displaying the Item Specification Validity Rules Summary
- Entering a Monitoring Specification Validity Rule
- Displaying the Monitoring Specification Validity Rules Summary
- Displaying Specification Summaries from the Navigator

## Requirements

Following are some requirements that were addressed in defining and managing specifications in Oracle Process Manufacturing (OPM) Quality Management.

### Can several item specifications with the same set of tests, but different ranges be set up?

Yes. Define the specification for an item and grade to distinguish specifications with the same test requirements, but different limits or targets. Use base and overlay specification functionality to refine a series of specifications.

#### Enter the Item Grade on a Specification

The entry of grade to grade-controlled item specifications facilitates the regrading of materials sampled and improves specification matching capabilities. Define several specifications for grade-controlled items. Compare results to these different specifications and change lot attributes under the appropriate circumstances. Use the overlay specification functionality to refine a series of specifications for an item as related to a base specification.

### Is there a way to set up a test that needs to be performed several times on a sample?

Yes. Define the test replicate on the specification as the number of times the test needs to run.

#### Specify the Number of Test Replicates for a Test on a Specification

To simplify data entry, test replicates are specified to denote the number of times a test should be performed on an instrument against the same sample. For example, if a test should be repeated three times on a sample, then the test can be defined on a single line of the specification record with a test replicate of three. The application adds result lines on the results record corresponding to the number of replicates specified on the applicable specification. For composite results and specification matching functionality, the result with the latest result date, acceptable value, and highest test replicate number is used.

### Does every test on a specification have to be used for evaluating results?

No. Mark a test as Optional to indicate that it is not required to meet a specification. Use the Consider Optional Tests Results parameter in the Process Quality Parameters window to configure whether an optional test that appears on the specification and results records contributes to the final disposition of the sample.

See: "Setting Up Process Quality Parameters."

#### Mark Tests as Optional

Mark a test as optional to indicate that it is not required to meet specification. Tests

marked as optional are not considered when selecting available inventory that matches the customer specification. Results of these tests are not included in the compositing of results. However, if results are entered for optional tests, then they can be included in the results set when assigning a final sample disposition of Accept, Accept with Variance, or Reject. Optional tests are not considered when updating the sample disposition, or material status and grade. They cannot be used to control batch step status based on quality results. Use the Consider Optional Tests Results parameter in the Process Quality Parameters window to configure whether an optional test that appears on the specification and results records contributes to the final disposition of the sample. Refer to "Setting Up Parameters" for details. For example, a new test is measured over time but does not factor into sample dispositions until its test limits are formalized based on the results collected. If an optional test result must be used, then its result evaluation follows the existing business rules to change sample disposition. An out-of-specification result for an optional test only permits the sample disposition to change to Accept with Variance, Reject, or Cancel.

### **Can the tests required when a lot expires be identified?**

Yes. A Lot Retest/Expiry indicator on the specification shows which tests need to be done when a lot expires.

#### **Indicate the Purpose of Retesting**

The specification Lot Retest/Expiry indicator identifies which tests need to be performed when retesting an expired lot, or when retesting is required. An indicator also appears on the sample record to identify the purpose of retest. Send an electronic notification to create a sample based on the dates for lot retesting or lot expiration scenarios. The corresponding results record lists only the tests marked by the specification Lot Retest/Expiry indicator.

### **Can results that are printed on the Certificates of Analysis be controlled?**

Yes. Set up certificate formatting options on the item specifications. The specification validity rule applies these options to the certificate type specified.

#### **Choose Quality Certificate Formatting Options on the Specification**

Specify whether to print specification targets, limits, and results on a quality certificate when you define a specification. You can format the certificate for customers who receive these documents. The Specification Validity rule uses settings for these options.

### **Can specifications developed for internal versus external use be controlled?**

Yes. Use specification validity rules to control item specifications developed for inventory, WIP, customer shipment, and supplier receipts. Configure the customer display on the Tests window and the report precision on individual specifications.

#### **Validity Rules and Status Control Specification Use**

The item specification validity rule provides the specific information for how and when an item specification version applies to inventory, process execution, order management, and receiving operations. The item specification validity rule controls the:

- Intended use of the specification, including inventory, WIP, customer, or supplier
- Certificate of Analysis or Certificate of Conformance requirements at invoice, at shipment, or from supplier
- Associated sampling plan
- Inventory update for the sample quantity
- Batch step completion based on quality sampling and results
- Lot attributes update with default in-specification and out-of-specification material statuses, with the exception of the WIP item specification validity rule

## **Can customer test results on certificates they receive be formatted?**

Yes. Select the certificate type on the specification validity rule.

### **Select the Certificate Type on the Item Specification Validity Rule**

Select the Certificate of Conformance or Certificate of Analysis on the item specification validity rule. You can specify the type of quality certificate to send to customers who receive these documents.

## **Understanding Specifications**

Specifications state the quality conformance requirements for materials, such as an item or a lot, or for environmental conditions, such as a resource or a subinventory locator.

### **Item Specifications**

Item specifications identify a target or ideal result for each quality test performed by listing test requirements that specify these characteristics or attributes. When you complete the initial quality setup, then combine tests and test methods to design specifications. The specifications entered are used to compare against actual test results from samples taken. For range-validated tests, define the minimum and maximum acceptable range values for the test as well as the out-of-specification action to perform when a test fails. View or update a specification only if your responsibility is associated with the specification owner organization.

From the owner organization, you can copy a specification with the status Approved for General Use to one or more organizations associated with your responsibility.

## Monitoring Specifications

Create a specification for a set of calibration tests on a resource or locator. A resource can be an instrument in a quality laboratory, or a piece of equipment in a plant. View the scheduled tests for this specification in context with the sample load for an instrument. Monitoring specifications are used to list the acceptable conditions for each variant storage condition in a stability study. When you create a monitoring specification, the Item and Grade fields on the Specifications window cannot be entered.

## Using Specification Versions and Status Approval

Specification name, version, and the approval processes provide the flexibility and control required to manage quality specifications. The combination of Spec and Version fields lets you define several specifications for the same item, parent lot, and lot combination, batch work in process, individual customers, suppliers, resources, or subinventory locators. Status lets you determine the approval level of a specification. Use the Status Approval workflow to ensure that the appropriate internal or external individuals are notified when a quality specification version is created or modified. The combination of version control and status control lets you track changes to the specification record, and helps enforce consistency when evaluating results against specification requirements.

## Creating a Base and Overlay Specification

Define new specifications either as a base specification, or as an overlay specification that references a base specification. The base specification contains the framework as a standard set of tests, or all possible tests to build overlays. Version and status control on the base specification affect the definition and usage of the dependent overlay specifications. You can only create an overlay specification from a base specification that has a status of Approved for Lab Use, or Approved for General Use. Configure the overlay specification to exclude tests carried over from the base specification. You can also create several overlays to model various test frequencies. The overlay specification can include additional tests. For example, you can create an overlay specification for purposes of customer acceptance of the material or to fulfill regional regulatory requirements. Base and overlay specifications can be created for both item and monitoring specification types. Copy a base specification with the status Approved for General Use to one or more inventory organizations. Overlay specifications associated to the base specification are also copied.

## Setting Up Test Requirements

Set up test methods and tests prior to entering a specification. Refer to "Entering Test Methods" and "Entering Tests" for discussions of test requirements.

## Understanding Test Sequence

Test sequence is a sequence number entered in the Seq field on a specification. Test sequence specifies the relative sort order of tests that display in a specification and results set. When a test is added to a specification, the application enters the test sequence number as a sequential integer multiple of ten. You can override the application-assigned sequence (Seq) by entering a different number. When you save changes, the application sorts the list of tests again in ascending order based on the test sequences on the specification. However, the test sequence cannot be changed on the Results window. When you add a new test to the set of results, it is added to the end of the set.

## Marking Optional Tests

Mark a test as optional on a specification to indicate that it is not required criteria to determine the quality conformance or acceptability of an item. Tests that are marked optional are not considered in specification matching.

## Setting the Lot Retest/Expiry indicator to Indicate the Purpose of Retesting

The Lot Retest/Expiry indicator identifies tests on the specification that need to be performed when retesting an expired lot, or when retesting is required at specified intervals. Set this indicator for each test on a specification. The Lot Retest/Expiry indicator is also included on the sample record to identify it for retesting purposes. When a notification is sent to create a sample based on lot retesting or lot expiration dates, the sample record is marked for lot retest. Results are expected for these tests when they are selected as Lot Retest/Expiry tests on the specification.

## Recommending Lot-Specific Interclass UOM Conversions Based on Test Results

Use quality test results to update a quality attribute that varies from lot to lot in inventoried material. For example, when the active ingredient of a raw material varies across lots, despite the standard potency established for all lots of a particular item, you adjust for this variability by storing a lot conversion factor between the primary and secondary units of measure for the material based on quality test results for the specific attribute. The conversion factor is recommended for multiple test replicates when testing is in progress or complete. It is also recommended for the latest test replicate when the final sample group is assigned. When a result is entered for a sample from a supplier source where the lot is not yet received into inventory, the lot-specific interclass UOM conversion update must be done manually.

## Understanding Experimental Error Used in Tests

Experimental error accounts for inaccuracy and imprecision in test results by defining an action zone around the specification limits or target as well as associated user actions

such as retesting. Experimental error is defined initially at the test level for Numeric Range, Numeric Range with Display Text, and Expression test data types only. The Experimental Error region is calculated from either a percentage of the entire test range or from a number representing the tolerance around the specification minimum or maximum. Experimental error regions must not overlap or have gaps with respect to the specification limits or the target. If they do, then an error displays when the specification is validated. Associate an action code to each of the experimental error regions for a test. If no experimental error regions are defined for a test, then action codes cannot be assigned. Override the experimental error values and actions defaulting from the test definition at the specification level. When you enter a result that is within the experimental error region, the application displays a warning message with the associated experimental error region action code. If a result falls within an experimental error region that is also outside the specification limits, then the experimental error action code takes precedence over any out-of-specification action that is predefined on the specification.

Refer to "Entering Experimental Error" for more information.

## **Indicating Certificate Formatting Options on the Specification**

You can specify whether to print specification targets, limits, and results on a quality certificate when you enter a specification. If a generic or customer-specific test alias was previously specified during test definition, then the alias is used to generate the quality certificate. These formatting options are used when generating a quality certificate.

## **Specifying the Expiration of Tests on a Specification**

You can specify the time window that a sample is viable for analysis. This information assists in planning laboratory tests and managing time-sensitive tests.

## **Using Item Specification Validity Rules**

The Validity Rules for Item Spec window lets you define the validity rule type as inventory, WIP, customer, or supplier for item specifications for the process-enabled organization you select. It also lets you assign date ranges within which the specification is effective. With the appropriate responsibility, you can override the system default values for the indicators that control the inventory update for the sample quantity, batch step status, and lot attributes update. When associating a specification version to a sample, the application uses a predefined hierarchy to select the specification validity rule that most closely meets the information identified with the sample. Select Update Inventory Quantity in the Process Quality Parameters window to enforce an inventory transaction for drawing the sample quantity and to decrease inventory accordingly.

See: "Setting Up Parameters."

If an item substitution affects the quality specifications required for a batch, then you can change the specification association for a sample during sample creation or

specification comparison. Refer to the *Oracle Process Manufacturing Product Development User's Guide* for detailed information on item substitution

## Specifying Certificate Type on the Specification Validity Rule

A results set that has a sample group disposition of Accept or Accept with Variance must exist before you print a Certificate of Analysis. Select the Certificate Type on the Specification Validity Rule to designate either Certificate of Conformance or Certificate of Analysis as the type of quality certificate to generate, and whether the certificate is required at invoice, at shipment, or from the supplier.

## Creating a Monitoring Specification Validity Rule

Monitoring specification usage is controlled by the monitoring specification validity rule. Specify either of these attribute groups:

- Organization, Subinventory, or Locator
- Organization, Resource, or Resource Instance

The monitoring specification is used primary for controlling the environmental conditions in a stability study, but it is not limited to this functionality. Create and use monitoring specifications for other resources or locators to assess as part of your quality operations in the supply chain.

## Matching Customer Specifications in Oracle Order Management

The specification matching process only works with Oracle Order Management. In order for specification matching to function properly, set up a specification for the item to match. The specification must have an effective customer specification validity rule that coincides with the scheduled ship date. If a test has more than one replicate in the customer specification, then only the most recent replicate is considered in the matching process. Sample dispositions must be marked Accept or Accept with Variance. All tests not marked as optional in the specification must have a result, and they must be marked In-spec.

The specification matching procedure accepts and searches for any combination of parent lots, lots, and locators. Searches for locators require that an active subinventory is available for the item. This allows the procedure to be used for non-lot-controlled items.

The search for a matching customer specification delivers:

- Results that are in-specification
- Results that are out-of-specification
- No matching results

### Accessing Specification Matching from Oracle Order Management

You can view the matching customer specifications in Oracle Order Management from the Sales Order Allocations window or from the Oracle Inventory Transact Process Move Orders window using the Manual Allocate option.

The Quality Match field on the Available Inventory tab of these windows displays the level at which the specification matching results correspond to the customer specifications for the line item selected. If a result corresponds to the entry on the Quality Match field, then one of these values displays:

- Acceptable (Yes)
- Unacceptable (No)
- Not Applicable (Blank)

Click Review Spec to display the specification, specification version, and customer specification validity rule associated to the selected line item. Click Review Results to display results associated to the selected line item.

Refer to *Using Oracle Order Management with Process Inventory* for more information on these applications.

Refer to "OPM Product Analysis Workbook" in the *Oracle Business Intelligence System User's Guide* for more information on customer specification matching based on the Oracle Process Manufacturing (OPM) Order Fulfillment application.

### Finding a Customer Specification

To find a customer specification, the specification matching operation uses the base customer hierarchy. In the specification matching process, it then considers local, global, and other plant specification validity rules. Refer to Appendix B for detailed information on customer specification matching.

Refer to *Using Oracle Order Management with Process Inventory* for additional information.

### Using Lot UOM Conversions Based on Quality Results

Use quality test results to propose a new lot-specific UOM for an item lot. This is useful for items that have attributes that vary from lot to lot. A sample is assigned a final disposition of Accept, Accept with Variance, or Reject, and you can make a lot UOM conversion update based on the final results. You can also view historical recommendations for prior test replicate results against the sample.

For example, the standard protein concentration of item ABC is:

1 milliliter (mL) = 0.10 Protein Concentration Unit (PCU)

Lot1 of item ABC is received, and the protein concentration determined by quality testing is:

1 mL = 0.13 PCU

The actual potency of the lot is 0.03 PCU greater than the standard protein concentration for the item. It is useful to create a precise lot UOM conversion for item ABC Lot1 so that 1 mL = 0.13 PCU. If several samples are taken for the same lot and the results are composited, then the average composite result becomes the conversion factor.

Lot UOM conversions from quality results are proposed when a sample group disposition changes to Accept, Accept with Variance, or Reject. The UOM Conversion tab on the Quality Change Disposition window displays lot UOM conversions derived from sample group results. Accept the recommended conversions, or reject them. After an e-signature is processed for the sample disposition change, the Oracle Process Manufacturing (OPM) Quality UOM Conversion workflow sends a notification with the UOM conversion information to each of the defined workflow roles. In this notification, a link is created to the Oracle Inventory Lot Specific Conversions window that displays the proposed conversion. Transactions and inventory balances can be updated based on the recommended lot-specific UOM conversions. The lot UOM conversions are performed based on acceptance of the proposed conversions in OPM Quality Management. When this process is complete, close out the workflow notification.

## Prerequisites

- Create inventory parent lots and lots.
- Set up the OPM Quality UOM Conversion workflow.

## To set up for item lot UOM conversions:

1. Decide which item lot UOM conversions are dependent on quality results. You can only apply UOM conversions to items that are lot controlled.

From UOM = X \* To UOM, where X is the result value, and the From UOM and To UOM are UOMs that are specified on specification test. The From UOM defaults to the primary UOM of the item. You can select a different From UOM.

For example, mL is entered as ML in the application. A UOM conversion is desired for item ABC, lot LOT1 for protein concentration between the ML UOM and the Protein Concentration Unit (PCU) based on quality results. The From UOM is ML and the To UOM is PCU. The base UOM for volume is L and 1L = 1000 ML.

2. Create the tests to generate lot UOM conversion recommendations based on quality results.

For example, create a numeric test, Protein Concentration%, with a test unit of %, since the concentration is recorded as a percentage. Create an expression test called

Protein Concentration Expression with a test unit of PCU\_TEST. The expression for this is (Protein Concentration %) /100. This expression is created to obtain the 1ML = X PCU conversion where X is the result value.

3. Create the desired specification.

Add tests to the specification and select the Calculate UOM Conversion next to the conversion tests. Specify the From UOM and To UOM for the conversion for the test. The From UOM displays the primary UOM for the item. Specify the To UOM for the conversion. The To UOM cannot belong to the same UOM class as the From UOM. Two test lines that belong to a single specification can reference the To UOMs that belong to the same UOM Class.

For example, the tests Protein Concentration % and Protein Concentration Expression to specification Spec1 for item ABC and lot LOT1. Select the Calculate UOM Conversion indicator for test Protein Concentration Expression, and enter the From UOM as ML and a To UOM as PCU.

4. Save and approve the specification.
5. Create and approve a specification validity rule that applies to the desired lot.

### To convert units of measure based on quality results:

1. Record samples and results for all tests saved on the item specification created in the previous setup task.

For example, create the sample PR1 00093. There is one sample in the sample group for item ABC, lot LOT1 using the specification Spec1. Enter the results for the sample PR1 00093 as follows:

Test	Test Unit	Result	Auto UOM Conv Indicator	From UOM	To UOM
Protein Concentration %		10	N/A	N/A	N/A
Protein Concentration Expression	PCU_TEST	10/100 = 0.1	Selected	ML	PCU

2. Navigate to the **Quality Change Disposition** window.
3. Change the sample group disposition to **Accept**, **Accept with Variance**, or **Reject**.

4. Click the **UOM Conversion** tab. The application enters all data displayed on this tab:
  - If at least one test on the specification has the Calculate UOM indicator selected
  - If the **Change Disposition To** field displays **Accept**, **Accept with Variance**, or **Reject**
  - If the sample group source is **Inventory** or **Supplier**

Data appears on this tab even when test results are out-of-specification.  
If a lot UOM conversion already exists for the lot, then the current conversion between the UOM class of the base UOM and the UOM class of the To UOM is displayed below the new proposed conversion.
5. Select the **Recommend** indicator next to the desired UOM conversions. If this indicator is not selected, then the proposed conversion is not used in inventory.
6. Click **OK** to change the disposition of the sample group.
7. Provide an e-signature for the disposition change if one is required.
8. Receive the OPM Quality UOM Conversion workflow notification.
9. Click the **UOM Conversion** link to the **Oracle Inventory Lot Specific Conversions** window, and save to create the conversions.

## Understanding the Status Approval Workflow

When the Oracle Process Manufacturing (OPM) Quality Spec Status Change Approval workflow and the OPM Quality Spec Validity Rule Status Change Approval workflow are activated in Oracle Process Manufacturing Quality Management, new versions of specifications and their specification validity rules require a series of approvals that result in reassigning their statuses through a predefined approval process. Laboratory approval is optional.

Stability study statuses are preseeded. Refer to "OPM Quality Stability Study Change Status Workflow" in Appendix C for additional information.

## Setting Up the Status Approval Workflows

Set up the workflows using the Approvals Management Business Analyst responsibility. Contact a system administrator if you are not sure that this is set up.

## Enabling the Status Approval Workflow

Enable workflows using the Workflow Administrator Event Manager responsibility.

Once workflows are set up and operating, each workflow is activated by changing the Status of a specification from New to any of the other available status.

## Adding and Editing Status Codes to the Status Approval Workflow

If you modify or delete any of the predefined status codes that are supplied with this application, then the workflows do not run as described in this documentation. Add or edit status codes as described in "Adding and Editing Status Codes."

## Running the Status Approval Workflow

When an item specification, or item validity rule is created, workflows run as follows:

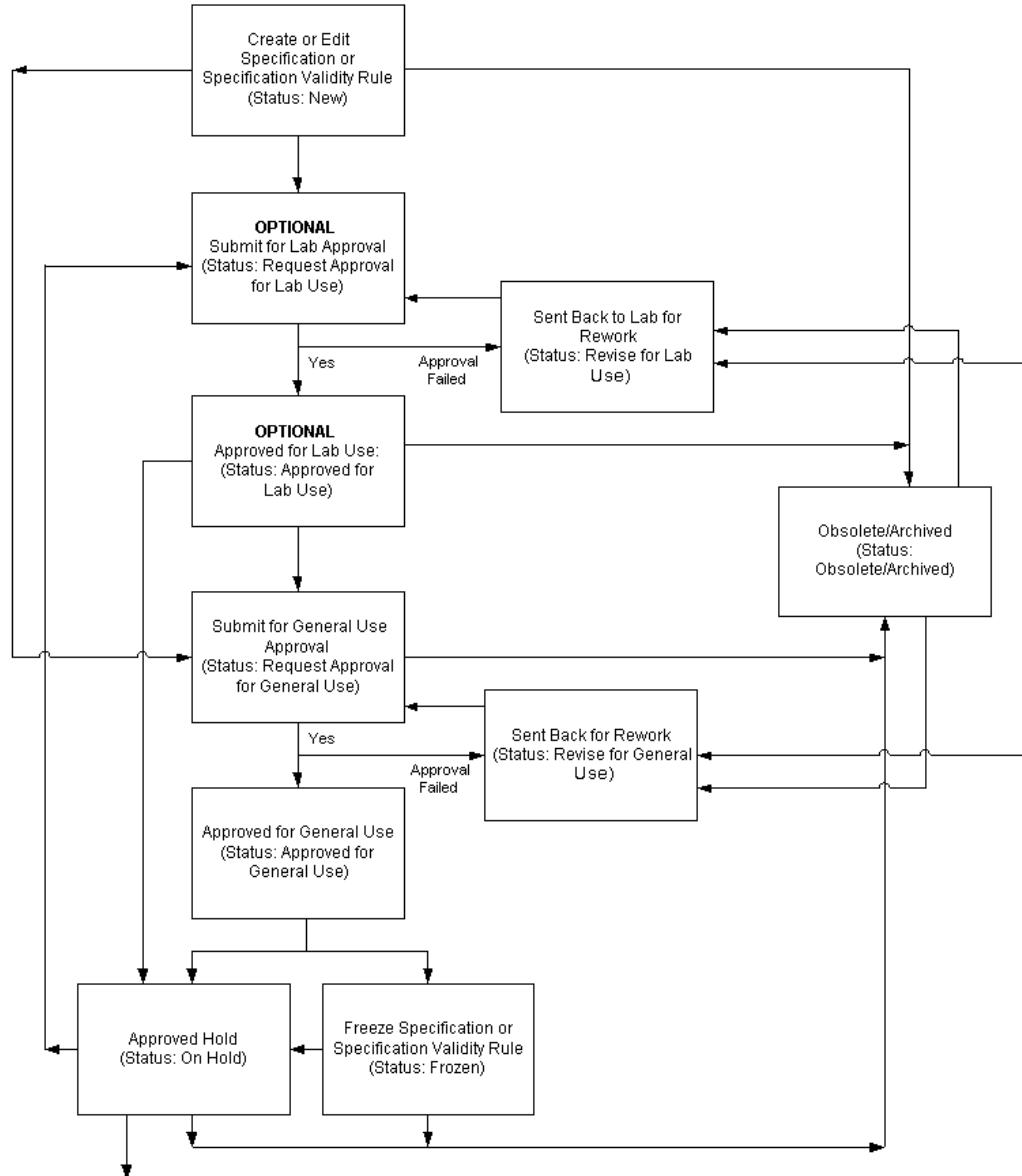
1. Upon creation, by default, the **Status** for a specification or validity rule is assigned as **New**.
2. If you choose **Change Status** from the **Actions** menu and then select **Approved for Laboratory Use**, then the workflow changes Status to **Request Approval for Laboratory Use**. Once approved, Status changes to **Approved for Laboratory Use**.
3. If you choose **Change Status** from the **Actions** menu and then select **Approved for General Use**, then the workflow changes Status to **Request Approval for General Use**. Once approved, Status changes to **Approved for General Use**.
4. Assign the Status as **Obsolete** or **Archived**.
5. An **Approved for Laboratory Use** status are assigned these statuses:
  - On Hold
  - Obsolete
  - Archived
6. An **Approved for General Use** status are assigned these statuses:
  - On Hold
  - Frozen
  - Obsolete
  - Archived
7. A **Pending Approval for Laboratory** status or a **Pending Approval for General Use** status are assigned these statuses:
  - Obsolete

- Archived

8. Specification validity rules that:

- Fail the approval of **Pending Approval for Laboratory Use** Status are assigned **Revise for Laboratory Use**.
- Fail the approval of **Request Approval for General Use** Status are assigned the **Revise for General Use**.

The following depicts the previously described workflows for versions of specifications and specification validity rules:



## Disabling the Status Approval Workflow

Disable the status approval workflow using the Workflow Administrator Web Applications responsibility. If the workflow is disabled, then you can change the status of a specification or a validity rule manually. However, the status change does not initiate a workflow.

## Adding and Editing Status Codes

Add to or edit the predefined status codes. Modification or deletion of the predefined status codes that are supplied with the application may result in the workflows not

working properly.

Stability studies have a preseeded status approval workflow. Refer to the "OPM Quality Stability Study Change Status Workflow" topic in Appendix C for additional information on these customized status codes.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Read the "Understanding the Status Approval Workflow" topic.

### To add a new status code:

1. Navigate to the **Status Codes** window.
2. Choose **New** from the **File** menu. A new row displays.
3. Enter a new **Status Code**. The number you enter is sorted into ascending order with the other status codes when you save and reopen the Status Codes window.

Codes entered between two predefined codes, such as 101 to 199, or 201 to 299 are included in the workflow associated with the predefined status code with the same first digit. For example, if you enter the code 110, then it becomes part of the workflow associated to code 100. If you enter a code number 699, then it becomes part of the workflow associated to code 600. Predefined status codes display in a table at the end of this task. Required.
4. Enter a **Description** for the status code. Required.
5. Enter the information to display on the Status field in the **Meaning** field. Required.
6. **Enable Version** determines whether the status code entered is set up for version control. Any modification made to a specification or a specification validity rule while it is set to the status entered in the Meaning field initiates or bypasses activation of a new version depending on the selection you make here, and the value entered for the specification version control profile option.
  - Select **Enable Version** if you want the status code to enable version control when a modification is made to a specification or specification validity rule. The specification version control profile option must be set to Yes or Optional.
  - Deselect **Enable Version** if you want the status code to bypass version control when a modification is made to a specification or specification validity rule.
7. Save the window.

8. Click **Details** to enter Status Details as described in the "Entering Status Details" topic.

The following are required predefined status codes:

<b>Code</b>	<b>Meaning</b>	<b>Description</b>	<b>Enable Version</b>
100	New	Can make changes at any time, assuming security access is granted.	Yes
200	Request Approval for Laboratory Use	Submitted for approval of use in the laboratory.	No
300	Revise for Laboratory Use	Approval has failed and rework is required.	No
400	Approved for Laboratory Use	Can be used in laboratory.	Yes
500	Request Approval for General Use	Submitted for final approval.	No
600	Revise for General Use	Approval has failed and rework is required.	Yes
700	Approved for General Use	Can be used for production batches and cost rollups.	Yes
800	On Hold	Cannot be used until status is changed.	No

Code	Meaning	Description	Enable Version
900	Frozen	Prevents further changes to specification, specification validity rule, and any dependent data. Both specification and specification validity rule can still be used.	No
1000	Obsolete/Archived	Can no longer be used unless status is changed.	No

### To edit an existing status code:

1. Navigate to the **Status Codes** window.
2. Edit the following fields as required:
  - **Description** to change the explanation of the status code.
  - **Meaning** to change the information that displays on the Status field in the application.
3. **Enable Version** determines whether the status code entered is set up for version control. Any modification made to a specification or a specification validity rule while it is set to the status entered in the Meaning field initiates or bypasses activation of a new version depending on the selection you make here, and the value you select for Version Control in the Process Quality Parameters window.
  - Select Enable Version if you want the status code to enable version control when a modification is made to a specification or specification validity rule. The Version Control indicator in the Process Quality Parameters window must be set to Yes or Optional.
  - Deselect Enable Version if you want the status code to bypass version control when a modification is made to a specification or specification validity rule.
4. Click **Details**. The **Status Details** window displays.
5. Edit the following fields as required:

- **Target Status** to change the code that appears as the destination status on the **Quality Change Status** window. Required.
- **Rework Status** to change the destination for the listed status code when it is not accepted and must be reworked.
- **Pending Status** to change the destination of the listed status code when it enters the approval workflow, and is pending approval.

6. Edit the **Workflow Indicator** by selecting:

- **Enable or Disable Workflow** to indicate that the fields listed in the row enable or disable the workflow.
- **Workflow Approval** to indicate that the fields listed in the row require workflow approval.
- **No Workflow Approval** to indicate that the fields listed in the row do not require workflow approval.

Required.

7. Click **OK**.

8. Save the window.

## Entering Status Details

The Status Details window lets you enter a target status for a new status code. You can enter rework status, pending status, and indicate how you want workflow to manage the status entered.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

### To enter status details:

1. Navigate to the **Status Details** window.
2. Enter a **Target Status** for the new status code. This code appears as the destination status on the **Quality Change Status** window. Enter several destinations for each status code. They must be entered on separate lines. Required.
3. Optionally, enter a **Rework Status**. This code defines the destination for the listed status code when it is not accepted and must be reworked.

4. Optionally, enter a **Pending Status**. This code defines a destination of the listed status code when it enters the approval workflow and is pending approval.
5. Select one of the following as **Workflow Indicator**:
  - **Enable or Disable Workflow** to indicate that the fields listed in the row enable or disable the workflow.
  - **Workflow Approval** to indicate that the fields listed in the row require workflow approval.
  - **No Workflow Approval** to indicate that the fields listed in the row do not require workflow approval.

Required.
6. Click **OK**.
7. Save the window.

## Finding a Status Code

The Find Status Codes dialog box lets you find a status code by code number, description, enable version, or mark for purge status.

### To find a status code:

1. Navigate to the Find Status Codes dialog box.
2. Enter one or more of the following fields to narrow your search:
  - **Status Type** as Specifications or Stability Study.
  - **Status Code** to find a specific code number.
  - **Description** to find a specific status code description.
  - **Enable Version** determines whether the status code entered is set up for version control. Any modification made to a specification or specification validity rule while it is set to the status entered in the Meaning field initiates or bypasses activation of a new version depending on the selection you make here and the value you select for Version Control in the Process Quality Parameters window.
 

Select Enable Version to find the status codes that enable version control when a modification is made to a specification or specification validity rule.

Clear Enable Version to find the status codes that bypass version control when

a modification is made to a specification or specification validity rule.

- **Mark For Deletion** lets you find status codes with the status:
  - Yes** indicating the status code has been marked for purge
  - No** indicating that the status code has been undeleted.

3. Click **Find** to display the results of your query.
4. Click the down arrow to display all status codes that were found.
5. Click **New** to enter a new status code. The **Status Codes** window displays.

## Understanding Specification Version Control

Some businesses require version control to generate an audit trail. By enforcing version changes you define rules for modifying quality specifications. Version control lets you determine if an existing version can be modified, or if a new version must be created. Quality Management lets you:

- Force the creation of new versions so that transaction sources stay intact.
- Deliver a combination of forced version creation and no version control.
- Provide no version control.

These decisions are made at the organization level with proper assignment of User Responsibilities. Status must be Approved for General Use for version control to be active. All other statuses do not require that a new version be created each time a change is made.

Version control does not validate the fields on a specification header. These fields cannot be changed once a specification is saved. A new specification must be created in order to change these fields, whether or not version control is used. Version control does not take the Status field into account when determining whether a new version should be created. This is also true for Mark for Purge and Undelete functions.

## Setting Up Specification Version Control

Navigate to the Process Quality Parameters window. Select one of the following for **Version Control**:

- **Yes** to activate version control. Any change requires a new version.
- **No** to indicate that version control is not activated. You can make changes to the existing version.

- **Optional** to indicate that version control is optional. You can create a new version if a change is made to the existing version.

You can set version control to an appropriate level of activation. It is recommended to set version control initially to Optional. You are notified when you attempt to save changes. The setting of these options is based on your individual business requirements.

## Understanding License Plate Numbers for Containerization

License Plate Numbers (LPN) uniquely identify each container in the supply chain. A license plate number is a unique identifier for a collection of items in a single location. LPNs store their contents, including item, revision, lot quantity, current location, organization, subinventory, locator and serial numbers.

The LPN enables you to track the contents of each container. You use LPN to store and transact inventory throughout the supply chain. You can also individually transact LPNs during the packing or unpacking, reservation, and shipment sealing processes.

When a product is yielded into containers, the product with a single lot is yielded into multiple containers or multiple lots into multiple containers. Each of the containers would be equivalent to an LPN.

You can now enter an LPN for containerization as the requirement to yield the product from the desktop application as well.

You can enter an LPN number for a product or associate to a lot number in the yield transaction. The LPN information for yielding is entered manually. You can enter the product lot information in the Material Transaction window. You cannot associate the LPN information to pending lots or products.

You can create an item sample against the lot and optionally enter an LPN and then apply an item specification based on the specification matching hierarchy rules. You can also enter an LPN, or Delay an LPN entry for a product. For example, in batch creation, the sample is used against the lot. Once the material is tested and filled into an LPN container, the specified LPN is associated with the sample (this is known as delayed entry of LPN for a sample).

Although an LPN may be specified for a sample, there is no requirement to define a quality specification at the LPN level.

You can query a sample record based on its LPN for results entry and evaluation. The results can be used to change the lot status accordingly. If a particular container within the lot requires a status that is different from other containers in the same lot, then a lot split transaction must be performed, because status is maintained at the lot level not at the LPN level.

**Note:** LPNs are applicable only for Warehouse Management System (WMS) enabled organizations.

Refer to the *Material Management* chapter of the *Oracle Warehouse Management Users Guide Release 12* for detailed information on the license plate numbers.

## Entering a Specification

The Specifications window lets you define, view, or edit a quality specification.

The window associates tests, targets, actions for results, and certificate formatting options with Specification Validity Rules to create usable, valid quality specifications. You can enter an item specification or a monitoring type specification.

Select a context organization that your responsibility can access using the Organizations window.

## Entering a Base Specification

The creation of a base specification provides a template to maintain a set of common tests and targets that you can propagate into overlay specifications. This process lets you customize individual test and target requirements on the overlay without compromising the integrity of the base specification. You cannot create overlay specifications with the same name.

## Entering an Overlay Specification

The creation of an overlay specification lets you add new tests and targets to a base specification. You can override the test line data on the base specification. You can also exclude certain tests included in the base specification that do not apply to your customized evaluation needs. Refer to the "To create an overlay specification" task for the procedure to create an overlay specification.

## Entering a Monitoring Specification

A monitoring specification defines the details of the storage condition for each variant in the stability study. The monitoring specification provides the test requirements needed to evaluate the acceptability of environmental conditions for a variant storage condition in a stability study. Use the monitoring specification to define and monitor environmental conditions outside the stability study. Refer to the "Entering Monitoring Samples" topic for additional information on taking samples for the monitoring specification. Select the Spec Type as Monitoring to create a monitoring specification and follow the procedure to enter a specification.

## Workflow Procedures

Refer to "Appendix C" for additional information on workflow procedures.

## E-Record and E-Signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix D" for additional information on e-record and e-signature approvals associated with this window.

You can use folders, flexfields, and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Define tests, test methods, and sampling plan.
- Set up the process quality parameters using the Process Quality Parameters window.
- Select an organization that your responsibility can access using the Organizations window.

## To enter a base specification:

1. Navigate to the **Specifications** window.
2. Enter **Spec** as the name for the specification. Required.
3. Enter a **Version** for the specification. Required.
4. After entering all relevant information and saving the specification with the default **Status** of **New**, return to this window to change specification status by choosing **Change Status** from the **Actions** menu. Depending on whether the status approval workflows are enabled, a different set of statuses is available.

Select a **Status** for the specification you are entering from one of the following:

- **Approved for Laboratory Use** to indicate that the specification is approved for laboratory use.
- **Approved for General Use** to indicate that the specification is approved for use in work in process.
- **Obsolete/Archived** to indicate that the specification is no longer approved for use and is obsoleted, archived, or both.

If the status approval workflows are enabled when you select:

- **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers have accepted the specification, then

its Status changes to Approved for Laboratory Use.

- **Approval for General Use**, then Status changes to **Request Approval for General Use** until all approvers have accepted the specification, then its Status changes to Approved for General Use.

5. Enter a brief **Description** of the specification. Required.
6. Select **Spec Type** as:
  - **Item** to enter a specification for a process quality-enabled inventory item.
  - **Monitoring** to enter a specification to monitor an environmental condition.
7. Do not select the **Overlay** indicator. This ensures you enter a base specification. Refer to the "To create an overlay specification" task for the procedure to create an overlay specification.
8. **Base Spec** displays the base specification.
9. **Version** displays the version of the base specification.
10. Enter the **Item** code for the material being specified as listed on the Item Master. The item must be associated with the context inventory organization and set up as process quality-enabled in the Item Master. Refer to the *Oracle Inventory User's Guide* for detailed information. The item description displays. Required if the Spec Type is Item. You cannot enter an item for a Monitoring type specification.
11. Enter the item **Revision** for revision-controlled items.
12. Enter a **Grade**. If the item is lot-controlled and grade-controlled, then the grade on this specification is used to update the grade of a lot. You cannot enter a grade for a Monitoring type specification.
13. The **Owner Organization** defaults from the context organization and displays your default organization. You can designate an organization as the owner organization for many specifications.
14. The **Owner** of this specification displays. Change this entry to anyone who has access to the Owner Organization. Required.

### Targets

15. Enter **Seq** as the sequence of the test in the specification. This field populates with an integer number beginning with 10. Each test added increases the number displayed in this field by 10. Required.

16. Enter the **Class** code for this test. This field defaults from the test entered. You cannot enter a class for a Monitoring type specification.
17. Enter a predefined **Test** code for this specification. The list of tests available for entry is filtered if a test class was entered. Required.
18. Enter the test **Method**. This field defaults from the **Tests** window.
19. **From Base** is display only. It is cleared when the test in the row is not from the base specification.
20. The **Exclude** indicator is selected when the test listed in the row is eliminated from an overlay specification. If you are entering an overlay specification, select the indicator to exclude a test, or deselect the indicator to include a test from the overlay specification.
21. The **Modify** indicator is selected to amend data on the test line. The base data is protected from modification until the indicator is selected. If the Modify indicator is disabled, then data on the test line reverts to its original base state, and is protected from updates. You can only select this indicator when the test listed in the row is derived from the base specification.
22. Enter the specification **Target** value for the test code. Depending on the test data type, the specification target may or may not be validated. For example,
  - For **Non-Validated** test data types, the specification target is not validated. Any entry is accepted in this field, including a blank.
  - For **Numeric Range**, **Numeric Range with Display Text**, or **Text Range** test data types, enter a value within the specification limits as defined in the **Minimum** and **Maximum** fields. Tighten the specification limits for a test by entering new values in the **Minimum** and **Maximum** fields to replace the default values of the test range.
  - For **List of Test Values** test data types, enter a valid value from the list of values available for the test.
  - For **Expression** test data types, enter a value within the calculated expression test specification limits.
23. Enter the specification **Minimum** value that is acceptable to meet specification requirements, if the test data type is **Numeric Range**, **Numeric Range with Display Text**, **Text Range**, or **Expression**. This field defaults from the **Tests** window.
24. Enter the specification **Maximum** value that is acceptable to meet specification requirements, if the test data type is **Numeric Range**, **Numeric Range with Display Text**, or **Text Range**, or **Expression**. This field defaults from the **Tests** window.

25. **Unit** displays the default quality unit of measure for the test entered. This field defaults from the **Tests** window.
26. Enter the **Quantity** of material required to perform the test. This field defaults from the **Tests** window.
27. **UOM** displays the unit of measure in Oracle Inventory for the test quantity. This field defaults from the **Test Method** window.
28. Enter **Replicate** as the number of times that the test is repeated for the same sample. This field defaults from the **Test Methods** window.
29. Enter the test **Priority** as **Low**, **Normal**, or **High**. Test priority identifies the relative priority of a test, and used to sort tests listed in a specification. Test priority is defined initially at the test level. You can override it here at the specification level.
30. Select **Optional** if the test is not required for the specification. You can indicate that a Result Set is complete even if an optional test is incomplete. Use Consider Optional Tests Results in the Process Quality Parameters window to configure whether an optional test that displays on the specification and results records contributes to the final disposition of the sample.

See: "Setting Up Process Quality Parameters"

31. Select **Lot Retest/Expiry** to indicate whether this test is required for lot retesting or expiration testing.

### **Actions**

32. The following fields display the values entered on the **Targets** tab:
  - **Seq** displays the sequence of the test in the specification. This field populates with a number beginning with 10. Each test added increases the number displayed in this field by 10. Required.
  - **Class** code displays the class for this test data type. This field defaults from the **Tests** window.
  - **Test** displays the test code for this specification. Required.
33. Enter the **Out of Spec Action** as the action to take if the result of the test falls outside the specification range. This action displays a message window on the **Results** window.
34. **Description** displays a brief explanation of the action entered.
35. Enter one of the following in the Interval field, depending on how you implement action codes in Oracle Inventory:

- Enter the number of days between the expiration date and the date that the action must be taken.
- Enter the number of days after the failed quality test date that the action must be taken.

36. **Error Type** displays the type of numerical or percentage Experimental Error associated with a numeric-based test. This defaults from the **Tests** window.

37. **Calculate UOM Conversion** functions with the **From UOM** and **To UOM** fields to convert the item primary UOM to a desired To UOM:

- Select Calculate UOM to use the test result as an item lot conversion in Oracle Inventory.
- Deselect Calculate UOM if you do not want the result value for this test to be used as an item lot conversion in the Oracle Inventory .

**Note:** Calculate UOM Conversion is disabled if the Spec Type is Monitoring.

38. The **From UOM** field displays the specification item in its primary UOM. You can select a different From UOM.

39. Enter the **To UOM** as the desired item lot conversion UOM. The UOM class must differ from the From UOM class and other UOM classes used on tests that belong to the specification. Required if the Calculate UOM Conversion indicator is selected. Refer to the "Using Lot UOM Conversions Based on Quality Results" topic for an example of the OPM Quality Management UOM conversion process.

40. The following fields are entered on a test-specific basis on the **Experimental Error** window:

- **Below Minimum** displays the percentage or number to be used in calculating the experimental error region below the specification minimum. This is the beginning of the action zone at the low end of the specification.
- **Below Minimum Action** displays the Action code associated with the Below Minimum experimental error region.
- **Above Minimum** displays the percentage or number to be used in calculating the experimental error region above the specification minimum. This is the end of the action zone at the low end of the specification.
- **Above Minimum Action** displays the Action code associated with the Above

Minimum experimental error region.

- **Below Maximum** displays the percentage or number to use in calculating the experimental error region below the specification maximum. This is the beginning of the action zone at the high end of the specification.
- **Below Maximum Action** displays the Action code associated with the Below Maximum experimental error region.
- **Above Maximum** displays the percentage or number to use in calculating the experimental error region above the specification maximum. This is the end of the action zone at the high end of the specification.
- **Above Maximum** displays the Action code associated with the Above Maximum experimental error region.

### Formatting

41. The following fields display the values entered on the **Targets** tab:
  - **Seq** displays the sequence of the test in the specification. This field populates with a number beginning with 10. Each test added increases the number in this field by 10. Required.
  - **Class** code displays the class for this test data type. This field defaults from the **Tests** window.
  - **Test** displays the test code for this specification. Required.
42. **Alias** displays an alternate name for the test. This field defaults from the **Tests** window.
43. Select **Print Spec** to print the specification target, minimum, and maximum values for this test on quality certificates. Deselect if you do not want to print these values on quality certificates.
44. Select **Print Result** to print the result of this test on quality certificates. Deselect if you do not want to print results on quality certificates.
45. Enter **Stored Precision** as the number of decimals to store and display for the specification target, minimum, maximum, and test result. This value defaults from the value entered on the **Tests** window. Required.
46. Enter **ReportPrecision** as the number of decimals to print on quality certificates for the specification target, minimum, maximum, and test result. This value defaults from the value entered on the **Tests** window. Required.

## Planning

47. The following fields display the values entered on the **Targets** tab:

- **Seq** displays the sequence of the test in the specification. This field populates with a number beginning with 10. Each test added increases the number in this field by 10. Required.
- **Class** code displays the class for this test data type. This field defaults from the **Tests** window.
- **Test** displays the test code for this specification. Required.

48. The following fields function as a single entry for the test expiration time:

- Enter **Test Expiration Days** as the number of days allowable for the test to run after the sample is drawn.
- Enter **Test Expiration Hours** as the number of hours allowable for the test to run after the sample is drawn.
- Enter **Test Expiration Minutes** as the number of minutes allowable for the test to run after the sample is drawn.
- Enter **TestExpiration Seconds** as the number of seconds allowable for the test to run after the sample is drawn.

For example, if a test expiration is 1 day, 6 hours, and 30 minutes after the sample is drawn, enter:

- 1 in the **Test Expiration Days** field
- 6 in the **Test Expiration Hours** field
- 30 in the **Test Expiration Minutes** field

49. Save the window.

## To enter validity rules for the specification:

1. Click **Validity Rules**. The **Validity Rules Summary for Item Spec** window displays.
2. Click **New** to create a new validity rule.
3. Enter appropriate information on the window. Refer to the "Entering Specification Validity Rules" topic for additional information.

4. Save the window.

### To duplicate the specification:

1. Choose **Duplicate**, then choose **Record Above** from the **Edit** menu. All fields are copied.
2. Choose **Record Above** from the **Edit** menu. All fields are copied.
3. Enter a new **Name**, **Version**, and changes to other fields.
4. Save the window.

### To mark a specification for purge:

Choose **Mark for Purge** from the **Actions** menu. The record is marked for deletion.

### To edit text in the specification:

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.
2. Make appropriate text changes.
3. Save the window.

### To display test details:

1. Select the desired test.
2. Choose **Tests** from the **Actions** menu. The **Tests** window displays for the selected test.

### To create an overlay specification:

1. Enter the required specification header information for an item specification or a monitoring specification.
2. Select the **Overlay** indicator.
3. Select the **Base Spec** and **Version** with a status of Approved for Lab Use or Approved for General Use to generate the overlay specification. The Tests region of the window displays all data copied from the selected base specification. The From Base indicator is cleared if a test line was not derived from the base specification.

4. Select the **Exclude** indicator to exclude a test from the overlay specification.
5. Select the **Modify** indicator to modify other applicable fields in the row. If you select this field, then depending on the test type, enter each of the fields in the row to modify.
6. Select the next **Seq** to add a test to the overlay specification. Enter all necessary test information.
7. Save the window.
8. Create a specification validity rule. Refer to the "Entering Specification Validity Rules" topic for additional information.

### To create a monitoring specification:

1. Enter the required specification header information for a monitoring specification.
2. Select **Spec Type** as **Monitoring**.
3. Enter all necessary test information for the monitoring specification as discussed in the "To enter a base specification" task.
4. Save the window.
5. Create a monitoring specification validity rule. Refer to the "Entering a Monitoring Specification Validity Rule" topic for additional information.

### To assign a test group to a specification:

1. Navigate to the **Specifications** window.
2. Query the desired specification to assign a test group.
3. Choose **Add Test Group** from the **Actions** menu. The **Test Group** window displays. Add tests to a specification that has a status of New, Revise For General Use, or Revise For Lab Use. If the flexfield for specification tests is mandatory, then you cannot use this option.
4. Query the desired **Test Group** as the test class that is also group enabled. The window displays all tests included in that test group.
  - **Ordering** is the sequence of the test in the group as entered on the Tests window.
  - **Test** is the name of the test entered.

- **Description** is the description of the test code.
- **Data Type** is the test data type as described in "Understanding Tests."
- **Qty** is the amount of material required for the test. This defaults from the test quantity specified for the test method.
- **UOM** is the unit of measure for the test quantity defined in the test method.

5. Select **Include** to indicate the tests in the group to be copied to the specification. The Include indicator is disabled for tests that were previously added to the specification. To include an additional test replicate on the specification, increase the replicate by one.
6. Click **OK**. Selected tests are added to the specification.
7. Save your work.

## Copying a Specification

You can copy a specification to one or more local organizations that are different from the owning organization. After the specification is copied, the local organization becomes the owner organization and you can make changes to the copied specification locally. If overlay specifications are associated to the copied specification, then they are copied along with the selected base specification. The Copy Specification menu option is enabled if the status of the specification is Approved for General Use.

### To copy a specification:

1. Navigate to the **Specifications** window.
2. Choose **Copy Specification** from the **Actions** menu. The **Copy Spec** window displays.
3. **Owner Organization** defaults from the Specifications window and displays the owner organization of the source specification.
4. **Specification** displays the source specification name.
5. **Version** displays the version of the source specification.

### Copy To

6. Enter the local inventory organizations to which you are copying the specification in the **Organization** fields.
7. **Specification** displays the specification name of the copied specification. The owner

organization name to which it is copied to is appended to the specification name. If you edit the default specification name, ensure that it is unique.

8. The **Version** defaults to 1. You can edit the version.
9. Click **Copy** to save a copy of the specification to each local organization you specify.

## Finding an Item Specification

The Find Specifications dialog box lets you find a specification based on its code, version, item or monitoring specification type, status, item, grade, or owner organization. You can also find item specifications that are overlays to a base specification, and identify base specifications by version.

### Prerequisites

- Enter an item specification or a monitoring specification.

### To find a specification:

1. Navigate to the Find Specifications dialog box.
2. Enter any of the following to narrow your search:
  - **Spec** code entered for the specification
  - **Version** number of the specification
  - **Spec Type** as Item or Monitoring
3. Select **Overlay** to find overlay specifications of a specific base specification, and leave the Base Spec field blank to find all overlay specifications. Deselect Overlay to exclude overlay specifications from the search.
4. Enter any of the following to narrow your search:
  - **Base Spec** as a specific base specification
  - **Base Spec Version** as a specific base specification version
  - **Status** as the specification status
  - **Item** code as the item code for the material being specified as it is listed on the Item Master. The item must be set up as process quality-enabled.
  - **Revision** as the item revision, if the item is revision-controlled

- **Grade** as the assigned to the item listed in the specification
- **Owner Organization** as the owner organization entered for the specification
- **Owner** as the owner of the specification

5. Select **Marked for Deletion** as:

- **Yes** if you want find specifications that are marked for deletion.
- **No** to exclude specifications that are marked for deletion.
- Leave this field blank to limit your search based on whether a specification is marked for deletion.

6. Click **Find**. The **Specifications** window displays the results of the search.

### To create a new specification from the Find Specifications dialog box:

1. Click **New**. The **Specifications** window displays.
2. Create a new specification as described in the "Entering a Specification" topic.
3. Save your work.

## Entering an Item Specification Validity Rule

The Item Spec Validity Rules window lets you define the usage of the specification validity rule at the inventory, work in process, customer, and supplier levels.

Define specification validity rules for each process quality-enabled item in your inventory, for each customer or supplier that you sell to or buy from, or for each recipe or work in process batch that you produce. Also, you can define a specification validity rule for an item grade.

### E-record and E-signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix D" for additional information on e-record and e-signature approvals associated with this window.

Refer to "Solutions" for additional information.

Refer to "Appendix B" for the hierarchies of validity rules.

You can use folders, flexfields, and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Enter and save a specification.
- Optionally, enter a sampling plan.

## To enter an item specification validity rule:

1. Navigate to the **Item Spec Validity Rules Summary** window.
2. Click **New**.
3. **Spec** displays the specification name. This defaults from the Specifications window.
4. **Version** displays the specification version.
5. **Item** displays the item code for which you are creating the specification validity rule. The item must be set up as process quality-enabled in the Item Master in Oracle Inventory. If the item is an engineering item, then the organization must be process-enabled and set up as a research and development lab.
6. **Revision** displays the item revision, if the item is revision-controlled.
7. **Grade** displays the grade associated to the item on the specification, if the item is grade-controlled.
8. **Spec Status** displays the status of the specification used in the validity rule. Specification status is discussed in "Entering a Specification."
9. Click one of the following to create a validity rule for the item and optional grade entered:
  - **Inventory** to create a specification validity rule for inventoried item. Proceed to step 10.
  - **WIP** to create a specification validity rule for work in process (WIP). Proceed to step 23.
  - **Customer** to create a specification validity rule for a customer. Proceed to step 34.
  - **Supplier** to create a specification validity rule for a supplier. Proceed to step 45.

### Inventory

10. **Organization** displays the default process-enabled organization for the validity rule.

11. After entering all relevant information and saving the validity rule with the default **Validity Rule Status** of **New**, return to this window to change specification status by choosing **Change Status** from the **Actions** menu. Depending on whether status approval workflows are enabled, a different set of statuses is available.

Select a **Status** for the specification you are entering:

- **Approved for Laboratory Use** to indicate that the validity rule is approved for laboratory use.
- **Approved for General Use** to indicate that the validity rule is approved for use in work in process.
- **Obsolete/Archived** to indicate that the validity rule is no longer approved for use and is obsoleted, archived, or both.

If status approval workflows are enabled, when you select:

- **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers accept the validity rule, then its Status changes to Approved for Laboratory Use.
- **Approval for General Use**, then Status changes to **Request Approval for General Use** until all approvers accept the validity rule, then its Status changes to Approved for General Use.

12. Enter the **Parent Lot** for the specification validity rule to apply to all lots of the parent lot. Refer to "Understanding Sampling" for detailed information on sampling parent lots.
13. Enter the **Lot** for the specification validity rule to apply to a specific lot. Leave the field blank to apply to all lots.
14. Enter a **Subinventory** code to create the specification validity rule for a particular subinventory in the specified inventory organization. Leave the field blank to indicate that the specification validity rule is applicable to all subinventories within the organization.
15. Enter a **Locator** to create this specification validity rule for a particular locator of the specified subinventory. Leave this field blank to indicate that the validity rule is applicable to all locators within the subinventory.

#### Control

16. The **Delayed LPN Entry** checkbox will be enabled for a WMS enabled organization. Select **Delayed LPN Entry** to enable the entry of an LPN number during the final disposition of a sample. Deselect to prevent an LPN number from being entered during the final disposition of a sample. If you enter an LPN number during sample creation, then the LPN number cannot be changed when assigning the sample

disposition.

17. The following controls default from the process quality parameters configured by the inventory organization:
  - **Create Samples Automatically** to enable automatic sample creation. This defaults from the Process Quality Parameters window. Deselect to disable automatic sample creation using this validity rule.
  - **Update Inventory Quantity** to enforce an inventory transaction for drawing the sample quantity and to decrease inventory by the sample amounts taken for testing. Update Inventory Quantity defaults from the process quality parameters for the organization specified. The item must be transactable in the inventory organization. This indicator is not enabled if the item is serial controlled.
  - **Control Lot Attributes** to control lot status, grade, and hold date based on the final disposition of the sample group. This indicator defaults from the process quality parameter for the organization specified. Specify the **In-Spec** and **Out-Spec** material statuses.
  - Select **Lot Optional on Sample** to skip the entry of a lot during sample creation for a lot-controlled item. Deselect this selection to require a lot to be entered on a sample.
  - Select **Delayed Lot Entry** if Lot Optional On Sample is selected to enable the entry of a lot during the final disposition of a sample. Deselect to prevent a lot from being entered during the final disposition of a sample. If you enter a lot number during sample creation, then the lot cannot be changed when assigning the sample disposition.
18. To define **Effective Dates** for this validity rule:
  - Enter **From** as the starting date and time for the validity rule. This defaults to the current system date and time.
  - The **To** date indicates the date and time the validity rule is no longer effective. Leave this field blank until you stop this validity rule from being effective.
19. To define **Certificate**, select **Certificate Type** as:
  - **Certificate of Analysis** to generate a certificate of analysis when this validity rule is selected.
  - **Certificate of Conformance** to generate a certificate of conformance when this validity rule is selected.

When you select the certificate type, choose any of the following to indicate at

which stage the certificate is generated or required:

- Select **Invoice** to generate it at invoice time.
- Select **Shipment** to generate it when the item is shipped.
- Select **Supplier** if the certificate is required when the item is received from a supplier.

20. Enter the **Name** of the **Sampling Plan** to associate to this validity rule. If the sample quantity defined on the sampling plan is not greater than or equal to the sum of the planned test quantities on the specification, then a warning message displays. The following fields display when a sampling plan is specified:

- **Count** displays the number of samples to take at each instance of the sampling frequency entered.
- **Quantity** and **UOM** indicate the sample size, or the amount of material and its inventory unit of measure.
- **Per** indicates the sampling frequency period. Count, Frequency Type, and Frequency Period or Per fields work together to define the number of repetitions for sampling.

21. Save the window.

#### **WIP**

22. Select a process-enabled inventory **Organization**. The organization is defined as a Plant or research and development Laboratory organization. If the item is an engineering item, then the organization must be defined as a research and development laboratory.

23. After entering all relevant information and saving the validity rule with the default **Validity Rule Status** of **New**, return to this window to change specification status by choosing **Change Status** from the **Actions** menu. Depending on whether status approval workflows are enabled, a different set of statuses is available.

Select a **Status** for the specification you are entering from one of the following:

- **Approved for Laboratory Use** to indicate that the validity rule is approved for laboratory use.
- **Approved for General Use** to indicate that the validity rule is approved for use in work in process.
- **Obsolete/Archived** to indicate that the validity rule is no longer approved for use and is obsoleted, archived, or both.

If status approval workflows are enabled, when you select:

- **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers accept the validity rule, then its Status changes to Approved for Laboratory Use.
- **Approval for General Use**, then Status changes to **Request Approval for General Use** until all approvers accept the validity rule, then its Status changes to Approved for General Use.

If status approval workflows are enabled, when you select:

- **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers accept the validity rule, then its Status changes to Approved for Laboratory Use.
- **Approval for General Use**, then Status changes to **Request Approval for General Use** until all approvers accept the validity rule, then its Status changes to Approved for General Use.

24. Enter the **Batch** number for which this validity rule is applicable. If you enter a valid batch number, then the following fields display with batch-specific information:

- **Recipe** indicates the recipe and **Version** used in the batch.
- **Formula** indicates the formula and **Version** used in the batch.
- **Formula Line** indicates the line in the formula controlled by this validity rule. The formula line **Type** displays.
- **Routing** indicates the routing associated to the recipe and **Version** used in the batch.
- **Operation** indicates the operation controlled by this validity rule and its **Version**.

If a batch number is not entered, then enter a recipe, formula and version, formula line, routing, or operation and version.

**Note:** If a batch is specified, then the material detail line is used instead of the formula line.

25. Enter **Step** and **Charge** on a new WIP specification validity rule, for the sample from a WIP source with the specified step or charge can get the specification for this validity rule.

26. **Control** indicates what to affect with this validity rule. The following controls default from the process quality parameters configured by the inventory organization:

- **Create Samples Automatically** to enable automatic sample creation. This defaults from the Process Quality Parameters window. Deselect to disable automatic sample creation using this validity rule.
- **Update Inventory Quantity** to decrease inventory by the sample amounts taken for testing. This indicator defaults from the process quality parameters for the organization specified. This is disabled if the item is serial controlled.
- **Control Batch Step Status** to control the batch step status for the selected validity rule.
- **Control Lot Attributes** to control lot status, grade, and hold date based on the final disposition of the sample group. This defaults from the process quality parameters for the organization. Specify **In-Spec** and **Out-Spec** material statuses.

27. The **Delayed LPN Entry** checkbox will be enabled for a WMS enabled organization. Select **Delayed LPN Entry** to enable the entry of an LPN number during the final disposition of a sample. Deselect to prevent an LPN number from being entered during the final disposition of a sample. If you enter an LPN number during sample creation, then the LPN number cannot be changed when assigning the sample disposition.

28. Select **Lot Optional on Sample** to require a lot to be entered for a sample of a lot-controlled item. Deselect if you do not want to require a lot to be entered on a sample for a lot-controlled item. This defaults from the Process Quality Parameters window.

29. If **Lot Optional On Sample** is selected, then **Delayed Lot Entry** is available. This field defaults from the selection in the Process Quality Parameters window. Update this field if the item specification validity rule status is changed to Approved, Frozen, or Obsoleted/Archived. If **Delayed Lot Entry** is selected, then the samples created must have lot entered after sample creation. If you enter a lot number during sample creation, then the lot is used to choose a sample group and it cannot be changed.

30. To define **Effective Dates** for this validity rule:

- Enter **From** as the starting date and time for the validity rule. This defaults to the current system date and time.
- The **To** date indicates the date and time the validity rule is no longer effective. Leave this field blank until stop this validity rule from being effective.

31. To define **Certificate**, select **Certificate Type** as:
  - **Certificate of Analysis** to generate a certificate of analysis when this validity rule is selected.
  - **Certificate of Conformance** to generate a certificate of conformance when this validity rule is selected.

When you select the certificate type, choose any of the following to indicate at which stage the certificate is generated or required.

  - Select **Invoice** to generate it at invoice time.
  - Select **Shipment** to generate it when the item is shipped.
  - Select **Supplier** if the certificate is required when the item is received from a supplier.
32. Enter the **Name** of the **Sampling Plan** to associate to this validity rule. If the sample quantity is not greater than or equal to the sum of the planned test quantities on the specification, then a warning message displays. The following fields display when a sampling plan is specified:
  - **Count** displays the number of samples to take at each instance of the frequency entered.
  - **Quantity** and **UOM** indicate the sample size, or the amount of material.
  - **Per** indicates the frequency period. Count, Frequency Type, and Frequency Period or Per fields work together to define the number of repetitions for sampling.
33. Save the window.

**Customer**

34. **Organization** displays the default organization for the validity rule.
35. After entering all relevant information and saving the validity rule with the default **Validity Rule Status** of **New**, return to this window to change specification status by choosing **Change Status** from the **Actions** menu. Depending on whether status approval workflows are enabled, a different set of statuses is available.

Select a **Status** for the specification you are entering from one of the following:

- **Approved for Laboratory Use** to indicate that the validity rule is approved for laboratory use.
- **Approved for General Use** to indicate that the validity rule is approved for use

in work in process.

- **Obsolete/Archived** to indicate that the validity rule is no longer approved for use and is obsoleted, archived, or both.

If status approval workflows are enabled, when you select:

- **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers have accepted the validity rule, then its Status changes to Approved for Laboratory Use.
- **Approval for General Use**, then Status changes to **Request Approval for General Use** until all approvers have accepted the validity rule, then its Status changes to Approved for General Use.

36. Enter the **Customer** number for which the specification validity rule is applicable. Required.
37. Enter the **Operating Unit** to narrow the selection of a customer ship-to-location or bill-to-location for the specification validity rule.
38. Enter the **Customer Location** as the ship-to-location or bill-to-location to which the specification validity rule applies.
39. Enter the **Order** number from existing orders in the Oracle Order Management application for the operating unit specified.
40. **Type** displays the sales order type code from those that are set up for the operating unit in the Oracle Order Management application. This field only displays when an order is specified.
41. **Line** displays the sales order lines associated to the entry made in the Order field.
42. **Control** indicates what to affect with this validity rule. Select **Lot Optional on Sample** if you do want to require a lot to be entered on sample of a lot-controlled item. Deselect this selection if you do not want to require a lot to be entered on a sample for a lot-controlled item. This defaults from the Process Quality Parameters window.
43. To define **Effective Dates** for this validity rule:
  - Enter **From** as the starting date and time for the validity rule. This defaults to the current system date and time.
  - The **To** date indicates the date and time the validity rule is no longer effective. Leave this field blank until you need to stop this validity rule from being effective.

44. To define **Certificate** select **Certificate Type** as:

- **Certificate of Analysis** if you want a certificate of analysis when this validity rule is selected.
- **Certificate of Conformance** if you want a certificate of conformance when this validity rule is selected.

When you select the certificate type, choose one or more of the following to indicate at which stage the certificate is generated or required.

- Select **Invoice** to generate it at invoice time.
- Select **Shipment** to generate it when the item is shipped.
- Select **Supplier** if the certificate is required when the item is received from a supplier.

45. Enter the **Name** of the **Sampling Plan** to associate to this validity rule. If the sample quantity is not greater than or equal to the sum of the planned test quantities on the specification, then a warning message displays. The following fields display when a sampling plan is specified:

- **Count** displays the number of samples to take at each instance of the frequency entered.
- **Quantity** and **UOM** indicate the sample size, or the amount of material.
- **Per** indicates the frequency period. Count, Frequency Type, and Frequency Period or Per fields to define the number of repetitions for sampling.

46. Save the window.

### **Supplier**

47. Select a process-enabled inventory **Organization**. Required.

48. After entering all relevant information and saving the validity rule with the default **Validity Rule Status** of **New**, return to this window to change specification status by choosing **Change Status** from the **Actions** menu. Depending on whether status approval workflows are enabled, a different set of statuses is available.

Select a **Status** for the specification you are entering from one of the following:

- **Approved for Laboratory Use** to indicate that the validity rule is approved for laboratory use.
- **Approved for General Use** to indicate that the validity rule is approved for use

in work in process.

- **Obsolete/Archived** to indicate that the validity rule is no longer approved for use and is obsoleted, archived, or both.

If status approval workflows are enabled, when you select:

- **Approved for Laboratory Use**, then Status changes to **Request Approval for Laboratory Use** until all approvers accept the validity rule, then its Status changes to Approved for Laboratory Use.
- **Approval for General Use**, then Status changes to **Request Approval for General Use** until all approvers accept the validity rule, then its Status changes to Approved for General Use.

49. Enter the **Supplier** code for whom this validity rule is effective. Required. The supplier name displays.
50. Enter **Operating Unit** as the operating unit number of the supplier for which the validity rule is effective.
51. Enter **Site** as the supplier site number for which this validity rule is effective.
52. Enter **PO** as the purchase order number for which this validity rule is effective.
53. Enter **PO Line** as the purchase order line number for which this validity rule is effective.
54. **Control** indicates what to affect with this validity rule. The following controls default from the process quality parameters configured by the inventory organization. Select:
  - **Create Samples Automatically** to enable automatic sample creation. This defaults from the Process Quality Parameters window. Deselect this selection to disable automatic sample creation using this validity rule.
  - **Update Inventory Quantity** to decrease inventory by the sample amounts taken for testing. This indicator defaults from the process quality parameters for the organization specified.
  - **Control Lot Attributes** to control lot status, grade, and hold date based on the final disposition of the sample group. This indicator defaults from the process quality parameters for the organization specified. Specify **In-Spec** and **Out-Spec** material statuses.
55. The **Delayed LPN Entry** checkbox will be enabled for a WMS enabled organization. Select **Delayed LPN Entry** to enable the entry of an LPN number during the final

disposition of a sample. Deselect to prevent an LPN number from being entered during the final disposition of a sample. If you enter an LPN number during sample creation, then the LPN number cannot be changed when assigning the sample disposition.

56. Select **Lot Optional on Sample** to require a lot to be entered on a sample for a lot-controlled item. Deselect this selection if you do not want to require a lot to be entered on a sample for a lot-controlled item. This defaults from the Process Quality Parameters window.
57. If Lot Optional On Sample is selected, then **Delayed Lot Entry** is available. This defaults from the selection on the Process Quality Parameters window. Update the indicator when the item specification validity rule status is changed to Approved, Frozen, or Obsolete/Archived. If you select Delayed Lot Entry, then samples created must have lot number entered after sample creation. If the lot number is entered during sample creation, then the lot is used to choose a sample group and it cannot be changed.
58. Enter the **Name** of the **Sampling Plan** to associate to this validity rule. If the sample quantity is not greater than or equal to the sum of the planned test quantities on the specification, then a warning message displays. The following fields display when a sampling plan is specified:
  - **Count** displays the number of samples to take at each instance of the frequency entered.
  - **Quantity** and **UOM** indicate the sample size, or the amount of material.
  - **Per** indicates the frequency period. Count, Frequency Type, and Frequency Period or Per fields to define the number of repetitions for sampling.
59. Save the window.

## Displaying the Item Specification Validity Rules Summary

The Item Spec Validity Rules Summary window displays a complete list of item specification validity rules for an item and its optional grade combination.

You can use folders, flexfields, and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

### To display a summary of item specification validity rules:

1. Navigate to the **Item Spec Validity RulesSummary** window. The specification name and version display in the window title.

2. **Spec** displays the specification name. This defaults from the Specifications window.
3. **Version** displays the specification version.
4. **Item** displays the item code for the item specification.
5. **Revision** displays the item revision, if the item is revision-controlled.
6. **Grade** displays the default grade for the item, if the item is grade-controlled.
7. **Spec Status** displays the status of the item specification validity rule.
8. The following fields are display only:
  - **Organization** displays the default organization for the specification validity rule. This defaults from the Process Quality Parameters window.
  - **Specification Type** is the type of specification that is associated to the validity rule:
    - **Inventory** for inventoried items
    - **WIP** for work in process materials
    - **Customer** for customer items
    - **Supplier** for vendor items
  - **Deleted** displays **Yes** if the specification validity rule is marked for deletion, or **No** if it is not marked for deletion.
  - **Spec Validity Rule Status** is the status of the specification validity rule.
  - **Start Date** is the effective start date and time for the selected validity rule.
  - **End Date** is the effective end date and time for the selected validity rule. If this field is blank, then the validity rule is in effect.
  - **Parent Lot** is the parent lot associated to the selected validity rule, if the item is child lot-controlled. The field applies to specification validity rule for the inventory specification type.
  - **Lot** is the lot associated to the selected validity rule, if the item is lot-controlled. This field applies to specification validity rules for the inventory specification type.
  - **Subinventory** is the specific subinventory associated to the selected validity rule. This field applies to specification validity rules for the inventory specification type.

specification type.

- **Locator** is the locator of the item associated to the selected validity rule if the item or subinventory has locator control. This field applies to specification validity rules for the inventory specification type.
- **Update Inventory Quantity** indicates whether the selected validity rule is set to decrease inventory by the sample amounts taken for testing.
- **Control Lot Attributes** indicates whether the selected validity rule controls lot status based on the disposition of the sample. This field applies to specification validity rules for the WIP specification type.
- **In-Spec Lot Status** is the default material lot status for results that are within specification limits for the selected validity rule.
- **Out-of-Spec Lot Status** is the material lot status for results that are outside of specification limits for the selected validity rule.
- **Control Batch Step Status** indicates whether the validity rule controls the batch step status for the selected validity rule. This field applies to specification validity rules for the WIP specification type.
- **Lot Optional On Sample** indicates whether entry of a lot number is required when a sample is taken. If this field is selected, then entry of the lot number entry at sampling is optional. If **Lot Optional On Sample** is not selected, then a lot number must be entered when a sample is taken.
- **Certificate Type** indicates whether the validity rule prints a Certificate of Analysis or a Certificate of Conformance for the selected validity rule.
- **Certificate Type at Invoice** indicates whether the certificate type selected is generated at invoice time for the selected validity rule.
- **Certificate Type at Shipment** indicates whether the certificate type selected is generated when the item is shipped for the selected validity rule.
- **Certificate Type from Supplier** indicates whether the certificate type selected is generated when the item is received from a supplier for the selected validity rule.
- **Batch** is the batch associated to the selected validity rule. This field applies to specification validity rules for the WIP specification type.
- **Recipe** is the recipe used in the batch associated to the selected validity rule. This field applies to specification validity rules for the WIP specification type.

- **Recipe Version** is the recipe version used in the batch associated to the selected validity rule. This field applies to specification validity rules for the WIP specification type.
- **Formula** is the formula used in the batch and the **Formula Version** for the selected validity rule. This field applies to specification validity rules for the WIP specification type.
- **Routing** is the routing and **Routing Version** associated to the recipe used in the batch for the selected validity rule. This field applies to specification validity rules for the WIP specification type.
- **Step** is the batch step associated to the routing for the selected validity rule. This field applies to specification validity rules for the WIP specification type.
- **Operation** is the operation and **Operation Version** controlled by the selected validity rule. This field applies to specification validity rules for the WIP specification type.
- **Charge** is the charge associated to the routing for the selected validity rule.
- **Order** is the purchase order number for the selected validity rule. This field applies to specification validity rules for the supplier specification type.
- **Order Line** is the purchase order line number for the selected validity rule. This field applies to specification validity rules for the supplier specification type.
- **Ship-To-Location** is the location for the specified customer and operating unit for the selected specification validity rule. This field applies to specification validity rules for the supplier specification type.
- **PO** is the purchase order number, and purchase order type for the selected specification validity rule. This field applies to specification validity rules for the supplier specification type.
- **PO Line** is the purchase order line number for which the selected validity rule is effective. This field applies to specification validity rules for the supplier specification type.
- **Supplier** is the supplier for which the selected validity rule is effective. This field applies to specification validity rules for the supplier specification type.
- **Site** is the supplier site for which the selected validity rule is effective. This field applies to specification validity rules for the supplier specification type.

9. Click the drill-down indicator next to a validity rule to display the **Specification Validity Rules** window.

## To enter a new validity rule:

Click **New** in the **Item Spec Validity Rules Summary** window to display the **Item Spec Validity Rules for Item Spec** window where you can enter a new validity rule.

## To edit an existing validity rule:

1. Select the validity rule to edit in the **Item Spec Validity Rules Summary** window.
2. Click **Edit**.
3. Make appropriate edits.
4. Save the window.

## To display the E-Record Generic Query:

Choose **E-Record Details** from the **Actions** menu. The **E-Record Generic Query** displays if this option is available in your application. Refer to "Appendix D" for information on e-records.

## Entering a Monitoring Specification Validity Rule

The Monitoring Spec Validity Rules window lets you enter a new validity rule for a monitoring specification.

### E-record and E-signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix D" for additional information on e-record and e-signature approvals associated with this window.

You can use folders, flexfields, and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

### Prerequisites

- Enter and save a monitoring specification.
- Optionally, enter a sampling plan.

## To enter a monitoring specification validity rule:

1. Navigate to the **Monitoring Spec Validity Rules Summary** window.

2. Click **New**.
3. **Specification** displays the monitoring specification name.
4. **Spec Status** displays the approval status of the monitoring specification.
5. Select **Rule Type** as:
  - **Resource** to create a validity rule for a resource such as a refrigerator, environmental chamber. If you select this field, then enter information in the Resource region.
  - **Location** to create a validity rule for a location such as a subinventory and locator. If you select this field, then enter information in the Location region.
6. **Spec Validity Rule Status** indicates the status of the monitoring specification validity rule. Change the status of the validity rule after you enter and save all the following information.
7. Enter the following information in the Resource region for a resource validity rule:
  - **Name** as the name of the generic resource for the validity rule.
  - **Resource Organization** as the inventory organization where the monitoring specification validity rule applies.
  - **Instance** as the specific instance of the resource in the resource organization where the validity rule is defined.
8. Select the following information in the Location region for a locator validity rule:
  - **Organization** as the process-enabled inventory organization associated to the locator validity rule.
  - **Subinventory** as the subinventory of the specified organization to which the specification validity rule applies.
  - **Locator** from the list of locators associated with the subinventory you select. Locator is the subinventory locator where the specification validity rule applies if the subinventory exists for the locator.
9. In the Effective Dates region, enter:
  - **From** as the start date for the monitoring specification validity rule. Required.
  - **To** as the end date for the monitoring specification validity rule. Leave this field blank if there is no end date for the monitoring specification validity rule.

10. In the Sampling Plan region, enter:
  - **Name** as the name of the sampling plan.
  - **Count** as the number of samples to take at each instance of the frequency entered. Required.
  - **Qty** as and **UOM** as the sample size, or the amount of material needed to take a sample from the material requiring inspection. This is expressed in the primary inventory unit of measure. Required.
  - **Per** as the frequency period. Count, Frequency Type, and Frequency Period or Per fields to define the number of repetitions for sampling.
11. Save the window.
12. Choose **Change Status** from the **Actions** menu to change the status of the validity rule entered to Approved for General Use.
13. Save the window.

#### **To change the status of a monitoring specification validity rule:**

1. Query the desired monitoring specification validity rule.
2. Choose **Change Status** from the **Actions** menu.
3. Make appropriate changes.
4. Save the window.

#### **To mark a monitoring specification validity rule for purge:**

Choose **Mark for Purge** from the **Actions** menu. The record is marked for deletion.

#### **To edit text in the monitoring specification validity rule:**

1. Choose **Edit Text** from the **Actions** menu
2. Make appropriate text changes.
3. Save the window.

## To display the E-Record Generic Query:

1. Choose E-Record Details from the Actions menu. The E-Record Generic Query displays if this option is available in your application.
2. Refer to "Appendix D" for information on e-records.

## Displaying the Monitoring Specification Validity Rules Summary

The Monitoring Spec Validity Rules Summary window displays the monitoring specifications entered. Fields on this window are display only. If you need to enter a new monitoring specification, then click New and refer to the "Entering a Monitoring Specification Validity Rule" for more information.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Enter and save a monitoring specification validity rule.

## To display a list of monitoring specification validity rules:

1. Navigate to the Monitoring Spec Validity Rules Summary. The specification name and version display in the window title.
2. The following fields are display only:
  - **Specification** displays the monitoring specification name.
  - **Spec Status** displays the approval status of the monitoring specification.
  - **Organization** displays the organization associated to the validity rule type displayed.
  - **Rule Type** displays the rule entered for the monitoring specification as Physical Location or Resource.
  - **Deleted** displays **Yes** if the monitoring specification validity rule is marked for deletion, or **No** if it is not marked for deletion.
  - **Spec Validity Rule Status** displays the current status of the monitoring specification validity rule.
  - **Start Date** displays the effective start date for the monitoring specification

validity rule.

- **End Date** displays the end date for the monitoring specification validity rule, if one was entered.

3. If the rule type entered is for a resource monitoring specification, then:
  - **Resource** displays the generic resource for the monitoring specification validity rule.
  - **Instance** displays the specific resource for the monitoring specification validity rule.
4. If the rule type entered is for a location monitoring specification, then:
  - **Subinventory** displays the subinventory where the specification validity rule applies.
  - **Locator** displays the locator in the subinventory where the specification validity rule applies if the subinventory is locator controlled.
5. **Sampling Plan** displays the current monitoring specification sampling plan, if one is entered.
6. Close the window.

## Displaying Specification Summaries from the Navigator

The Specification Summary window lets you view a list of specifications by individual specification, customer, supplier, item, owner organization, or status.

This window displays item specifications, including base and overlay specifications. It does not display monitoring specifications.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Enter and save specifications.
- Enter and save specification validity rules.

## To display the Specification Summary window:

1. Navigate to the **Quality Workbench**.

2. Select **Show Active Specs** to display only those specifications that are active, where specification statuses are either Approved for Lab Use, or Approved for General Use. Deselect this indicator to display all specifications.
3. Select **View By**:
  - **Specifications** to display an alphanumeric sort of specifications. Expand the Specifications node. Select the desired specification node to display the **Specification Summary** window. Drill down to tests, customer validity rules, and inventory validity rules.
  - **Customer** to sort specifications by customer. Expand the desired customer node. Select each unexpanded specification node to display the **Specification By Item** window. Drill down to individual specifications, Tests, and Customer Validity Rules.
  - **Supplier** to sort specifications by supplier. Expand the Specifications By Supplier node. Expand the desired supplier node. Select each unexpanded specification node to display the **Specification By Item** window. Drill down to individual specifications, Tests, and Supplier Validity Rules.
  - **Item** to sort specifications by item. Select the unexpanded item to display the **Specifications by Item** window. Expand the item node to display the **Specification Summary** window for the item. Drill down to individual tests, customer validity rules, and inventory validity rules.
  - **Owner Organization** to sort the specifications by owner organization. Select the unexpanded Specifications By Status node to display the **Specifications By Status** window. Drill down to individual specifications, tests, customer validity rules, inventory validity rules, supplier validity rules, and WIP validity rules.
  - **Status** to display the **Specifications By Status** window.

**Note:** Views are restricted to the organizations that your responsibility can access.

4. The following fields are display only on the **Specification By Customer**, **Supplier**, **Item**, **Owner Organization**, or **Status**, and **Specification Summary** windows:
  - **Specification** displays the name of the specification.
  - **Version** displays the specification version.
  - **Description** displays a brief description of the specification.
  - **Owner Organization** displays the owner organization.

- **Item** displays the code for the material specified as it is listed on the Item Master.
- **Item Revision** displays the item revision, if the item is revision-controlled.
- **Status** displays the status defined by the specification.

5. Click **Specification** to display the **Specifications** window.

---

# Samples

This topic includes procedures for entering and finding item samples and monitoring samples. Procedures for displaying sample groups and displaying sample summaries on the navigator are also provided.

This chapter covers the following topics:

- Requirements
- Understanding Sampling
- Entering Item Samples
- Entering Monitoring Samples
- Finding Samples
- Displaying Sample Groups
- Displaying Sample Summaries from the Navigator
- Displaying the Samples Summary Window

## Requirements

Following are some requirements that customers have for samples in Oracle Process Manufacturing (OPM) Quality Management.

### Can the application help me plan sample collection?

Yes. Use the optional sampling plan to set up the sampling process in your facility. A Sample Creation Notification workflow helps manage the sample collection process. You can set up automatic sample creation so that the application creates planned sample records with the default sample group information such as batch, step, and item.

#### Use a Sampling Plan to Schedule Sample Collection

Define both the sampling frequency and sample quantity with the optional sample plan

that is set up prior to creating specifications and taking samples. Use the sampling plan with the Sample Creation Notification workflow. Use automatic sample creation when a lot is yielded to simplify data entry of production sampling in high volume production environments, or at various points in the supply chain.

## **Can I reserve a sample in case of sample breakage, leakage in transit to a testing facility, or future quality audits?**

Yes. If you experience sample breakage, leakage, or spoiling during transit to a testing facility, then retain a reserve sample until testing is complete. For quality audits, retain an archive sample for future testing.

### **Reserve a Physical Sample without Testing**

Sometimes samples break or leak in transit to the testing facility. If you need the insurance of a replacement sample, then take an extra sample and mark it as Retain or Reserve. You can select reserve sample material during testing of the original sample. Create a Retain As Archive sample. If future testing is required, then change the disposition of this sample to Pending and send it for testing.

## **Can I track the lifecycle of a sample?**

Yes. Record dates for when the sample is drawn and when it expires. If the sample is pulled from storage, specify the date and time it was retrieved, when the quality laboratory received it, and when analysis is due.

### **Enter Sample Dates to Track the Complete Sample Lifecycle**

Manage samples from the moment they are drawn and stored to when they are retrieved for testing. Enter additional dates for when analysis is required and when the sample expires. This helps you manage lab activities and ensures proper sample disposal.

## **Can I indicate which samples are designated for lot retesting purposes?**

Yes. Select the Lot Retest/Expiry indicator for a sample when retesting an expired lot. Samples are marked appropriately to trace them in the storage subinventory if you need to retest the same material periodically.

### **Set the Lot Retest/Expiry Indicator to Indicate the Purpose of Retesting**

The Lot Retest indicator is included on the Sample record to identify the purpose of retest as a lot retest or expiration test. A notification can be sent to create a sample based on lot retesting or lot expiration requirements.

## **Can I track sample quantities after testing is completed?**

Yes. Track the quantity of sample remaining based on the actual test quantities recorded. You can also track the physical storage subinventory and locator of a sample

taken for quality testing purposes using the Sample Storage Summary inquiry.

### Track Sample Quantities and Storage Locators

Track remaining sample quantities on the Samples Summary window based on the actual test quantities recorded. Use the Sample Storage Summary inquiry to track the physical storage subinventory and locator for all your samples.

## Understanding Sampling

Acceptance sampling supports quality inspection of materials during various points in the supply chain. This includes sample collection at events such as receiving, batch creation, batch step release, production yield, and lot expiration. Sampling inspection also occurs for material received from suppliers, for work in process material, for inventory, for specific customers, and for shipments. Samples are also created as part of a stability study for a particular item.

You can take multiple samples from the same source, and their collective disposition can be used to control and update other processes in the supply chain. Samples can be taken to monitor environmental conditions of locators or resources used for material storage.

Refer to "Setting Up Sampling Plans" for a discussion of the sampling plan.

Samples are sent to a quality laboratory organization for testing. The organization must be process-enabled and defined a Quality Laboratory in the Process Quality Parameters window. For detailed information on inventory organizations, refer to the *Oracle Inventory User's Guide*.

If an item substitution affects the quality specifications required for a batch, then you can change the specification association for a sample during sample creation or specification comparison. Refer to the *Oracle Process Manufacturing Product Development User's Guide* for detailed information on item substitution.

## Defining a Sample Numbering Scheme

You can set up a manual or automatic document numbering scheme for samples in the Process Quality Parameters window. If you create a sample with Assignment Type as Automatic, then the sample number is generated automatically. Automatic sample numbers are noneditable, sequential numbers. If you create a sample with Assignment Type as Manual, then you can enter the sample number.

## Defining and Applying Sampling Plan

Sampling methodologies are definable and maintainable using a sampling plan. The sampling plan lets you define the number of required, reserved, and archived samples. It also lets you specify the sample quantity and sampling frequency. Set up the optional sampling plan prior to creating specifications and samples. It becomes effective for an item, and optionally for a grade, when it is associated with a Specification Validity Rule.

When a specification is associated to a sample, some data from the sampling plan defaults into the sample record:

- Sample quantity
- Number of samples required

Refer to "Setting Up Sampling Plans" for more information.

## Creating an Item Sample

The sampling process can be performed whether the Sample Creation Notification workflow is enabled or disabled. Following are the conditions:

### Sample Creation Notification Workflow is Activated

You receive a notification to take samples when the Specification Validity Rule in effect requires sampling for an event. If a sampling plan is defined, then the notification window displays details of the applicable sampling plan.

If a batch creation triggered a sample notification, then the batch number defaults as the sample source information. Optionally, if the batch step is not entered by default, then enter the batch step where the sample was taken and save the sample.

Once testing is complete, results are entered against the sample. Enter or update additional sample details such as sample expiration date and time and the storage subinventory and storage locator on the sample record. Run the Inventory Date Notification concurrent program in Oracle Inventory to either send a notification to manually or automatically create samples based on lot retest or lot expiry. The concurrent request can launch the Lot and Serial Date Notification workflow, which raises the business events for reaching the lot retest or expiry date. The Inventory Date Notification concurrent request searches for item lots that are process quality-enabled in a process-enabled inventory organization. Refer to the *Oracle Inventory User's Guide* for detailed information on the concurrent request parameters.

When a batch is terminated, the Sample Creation Workflow notifications that are open are canceled. Manage any samples that are created against the batch.

### Understanding Automatic Sample Creation

Automatic sample creation simplifies data entry and integrity when sampling in high volume production environments, or at various points in the supply chain. When you set up automatic sample creation, the application creates planned sample records with the default sample group information such as batch, item, and optional lot. This is based on a business event in the application. Existing business events that can trigger the sample creation workflow include lot expiration and retest, inventory adjustment, batch or batch step creation, batch step release, and receiving material into inventory or a receiving location. Automatic sample numbering and the sampling plan information such as sample count, sample quantity, and UOM, provide the information to create several sample records simultaneously, and associate these samples to a sample group.

The application can create required, archive, and reserve sample record types. When samples are taken physically, you can update the planned sample records with details that include the actual sample quantity taken, date drawn, and sample expiration date.

Responsibilities: Workflow Administrator Event Manager, AME Application Administrator, Quality Manager

- Setting up for automatic sample creation:
  - Set the process quality parameter for sample Assignment Type to Automatic for automatic document numbering of samples in the creation organization. Required.
  - Enable the business event that triggers automatic sample creation. Required.
  - Set up the quality workflow for notification of planned samples created by the system. Optional.
  - Define a sampling plan. Required.
- To use automatic sample creation:
  - Create an item specification with a specification validity rule that has Create Samples Automatically enabled and a sampling plan associated.
  - Trigger the business event, for example, create inventory, create a batch, release a batch step, receive into a receiving locator or inventory.
  - Open the workflow notification or query the sample group through the Quality Workbench, Samples Summary, or Sample Groups window to view the planned samples created by the application.
  - Take physical samples by changing the sample disposition from Planned to Pending or Retain. Enter the actual sample quantity and date drawn.

#### **Sample Creation Notification Workflow is Not Activated**

Determine the material to sample. This includes items that require retesting and items that require evaluation of their expiration date. Refer to "Reports and Inquiries" for reports to run that assist in this process. When the Sample Creation Notification workflow is not enabled, create a sample directly using the Item Samples window.

#### **Delaying the Entry of Lot Numbers**

Delayed lot entry lets you create a sample without entering a lot number. It postpones the identification of a lot number during sample creation until it is known at the time of assigning a final disposition. This delay accommodates sampling processes in which the material is analyzed before delivery to inventory. When assigning a final sample group

disposition, the lot is specified, so that quality-driven updates to the lot status, grade, hold date, reason code, and the recommended lot-specific unit of measure conversions can occur simultaneously. For WIP and Supplier samples, the lot must belong to the batch or receipt specified at the time of sampling. After the lot number is entered at disposition time, it displays in all the sample records within the sample group for genealogy purposes.

### Setting Up for Delayed Lot Entry

The Delayed Lot Entry indicator is available when Lot Optional on Sample is selected in the Process Quality Parameters window or the Validity Rules for Item Spec window. Select Delayed Lot Entry to permit the entry of a lot number only when the sample is assigned a final disposition of Accept, Accept with Variance, or Reject. Deselect to permit the entry of a lot number only at sample creation for supplier, inventory, or WIP sources.

### Prerequisite

Select Lot Optional on Samples and Delayed Lot Entry in the Process Quality Parameters window and in the applicable specification validity rule.

To delay the entry of a lot numbers on a sample:

1. Create a sample without entering a lot number. The Lot field is protected after you save the sample.
2. Enter and evaluate results.
3. Assign a final sample group disposition and enter the following:
  - Lot number, to update all sample records in the sample group.
  - Lot update information, including requirements for status, grade, hold date, and the UOM conversion recommendation.
  - Lot number and appropriate lot update information displays for all the samples in the sample group. If the sample group has a single sample, then update the sample to a final disposition to enter the lot number. Otherwise, composite results before you assign a final sample group disposition and enter the lot number.

## Accounting for Sample Quantity Drawn from a Batch

This feature reflects the sample quantity taken from a batch by modeling the sample as a batch byproduct. An inventory transaction for this sample byproduct is created automatically based on the reason code defined on the Process Quality Parameters window.

## Responsibilities

Formulator, Process Engineer, Production Supervisor, Quality Manager

## Prerequisites

- Configure the Process Quality Parameter for Inventory Transaction Reason.
- Set up an item for the material to sample from the batch.

To update the batch with the sample quantity:

1. Create a formula by entering the item to sample as a byproduct formula line:
  - Set the byproduct quantity equal to the quantity you plan to take as a sample.
  - Set the Yield Type to Manual, and the Byproduct Type to Sample.
2. Change the status of the formula to Approved for General Use.
3. Create a recipe that contains the formula.
4. Create a recipe validity rule for the recipe and the organization in which you will run the batch.
5. Change the status of the recipe and the status of the recipe validity rule to Approved for General Use.
6. Create and approve a specification for the item.
7. Create and approve a WIP specification validity rule, specifying the recipe, formula, and formula line at which the sample byproduct is yielded. Ensure that the Update Inventory Quantity indicator is selected
8. Create a batch from the recipe. If the Sample Creation Notification workflow is enabled, then the system prompts for the creation of the WIP sample when the batch is created.
9. Release the batch.
10. Create a sample for the item in the batch. An inventory transaction is created for the byproduct line in the batch. If the Sample Creation Notification workflow is not enabled, then use the Get Spec function to tie the sample record to the applicable WIP Specification Validity Rule for the sample byproduct line in the batch.

## Terminating Batches

When a batch is terminated, the sample creation workflow notifications that are open

are canceled. Manage any samples that are created against the batch.

## Recording Sample Expiration Date

Record the sample expiration date and time to indicate sample shelf life. The sample expiration date and time defaults to the corresponding lot expiration date. This date is stored for informational purposes, and used as a reminder to complete required testing, and properly dispose of the sample..

## Grouping Samples

Samples that originate from the same source or business event can be grouped together as a sample group so that the composite of their results can be reported or used to control inventory, production, receiving, shipping, and allocation processes.

If samples are not created using the workflow, then they can still be grouped by the Get Spec function that associates the same specification and version to these samples. Refer to "Appendix B" for the hierarchies used. The specification validity rule for this specification and version identifies the sampling plan where the required sample count is number of samples required in the sample group. When a new sample and sample group are created and a sampling plan is not specified in the specification validity rule, then the number of samples required in the sample group (and reflected in the sample record) is one.

By default, when you click Get Spec or save the sample record the application groups samples associated to the same specification and version until the sample group has a final disposition. For example, if the sampling plan requires three samples, then the first sample record has a sample instance of one of the three samples required. Each time a sample is added to a sample group, the total samples required increases by one, and each new instance is numbered appropriately in the series. When you use the Get Spec function, you can also create a new sample group instead of adding the new sample to an existing sample group.

The Get Spec function retrieves item specifications for item samples and monitoring specifications for monitoring samples. You can continue to add samples to a sample group while the sample group disposition is Pending, In Progress, or Complete. Samples with a disposition of Complete revert to In Progress when you add a test.

## Understanding Parent Lots and Lots

Lots can be created with a reference to a parent lot. A sample or sample group can represent the quality characteristics of a single lot or multiple lots, indicated by specifying a parent lot only. For samples against a particular lot, the final sample group disposition can update lot attributes such as material status and grade for the lot specified. For samples against a parent lot only, the lot attributes update can apply to all lots one level below the parent lot.

## Changing Disposition and Compositing Results for a Sample Group

An item sample group contains one or more samples that share the same organization, item, and source, and optionally, the same lot. Tie the sample group to a specification and specification validity rule at the Item Samples window for the first sample created. This must be done before assigning a sample group disposition or creating composite results.

## Determining Quality Characteristics

Quality characteristics for a lot are determined through inspection samples or by associating a sample with another sample group. You can do this by using the parent lot disposition, results association between item samples, or lot transactions such as split, merge, or translate. For example, a lot split transaction can inherit the quality sample taken against the source lot through to the destination lot. Refer to "Associating Results to Another Sample" topic and to the Oracle Inventory User's Guide for detailed information on lot transactions. The Lot Genealogy inquiry or the specification matching functionality using the Select Available Inventory window initially searches for samples taken against the specified lot before using the inherited sample group association to retrieve the samples.

## Determining Sample Disposition Manually

Assign a control sample disposition manually, by responsibility, when the Sample Creation Notification workflow is not enabled. To assign a new disposition, choose Change Disposition from the Actions menu on the Samples window. The following summarizes sample disposition change possibilities:

- Change from Planned to:
  - Pending
  - Retain
  - Cancel
- Change from Pending to:
  - Cancel
  - Retain prior to the sample being saved.
- Change from Retain to:
  - Pending in anticipation of sample analysis..
  - Cancel to terminate analysis

- Change from In Progress to:
  - Accept with Variance if results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
  - Reject if results are recorded and at least one is not acceptable.
  - Cancel to terminate additional analysis.
- Change from Complete to:
  - Accept if results are recorded and acceptable, and sample results are within the limits of the specification.
  - Accept with Variance if results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
  - Reject if results are recorded and at least one is not acceptable.
  - Cancel to terminate additional analysis.
- Change from Accept to:
  - Accept with Variance if results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
  - Reject if results are recorded and at least one is not acceptable.
  - Cancel to terminate additional analysis.
- Change from Accept with Variance to:
  - Reject if results are recorded and at least one is not acceptable.
  - Cancel to terminate additional analysis.
- Change from Reject to:
  - Cancel to terminate additional analysis.

## Using the Sample Storage Summary Inquiry

The Sample Storage Summary inquiry lets you find item samples based on their storage subinventory and storage locator. The Item Inquiry window in the Oracle Inventory application is used to find the sample storage locator based on the item and lot number.

## Understanding Retained, Archive, and Reserve Samples

Following is a discussion that describes the differences among retained, archive, and reserve samples:

### Retained Sample

A Sample Disposition of Retain identifies that a sample is stored for possible future testing. Retained samples can be used as a control group for subsequent samples that have been tested against the same sample source. Samples drawn from the same source can be separated into aliquots, or fractional samples. These samples can be used for standard quality testing, archived into storage for investigative or forensic testing, or reserved as a backup for possible future testing. A retained sample is classified by its use or type.

Retained samples can be submitted for analysis later according to the specification assigned to the sample group. You can change the sample disposition of a standard testing sample from Retain to Pending to indicate that analysis is expected, and initiate the optional OPM Quality Test notification workflow if it is enabled. For example, a stability sample is created and put into storage. Later, it is pulled for time point testing according to an item specification. Samples with a disposition of Retain are not available for entry of results until the sample disposition is changed to Pending. You cannot change the disposition of a tested sample to a disposition of Retain.

The samples for archive and reserve use do not contribute to the total number of samples required in a sample group based on a sampling plan. Therefore, it is important to distinguish these samples for traceability purposes. A standard testing sample is created based on the sampling plan definition.

### Archive Samples

The archive sample can be used to research a market complaint. This sample is stored immediately in sample archives without any default specification assignment or initial testing. When analyzed, select the specification or add tests manually to an archive sample. The archive sample can progress through the existing sample dispositions (Pending, In Progress, Complete, Accept, Accept with Variance, Reject, or Cancel), but it remains in an archived state without any of the subsequent updates to inventory and production based on the specification validity rule.

- Requirements for setting up archive samples:
  - Specify the document numbering assignment type for samples in the creation organization where the samples are taken. Required.
  - Define a sampling plan. Optional.
  - Create and approve item specifications and specification validity rules. Optional.

- To use archive samples:
  - Create an item sample retained as an archive sample. Associate it to a specification with a sampling plan. Optional.
  - Query the archive sample, change the sample disposition to Pending, and optionally, schedule tests from the associated specification upon request for investigation.
  - Perform tests, enter results, and change sample disposition when the analysis is complete.

### Reserve Samples

This type of retained sample is set aside as additional inventory from the same sample source. A reserve sample is used as a backup supply of additional testing material when one or more tests are repeated due to instrumentation problems or reagent failure. Its quantity is consumed when the original sample for standard quality testing is insufficient to complete all required testing. A reserve sample remains in the Retain sample disposition and can only be changed to a disposition of Cancel. This supports the recording of results that are performed against a reserve sample, but reported against the original sample for standard quality testing.

- Requirements for setting up reserve samples:
  - Set up document numbering assignment type for samples in the creation organization where samples are taken. Required.
  - Define a sampling plan. Optional.
  - Create and approve item specifications and specification validity rules. Optional.
- To use reserve samples:
  - Create item samples in the same sample group as a required sample, and retain an additional sample as the reserve sample. Optionally, associate these samples to a specification with a sampling plan.
  - Enter results against the required sample. When the remaining sample quantity of the required sample is insufficient for continuing analysis, select the reserve sample for the test where an additional testing quantity is needed, and enter results.
  - Change the sample disposition of the required sample when analysis is complete.

## **Creating Stability Study Samples**

Stability study sample records are created by the application when the planned stability study is approved. These samples are based on the:

- Number of samples per time point
- Number of retained samples for a variant
- Sample quantity and UOM defined for a variant

These system-generated item samples are automatically associated to a stability study as identified by the sample source fields. You cannot create stability samples manually through the Samples window.

## **Creating a Monitoring Sample**

You create a monitoring sample on the Monitoring Samples window. Monitoring samples are taken to check the acceptability of environmental conditions for each variant storage condition in a stability study. You take these samples for tests defined in a monitoring type specification. Refer to "Understanding Specifications" for additional information.

## **Delaying the Entry of Lot Numbers**

To display the Delayed Lot Entry indicator on the Validity Rules for Item Specifications window, you must select it on the Process Quality Parameters window. If a WIP, Inventory, or Supplier sample is created with the Delayed Lot Entry indicator enabled, then you can create a sample without entering a lot number. Enter the lot number when you enter a final disposition for the sample or sample group.

### **Setting Up on the Process Quality Parameters Window**

The Delayed Lot Entry indicator is available when Lot Optional is selected. The field defaults to null. Select Delayed Lot Entry to permit the assignment of a lot number after sample creation for a supplier, inventory, or WIP specification validity rule. The sample must have a final disposition of Accept, Accept with Variance, or Reject. Deselect to permit the assignment of a lot number only at sample creation for a supplier, inventory, or WIP specification validity rule.

### **Implementation Considerations**

Following is a summary of implementation considerations:

- If you enter a lot when you create the sample record, then delayed lot entry is not permitted. The Lot Optional indicator must be selected on a valid item specification validity rule. Do not select Update Inventory Quantity.
- Enter a lot number for all the samples in a sample group, because all samples in the

sample group are affected. If the lot number changes across samples, then create separate sample groups that correspond to each lot.

- The Lot field is not available on the Item Samples window after you save the sample. Enter the lot number when you change the sample group to a final disposition of Accept, Accept with Variance, or Reject. Changing to a final sample group disposition controls several updates to inventory lot attributes. Receiving or in-process inspection results also reflect the quality characteristics of the material inventoried. Therefore, you can enter the lot number simultaneously with updates to its lot attributes such as lot status, grade, hold date, and reason code and the recommended lot-specific unit of measure conversions.
- The lot entered must belong to the receipt or batch identified on the supplier or WIP sample record.
- The specification matching logic associated to the Get Spec button is based on the sample source information entered when you create a new sample. If a lot is not entered on a new sample record, then it is not included as specification matching criteria.

### **Process Flow for Delayed Lot Entry**

1. Create a sample without entering a lot number. The Lot field is protected after you save the sample.
2. Enter and evaluate results.

- Assign a final sample group disposition and enter the following:
- Lot number, to update all sample records in the sample group Lot update information, including requirements for status, grade, hold date, and the UOM conversion recommendation

Lot number and appropriate lot update information displays for all the samples in the sample group. If the sample group has a single sample, then update the sample to a final disposition to enter the lot number.

### **Quality Change Disposition Window**

Lot is required if:

You access this window from the Composite Results window for a sample group or from the Item Samples window if the sample is the only sample in the sample group.

- The Source field is Supplier, Inventory, or WIP for the sample or sample group.
- The item is process quality-enabled and lot-controlled.
- There is no lot specified on the sample or sample group, and Lot Optional on Sample is selected.

- Delayed Lot Entry is selected for the supplier, inventory or WIP specification validity rule associated to the sample.
- The current disposition is changed to a final disposition of Accept, Accept with Variance, or Reject. An error message displays if the lot is entered and the sample disposition is not updated.

A sample or sample group can represent the quality characteristics of a single lot or multiple lots, indicated by specifying a parent lot only. For samples against a particular lot, the final sample group disposition can update lot attributes such as material status and grade for the lot specified. For samples against a parent lot only, the lot attributes update can apply to all lots one level below the parent lot.

## Entering Item Samples

The Item Samples window lets you create samples from the following sources:

- Inventory
- WIP
- Supplier
- Customer

Refer to the "Understanding Sampling" topic for an explanation of sampling.

**Note:** You cannot create stability study samples from this window. However, you can query a sample with the Stability Study source from this window. Refer to the "Stability Studies" topic for additional information. You cannot create monitoring sample from this window. Refer to the "Entering Monitoring Samples" topic for additional information.

## Using the Item Samples Window with Sample Creation Notification Workflow Activated

A sample group is created by a transaction event such as a receiving transaction, or an inventory transaction. If the Item Samples window is accessed from the Sample Creation Notification workflow, then the Item Samples window displays the following information:

- Organization
- Specification Name, Version, and Grade
- Source data, depending on where the sample is created

- Item and Item Revision
- Date Drawn
- Default for Update Inventory Quantity box, based on the Specification Validity Rule
- Priority as Normal
- Disposition as Planned or Pending

If a sampling plan is associated to the specification validity rule in effect, then Retain As, Sample Quantity, Sample Quantity UOM , and Samples Required fields also default in the Item Samples window. Enter the following information:

- Sample Number, unless automatic sample numbering is enabled
- Sample Description
- Parent Lot
- Lot, unless defaults are available from the sample group
- Lot Retest
- Quality Laboratory
- External ID
- Storage Organization
- Storage Subinventory
- Storage Locator

## Using the Item Samples Window with Sample Creation Notification Workflow Inactivated

When you create a sample without using a workflow notification, the Item Samples window displays the following information:

- Disposition is Pending
- Source defaults to Inventory
- Update Inventory Quantity box is cleared
- Sample Priority defaults to Normal

Enter the following minimum required information:

- Sample, unless automatic sample numbering is enabled
- Sample Description defaults from the item entered
- Retain As an Archive, Reserve, or required sample
- Source data, based on where the sample is created
- Lot for lot-controlled items unless marked Optional on the Process Quality Parameters window
- Quantity
- UOM
- Date Drawn, which defaults to the current date and time

## E-Record and E-Signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix D" for additional information on e-record and e-signature approvals associated with this window.

You can use folders, attachments, and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*.

## Prerequisites

- Set up a quality lab organization where sample testing is performed.
- Set up Process Quality Parameters for required indicators and configurations including Exact Spec Match, Update Inventory Quantity, Lot Optional, Manual Spec Selection, Create Samples Automatically, Delayed Lot Entry, Control Batch Step Status, Inventory Transaction Reason, Update Inventory Quantity, Control Lot Attributes, In-Spec Status, Out-of-Spec Status, and Consider Optional Test Results in the Process Quality Parameters window.
- Set up document numbering for automatic or manual sample numbering in the organization where you take samples in the Process Quality Parameters window.  
Enter tests, and optionally create an approved specification and specification validity rule for sampling.
- Optionally, enter a sampling plan.
- Optionally, set up and activate the Sample Creation Notification workflow.

- Set up parent lots, lots, and lot attributes.

## To enter an inventory sample:

1. Navigate to the **ItemSamples** window. The process-enabled organization displays in the window title. Select a different organization using the **Organizations** window.
2. Enter the **Sample**. If automatic sample numbering is selected, then the **Sample** field is blank and disabled until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Required.
3. Enter the **Disposition** as the sample status:
  - **Planned** when the sample is scheduled to be taken.
  - **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.
  - **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.
  - **Cancel** when the sample is canceled.
 Required.  
 Refer to "Understanding Sampling" for an explanation of how to change sample disposition.
4. Enter a **Description** for the sample. If you do not enter a description, then the item description defaults from the item entered.
5. If **Retain** is the disposition, then enter **Retain As** to indicate whether the sample type is an Archive, Reserve, or required sample.
6. Enter **Item** as the process quality-enabled item sampled. A description of the item displays. Required.
7. Enter the item **Revision**. If the item is not revision-controlled, then this field is disabled. Required.
8. Enter a **Priority** for the sample as:
  - **Normal** to indicate that the sample has the usual processing requirements.
  - **Low** to indicate that the sample has minimal urgency for processing.
  - **High** to indicate that the sample has urgent processing requirements.

9. Select the sample **Source** as **Inventory**.
10. Select the restricted or non-restricted **Subinventory** where the item sampled is located.
11. Select the restricted or nonrestricted **Locator** if the subinventory and item are locator-controlled. Locator control is defined at the organization, subinventory, or item level. .

**Note:** Restricted subinventories indicate whether to restrict transactions of an item to or from a subinventory specified in a list you define using the Item/Subinventory Information window in Oracle Inventory. Restricted locators indicate whether to restrict a transaction of the item to or from a locator specified in the list you define using the Item/Subinventory Information window in Oracle Inventory. You cannot restrict locators unless you also restrict subinventories.

12. Enter the sample item **Parent Lot**, if the item is child lot-controlled. Refer to "Understanding Parent Lots and Lots" for detailed information on parent lots and lots.
13. Enter the sample item **Lot** code. Edit this field if the item entered is child lot-controlled. Lot is not required if marked as optional for samples on the Process Quality Parameters window.
14. Enter the **LPN** for the inventory sample to consume. You can select the LPN number from the LOV. This field is enabled only for WMS enabled organizations.
15. **Lot Retest** is selected if the sample is taken for lot retesting. If the Lot Expiry/Retest Notification workflow is running, then this field defaults.
16. **Name** is the item specification name.
17. **Version** is the item specification version.
18. **Grade** is the grade associated to the specification version.

**Note:** If the sample was previously associated to a specification using the Sample Creation Notification workflow, then the Get Spec function is disabled. If a sample source field (Lot, Subinventory, or Locator) is changed, then the Spec, Version, and Grade fields are cleared. You can also save a sample without having a specification associated to it.

19. Click **Get Spec** to associate a specification for this sample. The Specification Association dialog box displays.
20. Select one of the following:
  - **Use Default** displays the specification, version, and grade with a specification validity rule that exactly or best matches the sample source information entered. The specification match depends on the process quality parameter Exact Spec Match in the Process Quality Parameters window. Select Exact Spec Match if a specification needs to be an exact match. Deselect if a specification does not need an exact match. The best match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in "Appendix B".
  - **Use Alternate** to select a specification that is different from the default specification for the sample. If Manual Spec Selection is enabled in the Process Quality Parameters window, then select Use Alternate. Select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

**Note:** If there is an existing sample group that matches the sample source and specification selected, then the Created On, Samples Taken, and Samples Required fields display. Deselect **Create New** to add the new sample to the existing sample group. Select **Create New** to add the new sample to a new sample group. If no sample group information is retrieved, then **Create New** defaults as selected.

21. Click **OK** to continue. The Spec, Version, and Grade display for the specification selected.

### Identity

22. Enter the **Quality Laboratory** as the inventory organization where the sample is tested.

### Quantities

23. The **Update Inventory Quantity** indicator is selected when the sample transaction updates the amount of sample in inventory. When you enter a specification, Update Inventory Quantity is set to the value on the specification validity rule.
24. Enter the sample **Quantity** in its inventory **UOM**. This is the item primary UOM, or another UOM with a valid conversion. The value defaults from the quantity entered on any associated sampling plan. Required.

25. **Remaining Quantity** displays the balance of sample remaining after the actual test quantities are deducted at the time of result entry. **UOM** displays the unit of measure. It is expressed in the same UOM as the sample quantity.

#### Dates

26. Enter **Drawn** as the date and time the sample was taken. This field defaults to the current system date and time. Required.

27. **Retrieved** displays the date and time the stability sample was pulled from storage for testing by the quality laboratory. This date defaults from the stability study.

28. Enter **Received** as the date and time the sample was received for testing by the quality laboratory.

29. Enter **Required** as the date and time when the sample analysis must be completed.

30. Enter **Expired** as the date and time when the sample expires.

#### Sample Group

31. The following fields for the sample group are display only:

- **Sample Instance** is the sample iteration with respect to the total number of samples in the sample group based on the samples taken.
- **Samples Taken** is the total number of samples already taken for the sample group.
- **Samples Required** is the total number of samples required in the sample group based on the sampling plan requirement.

#### Storage

32. Enter **External ID** as an alternate or cross-reference code for the sample. For example, if the sample is recorded on another test database, then enter the sample ID recorded on the external system.

33. Select a **Storage Organization** as the inventory organization where the sample is stored.

34. Enter **Storage Subinventory** as the subinventory where the remaining sample quantity is stored. The description of the storage subinventory displays. If the item is restricted, then the storage subinventory is restricted. Query item samples by storage subinventory and locator using the Sample Storage Summary inquiry.

35. Enter a **Storage Locator** for the sample. If the sample storage locator is:

- Restricted, then a valid locator must be entered for the specified storage

subinventory. The LOV displays valid locators for the Storage Subinventory entered.

- Non-restricted, then you do not have to specify a valid locator for the specified storage subinventory. Enter a storage locator in this field; however there is no LOV.

This field is protected from entry if the storage subinventory does not exist for the locator. If a Storage Subinventory is entered, then this field is required.

**Note:** Restricted subinventories indicate whether to restrict transactions of an item to or from a subinventory specified in a list you define using the Item/Subinventory Information window in Oracle Inventory. Restricted locators indicate whether to restrict a transaction of the item to or from a locator specified in the list you define using the Item/Subinventory Information window in Oracle Inventory. You cannot restrict locators unless you also restrict subinventories.

## Approvers

36. Enter the **Sampler** as a code for the individual who withdrew the sample. The name of the individual appears in the field next to this code. This field defaults to the current user.

**Note:** If you intend to set up workflow and Oracle E-Records events against samples, then do not enter Sampler, Sample Approver, or Inventory Approver. Refer to "Appendix D" for additional information.

37. Enter the **Sample Approver** as the individual who is responsible to approve the sample.

38. Enter the **Inventory Approver** as the individual who can approve the item to release to production.

## Composite Results

39. If the sample belongs to a sample group with composited results, then the Composite Results tab is enabled. The following fields are display only:

- **Specification** indicates the specification name used for the composite results.
- **Version** indicates the specification version used for the composite results.
- **Grade** indicates the grade defined by the specification displayed.

- **Validity Rule Use** indicates the type of validity rule in use to composite the results.
- **Date Composited** indicates the date and time the composite results were saved.
- **Disposition** indicates the disposition of the sample based on the composite results.

40. Click **View** to display the **Composite Results** window for this sample.

### Spec Disposition

41. If the specification associated to the sample was replaced through specification comparison, then the history of sample dispositions against each specification displays. The following fields are display only:

- **Specification** indicates the specification name associated to the sample.
- **Version** indicates the specification version.
- **Grade** indicates the grade assigned to the specification displayed.
- **Disposition** indicates the disposition of the sample with respect to the specification displayed.
- **Validity RuleUse** indicates the type of specification validity rule used.
- **Control Lot Attributes** indicates if a lot status, and optionally a grade is dependent on the specification displayed.

### Comments

42. Enter **Comments** for the sample.

43. Save the window.

### To enter a WIP sample:

1. Navigate to the **ItemSamples** window. The context organization displays in the window title. Select a different organization using the **Organizations** window.
2. Enter the **Sample**. If automatic sample numbering is selected, and the sample is a new record, then the Sample field is blank and disabled until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Use automatic sample numbering for samples generated in a stability study. Required.
3. Enter the **Disposition** as the sample status:

- **Planned** when the sample is scheduled to be taken.
- **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.
- **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.
- **Cancel** when the sample is canceled.

Required.

Refer to "Understanding Sampling" for an explanation of how to change sample disposition.

4. Enter a **Description** for the sample. If you do not enter a description, then the item description defaults from the item entered.
5. If **Retain** is the disposition, then enter **Retain As** to indicate whether the sample type is an Archive, or Reserve sample.
6. Enter the **Item** as the process quality-enabled item sampled. A description of the item entered displays. Required.
7. Enter the item **Revision**. If the item is not revision-controlled, then this field is disabled. Required.
8. Enter a **Priority** for the sample as:
  - **Normal** to indicate that the sample has the usual processing requirements.
  - **Low** to indicate that the sample has minimal urgency for processing.
  - **High** to indicate that the sample has urgent processing requirements.
9. Select the sample **Source** as **WIP**.
10. Enter **Batch** as the batch number for the WIP sample.

If the sample is created through the Sample Creation Notification workflow, then the following defaults as the sample source:

- Batch number
- Batch step, if applicable
- Recipe number and version
- Formula number and version

- Routing number and version
- Operation number and version

If the sample is created manually, then one of the following is required for the sample source:

- Batch number, if the sample is created in a plant or lab organization.
- Recipe number and version, if the sample is created in a lab organization.

**Note:** If a batch is specified, then the material detail line is used instead of the formula line.

11. Enter the **Line** as the line sequence for the item listed in the batch or formula.
12. **Type** defaults from the material or formula line entered, and indicates the type of consumption or yield that is applicable to the formula line.
13. Enter the **Step** as the batch step, if it is applicable.
14. Enter the step **Charge** as the charge controlled by the listed specification.
15. Enter the **Subinventory** where the WIP item is yielded and the sample is taken.
16. Enter the **Locator** if the subinventory exists for the locator and the item is locator controlled. Locator control is defined at the organization, subinventory, or item level, in that order.
17. Enter the sample item **Parent Lot** code if the item is child lot-controlled. Refer to "Understanding Parent Lots and Lots" for detailed information on parent lots and lots.
18. Enter the sample item **Lot** code. Edit this field if the item specified is lot-controlled. If Lot Optional On Samples is selected on the specification validity rule associated to the sample or if you enter a parent lot, then Lot is not required.
19. Enter the **LPN** for the WIP sample to consume. You can select the LPN from the LOV. This field is enabled only for WMS enabled organizations.
20. Enter the **Recipe** and version if the sample is created in a lab organization and a batch number is not entered.
21. **Formula** displays the formula used in the batch and its version. If a recipe is entered, then these fields default.
22. **Routing** displays the routing used in the batch and its version. If a batch is entered,

then routing and routing version default from the batch. If a valid recipe is entered, then the routing associated to the recipe displays. You cannot change these fields.

23. **Operation** displays the operation and version associated to the routing and step displayed. These fields are blank if a routing and step are not entered.

**Note:** If the sample was previously associated to a specification using the Sample Creation Notification workflow, then the Get Spec function is disabled. You can also save a sample without having a specification associated to it.

24. Click **Get Spec** to associate a specification for this sample. The Specification Association dialog box displays.
25. Select one of the following:
  - **Use Default** displays the specification, version, and grade with a specification validity rule that exactly or best matches the sample source information entered. This depends on the value entered for the process quality parameter Exact Spec Match in the Process Quality Parameters window. Select Exact Spec Match if a specification needs to be an exact match. If a specification does not need an exact match, then deselect. The best match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in "Appendix B."
  - **Use Alternate** to select a specification that is different from the default specification for the sample. Select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

**Note:** The Created On, Samples Taken, and Samples Required fields display if there is an existing sample group that matches the sample source and specification selected. Deselect Create New to add the new sample to the existing sample group. Select Create New to add the new sample to a new sample group. If no sample group information is retrieved, then Create New defaults as selected.

26. Click **OK** to continue. The specification Name, Version, and Grade display for the specification selected.

**Note:** The Identity, Storage, Approvers, Composite Results, Spec

Disposition, and Comments tabs have the same field definitions as those that appear in the "To enter an inventory sample" task. Refer to that task for this information.

27. Save the window.

### To enter a supplier sample:

1. Navigate to the **ItemSamples** window.
2. Enter the **Sample**. If automatic sample numbering is selected, and the sample is a new record, then the Sample field is blank and disabled until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Required.
3. Enter the **Disposition** as the sample status:
  - **Planned** when the sample is scheduled to be taken.
  - **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.
  - **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.
  - **Cancel** when the sample is canceled.Required.  
Refer to "Understanding Sampling" for an explanation of how to change sample disposition.
4. Enter a **Description** for the sample. If you do not enter a description, then the item description defaults from the item entered.
5. If **Retain** is the disposition, then enter **Retain As** to indicate whether the sample type is an Archive or Reserve sample.
6. Enter **Item** as the process quality-enabled item sampled. A description of the item entered displays. Required.
7. Enter the item **Revision**. If the item is not revision-controlled, then this field is disabled. Required.
8. Enter a **Priority** for the sample as:
  - **Normal** to indicate that the sample has the usual processing requirements.

- **Low** to indicate that the sample has minimal urgency for processing.
- **High** to indicate that the sample has urgent processing requirements.

9. Select the sample **Source** as **Supplier**.
10. Enter the **Supplier** number. Required.
11. Enter the **Operating Unit** corresponding to the supplier site. The operating unit must have an Oracle Process Manufacturing (OPM) fiscal policy to indicate that it is used for process manufacturing.
12. Enter the **Supplier Site** as the supplier site code that appears on the corresponding purchase order.
13. If the sample is associated to a purchase order, then enter the **PONumber** and **Line** number.
14. If the sample is associated to a receipt, then enter the **Receipt** number and receipt **Line** number.
15. Enter the receiving **Subinventory** and **Locator** for the material.
16. Enter the sample item **Parent Lot** code if the item is child lot-controlled. Refer to "Understanding Parent Lots and Lots" for detailed information on parent lots and lots.
17. Enter the sample item **Lot** code. Edit this field if the item you specified is lot-controlled. If Lot Optional On Samples is selected on the specification validity rule associated to the sample, then Lot is not required .
18. Enter the **LPN** for the Supplier sample to consume. You can select the LPN number from the LOV. This field is enabled only for WMS enabled organizations.
19. Enter the **Supplier Lot** number.

**Note:** If the sample was previously associated to a specification using the Sample Creation Notification workflow, then the Get Spec function is disabled. If any sample source fields (Lot, Subinventory, or Locator) are changed, then the Spec, Version, and Grade fields are cleared. You can also save a sample without having a specification associated to it.
20. Click **Get Spec** to associate a specification for this sample. The Specification Association dialog box displays.

21. Select one of the following:

- **Use Default** displays the specification, version, and grade with a specification validity rule that exactly or best matches the sample source information entered. This depends on the process quality parameter Exact Spec Match in the Process Quality Parameters window. Select Exact Spec Match if a specification needs to be an exact match. If a specification does not need an exact match, then deselect. The best match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in Appendix B.
- **Use Alternate** to select a specification that is different from the default specification for the sample. Select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

**Note:** If there is an existing sample group that matches the sample source and specification selected, then the Created On, Samples Taken, and Samples Required fields display. Deselect **Create New** to add the new sample to the existing sample group. Select **Create New** to add the new sample to a new sample group. If no sample group information is retrieved, then **Create New** defaults as selected.

22. Click **OK** to continue. The specification Name, Version, and Grade display for the specification selected.

**Note:** The Identity, Storage, Approvers, Composite Results, Spec Disposition, and Comments tabs have the same field definitions as those that appear in the "To enter an inventory sample" task. Refer to that task for this information.

23. Save the window.

### To enter a customer sample:

1. Navigate to the **ItemSamples** window.
2. Enter the **Sample**. If automatic sample numbering is selected, and the sample is a new record, then the Sample field is blank and disabled until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Use automatic sample numbering for samples generated in a stability study. Required.

3. Enter the **Disposition** as the sample status:
  - **Planned** when the sample is scheduled to be taken.
  - **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.
  - **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.
  - **Cancel** when the sample is canceled.

Required.

Refer to "Understanding Sampling" for an explanation of how to change sample disposition.
4. Enter a **Description** for the sample. If you do not enter a description, then the item description defaults from the item entered.
5. If **Retain** is the disposition, then enter **Retain As** to indicate whether the sample type is an Archive, or Reserve sample.
6. Enter **Item** as the process quality-enabled item sampled. A description of the item entered displays. Required.
7. Enter the item **Revision**, if the item is revision-controlled. If the item is not revision-controlled, then this field is disabled. Required.
8. Enter a **Priority** for the sample as:
  - **Normal** to indicate that the sample has the usual processing requirements.
  - **Low** to indicate that the sample has minimal urgency for processing.
  - **High** to indicate that the sample has urgent processing requirements.
9. Select the sample **Source** as **Customer**.
10. Enter the **Customer** name. Required.
11. Enter the **Operating Unit** corresponding to the ship-to or bill-to location. The operating unit must have an OPM fiscal policy to indicate that it is used for Process Manufacturing.
12. Enter one or both of the following fields only if you enter an operating unit:
  - **Ship-To** to indicate the ship-to location for the specified customer and operating unit.

- **Order** to indicate the order number. If you enter an order number, then **Type** displays the sales order type code from those set up for the operating unit in the Oracle Order Management application.

If you did not enter an operating unit, then leave both of these fields blank.

13. Enter the **Line** associated to the order.
14. Enter the sample item **Parent Lot** code if the item is child lot-controlled. Refer to "Understanding Parent Lots and Lots" for detailed information on parent lots and lots.
15. Enter the sample item **Lot** code. If the item you specified is lot-controlled, then edit this field. If Lot Optional On Samples is selected on the specification validity rule associated to the sample, then Lot is not required.

**Note:** If the sample was previously associated to a specification using the Sample Creation Notification workflow, then the Get Spec function is disabled. You can also save a sample without having a specification associated to it.

16. Enter the **LPN** for the Customer sample to consume. You can select the LPN from the LOV. This field is enabled only for WMS enabled organizations.
17. Click **Get Spec** to associate a specification for this sample. The Specification Association dialog box displays.
18. Select one of the following:
  - **Use Default** displays the specification, version, and grade with a specification validity rule that exactly or best matches the sample source information entered. This depends on the process quality parameter Exact Spec Match in the Process Quality Parameters window. Select Exact Spec Match if a specification needs to be an exact match. Deselect if a specification does not need an exact match. The best match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in Appendix B.
  - **Use Alternate** to select a specification that is different from the default specification for the sample. Select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

**Note:** The Created On, Samples Taken, and Samples Required

fields display if there is an existing sample group that matches the sample source and specification selected. Deselect **Create New** to add the new sample to the existing sample group. Select **Create New** to add the new sample to a new sample group. If no sample group information is retrieved, then **Create New** defaults as selected.

19. Click **OK** to continue. The Spec, Version, and Grade display for the specification selected.

**Note:** The Identity, Storage, Approvers, Composite Results, Spec Disposition, and Comments tabs have the same field definitions as those that appear in the "To enter an inventory sample" task. Refer to that task for this information.

20. Save the window.

### To view a stability study sample:

You cannot enter a stability study sample on the Item Samples window. However, you can display information about it.

1. Navigate to the **Variants** window.
2. Query the stability **Study** with the desired sample.
3. Select the variant **Num** that has the sample to view.
4. Click **Time Points**.
5. Select the **Time Interval** that has the sample to view.
6. Click **Samples**.
7. Select the sample to view.
8. Click **View Sample**.
9. The **Item Samples** window displays the desired variant time point sample.
10. The following fields are display only:
  - **Disposition** displays the sample status or disposition as:
    - **Planned** when the sample is scheduled to be taken.

- **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.
- **In Progress** when at least one result exists for the sample, but testing is not yet complete.
- **Complete** when testing of all required tests and all additional tests is complete.
- **Accept** when sample testing is complete, and results are in-specification.
- **Accept With Variance** when sample testing is complete, and at least one result is in the experimental error region or out-of-specification. However, the sample approver has accepted this with variance.
- **Reject** when sample testing is complete, and results are not acceptable, or out-of-specification.
- **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.
- **Cancel** when the sample is canceled.
- **Description** displays a description of the time point sample for the sample.
- **Retain As** indicates whether the sample type is an Archive, Reserve, or required sample.
- **Item** displays the process quality-enabled item sampled and its description.
- **Revision** displays the item revision, if the item is revision-controlled.
- **Source is Stability Study**.
- **Study** is the organization and study number.
- **Variant** displays the variant sampled.
- **Time Point** displays the variant time point sampled.
- **Scheduled** displays the date and time the sample is scheduled for testing.

**Note:** The Identity, Approvers, Composite Results, Spec Disposition, and Comments tabs have the same field definitions as those that appear in the "To enter an inventory sample" task. Refer to that task for this information.

## **Storage**

11. The following fields are display only:
  - **Storage Organization** displays the process quality-enabled inventory organization where the stability study sample is stored.
  - **Storage Subinventory** displays the storage subinventory for the variant time point sample.
  - **Storage Locator** displays the variant time point sample.
  - **Resource** displays the storage resource specified on the storage condition plan for the variant time point sample.
  - **Instance** displays the specific resource instance identified for the storage condition specified in the monitoring specification for the variant time point sample.

## **To mark a sample for deletion:**

Choose Mark for Purge from the Actions menu. The sample is marked for deletion.

## **To edit text:**

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.
2. Make appropriate text changes.
3. Save the window.

## **To compare specifications:**

Click Spec Comparison to compare specifications. Refer to "Specification Comparison" for additional information.

## **To change sample or sample group disposition:**

1. Choose **Change Disposition** from the **Actions** menu.
2. Enter the new sample disposition.
3. If the current sample completes testing for the entire sample group, then you can enter these additional fields if the **Control Lot Attributes** indicator is selected on the specification validity rule:

- Enter **Change Lot Status To** as the new or revised lot status.
- Enter **Change Grade To** as the new or revised grade.
- Enter **Reason Code** as a valid reason code for the change.

4. Enter **Hold Date** as the new or revised lot hold release date.
5. Select the recommended test results to store the lot-specific UOM conversion factors if **Calculate UOM Conversion** is selected on tests from the associated specification. Refer to "Using Lot UOM Conversions Based on Quality Results" for additional information.
6. Save the window.

### **Using a retained sample for testing:**

1. Query the sample with the disposition **Retain**.
2. Change the sample disposition to **Pending**.
  - For Retain As Archive samples, optionally select Schedule Spec Tests to assign tests from the associated specification upon request for investigation.
  - For Retain As Archive samples, the disposition remains as Retain and you cannot change it to Pending. Reserve samples can be selected for additional test quantities when testing against a required sample.
3. Navigate to the **Results** window to enter results for the sample when they become available. Refer to "Understanding Retained, Archive, and Reserve Samples" for detailed information.

### **To display the Results window:**

You can choose Results from the Actions menu, or click Results to display the Results window.

### **Managing samples for terminated batches:**

When a batch is terminated, the Sample Creation Workflow notifications that are open are canceled. Manage any samples that are created against the batch.

## **Entering Monitoring Samples**

The Monitoring Samples window lets you create a sample against a locator or resource

using the monitoring specification that is associated to it. The monitoring sample provides the information needed to evaluate the acceptability of environmental conditions for each variant storage condition in a stability study. Take these samples for tests defined in a monitoring specification. A monitoring sample is defined for:

- Organization, subinventory, locator to monitor a specific storage locator that needs to maintain a defined quality environment. For example, define FREEZER as a locator in subinventory WH1 to sample its temperature and humidity.
- Organization, resource, resource instance to monitor a specific storage resource that needs to maintain a defined quality environment. For example, define the resource CHAMBER, and the resource instance SERIALNUM-1000 to identify the specific environmental chamber used in a stability study.
- Monitoring samples cannot have a disposition of Retained.

## Prerequisites

- Set up a quality lab organization where sample testing is performed.
- Optionally, select Exact Spec Match in the Process Quality Parameters window.
- Enter tests, and create an approved specification and specification validity rule for sampling.
- Set up document numbering for the organization in which you take samples using Assignment Type in the Process Quality Parameters window.
- Optionally, enter a sampling plan.

## To enter a physical location monitoring sample:

1. Navigate to the **Monitoring Samples** window. The context organization displays in the window title. Select a different organization using the Organizations window.
2. Enter the **Sample**. If automatic sample numbering is selected, and the sample is a new record, then the Sample field is blank and disabled until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. Required.
3. Enter the **Disposition** as the sample status or disposition as:
  - **Planned** when the sample is scheduled to be taken.
  - **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.

- **Cancel** when the sample is canceled.  
Required.  
Refer to the "Understanding Sampling" topic for an explanation of how to change sample disposition.

4. Enter a **Description** for the monitoring sample.
5. Select the sample **Source** as **Physical Location**. Required.
6. Enter a **Priority** for the sample as:
  - **Normal** to indicate that the sample has the usual processing requirements.
  - **Low** to indicate that the sample has minimal urgency for processing.
  - **High** to indicate that the sample has urgent processing requirements.
7. Enter the **Subinventory** for the monitoring sample.
8. Enter the **Locator** in the subinventory for the monitoring sample.
9. Click **Get Spec** to retrieve the specification for this sample. The Specification Association dialog box displays.
10. Select one of the following:
  - **Use Default** displays the specification and version with a specification validity rule that exactly or best matches the sample source information entered. This depends on the process quality parameter Exact Spec Match in the Process Quality Parameters window. Select Exact Spec Match if a specification needs to be an exact match. If a specification does not need an exact match, then deselect. The best match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in "Appendix B".
  - **Use Alternate** to select a specification that is different from the default specification for the sample. Select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

**Note:** The Created On, Samples Taken, and Samples Required fields display if there is an existing sample group that matches the sample source and specification selected. Deselect **Create New** to add the new sample to the existing sample group.

Select **Create New** to add the new sample to a new sample group. If no sample group information is retrieved, then **Create New** defaults as selected.

11. Click **OK** to continue.
12. **Name** displays the effective default specification that best matches the sample source information, or the alternate you selected.
13. **Version** displays the version of the specification selected.

#### **Identity**

14. Enter the **Quality Laboratory** as the organization where the sample is tested.

#### **Dates**

15. Enter **Drawn** as the date and time the sample was taken. This field defaults to the current date and time.
16. Enter **Received** as the date and time the sample was received for testing.
17. Enter **Required** as the date and time when the sample is required to be taken.

#### **Storage**

18. Enter **External ID** as an alternate or cross-reference code for the sample. For example, if the sample is recorded on another test database, then enter the sample ID recorded on the external system.

#### **Comments**

19. Enter **Comments** for the sample.
20. Save the window.

### **To enter a resource monitoring sample:**

1. Navigate to the **Monitoring Samples** window. The context organization displays in the window title. Select a different organization using the **Organizations** window.
2. Enter the **Sample**. If automatic sample numbering is selected, and the sample is a new record, then the **Sample** field is blank and disabled until the record is saved, at which point a sample number is assigned. Otherwise, enter the number. **Required**.
3. Enter the **Disposition** as the sample status:

- **Planned** when the sample is scheduled to be taken.
- **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.
- **Cancel** when the sample is canceled.

Required.

Refer to "Understanding Sampling" for an explanation of how to change sample disposition.

4. Enter a **Description** for the monitoring sample.
5. Select the sample **Source** as **Resource**. Required.
6. Enter the **Resource** for the monitoring sample.
7. Enter the resource **Instance** for the monitoring sample.

Refer to the Oracle Process Manufacturing Planning user's guides for detailed information on entering resource information linked to the resource instance that identifies it.

8. Enter a **Priority** for the sample as:
  - **Normal** to indicate that the sample has the usual processing requirements.
  - **Low** to indicate that the sample has minimal urgency for processing.
  - **High** to indicate that the sample has urgent processing requirements.
9. Click **Get Spec** to retrieve the specification for this sample. The Specification Association dialog box displays.
10. Select one of the following:
  - **Use Default** displays the specification and version having a specification validity rule that best matches the sample source information entered. This match is based on the specification matching hierarchy described in "Specification Matching Business Rules" found in "Appendix B."
  - **Use Alternate** to select a specification that is different from the default specification for the sample. Select from a list of applicable specifications chosen from the specification matching hierarchy. This list is ordered based on the most specific to most generic match. If you select Use Alternate, then select the **Spec** as the alternate specification to use. The current **Version** and **Grade** display.

**Note:** The Created On, Samples Taken, and Samples Required fields display if there is an existing sample group that matches the sample source and specification selected. Deselect **Create New** to add the new sample to the existing sample group. Select **Create New** to add the new sample to a new sample group. If no sample group information is retrieved, then **Create New** defaults as selected.

11. Click **OK** to continue.
12. **Name** displays the effective default specification that best matches the sample source information, or the alternate selected.
13. **Version** displays the version of the specification selected.

#### **Identity**

14. Select the **Quality Laboratory** as the organization where the sample is tested.

#### **Dates**

15. Enter **Drawn** as the date and time the sample was taken. Defaults to the current date and time.
16. Enter **Received** as the date and time the sample was received for testing.
17. Enter **Required** as the date and time when the sample is required to be taken.

#### **Storage**

18. Enter **External ID** as an alternate or cross-reference code for the sample. For example, if the sample is recorded on another test database, then enter the sample ID recorded on the external system. This field is for informational purposes only.

#### **Comments**

19. Enter **Comments** for the sample.
20. Save the window.

### **To mark a sample for deletion:**

Choose **Mark for Purge** from the Actions menu. The sample is marked for deletion.

### To edit text:

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.
2. Make appropriate text changes.
3. Save the window.

### To change sample or sample group disposition:

1. Choose **Change Disposition** from the **Actions** menu.
2. Enter the new sample disposition.
3. Save the window.

### To display the Results window:

Choose **Results** from the Actions menu, or click **Results** to display the Results window.

### To display the monitoring specification:

Click **Specification**. The Specifications window displays the monitoring specification.

### To display the monitoring specification validity rules:

Click **Spec Validity Rule**. The Validity Rules for Monitoring Spec window displays the monitoring specification validity rules.

## Finding Samples

The Find Samples dialog box lets you find a sample by item, revision, parent lot, lot, disposition, priority, source, date and time drawn, specification, grade, quality laboratory, storage subinventory and locator, or external ID.

### Prerequisites

- Enter and save a sample.

### To find an item sample:

1. Navigate to the Find Samples dialog box. The process-enabled context organization

displays in the window title. Select an organization using the Organizations window.

2. Enter any of the following to narrow your search:
  - **Sample** code as the combination of the three-letter organization code and sample document number.
  - **Item** code as the process quality-enabled item associated to the sample.
  - **Revision** as the item revision, if the item is revision-controlled.
  - **Parent Lot** as the sample parent lot, if the item is child lot-controlled.
  - **Lot** as the sample lot, if the item is lot-controlled.
  - **LPN** as the LPN number for the sample. You can select the LPN number from the LOV. This field is enabled only for WMS enabled organizations.
  - **Disposition** of the sample as Pending, In Progress, Complete, Accept, Accept with Variance, Reject, Retain, or Cancel. If you leave this field blank, then it does not include sample disposition in the search.
  - **Retain As** to indicate whether the item sample was retained as an Archive or Reserve sample.
  - **Priority** of the sample as Normal, Low, or High. If you leave this field blank, then it does not include sample priority in the search.
3. Select one of the following as sample **Source**:
  - **Customer** to indicate that the sample source is for a customer sample. Enter Customer, Operating Unit, Customer Location, and Line.
  - **Inventory** to indicate that the sample source is for an inventory sample. Enter **Subinventory** and **Locator**.
  - **Supplier** to indicate that the sample source is for a supplier sample. Enter Supplier, Supplier Site, Operating Unit, Supplier Lot, Purchase Order number and Line, and Receipt and Line.
  - **Stability Study** to indicate that the sample source is for a stability study sample. Enter Study Name, Variant, Time Point, Scheduled, and Date Retrieved.
  - **WIP** to indicate that the sample source is for a work in process sample. Enter Batch, Recipe and its Version, Routing and its Version, Step, Charge, Operation and its Version, and Formula and its Version.

The fields listed in this step for each source type are described in the "Entering Samples" topic.

4. To narrow the search to a specific time interval that samples were drawn:
  - Enter the **Date Drawn From** field as the starting date and time for the search.
  - Enter the **To** field as the ending date and time for the search.
5. Enter the **Specification**, its **Version**, and an optional **Grade** for the search.
6. Enter the **Quality Laboratory** for sample processing.
7. Enter the **Storage Organization** for the sample.
8. Enter the **Storage Subinventory** for the sample.
9. Enter the **Storage Locator** for the sample.
10. Enter the **External ID** for the sample.
11. Select **Marked for Deletion** Yes to find samples that are marked for deletion. Select No to find samples that are not marked for deletion. If you do not want to limit your search based on whether a sample is marked for deletion, then leave this field blank.
12. Click **Find**. The **ItemSamples** window displays the results of the search.

### To find a monitoring sample:

1. Navigate to the Find Samples dialog box.
2. Enter any of the following to narrow your search:
  - **Sample** code as the combination of the three-letter organization code and sample document number.
  - **Disposition** of the sample as Pending, In Progress, Complete, Accept, Accept with Variance, Reject, Retain, or Cancel. If you leave this field blank, then it does not include sample disposition in the search.
  - **Priority** of the sample as Normal, Low, or High. If you leave this field blank, then it does not include sample priority in the search.
3. Select one of the following as sample **Source**:
  - **Physical Location** to indicate that the sample source is for a locator sample.

Enter the **Subinventory** and **Locator**.

- **Resource** to indicate that the sample source is for a resource sample. Enter the **Resource** and **Resource Instance**.

The fields listed in this step for each source type are described in the "Entering Samples" topic.

4. To narrow the search to a specific time interval that samples were drawn:
  - Enter the **Date Drawn From** field as the starting date and time for the search.
  - Enter the **To** field as the ending date and time for the search.
5. Enter the **Specification** and its **Version**.
6. Enter the **Quality Laboratory** for sample processing.
7. Enter **Storage Organization** as the process quality-enabled inventory organization where the physical location or resource monitoring sample is stored.
8. Enter the **Storage Subinventory** for the sample.
9. Enter the **Storage Locator** for the sample.
10. Enter the **External ID** for the sample.
11. Select **Marked for Deletion** as Yes to find samples that are marked for deletion. Select No to find samples that are not marked for deletion. If you do not want to limit your search based on whether a sample is marked for deletion, then leave this field blank.:
  - **Yes** to find samples that are marked for deletion.
  - **No** to find samples that are not marked for deletion.
  - Leave this field blank if you do not want to limit your search based on whether a sample is marked for deletion.
12. Click **Find**. The **MonitoringSamples** window displays the results of the search.

### To enter a new sample from the Find Samples dialog box:

1. Click **New**. The **MonitoringSamples** window displays.
2. Create a new sample as described in the "Entering Samples" topic.

## Displaying Sample Groups

The Sample Groups window lists all existing sample groups that share common sampling information. The query function lets you filter the sample groups of interest. For a selected sample group, view or add samples in the sample group. Create or view composite results for a sample group.

### Prerequisites

- Create samples.
- Complete testing and enter results for the samples.

### To display sample groups:

1. Navigate to the **Sample Groups** window. The Find Sample Groups dialog box displays. The context organization displays in the window title. Select an organization using the Organizations window.
2. Enter any of the following to narrow your search:
  - Sample as the sample number.
  - Item as the item number sampled.
  - Revision as the item revision, if the item is revision-controlled.
  - Parent lot as the parent lot number of the item sampled.
  - Lot as the lot number sampled, if the item is lot-controlled.
  - LPN as the LPN number for the sample group. You can select the LPN number from the LOV. This field is enabled only for WMS enabled organizations
  - Source
3. Click **Find**. The following fields are display only on the **Sample Groups** window:
  - **Source** indicates whether the sample source is Customer, Inventory, Locator, Resource, Supplier, Stability Study, or WIP.
  - **Creation Date** indicates the date and time of sample group creation.
  - **Item** indicates the process quality-enabled item sampled and its **Description**.

- **Revision** indicates the item revision, if the item is revision-controlled.
- **Parent Lot** indicates the parent lot number of the item sampled, if the item is child lot-controlled.
- **Lot** indicates the lot number sampled, if the item is lot-controlled.
- **LPN** indicates the LPN number for the sample group.
- **Disposition** indicates the sample group disposition as Planned, Retain, Pending, In Progress, Complete, Accept, Accept with Variance, or Reject.

### Samples

- **Required** indicates the total number of samples required in the sample group based on the sampling plan requirement.
- **Taken** indicates the total number of samples taken for the sample group based on the sampling plan requirement.
- **Lot Retest** indicates selected if the sample group is taken for lot retesting. This defaults from the Lot Expiry/Retest Notification workflow if it is used.
- **Archived Taken** indicates the total number of archived samples taken.
- **Reserved Taken** indicates the total number of reserved samples taken.

4. The following fields are display only for a customer sample source:

- **CustomerName** indicates the name of the customer.
- **Operating Unit** indicates the operating unit.
- **Order** indicates the order number.
- **Line** indicates the order line number.
- **Customer Location** indicates a ship-to or bill-to location.

5. The following fields are display only for an inventory sample source:

- **Subinventory** is the inventory subinventory code.
- **Locator** is the inventory locator code.

6. The following fields are display only for a physical location monitoring sample source:

- **Subinventory** indicates the subinventory for the monitoring sample.
- **Locator** indicates the locator in the subinventory for the monitoring sample.

7. The following fields are display only for a resource monitoring sample source:

- **Resource** indicates the resource for the monitoring sample.
- **Instance** indicates the specific instance for the monitoring sample.

8. The following fields are display only for a supplier sample source:

- **Supplier** is the supplier code.
- **Supplier Site** indicates the supplier site number.
- **Operating Unit** indicates the operating unit.
- **Supplier Lot** indicates the supplier lot number.
- **Purchase Order** indicates the purchase order number.
- **Line** indicates the purchase order line.
- **Receipt** is the receipt number.
- **Line** is the receipt line number.

9. The following fields are display only for a stability study sample source:

- **Study** indicates the stability study name.
- **Variant** indicates the variant for the sample group.
- **Time Point** indicates the time point tested for the sample group.
- **Schedule DateFrom** indicates the scheduled start date and time for drawing the sample group based on the stability study scheduled start date.
- **Schedule Date To** indicates the scheduled date and time for drawing the sample group based on the stability study scheduled end date.

10. The following fields are display only for a WIP sample source:

- **Batch** indicates the batch document number.
- **Recipe** indicates the recipe used in the batch and its **Version**.

- **Routing** indicates the routing that is associated to the recipe used in the batch and its **Version**.
- **Step** indicates the step number in the batch.
- **Charge** indicates the charge number in the step.
- **Operation** indicates the operation in the routing and its **Version**.

### To add a sample in a sample group:

1. Select the **Sample Group** to add a sample.
2. Click **Add Sample**. The **Item Samples** or the **Monitoring Samples** window displays, depending on the sample source.
3. Refer to the "Entering Samples" topic for more information on creating a sample.
4. Save the window.

### To view a sample in a sample group:

1. Select the **Sample Group** that has the sample.
2. Click **View Samples**.
3. Scroll through the samples to view the sample details.

### To create or view a composite results set:

1. Select the **Sample Group** to composite, or that has existing composite results to view.
2. Click **Composite Results**.
3. Refer to "Compositing Test Results" for information on compositing a results set.
4. Save the window.

### To find a sample group:

1. Choose **Find** from the **View** menu.
2. Enter any of the following to narrow your search:

- Sample
- Item
- Revision
- Parent lot
- Lot
- LPN as the LPN number for the sample.
- Source

3. Click **Find**.

Refer to the "Finding Samples" for a discussion of these fields.

### To select samples for mass entry from the Sample Groups window:

1. Select the sample group that has the samples to process.
2. Click **Mass Results**. The **Test** and **Description** display for each test.
3. Enter the **Tester** as the individual who enters results. Defaults to your current organization. Required.
4. Enter the **ResultDate** as the date and time the result was entered. Defaults to the current system date and time. Required.
5. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Deselect **Select** to remove tests you do not want to enter for the sample group.
6. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected. You cannot enter mass results for archive or reserve sample types.

## Displaying Sample Summaries from the Navigator

The Samples By... windows let you display summaries of item samples sorted by organization, item, disposition, test, test class, test method, and laboratory.

You can use flexfields and folders with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Enter and save samples.

## To display the Samples By... windows:

1. Navigate to the **Quality Workbench**.
2. Select **Show Active Samples** to display only those samples that are active. Active samples are defined as those samples that have a disposition of Pending or In Progress. Deselect this indicator to display item samples with all sample dispositions.
3. Select **View ByOrganization, Item, Disposition, Test, Test Class, Test Method, or Laboratory** to sort samples by organization, item, disposition, test, test class, test method, or laboratory.
4. Expand the node, and select the desired **Samples By...** window.
5. Drill down to item samples and results.
6. The following fields are display only on the **Samples By...** windows:
  - **Sample** displays the sample number.
  - **Mass Results Entry** indicates whether you can enter mass results for the sample group.
  - **Item** displays the code for the material being specified as it is listed on the Item Master in Oracle Inventory. The item must be set up as process quality-enabled.
  - **Date Drawn** displays the date and time the sample was taken.
  - **Revision** displays the item revision, if the item is revision-controlled.
  - **Disposition** displays the sample disposition as:
    - **Pending** when the sample is saved, and results are expected, but not yet recorded.
    - **In Progress** when at least one result exists for the sample, but testing is not yet complete.
    - **Complete** when testing of all required tests and all additional tests is complete.

- **Accept** when sample testing is complete, and results are in-specification.
- **Reject** when sample testing is complete, and results are not acceptable, or out-of-specification.
- **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition.
- **Retain As** indicates whether the sample type is an Archive, Reserve, or required sample.
- **Source** displays **Customer, Inventory, Monitoring, Supplier, Stability Study, or WIP** to indicate the sample source.
- **Parent Lot** displays the sample parent lot, if the item is child lot-controlled.
- **Lot** displays the sample lot.
- **LPN** displays the LPN number for the sample.
- **Specification** displays the item specification.
- **Specification Version** displays the item specification version.
- **Grade** displays the grade associated to the item specification.
- **Sample Quantity** displays the sample quantity taken.
- **Sample UOM** displays the inventory unit of measure for the sample.
- **Remaining Quantity** displays the quantity of the sample remaining from the original sample quantity taken.
- **Laboratory Organization** displays the quality laboratory that analyzes the sample.
- **External ID** displays an alternate or cross-reference code for the sample. For example, if the sample is recorded on another test database.
- **Source Comment** displays the origin of the material sampled in addition to the sample source.
- **Expiration Date** displays the sample expiration date and time.
- **Storage Organization** displays the organization where the sample is stored.
- **Storage Subinventory** displays the subinventory where the sample is stored.

- **Storage Locator** displays the restricted or non-restricted storage locator for the sample.
- **Sampler** displays the code for the individual that withdrew the sample.
- **Sample Instance** displays the sample iteration with respect to the total number of samples in the sample group based on the applicable sampling plan.
- **Samples Required** displays the total number of samples required in the sample group based on the sampling plan requirement.
- **Samples Taken** displays the total number of samples already taken for the sample group. The position of this sample is indicated.
- **Lot Retest** indicates whether the sample group is taken for lot retesting. This defaults from the Lot Expiry/Retest Notification workflow if it is used.

7. Click **View Sample** to display the **Item Samples** window for the selected sample.
8. Click **Create Sample** to display the **Item Samples** window where you can create a new sample.
9. Click **Results** to display the **Results** window.

### To select samples for mass entry from the **Samples By...** windows:

1. Select **Show Active Samples** to display only those samples that are active. Active samples are defined as those samples that have a disposition of Pending or In Progress. Deselect this indicator to display item samples with all sample dispositions.
2. Select **View ByOrganization, Item, Disposition, Test, Test Class, Test Method, or Laboratory** to sort samples by organization, item, disposition, test, test class, test method, or laboratory.
3. Expand the **Samples By...** node, and select the desired sample or sample group.
4. Click **Mass Results Entry** next to all samples that you want to select for entry of mass results. You cannot enter mass results for archive or reserve sample types.
5. Click **Mass Results Entry** to display the **Mass Results Entry Test Selection** window. The **Test** and **Description** display for each test.
6. Enter the **Tester** as the individual who enters results. Defaults to your current organization. Required.

7. Enter the **ResultDate** as the date and time the result was entered. Defaults to the current system date and time. Required.
8. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Deselect **Select** to remove tests you do not want to enter for the sample group.
9. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected. You cannot enter mass results for archive or reserve sample types.

## Displaying the Samples Summary Window

The Samples Summary window displays a summary of samples by organization.

You can use flexfields and folders with this window.

### Prerequisites

- Enter and save samples.

### To display summaries of sample information:

1. Navigate to the **Samples Summary** window. The context organization displays in the window title.
2. The following information is display only:
  - Organization
  - Sample
  - Sample Description
3. Click **Mass Results Entry** to display the **Mass Results Entry Test Selection** window. After selecting appropriate tests, click **Mass ResultsEntry** to display the Mass Results Entry window where you can enter test results.
4. The following fields are display only:
  - **Item** is the process quality-enabled item sampled.
  - **Revision** is the item revision, if the item is revision-controlled.
  - **Item Description** is the description on the Item Master.
  - **Sample Description** is the description of the sample.

- **Date Drawn** is the date and time the sample was drawn.
- **Disposition** is the current sample disposition.
- **Retain As** indicates whether the sample type is an Archive, Reserve, or required sample.
- **Source** is the sample source.
- **Parent Lot** is the sample item parent lot code, if the item is child lot-controlled.
- **Lot** is the sample item lot code.
- **Specification** is the specification associated to the sample.
- **Specification Version** is the specification version.
- **Grade** displays the grade associated to the item specification.
- **Sample Quantity** displays the sample quantity taken.
- **Sample UOM** displays the inventory unit of measure for the sample.
- **Remaining Quantity** displays the quantity of sample remaining from the original sample quantity taken.
- **Laboratory Organization** displays the quality laboratory that analyzes the sample.
- **External ID** displays an alternate or cross-reference code for the variant time point sample if the sample is recorded on another test database.
- **Source Comment** displays the origin of the material sampled in addition to the sample source.
- **Expiration Date** displays the sample expiration date and time.
- **Storage Organization** displays the storage organization for the sample.
- **Storage Subinventory** displays the storage subinventory for the sample.
- **Storage Subinventory** displays the storage subinventory for the sample.
- **Storage Locator** displays the restricted or non--restricted storage locator for the sample.
- **Sampler** displays the code for the individual that withdrew the sample.

- **Sample Instance** displays the sample iteration with respect to the total number of samples in the sample group based on the applicable sampling plan.
- **Samples Required** displays the total number of samples required in the sample group based on the sampling plan requirement.
- **Samples Taken** displays the total number of samples already taken for the sample group. The position of this sample is indicated.
- **Lot Retest** is selected if the sample group is taken for lot retesting. This defaults from the Lot Expiry/Retest Notification workflow if it is used.

**Note:** Additional fields displayed on the window depend on the sample source, and are the same as the source information described in "Entering Item Samples." Refer to this topic for field definitions.

### To select samples for mass results entry:

1. Select the sample group that has the samples to process.
2. Click **Mass Results Entry**. The **Test** and **Description** display for each test.
3. Enter the **Tester** as the individual who enters results. Defaults to your current organization. Required.
4. Enter the **ResultDate** as the date and time the result was entered. Defaults to the current system date and time. Required.
5. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Deselect **Select** to remove tests you do not want to enter for the sample group.
6. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected.



# 6

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## Results

This topic provides an overview of quality results, including the process for entering them. You are shown how to composite test results, compare specifications, change quality disposition, and manage expired lots.

This chapter covers the following topics:

- Requirements
- Understanding Results
- Entering Results
- Selecting Samples and Tests for Mass Results Entry
- Using the Mass Results Entry Window
- Displaying Test Details from Mass Results Entry
- Displaying Experimental Errors from Mass Results Entry
- Finding Samples from the Results Window
- Compositing Test Results
- Viewing Samples for Composed Results
- Adding Tests to Composed Results
- Comparing Specifications
- Finding Samples for Specification Comparison
- Changing Quality Disposition
- Associating Results to Another Sample

### Requirements

Following are some requirements that customers have for results in Quality Management.

## **Can individuals who perform tests be identified?**

Yes. The Results window includes a Tester field for each specific test.

### **Identify Individual Testers Who Perform Tests**

The Results window includes a Tester field for each specific test. Each tester must be defined as a valid Oracle user. The application uses the Tester field to sort and group result data for:

- Workflow notifications
- Result entry
- Activities for e-records and e-signatures

## **Can test quantities be tracked in testing?**

Yes. Manage the remaining sample quantity for testing based on actual test quantities used. Select a reserve sample if additional material is needed.

### **Manage Sample Quantity Used in Testing**

You can determine the sample quantity remaining after testing, and select a reserve sample to retest when there is insufficient or questionable material available.

## **Can test kit materials be tracked in testing?**

Yes. Test kit information is entered on the Results window. You can trace this material to its supplier and lot.

### **Identify Test Kit Item, or Lot Used in Testing**

For traceability purposes, test kit information is recorded on the Results window. This provides information about the material used in preparation or execution of a test. You can enter a test kit item as an inventory item in Oracle Inventory. In order to enter the test kit lot, the test kit item must be previously defined as a lot-controlled inventory item.

## **Is there a traceable record of external testing providers?**

Yes. Identify the lab where the test is done by an internal laboratory, or the test provider where the test is sent to an external laboratory for testing.

### **Record External Test Provider Information**

Enter the facility where the test is done by an internal laboratory, or the enter the test provider where the test is sent to an external testing facility. Each test provider must be defined as a valid supplier.

## Can retesting and resampling activities be enforced?

Yes. Retest and resample actions are designated upon reviewing results, so that a workflow notification can be sent to perform the test, or to take another sample.

### Assign Retest and Resample Actions When Evaluating Results

You can select a follow-up action on reviewing a test result. By associating existing action codes to the Retest and Resample Actions on the Process Quality Parameters window, the OPM Quality Testing and Sample Creation notifications are sent automatically. If the Retest Action is selected, then the test is added to the result set.

## Can results be summarized using any statistical methods?

Yes. View the arithmetic mean, standard deviation, median, or range statistics for composite test results of numeric data, and the mode statistic for composite nonnumeric data.

### Composite Test Results to Simplify Interpretation of the Results Set

You can composite results from different samples of the same item lot within a sample group, and display individual sample results. The process of compositing results simplifies the determination and reporting of one final set of results from a set of multiple samples within a sample group.

When there are several test replicates for a test on a single sample, the most recent test replicate result is used in the composite result statistics. The result used cannot be canceled, voided, or marked for deletion. The application calculates result statistics for numeric-based tests, including:

- Arithmetic mean
- Median
- Low, high, and range
- Standard deviation
- Mode

The Mode statistic is determined for List of Values and Text Range test types as the most frequently occurring result value. A user-definable value is enterable for Non-Validated test types.

This capability also provides options to exclude a sample or result, resample, or retest in order to derive the composite results set. You can save a new Results record that corresponds with the final set of composited results for an item and lot. The Certificate of Analysis prints the result average for each required numeric-based test that is not marked as optional on the specification.

## **Can lot status of an inspected item be updated automatically?**

Yes. When you choose the Control Lot Attributes option, the lot status is updated automatically when all sample results are in-specification, or one of the results is out-of-specification.

### **Update Lot Status Automatically Based on Results**

The application evaluates sample results to determine conformance with the associated specification. Sample disposition is updated to Accept or Reject appropriately based on the test results. The default lot status specified on the specification validity rule is used to update the lot status of the item lot tested.

## **Can previously analyzed samples be compared to customer requirements?**

Yes. Compare sample results to another quality specification to determine item conformance, and add appropriate tests to meet the specification used for comparison.

### **Compare a Sample to Another Specification**

You can compare a previously analyzed sample to another specification to determine whether the final results set meets the other specification requirements. Tests that were not performed previously and are part of the comparison specification can be added to the results set. The specification comparison capability evaluates results for a single sample across item specifications with the inventory, WIP, customer, and supplier validity rule types.

## **Can results be leveraged for adjusting lot-specific unit of measure conversions?**

Yes. Select the recommended lot UOM conversions based on results for designated tests.

### **Leverage Test Results to Recommend Item Lot UOM Conversions**

You can use quality test results to measure the variability of a lot attribute across item lots and to propose lot unit of measure conversions. These recommended conversions are sent using OPM Quality UOM Conversion workflow for inventory approval and adjustment.

## **Understanding Results**

Quality results serve as the basis for measuring actual material characteristics against expected quality records, and for assigning follow-up actions to be taken throughout the supply chain. Results are logged against an individual sample, where scheduled tests are driven by the specification and additional impromptu tests can be added to the sample analysis. After a technician enters results, a Quality Manager has the option to evaluate the results set against targets and limits to determine the sample disposition based on whether the results are acceptable. The collective disposition of samples in a

sample group can be used by the application for material lot usage decisions in production and inventory. Composite results and specification comparison capabilities also assist in result interpretation.

## Tracing Results by Testing Materials, Instruments, and Tester

The Results window has test kit information that helps you trace the material that is used in testing. If test results need to be investigated, then you can identify both the materials used in testing and the internal or external testing resources that performed the testing.

## Restricting the Decimals Displayed for the Result

Saved numeric results are restricted to the stored decimal precision or number of decimal places defined at the test or specification level.

## Entering a Result

To enter test results, your responsibility must have access to the quality laboratory. You can enter results by accessing the Samples Summary window from the following:

- Quality Manager and Quality Technician menus
- Product Development application, including these windows:
  - Formula Details
  - Process Operation Details Activities
  - Process Routing Details
  - Recipe Details
- Process Execution application, including these windows:
  - Batch Material Details
  - Oracle Inventory
    - Items
  - Workflow Notifications
- Process Operations application
  - Workbench

You can edit previously entered result values when the sample has a disposition of In

Progress or Complete.

## Assigning Result Evaluation and Sample Disposition Automatically

Test results are automatically evaluated for conformance to specification if the test is part of the specification associated to the sample. Results that are in-specification are assigned an evaluation of Accept. If the Control Lot Attributes indicator is enabled on the specification validity rule that is in effect, then the sample disposition can also update the lot status automatically. If all results are in-specification, then the sample disposition is set to Accept. If any of the results are out-of-specification, then the sample disposition is set to Complete and you can change the sample disposition to either Reject or Accept with Variance. The Oracle Process Manufacturing (OPM) Quality Sample Group Disposition workflow must be enabled without notification for the automatic sample disposition change.

## Assigning Result Evaluation Manually

The following result evaluations are possible:

- **Accept** confirms that the result meets the specification requirement.
- **Accept with Variance** indicates that the result falls within an experimental error region, or outside specification limits, but is considered acceptable.
- **Reject** indicates that the result for the test is rejected.
- **Experimental Error** indicates that the result falls within the experimental error regions for the test. You can change the evaluation to another selection. Refer to the "Entering Experimental Error" topic for an explanation of experimental error. Result sets or samples cannot be marked as Complete if any evaluations remain with this result evaluation.
- **Cancel** when the test is canceled.
- **Void** indicates that the test result is not reported due to a test result processing failure. The result cannot be reported because the test method itself failed.
- **Guaranteed by Manufacturer** when the manufacturer guarantees that the test result meets or exceeds customer specifications. Actual test results are not entered when you use this evaluation.

After entering a result, you can change the Evaluation field on the Results window from:

- Accept to Void
- Accept with Variance to Reject or Void

- Reject to Accept with Variance or Void
- Experimental Error to:
  - Accept, if the result is within specification limits
  - Accept with Variance, if the result is outside specification limits
  - Reject
  - Cancel
  - Void
- Null to any evaluation except Experimental Error
- Null to Cancel or Void

## Evaluating Expressions as You Report Results

Expression results cannot be entered directly. They are calculated from a mathematical expression, or by the results of tests referenced in the expression. You can calculate Expression test results before saving the results set. If all tests used in an expression have a result, then the expression is calculated irrespective of whether the result is within or outside specification limits. If tests used in an expression have replicates, then the most recent result replicate is used. Test results that are marked for deletion are not considered for expressions. The application displays a warning if the expression result is outside its limits.

### Evaluating Partial Expressions

You can use Oracle SQL\*Plus or a user defined PL/SQL NVL function to provide interim calculations of expressions that have missing test results.

Here is an example:

#### Example

$A = B + NVL(C, <\text{numeric value}>)$

where C is assigned a default numeric value to be used when C is not entered.

In this example expression, A is calculated when B is entered, even without the value of C. A default numeric value is assigned to C. If at a later point, the value of C is entered, then the expression is recalculated to include the actual value of C. Use the Recalculate option to recalculate the expression on an interim basis. The application recalculates the expression when you save your work.

## Compositing Test Results

The arithmetic mean of numeric results and the mode statistic for nonnumeric results

can be reported on a Certificate of Analysis when results are composited. The mean, median, high, low, range, standard deviation, and mode of numeric results are calculated statistics for numeric results. Text range results display the high, low, and mode values. You can enter text as the composite result for non-validated tests. If a test is replicated, then the most recent result replicate is included in the composited calculation. If a test is part of the specification that is tied to the sample and the sample group, then the composite result is evaluated automatically against the specification, and the specification information is displayed. Impromptu tests are displayed in the composite results set without specification information. You can exclude individual sample results from the calculation statistics for a test, add a test, exclude a sample, or add a sample to the composite results set.

Archive and reserve samples are not included in the composite results set. You can view results associated with a parent sample in context with composite results, however these results do not contribute to the calculated statistics.

## Comparing Specifications

You can compare results for an analyzed sample to another item specification with a status of Approved in a specific process-enabled inventory organization. The sample may already have an association with a current specification where results were evaluated against its limits to determine if they are in-specification. A comparison specification is selected for a side by side comparison of two specifications evaluated against the samples results. Tests from the comparison specification can be added to a results set to initiate additional testing. You can make the comparison specification the current specification applied to the sample so that a new sample disposition can be recorded against the new specification, if the new specification is approved for laboratory use or for general use.

You cannot compare specifications for a monitoring sample, because you should not replace the specification tied to a monitoring sample. Similarly, you should not retrieve stability samples from the Specification Comparison window. Any changes to a stability study or stability study sample for time point testing must be tracked within the stability study functionality, and not through the Specification Comparison window.

## Retesting Samples

In the case of retesting, where a previously performed test is added to the sample again, the replicate number on the Results window increases each time a test is added to the results set. For example, a test is usually run only once on a sample. The test is performed and a result is entered. If something occurs in the laboratory that requires the test to be run again, then you can add the same test to the results set again. The test appears on the Results window with a value 2 displayed in the Replicate field. You enter the repeated test result.

## Preventing Batch Step Completion

This feature prevents additional batch processing and the completion of a batch step until acceptable results are recorded and approved for the samples taken from the batch step.

You can control batch step status for quality control with a WIP specification validity rule specified for a particular routing step or batch step. Sampling at the batch step requires acceptable results for tests not marked as optional before the batch step can be completed.

### Responsibilities

Formulator, Process Engineer, Production Supervisor, Quality Manager

### Prerequisites

- Configure the process quality parameters, or a WIP specification validity rule to control batch step status. Required.
- Enable the Batch Creation, Batch Step Creation, and Batch Step Release workflow events. Optional.
- Enable the Production Sample Creation Notification. Optional

To prevent a batch step from completing until acceptable quality results are approved:

1. Create a formula.
2. Change the status of the formula to Approved for General Use.
3. Create a routing.
4. Change the status of the routing to Approved for General Use.
5. Create a recipe that contains the formula and routing.
6. Create a recipe validity rule for the recipe and the plant to produce the batch.
7. Change the status of the recipe and the status of the recipe validity rule to Approved for General Use.
8. Create and approve a specification for the product of the formula.
9. Create and approve a WIP specification validity rule, specifying the recipe, routing, or both, and routing step, or batch and batch step if these are already created. Ensure the Control Batch Step Status indicator is selected.
10. Create a batch from the recipe.

11. Release the batch.
  - From the Batch Steps window, the Batch Step Quality Status indicates Sample Required.
  - With the Production Sample Creation Notification workflow enabled, the application sends a notification for the creation of a WIP sample when the batch is created.
12. Release the batch step.
13. Create a sample from the open notification for the Sample Creation Notification workflow. You are not able to complete the batch step at this point, since no results are entered.
14. Enter and save results. If the sample group disposition for the batch step is Accept or Accept with Variance, then the Batch Step Quality Status is updated to Results In Spec, and you can complete the step.
15. Complete the batch step. If the batch step quality status does not reflect Results In Spec, then a message asking for override appears. Refer to "Removing the Override Control of Batch Step Completion" for additional information.

#### **Excluding the Override Control of Batch Step Completion**

Designated responsibilities can override the control of batch step completion despite the quality inspection requirement. The overriding of batch step completion privilege is granted to the menu associated to a responsibility. For example, the Production Supervisor menu can be granted this privilege. Exclude this override function from this responsibility by using the System Administrator responsibility.

1. Navigate to Application and choose Responsibility.
2. Query the appropriate responsibility name. For example, query Production Supervisor.
3. On the retrieved record, add the menu exclusion for the function Batch Steps:Complete without QC .
4. Save the record. This removes the override capability from the menu associated with this responsibility. When you try to complete a batch step, and results are not entered or in specification, then an error message displays.

#### **Controlling Updates to Lot Status, Grade, and Hold Date Based on Quality Test Results**

This feature helps determine material usage based on updates to lot status, grade, and hold date that are driven from quality results. An inventory, supplier, and WIP

specification validity rule can control the update of lot status depending on whether results are in or out-of-specification for all samples in a sample group. A sample disposition that is marked Accept or Accept with Variance is in-specification. A sample disposition that is marked Reject is out-of-specification.

For samples against a particular lot, the final sample group disposition can update lot attributes such as material status and grade for the lot specified. For samples against a parent lot only, the lot attributes update can apply to all lots one level below the parent lot.

#### Responsibility

Quality Manager

#### Prerequisites

- Enable the Control Lot Attributes indicator.
- Specify the default In-Specification and Out-of-Specification Lot Statuses.
- Disable the Lot Optional on Samples indicator on the Process Quality Parameters window and in an inventory or supplier specification validity rule.
- Configure the Process Quality Parameter for Inventory Transaction Reason.

To update the status and grade of the sampled lot, perform the following:

1. Create and approve a specification for the item or lot.
2. Create and approve an inventory or supplier specification validity rule. Ensure the Control Lot Attributes indicator is selected. The In-Specification Lot Status and Out-of-Specification Lot Status defaults if previously defined on the Process Quality Parameters window. Deselect the Lot Optional on Samples indicator so that updates can be enforced on a lot.
3. Create a sample.
  - If the Sample Creation Notification workflow is not enabled, then you can use the Get Spec function to associate the sample record to the applicable specification validity rule.
  - The lot number is required to update the lot status based on in-specification or out-of-specification results, lot grade, and hot hold release date.
4. Enter and save results for the sample.
5. Repeat the sample creation, results entry, and evaluation process if there are several samples to be taken from a single source.

6. When testing is complete for all samples required, specify or confirm the new lot status, grade, and hold date at the same time as you change the sample group disposition.
  - If all samples in the sample group have the disposition of Accept, then the lot status defaults to In-Specification.
  - If any of the samples have the disposition of Reject, then an Out-of-Specification lot status defaults into the Change Disposition window. This quality-driven lot status update affects all subinventories and locators of the lot.

## Completing Receiving Inspection Based on Sample Results

You can determine the receiving inspection result based on the status or acceptability of the samples analyzed in a quality laboratory. After you make a material receipt, the sample creation workflow and supplier specification validity rule expedite the sample drawing and testing process. When the receipt is routed for inspection, the collection plan specifies the requirements for sample collection. The collection plan is based on a template plan for receiving inspection of process-enabled items. Based on the outcome of sampling, you can enter an inspection result, and the accepted or rejected quantity of material. A sample group disposition of Accept or Accept with Variance permits you to enter an inspection result of Accept to approve the shipment. A sample group disposition of Reject only permits an inspection result of Reject, in which case the material is delivered to an alternate location for quarantine or returned to the vendor.

**Note:** A final disposition for the samples is required before completing the data collection at the receiving inspection. Mandatory collection elements must be entered or defaulted to save the inspection results.

### Responsibilities

Quality Inspector, Quality Manager, Quality Technician, System Administrator, and Purchasing Super User

### Prerequisites

#### Oracle Quality

- Configure the QA:PO Inspection profile option to Oracle Quality.
- Optionally, define a collection element for the Sample Group Disposition Description: Planned, Retain, Pending, In Progress, Complete, Accept, Accept with Variance, and Reject.
- Define and enable an inspection collection plan using the template OPM Receiving Inspection Collection Plan. Copy the following as Mandatory, Enabled and Displayed collection elements:

- PO Number (read only)
- Line (read only)
- PO Shipment (read only)
- PO Receipt (read only)
- Item Quantity
- UOM Sample Disposition Code (read only)
- Inspection Result Transaction Date
- Add an additional collection element for the Sample Group Disposition Description defined as a Mandatory, Enabled, Displayed, and Read Only collection element. Modify the description for this collection element according to translation needs.
- Associate the copied collection plan with the Receiving Inspection collection transaction.
- Optionally, define a specification requiring an inspection for the item and supplier. Refer to "Purchasing Data Collection" in the *Oracle Quality User's Guide* for detailed information on receiving inspections.

### **OPM Quality Management**

- Define an approved item specification validity rule and supplier specification validity rule with Lot Optional on Samples set to Yes.

Refer to "Specifications" for detailed information on entering a specification and item specification validity rule.

### **Approvals Management Engine (AME)**

- Enable the Process PO Receipt Creates business event and the OPM Quality Sample Creation subscriber workflow using the Workflow Administrator Event Manager.
- Define an AME rule and approvers for the Process Quality Receiving Transaction Sample Creation transaction using the Approvals Management Business Analyst responsibility.

Refer to the *Oracle Approvals Management Implementation Guide* and "Appendix C" for detailed information on setting up and using OPM Quality Management workflows.

### **Oracle Purchasing**

- Set up receiving options for receipt routing of the organization to Inspection Required.

#### **To determine receiving inspection results based on sample disposition:**

1. Receive against a purchase order line. A receipt is created.

2. If sampling is required for the receipt, then receive the workflow notification to take a sample.
3. Create the supplier sample.
4. Perform tests per the specification.
5. Enter results and assign evaluations and actions.
6. Assign a final sample disposition.
7. If multiple samples are taken, then enter and composite their results and assign a final sample group disposition.
8. Query the receipt. Enter the quantity received and the destination location. Receiving inspection is required for this receipt.
9. Select Inspection. The appropriate collection plan is retrieved.
10. Select the appropriate specification, if applicable.
11. Enter quality results in the collection plan. The sample group disposition for the most recent receipt line displays.
12. Enter the overall inspection result and accept or reject quantities.
13. Save the collection plan results to complete the receiving transaction.
14. Deliver the material into the desired location.

## Entering Results

The Results window lets a Quality Technician enter results for samples. For samples that are associated to a specification and version, a list of tests from the specification is provided for entry of results. You can add a test to the results set if this function is included in your responsibility. You can edit previously entered result values when the sample has a disposition of Pending, In Progress, or Complete. The application validates the result against the test range or valid test values unless the test is non-validated or guaranteed by the manufacturer. It also validates the result against the specification range if the test is part of the specification. If the result falls into an action zone for experimental error, then an operator message displays when you try to save the result. When you enter results without a specification tied to the sample, certain business rules driven by a specification and the specification validity rule cannot be enforced. You can also select Guaranteed by Manufacturer for each result.

A Quality Manager reviews results based on their conformance to specification as determined by the application. The manager can assign an evaluation of Accept, Accept

with Variance, Reject, Cancel, or Void, and a follow-up action for each result. You can access the Composite Results window from this window to aggregate results of multiple samples in a sample group. Also access the Specification Comparison window to compare results to other specifications.

## **E-Record and E-Signature Approvals**

There may be an e-signature event associated with this window. Refer to "Appendix D" for additional information on e-record and e-signature approvals associated with this window.

## **Managing Optional Tests without Results**

Tests that are marked Optional on the specification do not require result entry to finalize the sample disposition as Accept, Accept with Variance, or Reject. However, if you enter a result for an optional test, then you can configure whether the result contributes to the final disposition of a sample using Consider Optional Tests Results in the Process Quality Parameters window and this is enforced for the context organization. If an optional test result is included, then its result evaluation uses the existing business rules for changing the sample disposition. For example, an out-of-specification result for an optional test only allows the sample disposition to change to Accept with Variance, Reject, or Cancel.

Refer to "Assigning Guaranteed by Manufacturer Results" for more information on tests without results that are guaranteed by a manufacturer.

Refer to "Associating Selected Test Results to Another Sample" to associate results from a parent sample.

You can use folders, flexfields, and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## **Assigning Guaranteed by Manufacturer Results**

Manufacturers who repeatedly meet quality specifications defined by their customers establish a good performance record. They guarantee that the quality of their materials meets or exceeds customer specifications without actually sending test results to them. The practice of guaranteeing test results reduces the cost of full inspection on raw materials. By mutual agreement, the process of sampling and testing incoming materials is reduced. These results need to be marked as Guaranteed by Manufacturer in the results set. Tests that are guaranteed by one manufacturer may be required for other manufacturers who have not established a good performance record. The Quality Manager responsibility assigns this functionality.

Guaranteed by Manufacturer displays in the Evaluation column on the Results window for test results that are not entered because the manufacturer guarantees that the material meets specification for the identified tests. This includes results generated for customer samples.

Unlike the optional test result, a Guaranteed by Manufacturer test result is a required test that is needed to fulfill specification requirements. There are no results recorded for tests that are guaranteed by their manufacturers. The Quality Manager accepts the blank Guaranteed by Manufacturer result, the In Spec test indicator remains cleared, and the result can be assigned an evaluation of Accept with Variance.

If no result is reported for one of the referenced manufacturer-guaranteed tests, then Expression test calculations remain the same.

Results are not reported for tests that are guaranteed by a manufacturer, so composite results statistics for the sample group do not include them. Manufacturer guaranteed test results appear with a blank result on the View Samples by Test window and the result is omitted from calculating the number of tests included in composite results.

## Prerequisites

- Optionally, set up Process Quality Parameters for action codes to resample and retest.
- Set up quality laboratory organizations, and associate the appropriate samples and testers.
- Optionally, set up the process quality parameters Quality Laboratory and Consider Optional Tests Results in the Process Quality Parameters window.
- Enter a specification and a specification validity rule with a status of Approved for Laboratory Use or Approved for General Use.
- Enter a sample.
- Optionally, set up testers as application users.
- Optionally, set up test kits as items and lots.
- Optionally, set up test providers as suppliers.
- Optionally, set up action codes in Oracle Inventory for assigning follow-up quality actions after results are evaluated.
- Optionally, set up and activate the Testing Notification workflow.

## To enter test results:

To enter results for a test, your responsibility must have access to the quality laboratory. The quality laboratory is a process-enabled inventory organization where you test the sample.

1. Navigate to the **Results** window. Select a process-enabled inventory organization

that your responsibility can access using the Organizations window. The Find Samples window displays.

2. Query the **Sample** by sample number, disposition, item, item revision, lot, or LPN marked for deletion. You can select the LPN number that you want to use from the LOV. The sample number consists of the organization code and the document number. The sample description displays. Sample access is enforced at the test result level.
3. **Composited** indicates that results for the sample are aggregated with other samples from the same sample group. Composited does not display when results are not aggregated.
4. **Disposition** indicates the disposition of the sample as:
  - **Pending** when the sample is saved, and results are expected, but not yet recorded. Default.
  - **In Progress** when at least one result exists for the sample, but testing is not yet complete.
  - **Complete** when testing of all required tests and all additional tests is complete and result evaluations are assigned.
  - **Retain** when the sample is taken and put in storage. Results cannot exist for a sample with this disposition. Change the disposition to Pending before results entry.
  - **Planned** when the sample is scheduled for testing. Change the disposition to Pending before results entry.
5. **Spec** indicates the specification and **Version** associated to the sample.
6. **Remaining Sample Qty** displays the unused portion of the sample quantity with its **UOM**.
7. **Item** indicates the item code for the material sampled. Item defaults from the sample and must be set up as process quality-enabled in the Item Master. This field is blank for a monitoring sample.
8. **Revision** indicates the item revision, if the item is revision-controlled.
9. **Parent Lot** displays if the testing is done on a specific parent lot.
10. **Lot** displays if the testing is done on a specific lot .
11. **LPN** displays the LPN number associated with the queried sample.

12. **Batch** organization and document number display only for a WIP sample.

### Tests

13. **Seq** indicates the sequence of the test in the specification. This field defaults from the specification used when the sample was created. You can only edit this field when you add a new test. You cannot duplicate a sequence number within the same test set for different tests. Required.
14. **Test** is the predefined test code. This defaults from the specification used when the sample was created. You can duplicate a test within the same results set if you have appropriate access. For example, if retesting is required, then an additional test needs to be added.
15. **Test Method** indicates the test method used for the selected test, and it defaults from the specification. If there is no specification, then this field defaults from the test definition.
16. **Replicate** is the number of times the test is repeated. There are several result entries that correspond to the number of test replicates defined on a specification. If a test replicate is not specified for the test, then the field defaults to 1. Required.
17. Enter the **Result** for the test. You can select from the LOV for List of Test Values and Text Range test data types. The result entered must be within the test minimum and maximum ranges for Numeric Range, Numeric Range with Display Text, or Text Range test data types, or it must be in the list of valid values for the List of Test Values test data type. You cannot edit this field for the Expression test data type. You must have access to the laboratory assigned to the test in order to enter results. Result entry is optional for guaranteed by manufacturer tests.
18. **Test Unit** indicates the quality test unit of measure for the selected test.
19. Enter **Actual Result Date** as the date and time the result was recorded. You can use the LOV to select a date and time from the Calendar window. This field defaults to the system date and time. This date cannot be in the future, or prior to the system minimum date.
20. **Parent Sample** displays the parent or source sample if results are associated from another sample.
21. **Target** is the expected value to meet specification requirements if the test data type is Non-Validated, Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field defaults from the **Specifications** window.
22. **Minimum** is the minimum acceptable value to meet specification requirements, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field defaults from the **Specifications** window.

23. **Maximum** is the maximum acceptable value to meet specification requirements, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field defaults from the **Specifications** window.
24. **Priority** indicates the test priority. This defaults from the specification or the test definition. Test priority identifies the relative priority of the test among the tests listed in the specification.
25. **Planned Result Date** displays the date planned for result entry. This is calculated by adding the test duration from the test method to the sample date drawn.
26. **Test Alias** displays an alternate name for the test. This field defaults from the **Specifications** window.
27. **Test Class** displays a class name for the test. This field defaults from the test definition.
28. **Test Data Type** is the test type defined on the **Tests** window.
29. **Test Description** is a brief description of the selected test.
30. **Test By Date** displays the date that the test must be completed. This is calculated by adding the test expiration time from the specification (in days, hours, minutes, and seconds) to the sample date drawn.
31. **Test Unit Description** is a description of the unit of measure used for reporting test results.

#### **Internal**

32. **Seq** indicates the sequence of the test in the specification. This field defaults from the specification used when the sample was created. You can only edit this field when you add a new test. You cannot duplicate a sequence number within the same test set for different tests. Required.
33. **Test** is the predefined test code. This defaults from the specification used when the sample was created. You can duplicate a test within the same results set if you have appropriate access. For example, if retesting is required, then an additional test needs to be added.
34. Enter **Laboratory** as the process quality-enabled organization where the test is performed. You must have access to this laboratory to enter results. This field defaults to the quality laboratory organization specified at the time of sample creation. Required.
35. Enter the **Tester** as the person performing the test. The tester can be different from the individual who enters results. The field defaults to the current user.

36. Enter the **Reserve Sample** when the remaining sample quantity is insufficient to complete the selected test. The reserve sample must belong to the same sample group as the original sample queried. If a reserve sample is entered, then the actual test quantity is consumed from this sample.
37. **Planned Test Qty** displays the test quantity defined on the specification, or the test quantity that defaults from the test method. This is the quantity needed to perform the test.
38. Enter the **Actual Test Qty** as the quantity of sample used to perform the test. This field defaults from the planned test quantity. You can edit this field after result entry. When you save your work, the actual test quantity is subtracted from the remaining quantity of the sample selected.
39. **Test Qty UOM** displays the unit of measure for the test method. This UOM must be convertible to the primary UOM for the item.
40. Enter the **Test Kit Item** as the item number for the test kit, reagent, or other material required to perform the test. The item must be a part of the same inventory organization as the quality laboratory of the test on the sample.
41. Enter the **Test Kit Lot** as the test kit lot number. This entry ensures traceability to reagent lots if results require investigation. This field is only available if you enter a test kit item.
42. **Test Method Resource** displays the instrument defined for the test method associated to the test.
43. **Planned Resource** displays the generic resource that is planned to be used for performing the test. This defaults from the defined test method resource.
44. **Planned Resource Instance** displays the resource instance that is planned to be used for performing the test.
45. Enter the **Actual Resource** as the generic resource used for performing the test.
46. Enter the **Actual Resource Instance** as the resource instance used for performing the test.

#### **External**

47. **Seq** indicates the sequence of the test in the specification. This field defaults from the specification used when the sample was created. You can only edit this field when you add a new test. You cannot duplicate a sequence number within the same test set for different tests. Required.
48. **Test** is the predefined test code. This defaults from the specification used when the

sample was created. You can duplicate a test within the same results set if you have appropriate access. For example, if retesting is required, then an additional test needs to be added.

49. Enter the **Test Provider** as the supplier who performs the test. The LOV provides the current list of valid suppliers.
50. **Test Provider Description** displays a description of the test provider.

### Evaluation

51. **Seq** indicates the sequence of the test in the specification. This field defaults from the specification used when the sample was created. You can only edit this field when you add a new test. You cannot duplicate a sequence number within the same test set for different tests.
52. **Test** is the predefined test code. This defaults from the specification used when the sample was created. You can duplicate a test within the same results set if you have appropriate access. For example, if retesting is required, then an additional test needs to be added.
53. **Replicate** displays the test repetition number.
54. **Result** is the result for the selected test. You can select from the LOV for List of Test Values and Text Range test data types. The result entered must be within the test minimum and maximum ranges for Numeric Range, Numeric Range with Display Text, or Text Range test data types, or it must be in the list of valid values for the List of Test Values or Text Range test data types. You cannot edit this field for the Expression test data type.
55. **Test Alias** displays an alternate name for the test. This field defaults from the Specifications window.
56. **Test Class** displays an alternate name for the test. This field defaults from the test definition in the Tests window..
57. **Test Description** is a brief description of the selected test.
58. **In Spec** is determined by the application as the evaluation of conformance to the specification, and is:
  - Selected if the result conforms to the specification requirement for the test.
  - Cleared if the result does not meet the specification requirement, the test is a non-validated test data type, or the test is not part of the specification.

The In Spec indicators for test results that have an evaluation of Void or Cancel do not contribute to determining the disposition of the sample. For example, a

sample has three tests, T1, T2, and T3. Tests T1 and T2 are in-specification, and have evaluations of Accept. Test T3 test is out-of-specification, and has an evaluation of Accept with Variance. The sample for these tests cannot have disposition of Accept at this point. However, if the evaluation of Test T3 is changed to Void or Cancel, then the sample can have a disposition of Accept.

- Cleared for tests results that are guaranteed by the manufacturer.

**59. Enter Evaluation as:**

- **Accept** to confirm that the result meets the specification requirement.
- **Accept with Variance** if the result falls within an experimental error region, but is considered acceptable.
- **Guaranteed by Manufacturer** if the manufacturer guarantees that the test result meets or exceeds customer specifications. Actual test results are not entered when you use this evaluation.
- **Reject** to reject the result for the test.
- **Experimental Error** displays if the result falls within the experimental error regions for the test. Change the evaluation to another selection. Refer to the "Entering Experimental Error" topic for an explanation of experimental error.
- **Cancel** when the test is canceled.
- **Void** to indicate that the test result is not reported due to a test result processing failure. The result cannot be reported because the test method itself failed.

Refer to the "Understanding Results" topic for a complete discussion of the business rules associated to this field.

**60. Action** displays the action code set up in Oracle Inventory that is associated to the experimental error region, or the out-of-specification region for the test result. Select an action if there is no default from the specification.

**61. Optional** is selected when the test is not required for the specification. You can complete a result set that is missing optional test results.

**62. Target** is the expected value to meet specification requirements if the test data type is Non-Validated, Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field defaults from the **Specifications** window.

**63. Minimum** is the minimum acceptable value to meet specification requirements, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range,

or Expression. This field defaults from the **Specifications** window.

64. **Maximum** is the maximum acceptable value to meet specification requirements, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field defaults from the **Specifications** window.
65. **Priority** indicates the test priority. This defaults from the specification or the test definition. Test priority identifies the relative priority of the test among the tests listed in the specification.
66. **Actual Result Date** indicates the date and time for this result.
67. **Print Additional Test on COA** is selected when an additional test is included on the printout of the Certificate of Analysis.

#### **To edit a result:**

You can edit previously entered result values when the sample disposition is In Progress, Pending, or Complete.

1. Navigate to the Results window.
2. Query for an existing sample with the sample disposition In Progress or Complete.
3. Edit the Result in the desired test line.
4. Enter the Result Date.
5. Select the Evaluation if there is no default.
6. Select the Action if there is no default.

#### **To access the Allow Edit Results function:**

Make corrections to test results anytime before assigning a final sample disposition. The edit results feature is enabled when the user responsibility has access to the Allow Edit Results function (GMD\_ALLOW\_EDIT\_RESULT).

Changes to saved results are permitted only while the sample disposition is In Progress or Complete. The Quality Manager can correct result entry errors before finalizing the sample disposition.

#### **To mark a result record for purge:**

Choose Mark for Purge from the Actions menu. The result record is marked for deletion.

### To edit text in a result:

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.
2. Make appropriate text changes.
3. Save the window.

### To display the Item Samples or Monitoring Samples windows:

1. Choose **Samples** from the **Actions** menu. The corresponding **Item Samples** or **Monitoring Samples** window displays for the selected results set.
2. Refer to "Entering Samples" for information on samples.
3. Close the window.

### To display the Tests window:

1. Place the cursor on the desired test line.
2. Choose **Tests** from the **Actions** menu.
3. Refer to the "Entering Tests" topic for information on tests.

### To display the Test Methods window:

1. Place the cursor on the desired test line.
2. Choose **Test Methods** from the **Actions** menu.
3. Refer to the "Entering Test Methods" topic for information on test methods.
4. Close the window.

### To display the Specifications window:

1. Choose **Specifications** from the **Actions** menu.
2. Refer to the "Entering a Specification" topic for information on specifications.
3. Close the window.

## To add tests:

1. Place the cursor in the test details region.
2. Choose **Add Tests** from the **Actions** menu.
3. Enter a **Test Class** to narrow the list of tests.
4. Select the **Test** to add. The list of tests available is not limited to those tests listed on the specification.
5. **Test Qty** displays the planned test quantity defined on the specification or test method in its **Test Qty UOM**. If the test is not part of the specification, then you can edit this field.
6. Click **Add** to add the selected test to the results set.

## To assign a test group to a set of results:

1. Query the desired result set to assign a test group.
2. Choose **Add Test Group** from the **Actions** menu. You can add tests to a results set that has a sample disposition of Pending, In Progress, or Complete.
3. Query the desired **Test Class**. The window displays all tests included in that test class.
  - **Ordering** is the sequence of the test in the group as entered on the Tests window.
  - **Test** is the name of the test entered.
  - **Description** is the description of the test code.
  - **Data Type** is the test data type as described in "Understanding Tests."
  - **Qty** is the planned amount of material required for the test. If the test is passive and does not require a physical sample quantity, then leave this field blank.
  - **UOM** is the unit of measure for the test quantity defined in the test method.
4. Select **Include** to copy to the tests in the group to be copied to the results.
5. Click **OK**. Selected tests are added to the results.
6. Save your work.

## To change the disposition of the sample:

1. Choose **Change Disposition** from the **Actions** menu.
2. Refer to "Changing Quality Disposition."
3. Select a new disposition for the sample.
4. Click **OK** to save changes.

## To display the Composite Results window:

If there is at least one sample in the sample group, then this option is available.

1. Choose **Composite Results** from the **Actions** menu.
2. Refer to the "Compositing Test Results" topic for information on compositing test results.

## To display the Specification Comparison window:

1. Choose **Specification Comparison** from the **Actions** menu.
2. Refer to the "Comparing Specifications" topic for information on comparing specifications.

## To associate results from another sample:

1. Choose **Results Association** from the **Actions** menu.
2. Query the parent sample, select, and review results retrieved.
3. Click **OK** to associate the parent sample results selected to the current sample results record.
4. Close the window.

Refer to "Associating Results to Another Sample" for detailed information.

## To display the parent sample for an associated result:

1. Place the cursor on the desired test line that has a result association to a parent sample.
2. Choose **Parent Sample** from the **Actions** menu.

## Selecting Samples and Tests for Mass Results Entry

The Mass Results Entry Test Selection window lets you access the Mass Results Entry window by selecting a set of samples and tests prior to mass results entry. Select samples from either the Sample Groups window or Samples By... window. You can select item, monitoring, or stability samples with a disposition of Pending, In Progress, or Complete.

You can use folders with this window.

### Prerequisites

- Enter and save one or more samples that require multiple results to enter.

#### To select samples and tests for mass entry from the Sample Groups window:

1. Navigate to the **Sample Groups** window.
2. Select the sample group that has the samples to process.
3. Click **Mass Results**. The **Mass Results Entry Test Selection** window displays.
4. The **Test** and **Description** display for each test. You can select up to 20 tests assigned to samples at a time.
5. Enter the **Tester** as the individual who enters results. Defaults to the current user. Required.
6. Enter the **Result Date** as the date and time the result was entered. Defaults to the current system date and time. Required.
7. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Deselect **Select** to remove tests you do not want to enter for the sample group.
8. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected. You cannot enter mass results for archive or reserve sample types.

#### To select samples and tests for mass entry from the Samples By... windows:

1. Navigate to the **Quality Workbench**.
2. Select **Show Active Samples** to display only those samples that are active. Active samples are defined as those samples that have a disposition of Pending or In Progress. Deselect this indicator to display item samples with all sample

dispositions.

3. Select **View ByOrganization, Item, Disposition, Test, Test Class, Test Method, or Laboratory** to sort samples by organization, item, disposition, test, test class, test method, or laboratory.
4. Expand the **Samples By...** node, and select the desired top-level node that contains multiple samples. The appropriate **Samples By...** window displays.
5. Click **Mass Results Entry** next to all samples to select for entry of mass results.
6. Click **Mass Results Entry** to display the **Mass Results Entry Test Selection** window. The **Test** and **Description** display for each test.
7. Enter the **Tester** as the individual who enters the test result. Defaults to the current user. Required.
8. Enter the **ResultDate** as the date and time the result was entered. Defaults to the current system date and time. Required.
9. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Deselect **Select** to remove tests you do not want to enter for the samples. You can select up to 20 tests assigned to samples at a time.
10. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected. You cannot enter mass results for archive or reserve sample types.

#### To select samples and tests for mass entry from the **Samples Summary** window:

1. Navigate to the **Samples Summary** window.
2. Select the sample group that has the samples to process.
3. Click **Mass Results Entry**. The **Mass Results Entry Test Selection** window displays. The **Test** and **Description** display for each test.
4. Enter the **Tester** as the individual who enters the test result. Defaults to the current user. Required.
5. Enter the **Result Date** as the date and time the result was entered. Defaults to the current system date and time. Required.
6. Click **Select All** to select all tests, or **Select** the tests to enter for the sample group. Deselect **Select** to remove tests you do not want to enter for the sample group. You can select up to 20 tests assigned to samples at a time.

7. Click **Mass Results Entry**. The **Mass Results Entry** window displays to enter test results for all samples selected. You cannot enter mass results for archive or reserve sample types.

### **To select all tests for results entry:**

Click **Select All** on the Mass Results Entry Test Selection window to select all tests for results entry.

### **To clear all tests selected for results entry:**

Click **Clear All** on the Mass Results Entry Test Selection window to clear all tests selected for results entry.

## **Using the Mass Results Entry Window**

The Mass Results Entry window lets you enter results in a spreadsheet array for numerous samples without the need for extensive navigation. The primary purpose of this window is for results data collection on samples requiring testing, where result entry validation, expression test calculations, experimental errors, and e-signatures are supported. The samples listed can represent the same sample group material, resource, or locator, and can also span different sample groups for item and lot combinations, resources, or locators.

A sample can be listed several times in the array to correspond with the number of test replicates. You can enter results for each test in a column. Tests are assigned either by a specification, or manually added to each sample. Tests displayed are not necessarily common to each sample. You can view additional details about each sample and test, such as item, lot, and test method in context with the cell selected in the array. This unified view provides increased productivity by reducing window navigation and the requirement to drill down to enter results one at a time. It also gives you a tool to identify tests that still need to be performed on samples.

Refer to "Understanding Results" and "Entering Results" for additional features available after result entry.

Following is a typical scenario for entering mass results. Run 20 samples in duplicate for a chloride test. This generates 40 chloride test results to enter. Select the samples from the Sample Groups or Samples By... windows. Use the Mass Results Entry Test Selection window to select the chloride test for results entry. Navigate to the Mass Results Entry window. Enter the results, and save your work. If all test results are not complete, then return to the Mass Results Entry window, identify those samples that require a chloride test result, perform those tests, and enter the results.

## Prerequisites

- Create samples and assign a specification or add tests.
- Select samples for mass results entry from the Sample Groups or Samples By... windows.
- Select tests for mass results entry from the Mass Results Test Selection window.

## To use the Mass Results Entry window:

1. Navigate to the **Mass Results Entry** window.
2. The following fields are display only:
  - **Sample** is the combination of the three-letter organization code hyphenated with the sample number.
  - **Replicate** is the replicate number for the test listed.
3. Enter the test result for each test replicate.
  - If the cell is disabled from result entry, then the test is not assigned to the sample or your responsibility does not have the privilege to access the laboratory organization.
  - If a result was previously entered for the sample and test combination, then it appears with the Tester and Result Date in the array, and it cannot be edited.
4. Click **Test Details** to display the **Test Details** window to view detailed information for the current test and sample.
5. Click **Experimental Error** to display the Experimental Errors window to review any results that fall into an experimental error region and the associated action code assigned by the specification or test definition.
6. Save your work.

## To calculate expression test results:

Click Calculate Expression to calculate an expression test.

Refer to "Understanding Results" for additional information.

## To display experimental errors:

Click Experimental Error to display the Experimental Errors window.

Refer to "Displaying Experimental Errors from Mass Results Entry" for additional information.

## To display test details:

Click Test Details to display the Test Details window where you can view detailed information for the current test and sample.

Refer to "Displaying Test Details from Mass Results Entry" for additional information.

# Displaying Test Details from Mass Results Entry

The Test Details window displays the sample, test, and test method information associated to a specific sample when you select a cell in the Mass Results Entry window. Each cell represents a sample and test combination. This window can remain open. It refreshes as you change cursor focus in the Mass Results Entry window to reflect the current information associated to the cell.

## Prerequisites

- Enter and save tests.
- Enter and save samples.
- Use the Mass Results Entry window to enter sample test results.

## Displaying test details from the Mass Results Entry window:

1. Navigate to the **Test Details** window.
2. The following fields are display only:
  - **Sample Description** is the description for the sample.
  - **Item** is the process quality-enabled item associated to the sample.
  - **Revision** is the item revision, if the item is revision-controlled.
  - **Parent Lot** is the parent lot number. This displays if the item is child lot-controlled.
  - **Lot** is the sample lot.

- **Subinventory** is the subinventory code for the sample if its source is either inventory or locator.
- **Locator** is the locator code for the subinventory if the sample source is either inventory or locator.
- **Resource** is the resource for the sample if its source is resource.
- **Test Method** is test method assigned to the test.
- **Test Unit** is the unit of measure used for reporting test results.
- **Test Quantity** is the planned quantity of material required for testing. This field defaults from the test method or specification. **UOM** displays as the inventory UOM for the planned quantity.
- **Batch** is the batch number for a WIP sample.
- **Optional** is selected if the test is marked as optional on the specification. Otherwise, the test is required.
- **Display Label** is the text displayed for a Numeric Range with Display Text test type.
- **Expression** is the mathematical expression used to calculate an expression test type.

3. Click **Close**.

## Displaying Experimental Errors from Mass Results Entry

The Experimental Errors window summarizes any results entered on the Mass Results Entry window that fall into the experimental error regions. It also displays the assigned actions for these results as defined on a test or specification.

Refer to "Entering Experimental Error" for additional information.

## Prerequisites

- Enter and save tests.
- Enter and save test samples.
- Use the Mass Results Entry window to enter test results.

## To display experimental errors from the Mass Results Entry window:

1. Navigate to the **Experimental Errors** window.
2. The following fields are display only:
  - **Sample** is the combination of the three-letter organization code hyphenated with the sample number.
  - **Test** is the code for the test in the current specification.
  - **Replicate** is the replicate number for the test. The replicate corresponds to the number of times the test is assigned or added to the sample.
  - **Result** is the test result entered on the Mass Results Entry window.
  - **ActionCode** is the action code associated to the experimental error region for the test result.

## Finding Samples from the Results Window

The Find Samples dialog box accessed from the Results window lets you find a sample by sample disposition, item, lot, or marked for deletion status.

### Prerequisites

- Enter and save a sample.

## To find a sample from the Results window:

1. Navigate to the Find Samples dialog box. The context organization displays in the window title. Select a different organization using the Organizations window.
2. Enter any of the following to narrow your search:
  - **Sample** as the sample number.
  - **Disposition** of the sample as Pending, In Progress, Complete, Accept, Accept with Variance, Reject, or Cancel. If you leave this field blank, then it does not include sample disposition in the search.
  - **Item** as the process quality-enabled item associated to the sample. The item description displays.
  - **Revision** as the item revision, if the item is revision-controlled.

- **Lot** for the item associated to the sample.

3. Select **Marked for Deletion** as:
  - **Yes** to find samples that are marked for deletion.
  - **No** to find samples that are not marked for deletion.
  - Leave this field blank if you do not want to limit your search based on whether a sample is marked for deletion.
4. Click **Find**. The **Results** window displays the first sample that matches the search criteria.

## Compositing Test Results

The Composite Results window lets you aggregate results across samples for the same event or sample group. This window summarizes the composite statistics for results for each test. If results were previously composited, then you can view the existing composite results. Otherwise, the composite result set is created, and it incorporates the most recent data for the samples and results in the sample group. You can view the result for each sample that contributes to the statistics for each test. You can also create samples, and add tests to the composite results set.

## E-Record and E-Signature Approvals

There may be an e-signature event associated with this window. Refer to "Appendix D" for additional information on e-record and e-signature approvals associated with this window.

## Prerequisites

- Enter results.

## To composite test results:

1. Navigate to the **Sample Groups** window.
2. Select the row of the sample group to composite. Each row begins with a **Source**, followed by the **Item** and **Description**.
3. Click **Composite Results**. The **Composite Results** window displays.
4. The following fields describe the sample group, and are display only:

- **Sample Taken** indicates the number of samples taken for the event.
- **Disposition** indicates the disposition of the composite results set for the current specification associated to the sample group.
- **Item** indicates the process quality-enabled item code for the material sampled.
- **Revision** indicates the item revision.
- **Parent Lot** displays the parent lot number, if the item is child lot-controlled.
- **Lot** displays the lot number, if the item is lot-controlled.
- **LPN** indicates the LPN number for the sample.
- **Specification** displays the specification name.
- **Version** displays the specification version.

5. The following fields describe each composite result row, and are display only:

- **Test** indicates each test performed on the item listed.
- **Mean** indicates the arithmetic mean of the results composited.
- **Median** indicates the median value of the results composited.
- **Mode** indicates the most frequently occurring value of the results composited. If no value occurs more frequently than any other, then no value displays.
- **Low** indicates the lowest result value of the results composited.
- **High** indicates the highest result value of the results composited.
- **Range** indicates the range of values for the results composited. For numeric based tests, this is the high result value minus the low result value.
- **Deviation** indicates the standard deviation of the results composited.
- **Tests Used** indicates the number of test results that comprise the statistics. The number of tests used is equal to or less than the total number of result records used to composite the test.

6. Enter the **Non-Validated Result** for the Non-Validated test data type.

7. The following fields are display only:

- **In-Spec** indicates that the composite result is in-specification.

- **Total Tests** indicates the total number of test results available for composite results.
- **Associated Result** indicates that the composite result row reflects results associated from a parent sample group.
- **Report Precision** indicates the reporting decimal precision for the test according to the specification.
- **Unit** indicates the quality test unit of measure for the selected test.
- **Test Method** indicates the test method code for the test.
- **Test Data Type** indicates the test data type.
- **Test Description** indicates a brief description of the test.

8. Select **Accept** to accept the test results.
9. Click **Save Composite** to save the composited results.

### To view existing composite results:

1. Select the row of the sample group to view.
2. Click **Composite Results**.
3. You can composite results as described in steps 4 to 6 of the previous task.
4. Click **Save Composite** to save the composited results.

### To view samples contributing to the composite result for a test:

1. Select the row in the sample event or sample group.
2. Click **View Samples** to display the samples used to composite results for the selected test. Refer to the "Viewing Samples for Composited Results" topic to view the samples for a composited test. You can exclude samples from the composite result set and recalculate the statistics displayed on this window.

### To add samples to the composited results:

1. Click **Add Sample** to add a sample to the sample group.
2. Refer to the "Entering Samples" topic for more information on creating samples.

3. Save the window.

### To add a test to the composited results:

Click Add Test to display the Add Test To Samples window to add a test to the composited results.

Refer to "Adding Tests to Composed Results" for additional information.

## Viewing Samples for Composed Results

The View Samples For Test window lets you view samples in the sample group that comprise the composited results for a specific test. You can exclude samples, and recalculate the statistics displayed on this window.

You can use flexfields and attachments with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

### Prerequisites

- Enter and save samples.
- Enter and save results.
- Create and save composite results for the sample group.

### To display samples for composited results:

1. Navigate to the **Sample Groups** window.
2. Select the row of the desired sample group.
3. Click **Composite Results**.
4. Click **View Samples**. The **View Samples For Test** window displays. The sample organization displays in the window title.
5. The following fields are display only for each selected test:
  - **Target** indicates the specification target. This field displays only if a target was defined, and the test is part of the current specification tied to the sample.
  - **Minimum** indicates the specification minimum, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field displays only if the test is part of the current specification tied to the sample.

- **Maximum** indicates the specification maximum, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field displays only if the test is part of the current specification tied to the sample.
- **Test Method** indicates the test method code for the test.
- **Unit** indicates the quality test unit of measure specified at the test level for the selected test.
- **Test Data Type** indicates the test data type entered for the test.

6. The following fields list the samples that comprise the composite result for each selected test:

- **Sample** indicates the combination of the three-letter organization code and the sample number.
- **Result** indicates the test result for the sample.

7. Click **Exclude** to exclude the sample from the composited result for the test.

8. The following fields are display only:

- **Result Date** indicates the date and time the result was entered.
- **Tester** indicates the person performing the test. The tester can be different from the individual who enters results.
- **Parent Sample** indicates the combination of the three-letter organization code and the parent or source sample number, if one exists. The parent sample can belong to an organization that is different from the sample organization.
- **Disposition** indicates the disposition for the sample as Pending, In Progress, Complete, Accept, Accept With Variance, Reject, or Cancel.  
Refer to "Understanding Sampling" for a complete explanation of sample disposition.
- **Reserve Sample** indicates the retained sample for reserve use that is used to perform the test. Test quantities are consumed from this sample.

9. The following fields describe each selected test, result, and sample, and are display only:

- **Description** indicates a description of the sample.
- **Source** indicates the source of the sample as Customer, Inventory, Physical Location, Resource, Supplier, Stability Study, or WIP.

10. The following fields are display only and summarize the statistics of results that are not excluded from the composite:

- **Mean** indicates the arithmetic mean of the results composited.
- **Median** indicates the median value of the results composited.
- **Mode** indicates the mode value of the results composited.
- **Low** indicates the lowest result of the results composited.
- **High** indicates the highest result for the test in results composited.
- **Range** indicates the range of values for results composited. For numeric based tests, this is the high result minus the low result.
- **Deviation** indicates the standard deviation of the results composited.
- **Tests Used** indicates the number of test results that comprise the statistics. The number of tests used is equal to or less than the total number of result records used to composite the test.
- **Total Tests** indicates the total number of tests used to composite the results.

### To recalculate composite results:

1. Select or deselect **Exclude**.
2. Click **Recalculate**. The statistics displayed recalculate according to the changes made.
3. Click **OK**.

## Adding Tests to Composed Results

The Add Tests window lets you add a test to the results set of samples in the sample group. If the sample group disposition is Accept, Accept with Variance, or Reject, then tests cannot be added.

When adding a test, the planned test quantity and UOM fields default into the Results window from the Specification when the test is part of the specification, or from the Test Method when the test is not part of the specification.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Enter tests.
- Enter a specification.
- Enter samples.
- Enter test results.
- Composite test results.

## To add a test to the Composite Results window:

1. Navigate to the **Sample Groups** window.
2. Select the row of the desired sample group.
3. Click **Composite Results**. The **Composite Results** window displays. The context organization displays in the window title.
4. Click **Add Tests**. The **Add Tests** window displays.
5. Enter the **Test** to add. The test **Description** displays. Required.
6. Enter the **Test Qty** as the planned quantity of material required to perform this test. **Test Qty UOM** displays the unit of measure in Oracle Inventory for the test method. This UOM must be convertible to the primary UOM for the item.
7. Select **Include** to add the test to the selected sample.
8. The following fields are display only:
  - **Sample** is the combination of the three-letter organization code and the sample number.
  - **Disposition** indicates the disposition of the sample as Pending, In Progress, Accept, Accept with Variance, Complete, Cancel, or Reject.
  - **Description** indicates a description of the sample.
  - **Source** indicates the source of the sample as Inventory, WIP, Customer, or Supplier.
  - **Target** indicates the specification target. This field displays only if a target was defined, and the test is part of the current specification tied to the sample.

**Display** indicates the display text for the specification target for the test, if the test type is Numeric Range with Display Text.

- **Minimum** indicates the specification minimum, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field displays only if the test is part of the current specification tied to the sample.  
**Display** indicates the display text for the specification minimum for the test, if the test type is Numeric Range with Display Text.
- **Maximum** indicates the specification maximum, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression. This field displays only if the test is part of the current specification tied to the sample.  
**Display** indicates the display text for the specification maximum for the test, if the test type is Numeric Range with Display Text.
- **Unit** indicates the quality test unit of measure specified at the test level for the selected test.
- **Method** indicates the test method entered for the test.
- **Test Data Type** indicates the test data type entered for the test.
- **Expression** indicates the expression used for the Expression type test.

9. Click **Add**.

## Comparing Specifications

The Specification Comparison window lets you compare the current specification associated to the specific sample with a comparison specification that has a status of Approved in a specific process-enabled inventory organization to determine how closely the results set meets the comparison specification. These comparisons are useful for:

- Evaluating material conformance with a customer specification to determine if the current results also meet customer requirements. It is possible to add tests to the results set for this purpose.
- Regrading an item that has failed current specification requirements for a specific grade. For example, if the results do not meet grade A, you can compare specifications for grade B and determine if the results meet that grade. If they do meet grade B requirements, then you can reassign the material to grade B. It is possible to add tests to the results set to meet the new grade requirements for the comparison specification.

The results evaluated against the current specification are displayed when you access

the Specification Comparison window from the Item Samples or Results windows, since appropriate information about the sample and sample group is available. The specification comparison functionality does not apply to retained, monitoring, or stability study samples. The current specification must have a status of Approved for Laboratory Use or Approved for General Use.

With the current specification displayed for an item, you can select a comparison specification using the LOV in the Spec field of the Comparison Specification. A comparison displays. If no specification is tied to the sample and its results, then you can select a comparison specification using the Spec LOV.

You have the following options:

- If the comparison specification is Approved for General Use, then you can review acceptability of test results, add additional tests to meet the testing requirements for the current specification, or save the comparison specification as the current specification for the sample.
- When you save the comparison and the sample disposition is Accept or Accept with Variance, the application saves the Comparison Specification with a sample disposition of Complete.
- If the sample disposition against the current specification is not Accept or Accept with Variance, and you attempt to save the comparison, then the application asks you if you want to make the comparison specification the driving specification for the sample and sample group. If you enter Yes, then the application saves the comparison specification with any tests added, and it sets the sample disposition accordingly. If you enter No, then the application does not set the sample disposition, and the comparison is not saved.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Enter tests.
- Enter specifications.
- Enter samples.
- Enter results against samples.

## To compare results against current and comparison specifications:

1. Navigate to the **Specification Comparison** window. The context organization displays in the window title. The Find Sample dialog box displays.

2. Query the **Sample** to use for specification comparison using the Find Samples window. Required.
3. **Disposition** indicates the disposition of the sample as:
  - **Pending** when the sample is saved, and results are expected, but not yet recorded. Default.
  - **In Progress** when at least one result exists for the sample, but testing is not yet complete.
  - **Complete** when testing of all required tests and all additional tests is complete.
  - **Accept** when sample testing is complete, and results are in-specification.
  - **Accept With Variance** when sample testing is complete, and at least one result is in the experimental error region or out-of-specification. However, the sample approver has accepted this with variance.
  - **Reject** when sample testing is complete, and results are not acceptable, or out-of-specification.
  - **Cancel** when the sample is canceled.
4. **Item** displays the process quality-enabled item associated to the sample.
5. **Revision** displays the item revision.
6. **Parent Lot** displays the parent lot number if specified on the sample.
7. **Lot** displays the lot number if specified on the sample.
8. **LPN** displays the LPN number associated to this sample. Click Find.
9. Enter **Spec** as the comparison specification for reviewing results in the Comparison Specification section. You can select the LOV for the Spec field to find a specification based on grade, or an Inventory, WIP, Customer, or Supplier Specification Validity Rule.
10. The following fields are display only:
  - **Version** indicates the version of the comparison specification.
  - **Grade** indicates the item grade for the comparison specification.
  - **Status** indicates the status of the comparison specification and version.

## Current Specification

11. The following fields are display only:

- **Spec** indicates the current specification associated to the sample. Required.
- **Version** indicates the current specification version.
- **Grade** indicates the item grade for the current specification.
- **Status** indicates the status of the current specification.
- **Test** indicates the code for the test in the current specification.
- **Result** indicates the latest result replicate for the selected test for the current specification. The result must be within the test minimum and maximum ranges for Numeric Range, Numeric Range with Display Text, or Expression test data types, or it must be in the list of valid values for the List of Test Values or Text Range test data types.
- **Target** indicates the target for the current specification for the selected test.
- **Min** indicates the specification minimum for the current specification, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression.
- **Max** indicates the specification maximum for the current specification, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression.
- **In Spec** is selected if the result is within the specification minimum and maximum or in conformance with the current specification. In Spec is cleared, if the result is outside the specification minimum and maximum or the test is not part of the specification.

## Comparison Specification

12. The following fields are display only:

- **Target** indicates the target for the comparison specification, if defined, for the selected test.
- **Min** indicates the specification minimum for the comparison specification, if the test data type is Numeric Range, Numeric Range with Display Text, Text Range, or Expression.
- **Max** indicates the specification maximum for the comparison specification, if the test data type is Numeric Range, Numeric Range with Display Text, Text

Range, or Expression.

- **In Spec** is selected if the result is within the specification minimum and maximum or in conformance with the comparison specification. In Spec is cleared, if the result is outside the specification minimum and maximum or the test is not part of the comparison specification.

13. **Description** is the test description.
14. **Type** is the test data type.
15. **Unit** is the test unit for the test.
16. **Method** is the test method.
17. **Class** is the class code for the test data type.

### To use the comparison specification:

1. Click **Use Comparison Spec**. The comparison specification becomes the current specification, and the sample disposition is reset to Complete. If tests are added, then the disposition is set to In Progress.
2. You have the options to:
  - Select a new comparison specification.
  - Select a new comparison specification and add tests to the results set.
  - Change the disposition based on the new specification to Accept, Accept with Variance, or Reject.
3. Save the window.

### To add tests from the comparison specification:

1. Click **Add Tests**. The tests from the comparison specification that are not part of the current specification are added to the end of the results set.
2. If workflow is enabled, then required test notifications are sent.
3. Save the window.

### To view the sample associated to the sample group:

Click **View Sample** to display the **Item Samples** window. Refer to the "Samples" topic

for more information on samples.

### To display the current specification:

Choose **Current Specification** from the **Actions** menu. Refer to the "Specifications" topic for information on specifications. You can only view the specification.

### To display the comparison specification:

Choose **Comparison Specification** from the **Actions** menu. Refer to the "Specifications" topic for information on specifications. You can only view the specification.

### To change disposition:

Choose **Change Disposition** from the **Actions** menu. Refer to the "Changing Quality Disposition" topic for information on changing the disposition of a sample.

### To display the Item Samples window:

Choose **Sample** from the **Actions** menu. Refer to the "Samples" topic for information on samples.

## Finding Samples for Specification Comparison

The Find Samples dialog box lets you find a sample that is currently associated to a specification that you can use for comparison to another specification.

### Prerequisites

- Enter and save a specification.
- Enter and save samples.
- Enter and save results for samples.

### To find samples for specification comparison:

1. Navigate to the Find Samples dialog box. The context organization displays in the window title.
2. Enter any of the following to narrow your search:
  - **Sample** as the sample number.
  - **Item** as the item sampled.

- **Revision** as the item revision, if the item is revision-controlled.
- **Parent Lot** as the parent lot sampled.
- **Lot** as the lot sampled.
- **LPN** as the LPN number for the sample.
- **Disposition** as Pending, In Progress, Accept, Accept with Variance, Complete, Cancel, or Reject. If you leave this field blank, then it does not include sample disposition in the search.

3. Click **Find**. The **Specification Comparison** window displays any current specification that matches the parameters entered.

## Changing Quality Disposition

The Quality Change Disposition dialog box lets you change the disposition of a sample, or sample group to indicate the final review of the Quality Manager. When the sample or sample group disposition is finalized to Accept, Accept with Variance, Reject, or Cancel, then additional tests cannot be added. Changing to a final sample group disposition of Accept, Accept with Variance, or Reject can also update lot status, grade, hold date, and the item lot UOM conversion factors between UOM classes. The disposition of a sample or sample group can be assigned automatically or manually according to preseeded business rules. Sample groups that have only one sample have the same disposition as the single sample in that group.

You can access this dialog box from the following windows:

- Item Samples
- Monitoring Samples
- Results
- Specification Comparison
- Composite Results

A sample or sample group can represent the quality characteristics of a single lot or multiple lots, indicated by specifying a parent lot only. For samples against a particular lot, the final sample group disposition can update lot attributes such as material status and grade for the lot specified. For samples against a parent lot only, the lot attributes update can apply to all lots one level below the parent lot. Refer to the *Oracle Inventory User's Guide* for detailed information.

## Assigning Sample Disposition Automatically

The sample disposition is set automatically based on the status of sampling and testing as follows:

- Changes from Pending to:
  - In Progress if at least one result exists.
  - Complete if required results are recorded and assigned a result evaluation.
  - Accept if all results are recorded and acceptable, and sample results are within the limits of the specification.
  - Accept with Variance if all results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
  - Reject if all results are recorded and at least one is not acceptable.
- Changes from In Progress to:
  - Complete if required results are recorded and assigned a result evaluation.
  - Accept if all results are recorded and acceptable, and sample results are within the limits of the specification.
  - Accept with Variance if all results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
  - Reject if all results are recorded and at least one is not acceptable.
- Changes from Complete to:
  - Accept if all results are recorded and acceptable, and sample results are within the limits of the specification.
  - Accept with Variance if all results are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
  - Reject if all results are recorded and at least one is not acceptable.

## Assigning Sample Disposition Manually

You can change the sample disposition manually as follows:

- Change from Planned to:
  - Retain
  - Pending
  - Cancel
- Change from Retain to Pending, or Cancel
- Change from In Progress to Complete, or Cancel
- Change from Complete to:
  - Accept
  - Accept with Variance
  - Reject
  - Cancel

**Note:** Results with an evaluation of Cancel or Void are not considered when determining the sample disposition. For detailed information on how guaranteed and optional tests are used in determining the sample disposition, refer to "Managing Optional Tests without Results" and "Assigning Guaranteed by Manufacturer Results."

## Assigning Sample Group Disposition Automatically

The sample group disposition reflects the disposition of the samples that comprise the sample group for an event. This includes receiving, batch step release, and lot expiration. Disposition is set to:

- Planned if all the samples in the sample group are planned, but not yet taken.
- Pending if all the samples in the sample group are created, but not yet analyzed, or if all of the result evaluations are marked as Cancel.
- In Progress if at least one sample in the sample group has a result entered, but testing is not yet complete for all samples.
- Complete if all samples in the sample group have testing completed for all required and impromptu tests.

- Accept if all samples in the sample group have testing complete and have a sample disposition of Accept.
- Accept with Variance if all samples in the sample group are recorded, and at least one result is in an experimental error region, or out-of-specification. However, the sample approver must accept this variance.
- Reject if all samples in the sample group have testing complete and have a sample disposition of Reject.

## Assigning Sample Group Disposition Manually

You can change the sample group disposition manually as follows:

- Change from In Progress to Accept, Accept with Variance, Reject, or Cancel.
- Change from Complete to Accept, Accept with Variance, or Reject.

## Assigning a Lot during Sample Group Disposition

Delayed lot entry lets you create a sample without entering a lot number. It postpones the identification of a lot number during sample creation until it is known at the time of assigning a final disposition before movement into inventory. This delay accommodates sampling processes in which the material is analyzed before delivery to inventory.

When assigning a final sample group disposition, you can specify a lot, so that quality-driven updates to the lot status, grade, hold date, reason code, and the recommended lot-specific unit of measure conversions can occur simultaneously. For WIP and Supplier samples, the lot must belong to the batch or receipt specified at the time of sampling. Refer to "Delaying the Entry of Lot Numbers" for detailed information.

## Changing Lot Status

The application evaluates and defaults the lot status of a sampled lot based on whether or not the sample group meets the associated specification. You can also change the lot grade if the results meet the specification grade. Lot status and grade are used to allocate inventory properly for production and shipment, or to prevent failed lots from being sold or shipped. These decisions are based on your individual business requirements.

A sample taken against a lot-controlled item and a location-controlled subinventory can change the lot status for the subinventory and locator specified by the sample. You can perform a lot status change if the sample disposition is changed to Accept or Accept with Variance for in specification results or Reject for out-of-specification results.

## Changing Lot Hold Date

The Quality Change Disposition dialog box lets you update the hold release date for the sampled lot when changing the sample group disposition to Accept, Accept with Variance, or Reject. The lot hold date is determined by the normal duration of quality inspection or post-processing lead time after the lot is created with inventory. The Quality Manager can change the default hold date to release the lot earlier or later depending on required period of analysis. The lot must be specified on the sample and Control Lot Attributes must be enabled on the associated specification validity rule to display and update the lot hold date at the time of final disposition.

## Selecting an Inventory Transaction Reason Code

When you select an inventory transaction reason code on this window, you can only display those reason codes that you were granted permission to access. In order to view a reason code on this window, your responsibility must have security enabled for STSI and GRDI document types.

## Entering UOM Conversions

Refer to the "Using Lot UOM Conversions Based on Quality Results" for a complete explanation of how to enter lot unit of measure conversions based on quality results.

Refer to the *Oracle Inventory User's Guide* for more details on changing lot status and grade.

## Prerequisites

- Enter and save a sample.
- Optionally, enter results against the sample.

## To change the quality disposition of a sample:

1. Navigate to the Quality Change Disposition dialog box.
2. The following fields are display only:
  - **Sample** indicates sample number as a combination of the three-letter organization code and the sample number. This field is blank for a sample group.
  - **Item** indicates the process quality-enabled item sampled.
  - **Revision** indicates the item revision.

- **Parent Lot** indicates the parent lot sampled.
- **Lot** indicates the lot sampled.
- **LPN** indicates the LPN number for the sample.

**Note:** If the Delayed LPN Entry checkbox is selected for the chosen validity rule in the WMS-enabled organization, then you can enter the LPN number for the sample if the LPN number is blank. Please note that any change to material status maintained at the Lot level. By performing lot splits, you can associate different statuses for material that is assigned to the same LPN.

- **Spec** displays the specification, if one is associated to a sample, and the specification **Version**.

### Disposition

3. **Current Disposition** displays the present disposition of the sample.
4. **Retain As** displays the sample type as Archive or Reserve sample.
5. Enter **Change Disposition To** as:
  - **Pending** when the sample is saved, and results are expected, but not yet recorded. This is the default disposition.
  - **In Progress** when at least one result exists for the sample, but testing is not yet complete.
  - **Complete** when testing of all required tests and all additional tests is complete.
  - **Accept** when sample testing is complete, and results are in-specification.
  - **Accept With Variance** when sample testing is complete, and at least one result is in the experimental error region or out-of-specification. However, the sample approver has accepted this with variance.
  - **Reject** when sample testing is complete, and results are not acceptable, or out-of-specification.
  - **Retain** when the sample is reserved and put in storage. Typically, results do not exist for a sample with this disposition.
  - **Cancel** when the sample is canceled.

Required.

6. Select **Schedule Specification Tests** when you are changing an archive sample from a disposition of Retain to Pending.
  - Select this indicator to add all tests listed on the associated specification to the Results window.
  - Deselect this indicator to add tests directly to the sample on the Results window.
7. **Change Lot Status From** displays the current status of the lot.
8. Enter **Change Lot Status To** as the new lot status. This field defaults to the Lot Status or the Out-of-Spec Lot Status that is defined on the specification validity rule if the Control Lot Attributes indicator is selected.
9. **Change Grade From** displays the current lot grade.
10. Enter **Change Lot Grade To** as the new lot grade. This field defaults to the grade specified on the associated specification if the Control Lot Attributes indicator is selected on the specification validity rule.
11. Enter a **Reason Code** for a lot status change, grade change, or both. This defaults from the Process Quality Parameters window, and is restricted by reason code security.
12. Enter a **Hold Date** when the lot is released from quality hold for inspection. This date defaults from the Item Lots window in the Oracle Inventory application, and can be changed to reflect the expedition or delay in testing.

#### **UOM Conversions**

13. Select **Recommend** to indicate that you approve the displayed UOM conversion factor to be stored and sent for consideration as the item lot UOM conversion. Deselect this indicator to indicate that you do not want the conversion to be sent to Oracle Inventory.
14. **Test** displays the test used to process the conversion. This can be a numeric or an expression test. Refer to the "Using Lot UOM Conversions Based on Quality Results" topic for an explanation of how this test is entered and how it is used in the UOM conversion process.
15. **From UOM** displays the item primary UOM on the specification. Each of the conversions corresponds to a test on the specification where the Calculate UOM Conversion indicator is selected, the result value is entered, and the result status is not Cancel or Void. For example, the From UOM is in kilograms which is defined as

a Mass unit of measure type. The base unit of measure for Mass is pounds.

16. **Current** conversion displays the value of the existing lot UOM conversion for the item lot between the item primary UOM and the To UOM (the unit of measure to convert to). If this conversion exists, it must be converted to the item primary UOM and the To UOM since conversions are stored in the base units.
17. **Replicate** displays the test replicate number.
18. **Proposed** conversion displays the test result or proposed value of the existing lot UOM conversion for the item. The result for the specification test is used to calculate the UOM conversion.
19. **To UOM** displays the unit of measure to convert to as specified in the test listed in the specification. For example, the To UOM is in liters which is defined as a Volume unit of measure type. The base unit of measure for Volume is gallons.
20. **Proposed Conversion in Base UOM** is Item Base UOM (first field) equal to the calculated conversion factor (second field) multiplied by the base To UOM (third field). For example, one pound equals X gallons, where X is the calculated conversion factor. The second line is the inverse conversion.
21. Click **OK**.

## Associating Results to Another Sample

The Result Association window lets you associate test results from a parent (source) sample, to a child (target) item sample. You can associate results for a sample or sample group. This process prevents redundant data entry, and it maintains an association to the parent test result or parent composites test result. One of the benefits of results association is to leverage intermediate results for finished goods reporting.

In the results association process, all test results that are common to the parent and child sample or sample groups are associated. Parent sample or sample group results can be associated repeatedly in several other child samples or child sample groups. You cannot undo a result association after the child sample results are saved. If you make a mistake in associating a result, then you can delete the child sample, or void the result that was inherited through the association.

After results are associated to the child sample, you can review them and add new tests or replicates as required. Enter results for these additions and save your work. Generate a Certificate of Analysis based on the revised child sample.

Associated results appear on the Quality Workbench indicating the parent sample number. Tests with inherited results do not initiate Oracle Process Manufacturing (OPM) Quality Test Workflow Notifications, and do not contribute to the composite result statistics when the child sample results are aggregated.

## Prerequisites

- Create the parent sample.
- Enter and save test results for the parent sample. The parent sample must have a disposition of Accept, Accept with Variance, or Reject.
- Create the child sample, and change its disposition to Pending.

## To associate results for a single sample from the Results window:

1. Navigate to the **Results** window.
2. Query the child **Sample**.
3. Choose **Result Association** from the **Actions** menu. The **Result Association** window displays.
4. Select any of following fields to find a parent sample:
  - **Organization** is the organization of the sample.
  - **Item** is the sample item and its description.
  - **Parent Lot** is the optional sample parent lot.
  - **Lot** is the optional sample lot.
5. Enter **Source** as the source of the parent sample:
  - **Customer** indicates that the sample source is from a customer.
  - **Inventory** indicates that the sample source is from inventory.
  - **Supplier** indicates that sample source is from a supplier.
  - **WIP** indicates that the sample source is from work in process.
6. Select the desired **Parent Sample** group based on the selection criteria. Required. The **Organization**, **Creation Date**, and disposition of the sample group is retrieved.

### Include

7. Select **Text** to include text associated from the parent sample to the child sample.
8. Select **Flexfield** to include the flexfield associated from the parent sample to the child sample.

9. Select **Attachment** to include the attachment associated from the parent sample to the child sample.

### **Result Association**

10. The following fields are display only:
  - **Test** displays the predefined test code for each result.
  - **Parent Replicate** is blank because a composite result is used.
  - **Result** displays the composite test result from the parent sample group.
  - **Result Date** displays the date the result was entered on the parent sample.
  - **Child Replicate** displays the replicate number for the result in the child sample.
11. **Select** the test record.
12. Click **OK** to associate the parent sample results to the child sample.

### **To associate results from the Composite Results window:**

1. Navigate to the **Composite Results** window.
2. Query the child **Sample Group**.
3. Choose **Result Association** from the **Actions** menu. The **Result Association** window displays.
4. Query any of following fields to find a parent sample group:
  - **Organization** is the organization of the sample.
  - **Item** is the process quality-enabled sample item and its description.
  - **Parent Lot** is the optional sample parent lot.
  - **Lot** is the optional sample lot.
5. Enter **Source** as the source of the parent sample group:
  - **Customer** indicates that the sample group is from a customer.
  - **Inventory** indicates that the sample source is from inventory.
  - **Supplier** indicates that sample source is from a supplier.

- **WIP** indicates that the sample source is from work in process.

6. Select the desired **Parent Sample** based on the selection criteria entered. Required.

#### **Include**

7. Select **Text** to include text associated from the parent sample group to the child sample group.

8. Select **Flexfield** to include the flexfield associated from the parent sample group to the child sample group.

9. Select **Attachment** to include the attachment associated from the parent sample group to the child sample group.

#### **Result Association**

10. The following fields are display only:

- **Test** displays the predefined test code for each result.
- **Parent Replicate** displays the highest acceptable replicate of the most recent result for the parent sample.
- **Result** displays the test result.
- **Result Date** displays the date the result was saved.
- **Child Replicate** is blank because a composite result is used.

11. Select the test record.

#### **Parent Group Samples**

12. The following fields are display only:

- **Organization** is the organization where the sample is drawn.
- **Sample** is the combination of the three-letter organization code hyphenated with the sample number.

13. Click **OK** to associate the composited results to the target sample group.

#### **To display the parent sample for an associated result:**

1. Place the cursor on the desired test line that has a result association to a parent sample.

2. Choose **Parent Sample** from the **Actions** menu. The **Samples** window displays the parent sample for the associated result.
3. Close the window.

---

## Reports and Inquiries

This topic explains several preformatted reports that assist you in identifying items that need quality attention. Reports display results obtained from quality test samples taken from inventory, customers, suppliers, and production. A Certificate of Analysis or Certificate of Conformance report provides documentation that the items produced or shipped comply with test procedures and quality specifications prescribed by the customer. A sample storage inquiry helps you determine the physical storage subinventory and locator for each sample.

This chapter covers the following topics:

- Requirements
- Running the Item/Location Required Analysis Report
- Item/Location Required Analysis Report Description
- Running the Item/Location Test Results Report
- Item/Location Test Results Report Description
- Running the Customer/Supplier Test Results Report
- Customer/Supplier Test Results Report Description
- Running the Production Test Results Report
- Production Test Results Report Description
- Running the Certificate of Analysis or Conformance Report
- Certificate of Analysis or Conformance Report Description
- Making a Sample Storage Summary Inquiry
- Finding a Sample Storage Summary
- Generating Sample Labels

## Requirements

Following are some requirements that customers have for reports in Quality Management.

### Is there a report that identifies inventory that is near expiration?

Yes. Use the Item/Location Required Analysis report to identify inventory that requires retesting and the process quality-enabled items that require evaluation of expiration dating in a selected organization.

### Can inventory test results be identified separately from other test results?

Yes. Use the Item/Location Test Results report to display the results obtained from quality samples taken against inventory in a selected organization.

### Can supplier or customer sample test results be printed?

Yes. Use the Customer/Supplier Test Results report to display the test results for customer or supplier samples for a selected organization.

### Can production sample test results be viewed while material is being processed?

Yes. Use the Production Test Results report to display the test results for production samples for a selected organization.

### Does the application offer both Certificate of Analysis and Certificate of Conformance reports?

Yes. Use the Certificate of Analysis/Conformance report to provide verification that the process quality-enabled items produced or shipped comply with test procedures and quality specifications prescribed by the customer.

### Can sample storage subinventory and locator be identified?

Yes. Use the Sample Storage Summary inquiry to display the physical storage organization, storage subinventory, and storage locator of a sample taken for quality testing purposes. You can also find a sample storage summary for a specified organization.

## Running the Item/Location Required Analysis Report

The Item/Location Required Analysis report identifies inventory that needs attention. This includes process quality-enabled items that require retesting and items that require

evaluation of their expiration dating. The report lists the items and locators that need attention, the date the attention is required, and the action to take.

There must be a specification with an inventory specification validity rule or each item and lot combination for the item to appear on the report. You can select inventory from specific subinventories by lot status. You can include expired items, and those that require retesting and items that will expire or require retesting in the future. An expired lot must contain inventory to appear on the report.

## To submit the Item/Location Required Analysis report:

1. Navigate to the **Submit Request** window.
2. Enter **Item/Location Required Analysis Report** in the Name field.
3. Enter any of the following fields to narrow the scope of the report:
  - **Organization** is the process-enabled inventory organization that your responsibility can access. Required.
  - **From Subinventory** is the subinventory starting point for the report.
  - **To Subinventory** is the subinventory ending point for the report. This defaults to the From Subinventory.
  - **From Status** is the starting material status to include on the report.
  - **To Status** is the ending material status to include on the report. This defaults to the From Status.
  - **Expired Items** includes inventory items that expired.
  - **Retest Items** includes inventory items that require retesting.
  - **Future Expire** displays items that expire within a specified number of days from the current date and time. If you select **Yes**, then enter the specific number of days in the **Expire Within** field. If you select **No**, or leave this field blank, then do not make an entry in the Expire Within field.
  - **Future Retest** displays items that require retesting within a specified number of days from the current date and time. If you select **Yes**, then enter the specific number of days in the **Retest Within** field. If you select **No**, or leave this field blank, then do not make an entry in the Retest Within field.
  - **Exclusive Test** excludes inventory already tested within a specified number of days from the current date and time. If you select **Yes**, then enter the specific number of days in the **Exclusive Within** field. If you select **No**, or leave this field blank, then do not make an entry in the Exclusive Within field.

4. Click **OK**.
5. Complete the fields on the **Submit Request** window and click **Submit**. View or print the report.

## Item/Location Required Analysis Report Description

The first page of the report summarizes the report parameters submitted. The following field display on subsequent pages:

- **Organization** is the process-enabled inventory organization.
- **Item** is the process quality-enabled item sampled and a brief description.
- **Lot** is the lot sampled, if the item is lot-controlled.
- **Subinventory** is the subinventory of the item sampled and a brief description.
- **Locator** is the locator in the subinventory where the item was sampled, if the subinventory exists for the locator and a brief description.
- **Lot Status** is the current lot status of the item and a brief description.
- **Retest Date** is the scheduled retest date for the item.
- **Expire Date** is the current expiration date of the item.
- **Test** is the test name from the specification.
- **Spec Name** is the specification name.
- **Spec Target** is the specification target, if one is defined for the test.
- **Min. Value** is the specification minimum value defined for the test.
- **Max. Value** is the specification maximum value defined for the test.
- **Unit** is the test unit of measure for the test.

## Running the Item/Location Test Results Report

The Item/Location Test Results report displays the results obtained from quality samples against inventory for a specified organization.

## To submit the Item/Location Test Results report:

1. Navigate to the **Submit Request** window.
2. Enter **Item/Location Test Results Report** in the Name field.
3. Enter **Organization** as any valid organization you have privileges to access. Required.
4. Enter any of the following fields to narrow the scope of the report:
  - **From Sample** is the starting sample number for the report.
  - **To Sample** is the ending sample number for the report.
  - **From Item** is the starting item code for the report. The item must be process-enabled.
  - **To Item** is the ending item code for the report. The item must be process-enabled.
  - **From Lot** is the starting lot for the report.
  - **To Lot** is the ending lot for the report.
  - **From Subinventory** is the starting subinventory for the report.
  - **To Subinventory** is the ending subinventory for the report.
  - **From Locator** is the starting locator for the report.
  - **To Locator** is the ending locator for the report.
  - **From Result Date** is the starting result date for the report. The date defaults to the current date and time.
  - **To Result Date** is the ending result date for the report. The date defaults to the current date and time.

**Note:** From Result Date and To Result Date display the system date as the default. If you enter additional selection criteria such as From Sample, To Sample, From Item, or To Item, then the selection criteria must coincide with the From Result Date and the To Result Date to generate a meaningful report.

- Select one of the following to **Include** or exclude results as follows:

- **All Results** to include all results on the report, including those that are not in the specification.
- **Most Recent Final** to include only one result with the most recent result date for each test and exclude any results that are not in the specification from appearing on the report.
- Select the appropriate **Print Condition** to include the Edit Text associated to the Specifications and Results windows from the following options:
  - **None** to prevent the printing of specification text and result text on the report.
  - **Result Text** to print result text on the report. specification text is not printed.
  - **Spec Text** to print specification text on the report. Result text is not printed.
  - **Spec Text/Result Text** to print both specification text and result text.

5. Click **OK**. The **Submit Request** window displays.
6. Complete the fields on the **Submit Request** window and click **Submit**. View or print the report.

## Item/Location Test Results Report Description

The first page of the report summarizes the report parameters submitted. The following fields are displayed on subsequent pages:

- **Organization** is the process-enabled inventory organization and a brief description.
- **Item** is the process quality-enabled item and a brief description.
- **Lot** is the lot, if the item is lot-controlled and a brief description.
- **Subinventory** is the subinventory of the item.
- **Locator** is the locator in the subinventory , if the subinventory exists for the locator.
- **Test** is the test name from the specification.
- **Target** is the specification target for the test.
- **Unit** is the quality unit of measure for the test.

- **Minimum** is the specification minimum value defined for the test.
- **Maximum** is the specification maximum value defined for the test.
- **Target Display** is the display label for the specification target for Numeric Range with Display Text test type.
- **Min Display** is the display label for the specification minimum for Numeric Range with Display Text test type.
- **Max Display** is the display label for the specification maximum for Numeric Range with Display Text test type.
- **Effective From** is the starting effective date for the specification validity rule.
- **Effective Thru** is the ending effective date for the specification validity rule.
- **Target Text** is text associated to the specification used.
- **Result** is the test result.
- **Unit** is the quality unit of measure for the result.
- **Result Date** is the date the result was recorded.
- **Accept** indicates whether the result is accepted or not.
- **COA** indicates whether to print the Certificate of Analysis.
- **Sample Number** indicates the sample number corresponding to the result displayed.
- **Quantity** is the sample quantity.
- **UOM** is the inventory unit of measure for the sample.
- **Sample Date** is the date the sample was created.
- **In Spec** whether the result is in-or out-of-specification.
- **Result Text** is text associated with the results entered.

## Running the Customer/Supplier Test Results Report

The Customer/Supplier Test Results report displays the results of the quality test results entered for customers or suppliers for a specified organization.

## To submit the Customer/Supplier Test Results report:

1. Navigate to the **Submit Request** window.
2. Enter **Customer/Supplier Test Results Report** in the Name field.
3. Select the **Report Type** to indicate the type of test results report:
  - **Customer** for a customer report.
  - **Supplier** for a supplier report.
4. Enter any of the following fields to narrow the scope of the report:
  - **From Customer/Supplier** is the starting customer or supplier number.
  - **To Customer/Supplier** is the ending customer or supplier number.
  - **Organization ID** is the process-enabled organization. Required.
  - **From Item** is the starting item code for the report. The item must be process quality-enabled.
  - **To Item** is the ending item code for the report. The item must be process quality-enabled.
  - **From Lot** is the starting lot for the report.
  - **To Lot** is the ending lot for the report.
  - **From Result Date** is the starting result date for the report. The date defaults to the current date and time.
  - **To Result Date** is the ending result date for the report. The date defaults to the current date and time.
  - **From Sample** is the starting sample for the report.
  - **To Sample** is the ending sample for the report.
- Select one of the following to **Include** results as follows:
  - All Results** to include all results on the report, including those that are not in the specification.
  - Most Recent Final** to include only one result with the most recent result date for each test and exclude any results that are not in the specification from appearing on the report.

- Select the appropriate **Print Condition** to include the Edit Text associated to the Specifications and Results windows from the following options:
  - None** to prevent the printing of specification text and result text on the report.
  - Result Text** to print result text on the report. specification text is not printed.
  - Spec Text** to print specification text on the report. Result text is not printed.
  - Spec Text/Result Text** to print both specification text and result text.

5. Click **OK**. The **Submit Request** window displays.
6. Complete the fields on the **Submit Request** window and click **Submit**. View or print the report.

## Customer/Supplier Test Results Report Description

The first page of the report summarizes the report parameters submitted. The following fields display on subsequent pages:

- **Organization** is the process-enabled organization.
- **Item** is the item sampled and a brief description.
- **Lot** is the lot sampled, if the item is lot-controlled.
- **Subinventory** is the subinventory of the item sampled.
- **Locator** is the locator in the subinventory where the item was sampled, if the subinventory exists for the locator.
- **Test** is the test name from the specification.
- **Target** is the specification target for the test.
- **Unit** is the quality unit of measure for the test.
- **Minimum** is the specification minimum value defined for the test.
- **Maximum** is the specification maximum value defined for the test.
- **Target** is the text label for the specification target.
- **Min** is the minimum label for the specification minimum.
- **Max** is the maximum label for the specification maximum.
- **Effective From** is the starting effective date for the specification validity rule.

- **Effective Thru** is the ending effective date for the specification validity rule.
- **Target Text** is text associated to the specification used.
- **Result** is the test result.
- **Unit** is the quality unit of measure for the result.
- **Result Date** is the date the result was recorded.
- **Accept** indicates whether the result is accepted.
- **COA** indicates whether the Certificate of Analysis is required.
- **Sample Number** indicates the sample number corresponding to the result displayed.
- **Quantity** is the sample quantity.
- **UOM** is the inventory unit of measure for the sample.
- **Sample Date** is the date the sample was created.
- **In-Spec** indicates whether the result is in-or out-of-specification.
- **Result Text** is text associated with the results entered.

## Running the Production Test Results Report

The Production Test Results report displays quality test results entered for WIP samples for a specified organization.

### To submit the Production Test Results report:

1. Navigate to the **Submit Request** window.
2. Enter **Production Test Results Report** in the Name field.
3. Enter any of the following fields to narrow the scope of the report:
  - **From Sample** is the starting sample for the report.
  - **To Sample** is the ending sample for the report.
  - **From Batch** is the starting batch for the report.
  - **To Batch** is the ending batch for the report.

- **From Formula** is the starting formula for the report.
- **To Formula** is the ending formula for the report.
- **From Formula Version** is the starting formula version for the report.
- **To Formula Version** is the ending formula version for the report.
- **From Routing** is the starting routing for the report.
- **To Routing** is the ending routing for the report.
- **From Routing Version** is the starting routing version for the report.
- **To Routing Version** is the ending routing version for the report.
- **From Routing Step Number** is the starting routing step number for the report.
- **To Routing Step Number** is the ending routing step number for the report.
- **From Operation** is the starting operation for the report.
- **To Operation** is the ending operation for the report.
- **Organization** is the process-enabled organization for the report.
- **From Item** is the starting process quality-enabled item for the report.
- **To Item** is the ending process quality-enabled item for the report.
- **From Lot** is the starting lot for the report, if the item is lot-controlled.
- **To Lot** is the ending lot for the report, if the item is lot-controlled.
- **From Result Date** is the starting result date for the report. The date defaults to the current date and time.
- **To Result Date** is the ending result date for the report. The date defaults to the current date and time.
- Select one of the following to **Include** results as follows:
  - **All Results** to include all results on the report, including those not in the specification.
  - **Most Recent Final** to include only one result with the most recent result date for each test and exclude any results not in the specification from appearing on the report.

- Select the appropriate **Print Condition** to include the Edit Text associated to the Specifications and Results windows from the following options:
  - **None** to prevent the printing of specification text and result text on the report.
  - **Result Text** to print result text on the report. Specification text is not printed.
  - **Spec Text** to print specification text on the report. Result text is not printed.
  - **Spec Text** to print specification text on the report. Result text is not printed.

4. Click **OK**.
5. Complete the fields on the **Submit Request** window and click **Submit**. View or print the report.

## Production Test Results Report Description

The first page of the report summarizes the report parameters submitted. The following fields are displayed on subsequent pages:

- **Organization** is the process organization from which the sample is taken.
- **Batch** is the batch number of the sample.
- **Formula** is the formula used to produce the sample.
- **Version** is the formula version.
- **Routing** is the routing used to produce the sample.
- **Version** is the routing version.
- **Step** is the batch step number of the sample.
- **Charge** is the charge number of the sample.
- **Operation** is the operation used to produce the sample.
- **Version** is the operation version.
- **Item** is the process quality-enabled item sampled and a brief **Description**.
- **Lot** is the lot sampled, if the item is lot-controlled.

- **Subinventory** is the subinventory of the item sampled.
- **Locator** is the locator in the subinventory where the item was sampled, if the subinventory exists for the locator.
- **Test** is the test name from the specification.
- **Target** is the specification target for the test.
- **Unit** is the quality unit of measure for the test.
- **Minimum** is the specification minimum value defined for the test.
- **Maximum** is the specification maximum value defined for the test.
- **Target Display** is the display label for the specification target for Numeric Range with Display Text test type.
- **Min Display** is the display label for the specification minimum for Numeric Range with Display Text test type.
- **Max Display** is the display label for the specification maximum.
- **Effective From** is the starting effective date for the specification validity rule for Numeric Range with Display Text test type.
- **Effective Thru** is the ending effective date for the specification validity rule.
- **Target Text** is text associated to the specification used.
- **Result** is the test result.
- **Unit** is the quality unit of measure for the result.
- **Result Date** is the date the result was recorded.
- **Accept** indicates whether the result is accepted.
- **COA** indicates whether the Certificate of Analysis is required.
- **Sample Number** indicates the sample number corresponding to the result displayed.
- **Quantity** is the sample quantity.
- **UOM** is the inventory unit of measure for the sample.
- **Sample Date** is the date the sample was created.

- **Result Text** is text associated with the results entered.

## Running the Certificate of Analysis or Conformance Report

The Certificate of Analysis or Certificate of Conformance report verifies the process quality-enabled items produced or shipped comply with test procedures and quality specifications prescribed by the customer. A process manufacturer authorizes a Certificate of Analysis or Certificate of Conformance for shipment of supplies that usually require inspection upon receipt.

The Certificate of Conformance report presents data derived from quality management information. These reports are created primarily for items included on sales orders and shipped to customers. A customer may require certification of tests performed, and results generated on specific products sold to them. Potential customers review results certification before ordering products. Specifications with inventory or customer specification validity rules impact these reports. WIP and supplier specification validity rules have no impact.

Depending on the item lot status, certificate type specified on the specification validity rule that is in effect, and availability of information about a specific item, either a Certificate of Analysis or a Certificate of Conformance report is generated.

### The Certificate of Analysis Report

This report shows that certain tests were performed on an item, which specification limits or targets are required, what the test results are, and the date each result was entered. A Certificate of Analysis report is only generated when:

- The item is active and lot-controlled.
- The certificate type on the specification validity rule is set to Certificate of Analysis.
- Specifications and results exist for the item and lot selected.
- Print Spec and Print Result are selected on the specification.
- Results are within specification, have an evaluation of Accept or Accept with Variance, and are not marked optional or for deletion. The most recent replicate and composited result average is reported.
- Sampling group disposition is Accept or Accept with Variance.
- Sales Order shipment status is not VOID if a Sales Order, Bill of Lading, or shipping information are supplied as parameters.
- Items selected are not scheduled for deletion.

- Appropriate selection criteria are entered on the Certificate of Analysis Report window.
- Print Additional Test on Certificate of Analysis is selected on the Results window.

## **The Certificate of Conformance Report**

This report shows the tests that are performed on a specific item and what specification limits or targets are required. A Certificate of Conformance report can be generated when:

- The item is active and is not lot-controlled.
- The certificate type on the specification validity rule is set to Certificate of Conformance.
- Specifications exist for the item and tests on the specification are not marked as optional.
- Print Spec is selected on the specification.
- Appropriate selection criteria are entered on the Certificate of Analysis Report window.

## **Impact of Customer Specification Validity Rules on the Certificate of Analysis Report**

For specifications that have a customer specification validity rule in effect:

- The results are based on the specification with a customer specification validity rule, even if the sample was analyzed against another specification validity rule type. The decimal precision selected is used in the report.
- If a customer specification validity rule does not exist, then the inventory specification validity rule in effect for the item is used. If the inventory specification validity rule is used, then the organization, item, lot, and subinventory must be specified as report parameters before running the report.
- The organization, item, lot, and customer must be specified as report parameters before running the report.
- The Print Spec and Print Result indicators on the specification determine which tests and results are printed.
- The customer-specific test aliases are printed instead of the test code.

## To run the Certificate of Analysis report:

1. Navigate to the Certificate of Analysis Report window.

### Selection

2. As you enter data in the following fields, some of the fields fill automatically. This occurs in cases where a specific order, shipment, item, or lot is identified from the data supplied. Enter at least one of the following additional parameters to run the report:
  - **Organization** is the sample organization. You can retrieve and print the report if your responsibility has the privilege to access this organization.
  - **Item** is the process quality-enabled item sampled. A brief description displays.
  - **Revision** is the item revision.
  - **Lot** is the lot number. A brief description displays.
  - **Subinventory** is the subinventory code.
  - **Locator** is the subinventory locator code.
  - **Operating Unit** is the operating unit.
  - **Order Number** is the number of the sales order that contains the item.
  - **Customer** is the customer order number. The customer name entered on the sales order detail line displays if it is available.
  - **Order Number** is the number of the sales order that contains the item.
  - **Delivery** is the delivery number.

### Print Text Options

3. Select one of the following to print the report. Specification and result text that is added through the Edit Text feature on the Actions menu of the Specifications or Results windows appears only if the appropriate Print Text Options are selected on the Certificate of Analysis Report Parameters window:
  - **No Text** to suppress printing the Edit Text.
  - **All Text** to include Specification and result text.
  - **Specification Text Only** to include only specification text.

- **Result Text Only** to include only result text.

#### **Print Options**

4. Enter the number of **Copies** to print. To view the report, enter **0**, and a hard copy is not generated.
5. Enter the name of a **Printer**. **Style** displays the default report style.
6. Click **OK**.

#### **To view the Certificate of Analysis report:**

1. Choose **Requests** from the **View** menu.
2. Select **All My Requests**.
3. Click **Find**.
4. Select the current record indicator next to the requested **Certificate of Analysis** report to view. Make sure that the report phase is completed.
5. Click **View Output**. The output defaults to a \*.pdf file, but can be changed by the System Administrator.

### **Certificate of Analysis or Conformance Report Description**

Depending on the report, certain fields are blank when information is not available. The following are descriptions of the fields displayed:

One of the following titles prints on the report:

- **Certificate of Analysis** displays when selected as the certificate type on the specification validity rule.
- **Certificate of Conformance** displays when selected as the certificate type on the specification validity rule.
- **Customer** is the ship-to customer number and name from the sales order detail line.
- **Customer PO** is the purchase order number from the sales order header.
- **Order Number** is the customer sales order number from the sales order header.
- **Shipment Number** is the bill of lading number from the shipment header.
- **Ship Date** is the actual shipment date if it is available. If this date is not available,

then this field displays the scheduled shipment date.

- **Item** displays the process quality-enabled item sampled and a brief description.
- **Revision** is the item revision, if the item is revision-controlled.
- **Lot** is the lot sampled, if the item is lot-controlled.
- **Quantity Ordered (Qty1)** is the quantity and unit of measure ordered.
- **UOM** is the primary unit of measure for the quantity ordered.
- **Secondary Qty** is the number of items ordered in the secondary unit of measure, if the item is dual unit of measure controlled.
- **UOM** is the secondary unit of measure for the quantity ordered.
- **Quantity Shipped (Qty1)** is the quantity and unit of measure shipped.
- **UOM** is the primary unit of measure for the quantity shipped.
- **Qty2** is the number of items shipped in the secondary unit of measure, if the item is dual unit of measure controlled.
- **UOM2** is the secondary unit of measure for the quantity shipped.
- **Test/Method** displays the test name, test method, and description on which the result or specification is based. The test alias appears if it is defined for the test or for a specific customer.
- **Result** is the result value. Numeric results are rounded according to the decimal precision defined on the specification. The text equivalent displays for the Numeric Range with Display Text test data type. This information displays on the Certificate of Analysis, but it does not appear on the Certificate of Conformance. Target values for tests without a minimum and maximum appear in the Minimum column.
- **Min** is the specification minimum value defined for the test.
- **Max** is the specification maximum value defined for the test.
- **Test Unit** is the quality unit of measure for the target.
- **Specifications Text** is any Edit Text associated with the current specification when Specification Text Only or All Text are selected as Print Text Options.
- **Result Text** is any Edit Text associated with the current Result when Result Text Only or All Text are selected as Print Text Options.

## Making a Sample Storage Summary Inquiry

The Sample Storage Summary window displays the context organization which is also the physical storage organization, storage subinventory and locator of a sample taken for quality testing purposes for a specified organization. Sample attributes displayed are storage organization, item code, lot, sample number, sample quantity and unit of measure, date the sample was drawn, sampler, and sample source.

### To display a summary of samples stored:

1. Navigate to the **Sample Storage Summary** window.
2. Select a process-enabled organization from the **Organizations** window. The context organization or owner organization displays in the window title. The samples for the organization display.
3. The following fields are display only:
  - **Storage Organization** is the context organization, which is also the storage organization of the sample.
  - **Storage Subinventory** is the storage subinventory of the sample. This defaults to the supply subinventory for the item defined in the sample organization.
  - **Storage Locator** is the storage locator of the sample if it is locator-controlled.
  - **Item** is the process quality-enabled inventory item sampled and a brief description.
  - **Revision** is the item revision, if the item is revision-controlled.
  - **Parent Lot** is the parent lot number specified on the sample.
  - **Lot** is the lot number specified on the sample.
  - **Sample** is the sample number of the sample tested.
  - **Remaining Qty** is the sample quantity that remains after the test is performed.
  - **UOM** is the unit of measure in Oracle Inventory for the sample quantity.
  - **Sample Date** is the date drawn for the sample.
  - **Disposition** is the sample disposition.
  - **Retain As** is the sample type, which is Archive, Reserve, or required.

- **Source** is the type of material source (Inventory, WIP, Customer, and Supplier) where the sample is taken.
- **Comment** is the comments for the sample.

## Finding a Sample Storage Summary

The Find Sample Storage Summary window lets you find a sample storage summary for an organization.

### To find a sample storage summary:

1. Navigate to the **Find Sample Storage Summary** window. The context organization displays in the window title.
2. Enter any of the following criteria to narrow your search:
  - **Storage Organization** as the context organization, which is also the storage organization of the sample.
  - **Storage Subinventory** as the storage subinventory of the sample.
  - **Storage Locator** as the storage locator of the sample.
  - **Item** as the process quality-enabled inventory item sampled.
  - **Revision** as the item revision.
  - **Parent Lot** as the parent lot number specified on the sample.
  - **Lot** as lot number specified on the sample.
  - **Sample** as the sample number.
  - **Disposition** as the sample status.
  - **Retain As** as the sample type, which is Archive, Reserve, or required sample.
  - **Source** as the type of material source (Inventory, WIP, Customer, and Supplier) where the sample is taken.
3. Click **Find** to view the samples storage summary for the context organization.

## Generating Sample Labels

The Sample Label Generation report produces a character delimited flat file that you

can load into a generic form processor or documentation template designer to make commercial labels for samples. Enter a character to delimit the alphanumeric output.

## Prerequisites

- Enter samples.

### To generate sample labels:

1. Navigate to the **Submit Request** window.
2. Enter **Sample Label Generation** in the Name field.
3. Enter the **Organization Code**.
4. Enter the starting sample number in the **Sample Number From Range** and the ending sample number in the **Sample Number To Range** to generate a set of consecutive labels.
5. Enter an ASCII character as **File Delimiter**.
6. Click **OK**.
7. Complete the fields on the **Submit Request** window and click **Submit**.

### To view the Sample Label Generation report:

1. Choose **Requests** from the **View** menu.
2. Select **All My Requests**, and click **Find**.
3. Select the current record indicator next to the requested **Sample Label Generation** report to view. Make sure that the report phase is completed.
4. Click **View Output**. The output defaults to a specified file type. Your System Administrator can change this file type for purposes of submitting the character delimited flat file output to a generic form processor.

The organization code, sample number, and sample description are included with the other listed character-delimited flat file output. The following is an example of the report output for the sample label generator:



# 8

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## Stability Studies

This topic provides procedures for creating and managing stability studies including when they are performed, and what essential guidelines exist for stability testing programs. The topic also provides an overview of the stability study lifecycle management, including the creation of test interval plans and the creation of a storage condition plan. You are given guidance on the creation and management of a stability study, including the assignment of its material sources, editing stability study variants and time points, and defining its storage packages.

This chapter covers the following topics:

- Requirements
- Understanding Stability Studies
- Example of a Stability Program for Product X
- Managing the Stability Study Lifecycle
- Understanding the Stability Study Change Status Workflow
- Creating Test Interval Plans
- Generating a Series of Testing Periods
- Finding Test Interval Plans
- Creating a Storage Condition Plan
- Finding Storage Condition Plans
- Defining Storage Packages
- Finding Storage Packages
- Creating and Managing a Stability Study
- Finding Stability Studies
- Assigning Stability Study Material Sources
- Editing Stability Study Variants

- Finding Stability Study Variants
- Editing Variant Time Points

## Requirements

Following are some requirements addressed in defining and managing stability testing in Quality Management.

### Does the Oracle Process Manufacturing (OPM) stability studies capability adhere to the regulatory recommendations for a written testing program?

Yes. The stability study functionality is designed to assess the stability characteristics of products, and helps you evaluate product storage conditions and expiration dating. By supplying a repository for the collection and processing of this information, OPM stability studies assists in the documentation of a written testing program. Use the Oracle attachments functionality to link written materials to the stability study.

#### Use the Stability Study Window as a Launch Pad for the Entire Study

The Stability Study window lets you enter preliminary information about the study including its document number, description, and storage condition plan. Display the status of the study, the master item specification used to evaluate product performance, the laboratory organization conducting the study, and the owner of the study. Display additional information, including the number of variant material sources, storage conditions investigated, and packaging configurations investigated in the study. Once the study is launched, you can monitor all the dates associated to the study. At the completion of the study, the Stability Study window lets you enter recommendations for shelf life and storage specification for the material tested. Use Oracle attachments to link written materials to the stability study.

### Can sample size and test intervals be set up to evaluate the statistical criteria for each separate attribute?

Yes. Each of the statistical variables for the stability study can be set up to evaluate the effects of sample size, test interval, and the impact of environmental variables on each individual variant in the stability study.

#### Create a Test Interval Plan, Storage Condition Plan, and Variants

The Test Interval Plan window lets you simulate, evaluate, and select test intervals for the study to help you plan for statistical evaluations of study data. Use the Storage Condition Plans window to structure a set of storage conditions to apply to a study. Each storage condition includes a monitoring specification for the environmental chamber and the test interval plan. The application creates a variant for each storage condition, sample material source, and storage package combination. Edit these variants on the Variant window.

## **Can you retain additional samples?**

Yes. Set up the stability study for additional retained samples that are not tested as part of the study, but are retained for historical purposes.

### **Use Sample Disposition to Indicate Sample Retention**

Use sample disposition to indicate samples to retain in storage prior to stability testing.

## **Does OPM help identify that reliable, meaningful, and specific test methods were used in the stability study?**

Yes. Test reliability is assessed through standard procedures that document test performance. These measures include test sensitivity, test specificity, and test linearity. Set up specifications for each test referencing a test method. By comparing the results of these individual tests to accepted reference tests, you can assess the correlation to these methods as a measure of test accuracy.

### **Trace Results Back to Test Methods**

OPM Quality Management lets you trace a test result directly to the tester and test method used. The traceability of test method attributes includes the quantity of material required, the instrument used to perform the test, the number of replicates used, the identification of the test kit, the duration of the test, and the decimal precision of the result. Enter realistic test targets and acceptable ranges of test performance that meet or exceed the performance of accepted reference test methods by setting up specifications for each test performed. By incorporating control materials in each test run, monitor test performance. Use control materials to evaluate correlation to reference test method performance as an assessment of test accuracy.

## **Can several packages be investigated in the same study?**

Yes. Set up one or more packages or container closure systems to be investigated in the stability study.

### **Enter Package Configurations on the Stability Study Window**

Enter the Packages field as the total number of packaging configurations you plan to use to build the study. The default is one package. Study individual package closure systems to compare and contrast product performance in various packaging configurations.

## **Can an adequate number of batches of each product be tested in a single study to determine an appropriate expiration date?**

Yes. Determine the acceptable number of batches to evaluate in the study. Records of all data for expiration dating is maintained in a single referenced study for rapid retrieval and analysis.

### **Use the Material Source Field to Define Materials to Test**

The required number of source materials is defined on the Stability Study window. Identify the item, lot, and batches that become the basis for the stability study. Source materials can exist in inventory, or can be requested from production for the study.

### **Can accelerated stability studies be run simultaneously with materials in the recommended storage conditions?**

Yes. Set up the recommended storage condition variants in parallel to the accelerated studies. Evaluate basic stability information on the components, products, and container closure systems. Use this information to support tentative expiration dates when the full shelf life studies are not yet available. This indicative information helps you initiate long-term studies such as clinical investigations.

### **Use Storage Condition Plan and Variants to Deliver Both Standard and Accelerated Stability Testing**

Create a robust storage condition plan that includes both the standard and accelerated environmental storage conditions for materials to test in the stability study. Variants can then be tested in all specified environments simultaneously to deliver both standard and accelerated stability study test results.

## **Understanding Stability Studies**

Stability studies are performed in life sciences, chemical, and food and beverage industries to determine the effects of environmental conditions on product quality. Environmental conditions can impact product shelf life, and the viability of product formulation. Stability studies provide the supporting data that companies use to establish product storage requirements and expiration dating.

### **When are stability studies performed?**

Stability studies are performed at various stages of the product development process. Early stages of stability testing are typically performed on laboratory materials to determine if the material to be produced has any inherent sensitivities to storage or shipping environments. Many manufacturers perform accelerated stability testing at relatively high temperatures and humidities as a worst case scenario to determine what types of degradation products can experience after long-term storage. Materials produced in a full production run are tested under controlled temperature and humidity storage conditions that simulate environmental extremes. Results of testing on these materials provide valuable information about overall product stability, and serve as a basis for product claims on storage requirements and shelf life.

### **What are the essential guidelines for a stability program?**

There are a number of key national and international standards, laws, regulations, and

guidelines for Good Manufacturing Practice (cGMP). The U.S. Food & Drug Administration (FDA) provides compliance guidelines for drugs and medical devices. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a consortium of regulatory authorities from Europe, Japan, the United States, and experts from the pharmaceutical industry worldwide. This group discusses scientific and technical aspects of product registration. The ICH makes recommendations on the interpretation and application of technical guidelines and requirements for product registration.

Section 211.166 of the FDA guidelines requires companies who produce finished pharmaceutical products to have a written stability program. The results of this program are used in determining appropriate storage conditions and product expiration dating. This guideline specifies what to include in a stability program. The following summarizes some of the essentials presented in this guideline:

- A written testing program designed to assess the stability characteristics of drug products. The results of this stability testing program used in determining appropriate drug product storage conditions and expiration dating.
- The written program must be followed, and it must include:
  - Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability.
  - Storage conditions for samples retained for testing.
  - Reliable, meaningful, and specific test methods.
  - Testing of the drug product in the same container closure system in which the drug product is marketed.
  - Testing of drug products for reconstitution at the time of dispensing as directed in the labeling as well as after they are reconstituted.
  - Testing of an adequate number of batches of each drug product to determine an appropriate expiration date. Records of this data must be maintained.
  - Accelerated studies, combined with basic stability information on the components, drug products, and container closure system, is used to support tentative expiration dates provided full shelf life studies are not available and are being conducted.
  - Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies. There must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined.

## Example of a Stability Program for Product X

In the following program, both study protocols are run concurrently, so that expiration dating does not factor into the interpretation of results.

### Stability Study Protocol A - Measure of Active Ingredients Under Controlled Room Temperature and Humidity

There are two testing procedures to run:

- Within-lot stability at 25 deg C/30% RH - Batch 1, Lot X

A typical monitoring specification can be set up for temperature and humidity as follows:

- The temperature range is -10 deg C to 100 deg C. The target for a monitoring specification is 25 deg C, with a minimum of 24 deg C, and a maximum of 26 deg C.
- The humidity range is 0% RH to 100% RH. The target for a monitoring specification is 30% RH, with a minimum of 29% RH, and a maximum of 31% RH.
- Between-lot stability at 25 deg C/30% RH - Batch 2, Lot Y, Batch 3, Lot Z. Use the same monitoring specification that was designed for within-lot stability testing.

### Stability Study Protocol B - Measure of Active Ingredients Under Stressed Conditions

A robust stability study can contain within-lot and between-lot investigations for various combinations of temperature and humidity. This approach provides an extensive profile of material stability at a variety of temperatures and relative humidities. The following is an example of this type of study:

- Within-lot stability at specified ICH conditions for Batch 1, Lot X
  - 25 deg C/40% RH
  - 25 deg C/60% RH
  - 30 deg C/35% RH
  - 30 deg C/60% RH
  - 40 deg C/20% RH
  - 40 deg C/75% RH
  - 60 deg C/20% RH

- 60 deg C/75% RH
- Between-lot stability at specified ICH conditions for - Batch 2, Lot Y, Batch 3, Lot Z
  - 25 deg C/40% RH
  - 25 deg C/60% RH
  - 30 deg C/35% RH
  - 30 deg C/60% RH
  - 40 deg C/20% RH
  - 40 deg C/75% RH
  - 60 deg C/20% RH
  - 60 deg C/75% RH

Oracle Process Manufacturing (OPM) Quality Management stability studies let you create both simple and robust stability studies. The stability study owner remains in full control of the variants created for each time point, and monitors the progress of the study through workflow notifications. The workflow and Oracle E-Records events associated with the stability study document critical decisions to support the written study program.

## Managing the Stability Study Lifecycle

Following are stages that define a typical stability study lifecycle:

1. Setting Up for a Stability Study
2. Planning a Stability Study
3. Performing Initial Sampling and Testing
4. Approving a Stability Study Plan
5. Launching a Stability Study
6. Performing Stability Study Testing
7. Evaluating a Stability Study

## Setting Up for a Stability Study

Following are steps that describe the process of setting up for a stability study:

### Step 1: Create a test interval plan.

Define test interval plans before creating a storage condition plan for a stability study. Each test interval plan represents a unique set of testing time points that list the junctures at which you plan to test samples in the stability study. The frequency or intervals between time points vary depending on the purpose of a storage condition. For example, long-term, intermediate, or accelerated storage conditions can have very different frequencies between time points.

All test interval plans that use the storage conditions of a stability study must be either a base interval plan or an overlay of the base interval plan assigned to the storage condition plan. Define interval periods as the testing frequencies required by the storage condition.

- Define base test interval plan as the total set of testing time points used by each of the stability study storage conditions. If all storage conditions test the sample material at the same frequency or time intervals, then this is the only test interval plan you define.
- Define an overlay test interval plan when a stability study storage condition performs time point tests with a different set of time intervals from those defined in the base test interval plan. You can enter additional time points for the overlay interval plan. You cannot delete time points on the overlay interval plan that come from the base interval plan, however, you can exclude them.

### Step 2: Create monitoring specifications.

Create specifications to define the environmental monitoring criteria for the storage conditions. These are called monitoring specifications. A monitoring or nonitem specification must be created to include tests that support each required storage condition detail such as ambient temperature, relative humidity, and atmospheric pressure. Assign tests to the monitoring specifications. Create a specification validity rule to specify the resource or physical location to monitor.

### Step 3: Create a storage condition plan.

Create the required set of storage conditions. These conditions include a unique combination of temperature and relative humidity measurements that differentiate testing conditions for a stability study. The storage conditions created require the environmental monitoring of a defined equipment resource such as a refrigerator or a subinventory locator in a particular storage organization. The planned and actual storage condition parameters must be monitored for each storage condition combination. For example, 30 deg C/60% RH requires the monitoring of both the 30 deg C refrigeration and 60% RH ambient moisture content.

Define the two components of a storage condition plan:

- A monitoring specification to define the details of the storage condition for each one of the variants in the stability study
- A test interval plan to define testing time points by indicating the test intervals for each variant in the stability study

#### **Step 4: Create the storage packages.**

Decide on the package to use for the container closure system for the product to test in a particular organization. Create a storage package configuration.

#### **Step 5: Create base and overlay item specifications for the stability study.**

Create base and overlay item specifications that contain the tests you use in stability testing. These are usually based on the product release specifications which are a combination of physical, chemical, biological, and microbiological tests and acceptance criteria that determine the suitability of a product at the time of its release. The base specification serves as the default item specification when you create the stability study. You can associate the overlay specifications to time points when the stability testing requirements vary from the base specification.

#### **Step 6: Set up for sample numbering.**

Set up document numbering using the Samples tab in the Process Quality Parameters window for the organization where you plan to perform the sampling.

#### **Step 7: Set up for stability study numbering.**

Set up document numbering using the Stability Studies tab in the Process Quality Parameters window for the stability study organization.

## **Planning a Stability Study**

Following are steps that describe the planning of a stability study:

#### **Step 1: Create a stability study.**

Create a stability study with the following information:

- Item as the process quality-enabled item to test in the stability study
- Item revision, if the item is revision-controlled
- Inventory organization as the quality laboratory
- Master item specification to use in evaluating item performance in the stability study

- Study name to record a unique identifier for the stability study entity
- Protocol to enter as part of the study description to capture the purpose of the stability study
- Study start, notification lead time, testing grace period, and completion dates to define the beginning and end dates for study
- Study owner for subsequent approvals and notifications
- Study approval process with status control. Stability study status controls sample pull and testing notifications, and specifies how all associated samples are consumed, allocated, or used for testing in the study

Refer to the "Creating and Managing a Stability Study" topic for more information on creating a stability study.

#### **Step 2: Assign storage condition plan to the stability study.**

Assign the storage condition plan to the stability study. This plan consists of the monitoring specification that provides the details of the storage condition for each one of the variants in the stability study, and a test interval plan that defines the testing time points.

#### **Step 3: Identify source materials to be used in the stability study.**

Identify the item, lot, and batches that serve as the basis for the stability study. The source material can already exist in a material source inventory organization as lots or it can be selected, or requested as batch. Batches can be initial production batches for a new formulation, or a portion of routine production batches pulled for stability testing. This information includes the item, lot, batch number, date of manufacture or product yield date, sample quantity and UOM, recipe, recipe version used, and sample quantity.

#### **Step 4: Plan stability study variants and time points.**

Plan all variant storage conditions for each time point sample or sample group. Variants are defined by the unique combination of the stability study storage condition in a storage organization, the test interval plan, the package, and material source. Specify the default item specification, number of stability samples per time point, and the number of retained samples for the variant. You can configure the default item specification for the variant to select an overlay specification for a time point.

## **Performing Initial Sampling and Testing**

Following are steps that describe initial sampling and testing in a stability study:

#### **Step 1: Acquire initial samples from source materials.**

When acquiring the initial material to use as a basis for a stability study, the item lots

must be allocated or reserved as inventory for use only in the stability study. Material must be physically stored in a subinventory, locator, and container, or moved directly from the manufacturing floor to a staging area where initial testing is performed.

Samples used in stability studies reflect inventory consumption and sample movement into storage subinventory locators to manage environmental variants. An initial stability sample can be retained, or moved into a storage subinventory and locator.

#### **Step 2: Test initial samples and assign sample disposition.**

Define the test criteria to perform for the initial stability sample. If an approved, prerelease, laboratory specification exists for the material, then use that specification. If an approved production specification exists for the product, then use it for the initial sample testing. The selected sample specification must be entered as the master item specification defined in the stability study. The outcome of these tests determines whether an item lot or batch is used for continuing the stability study. Initial sampling and testing must indicate acceptable source material before the stability study is launched.

#### **Step 3: Select the initial sample group to associate initial samples with material sources.**

Associate the initial samples with a material source by selecting the appropriate sample group. Only initial sample groups with a disposition of Accept or Accept with Variance are listed. Make this association prior to launching the stability study.

## **Approving a Stability Study Plan**

Following are steps required to approve a stability study plan:

#### **Step 1: Approve the stability study.**

Use the Change Status action on the Stability Study window to request stability study approval. This initiates the Stability Study Change Status workflow which notifies the study owner of the request for status change in the stability study. The process of changing the status from NEW to a status of Stability Study Plan Approved is managed by the workflow. Oracle E-Records works with the workflow to enforce generation of an electronic record and capture of electronic signatures for each status change.

If material source lots are identified, then stability sample groups and samples are created by the application for the planned variants and time points. These samples are based on the:

- Number of samples per time point
- Number of retained samples for a variant
- Sample quantity and UOM defined for a variant

These system-generated item samples are automatically associated to a stability study as identified by the sample source fields. You cannot create stability samples manually through the Samples window.

If the material source is requested as a batch, then the appropriate workflow initiates for batch and sample creation. Prior to launching the stability study, specify a lot on the Material Sources window.

**Step 2: Schedule variant and time point testing.**

The application generates the schedule dates for all the testing time points based on the stability study scheduled start date. A sample group is generated for each testing time point to permit the assignment of a final disposition to each point.

**Step 3: Finalize acceptable material sources.**

Finalize the availability and acceptability of the lots for every material source listed on the Material Sources window. Specify the lot for any batch requested to produce as a material source. Enter material source organization as the inventory organization where the sample material is produced. Prior to launching the stability study, each material source must have an acceptable initial sample group. If you cannot finalize all material sources at this time, then finalize them before you launch the stability study.

**Step 4: Generate testing time point labels.**

The Testing Time Point Label Generation report produces a pdf file. For each testing time point, the report produces the name of the stability study, variant, testing time point, sample number, time point scheduled date, and sample quantity.

You can generate this report for:

- All testing time points for variants of a stability study
- All testing time points for an individual variant
- A specific time point for an individual variant

Regenerate the report for a specific variant time point if you add a time point to a variant during the study.

**Step 5: Put sample materials in storage packages and place them into variant storage conditions.**

If packaging is specified for the variant, then put the sample material for each variant time point in individual packages. If labels were generated, then apply them to the sample storage package. Place the materials in the defined variant storage conditions in the specified storage organization. Update the storage date of stability samples for each variant.

**Step 6: Verify sufficient stability sample quantities.**

Determine that there are sufficient sample materials to conduct the stability study. The total sample quantity must be validated to determine if there is sufficient quantity of material for each variant time point sample. This validation ensures there is sufficient material to complete the required analysis. Positive material identification is essential to a fully traceable stability study.

## Launching a Stability Study

Following are steps required to launch a stability study:

### **Step 1: Verify that material sources are finalized.**

If material sources are not finalized, then repeat steps 2 through 6 in the "Approving the Stability Study Plan" topic.

### **Step 2: Launch the approved stability study.**

Once all source materials have an initial sample group with an acceptable disposition, the stability study owner can launch the approved stability study.

## Performing Stability Study Testing

Following are steps required to perform stability study testing:

### **Step 1: Put the study in progress.**

Change the status of the stability study to In Progress.

### **Step 2: Receive notification to pull samples.**

You receive notification to pull samples for stability study testing. The Stability Study Testing Notification master workflow governs this process.

### **Step 3: Pull and test samples at each time point until testing is complete.**

Identify samples that require testing on the scheduled time point dates, and use the specification assigned to the time point to test the samples. If necessary, assign a retained sample for a variant to a point for time point testing.

### **Step 4: Monitor variant environmental conditions throughout the stability study.**

Use the monitoring specification to evaluate the environmental conditions used in the study. The Sample Group Rejection workflow notifies you when either a monitoring sample group, or a stability study time point sample group is rejected.

### **Step 5: Evaluate samples and sample groups used in the stability study.**

Enter results for time point testing and evaluate them against the specification assigned to the time point. The Sample Group Rejection workflow notifies you when either a monitoring sample group, or a stability study time point sample group is rejected.

## Evaluating a Stability Study

Following are steps that describe the evaluation of a stability study:

#### **Step 1: Complete stability study time point testing.**

The Stability Study disposition is complete when the scheduled testing time points have a final disposition required to perform the stability study analysis. The stability study owner determines testing is complete when all scheduled testing time points variants have a final disposition, or when a sufficient number of testing time points have a rejected disposition for a specific variant, in which case it would be unnecessary to continue testing.

#### **Step 2: Review test result data.**

The stability study owner reviews all test result data.

#### **Step 3: Determine whether additional testing is required.**

The stability study owner determines whether additional testing is required for any of the time points in the study.

#### **Step 4: Conclude the stability study.**

The stability study owner concludes the stability study by:

- Changing the status of the stability study to Completed
- Entering a study end date
- Entering the recommended shelf life derived from the results of tests performed on variants in the study that met the item specification
- Entering the recommended storage conditions derived from the monitoring specification used for the variants in the study that met the item specification

#### **Step 5: Communicate the results of the stability study.**

The stability study owner communicates the results of the stability study to appropriate individuals within the supply chain.

## **Understanding the Stability Study Change Status Workflow**

When the OPM Quality Stability Study Change Status workflow is activated the stability study requires a series of approvals that result in reassigning status through a predefined approval process.

Stability study statuses are preseeded. Refer to the "OPM Quality Stability Study Change Status Workflow" topic in "Appendix C" for additional information.

## **Prerequisites**

- Set up the workflow. Contact a system administrator if you are not sure this is set

up.

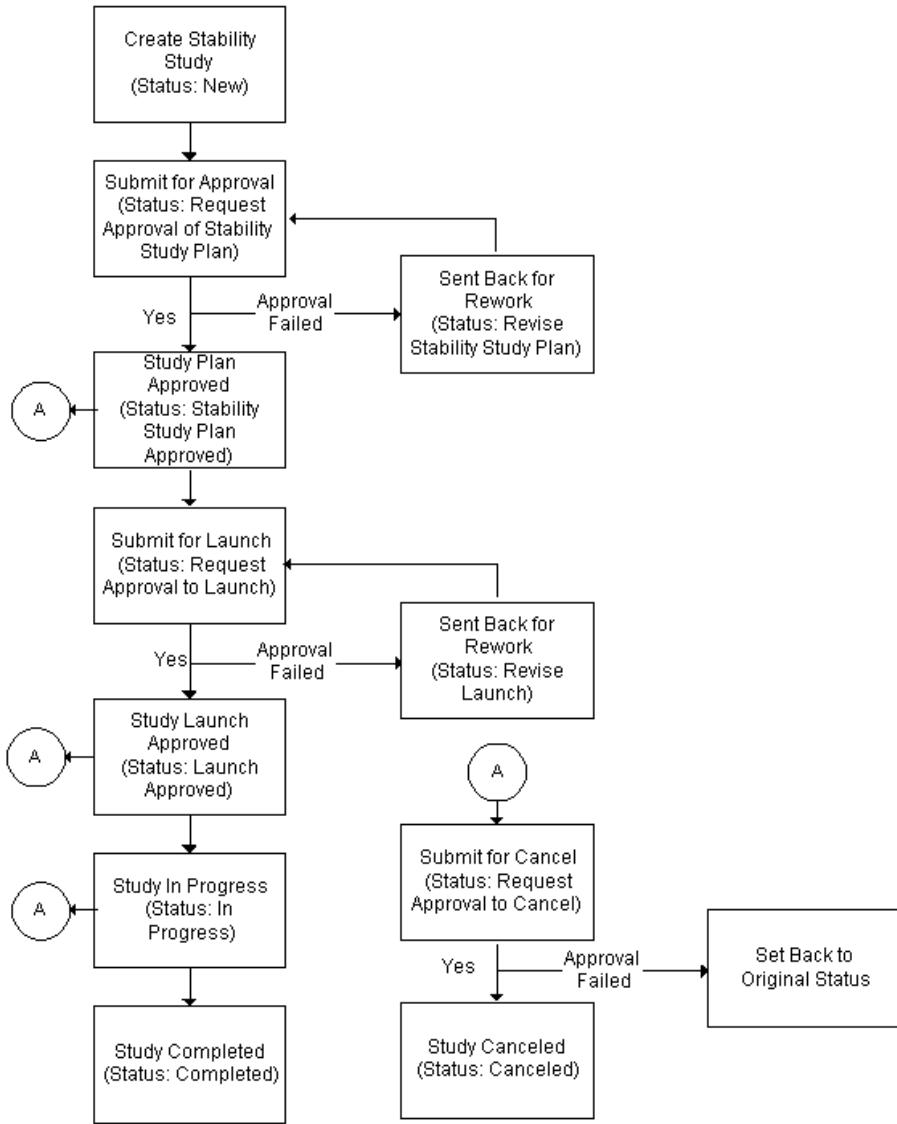
- Enable the workflow. Enable the Stability Study Change Status workflow by setting it up in the System Administration application. The workflow is activated initially by changing the status of a stability study from New to Request Approval of Stability Study Plan.

## To run the workflow:

Upon creation of a stability study, the default **Status** is **New**.

1. Choose **Stability Study Plan Approved** from the **Actions** menu to submit the stability study plan for approval. The status displays as **Request Approval of Stability Study Plan**.
  - If the stability study plan is approved, then the status changes to **Stability Study Plan Approved**. Proceed to step 2.
  - If the stability study plan is rejected, then the status changes to **Revise Stability Study Plan**. Repeat this step.
2. Choose **Launch Approved** from the **Actions** menu to submit the stability study for launch. The status displays as **Request Approval to Launch**.
  - If the stability study launch is approved, then the status changes to **Launch Approved**. Proceed to step 3.
  - If the stability study launch is rejected, then the status changes to **Revise Launch**. Repeat this step.
3. Choose **In Progress** from the **Actions** menu to perform stability study testing, .
4. Choose **Completed** from the **Actions** menu to complete the stability study, .
5. Choose **Canceled** from the **Actions** menu to cancel the stability study at **Stability Study Plan Approved**, **Launch Approved**, or **In Progress**. The status displays:
  - **Request Approval to Cancel from Approved Plan** if the stability study plan is approved, but not yet launched.
  - **Request Approval to Cancel From Approved Launch** if the stability study has an approved launch, but is not yet in progress.
  - **Request Approval to Cancel From In Progress** if the stability study is in progress.

The following depicts the previously described workflow:



## Creating Test Interval Plans

The Test Interval Plan window lets you simulate a set of test interval periods to use in a stability study. The initial test interval plan saved becomes a candidate base test interval plan. Once you save a base test interval plan, you can reuse it to create an overlay test interval plan. The overlay can exclude time periods, or add time periods to the base plan.

## Creating an Overlay Test Interval Plan

MONTH\_12 is a test interval plan that includes 12 periods spaced at one month each as follows:

MONTH-1, MONTH-2, MONTH-3, MONTH-4, MONTH-5, MONTH-6, MONTH-7, MONTH-8, MONTH-9, MONTH-10, MONTH-11, MONTH-12

When you recall MONTH\_12, make it the base plan for MONTH\_13, an overlay test interval plan that adds an additional month to the one year testing cycle. For example, MONTH\_13 includes 13 periods spaced at one month, with the last interval being MONTH-13.

With this approach, you can create many variations of test interval plans by entering a base test interval plan and modifying the overlay test interval plan to meet your specific requirements.

For example, 2\_YEAR is a test interval plan with a two year duration as follows:

- 1 WEEK
- 2 WEEKS
- 3 WEEKS
- 1 MONTH
- 2 MONTHS
- 3 MONTHS
- 6 MONTHS
- 12 MONTHS
- 18 MONTHS
- 2 YEARS

Use the Generate Test Intervals dialog box to enter a series of periods by defining a total duration and a frequency to repeat each period. The interval periods are resorted in ascending order by the simulated date when you save your work. Refer to the "Generating a Series of Testing Periods" topic for more information.

You can use flexfields with this window.

See: *Oracle Applications Flexfields Guide*

## Prerequisites

- Determine the baseline plan for all test intervals.
- Identify the plan variations for different testing frequencies.

## To enter a base test interval plan:

1. Navigate to the **Test Interval Plan** window.
2. Enter a name for the **Test Interval Plan**. Required.
3. Enter a **Description** of the base test interval plan. Required.
4. Do not select **Overlay** for the entry of a base test interval plan.
5. **Duration** displays a simulated measure of the total duration of the test interval plan after the interval periods are entered and saved.
6. **Simulation Start Date** is a baseline time when testing is required for the period if the stability study variant starts on the date displayed. This field defaults to the current system date with the time truncated to the hour for a new record. This tool helps you simulate actual dates for planning purposes. Required.

### Interval Period

7. Enter a **Period** as the name of the period. For example, enter MONTH-1 to indicate a period that is one month. When the Generate Test Intervals dialog box is used to enter periods, then this field has a period name prefix added to each interval period generated in the list. Required.
8. Enter the following fields to define an exact time point when testing is required from the start date. Each of the time intervals calculated from the start represent the sum of years, months, weeks, days, and hours from the simulation start date as follows:
  - Enter **Years** as the number of years from the simulation start date.
  - Enter **Months** as the number of months from the simulation start date.
  - Enter **Weeks** as the number of weeks from the simulation start date.
  - Enter **Days** as the number of days from the simulation start date.
  - Enter **Hours** as the number of hours from the simulation start date.

For example, to define a period that is 1 year, 3 months, and 15 days from the

simulation start date, enter a period name such as 1YR-3MO-15DA, and enter 1 in the Years field, 3 in the Months field, and 15 in the Days field.

9. **Simulated Date** displays the simulated calendar date and time for the period.
10. **From Base** indicates that the period displayed is from the base test interval plan. This field is disabled for the base test interval plan.
11. **Exclude** is disabled for the base test interval plan.
12. Save the window.

### To define an overlay test interval plan:

Define an overlay test interval plan when stability study variants require a set of time intervals different from those defined in a base test interval plan. Overlay test interval plans let you excludes periods from a base test interval plan and add new periods.

1. Enter a name for the overlay **Test Interval Plan**. Required.
2. Enter a **Description** for the overlay test interval plan. Required.
3. Select **Overlay**. Required.
4. Enter the **Base Test Interval Plan** to use for the overlay test interval plan.
5. **Duration** displays the simulated measure of the total duration for the overlay test interval plan.
6. **Simulation Start Date** is a baseline time when testing is required for the period if the stability study variant starts on the date displayed. This field defaults to the current system date with the time truncated to the hour for a new record. This tool simulates actual dates for planning purposes. Required.
7. Periods for the base test interval plan are marked with the **From Base** indicator.
8. **Exclude** can only be selected or cleared if the period displayed is from a base test interval plan. This lets you keep the period in the test interval plan. Select to include or exclude the period in any variant created using the overlay test interval plan.
9. The **Years**, **Months**, **Weeks**, **Days**, and **Hours** fields display only if the time point is derived from the base test interval plan. These fields display the specified time period from the simulation start date. You can enter these fields for interval periods that are added to this overlay test interval plan.
10. **Simulated Date** displays the simulated calendar date and time for the period.

11. Save the window.

### To include all periods from the base test interval plan:

Click **Include All** to include all periods from the base test interval plan in the overlay.

### To exclude all periods from the base test interval plan:

Click **Exclude All** to exclude all periods from the base test interval plan from the overlay.

### To add a new interval period to an overlay test interval plan:

1. Click the **Add Row** window control icon.
2. Enter a new interval period from the scheduled start date.
3. Save your work.

### To mark a test interval plan for deletion:

Choose **Mark for Purge** from the **Actions** menu. The test interval plan is marked for deletion.

### To generate a series of testing periods:

Choose **Generate Mass Intervals** from the **Actions** menu. Refer to the "Generating a Series of Testing Periods" topic for more information.

## Generating a Series of Testing Periods

The Setup Test Intervals dialog box provides a rapid way to enter a series of periods by defining a total duration and a frequency to repeat each period. Select this action if the test interval plan is not referenced by another overlay plan. If referenced, then you cannot modify the plan. For example, to enter 12 one-month periods, enter a 1 year duration with a frequency of 1 month. Or, enter a 12 month duration with a 1 month frequency.

The following conventions are used to generate testing periods:

- 1 year = 365 days
- 1 month = 30 days

You can adjust these periods once they are generated. These conventions distribute test interval periods uniformly for the study.

1. Navigate to the Setup Test Intervals dialog box.
2. Enter **Frequency** as the number of times to repeat a period in the defined duration. Select the **Frequency Unit** as Year, Month, Week, Day, or Hour. For example, for a frequency of three months, enter 3 and select Month. Required.
3. Enter **Duration** as the total of time to divide into periods. Select the **Duration Unit** as Year, Month, Week, Day, or Hour. For example, for a duration of 2 years, enter 2 and select Year.
4. Enter the **Period Name Prefix** as the interval period name to append as a prefix to each period listed.
5. Click **OK**.

The series of periods defined by the frequency and duration display on the Test Interval Plan window. For example, if you enter Test as the Period Name Prefix, assign a Frequency of 2 months, and a Duration of 1 year, then the window displays six rows of periods: Test-1, Test-2, Test-3, Test-4, Test-5, and Test-6.

### To generate contiguous sequences with the same prefix:

1. Generate the first sequence of periods.
2. Save the **Time Interval Plan**.
3. Generate the next contiguous sequence of periods.
4. Save the **Time Interval Plan**.

## Finding Test Interval Plans

The Find Test Interval Plans dialog box lets you find test interval plans, base test interval plans, overlays, and those test interval plans that are marked for deletion.

### To find a test interval plan:

1. Navigate to the Find Test Interval Plans dialog box.
2. Make no entries to find all test intervals plans. Enter any of the following parameters to narrow the search:
  - **Test Interval Plan** as the name of test interval plan.
  - **Base Test Interval Plan** as the name of the base test interval plan.

- **Marked for Deletion** to determine all test interval plans marked for purge.

3. Select **Overlay** to find overlays of test interval plans.
4. Click **Find**.

## Creating a Storage Condition Plan

The Storage Condition Plan window lets you structure a plan for the storage conditions to use in a stability study for a specific storage organization. The plan relates each condition to a monitoring specification. A storage condition plan is not associated to any specific item, and can be reused for several stability studies.

Define the two components of a storage condition plan:

- A monitoring specification to define the details of the storage condition for each one of the variants in the stability study. Refer to the "Understanding Specifications" topic for more information.
- A test interval plan to define testing time points by indicating the test intervals for each time point. Refer to the "Creating Test Interval Plans" topic for more information.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Identify the storage condition requirements for the stability study.
- Optionally, define the storage organization, resource and resource instance, or subinventory and locator that provide and maintain the required storage conditions.
- Create a monitoring specification for each of the storage conditions.
- Create a monitoring specification validity rule for each of the storage conditions.
- Create a test interval plan.

## To create a storage condition plan:

1. Navigate to the **Storage Condition Plan** window.
2. Enter the **Storage Condition Plan** name. Required.

3. Enter a **Description** for the storage condition plan. Required.
4. **Base Test Interval Plan** displays the default base test interval plan. Select any appropriate base test interval plan from the LOV. You cannot select an overlay test interval plan. Required.
5. **Duration** displays the total duration of the base test interval plan.

### Storage Details

6. Enter the **Spec Name** and **Spec Version** for each storage detail. The monitoring specification lists the tests, test targets, minimums, and maximums for the environmental condition required by the specified storage condition. Each monitoring specification entered here cannot have a status of Obsolete or On Hold.
7. Select **Storage Organization** as a process-enabled inventory organization. Required if you enter Subinventory and Locator.
8. Enter either a **Resource** or a **Storage Subinventory** and **Locator** combination:
  - **Resource** that meets the requirements for the storage condition. For example, enter a refrigerator that can meet the requirements for the monitoring specification. You can enter a generic resource that can be reassigned later on in the stability study.
  - **Storage Subinventory** and a **Locator**, if the subinventory exists for the locator, that meets the requirements for the storage condition.
9. **Test Interval Plan** displays the default base test interval plan. You can select an overlay test interval plan that is associated to the base test interval plan to override the default.
10. **Duration** is the default from the test interval plan.
11. Save the window.

### To mark a storage condition plan for deletion:

Choose **Mark for Purge** from the **Actions** menu. The storage condition plan is marked for deletion.

### To edit text in the storage condition plan:

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.
2. Make appropriate text changes.

3. Save the window.

## Finding Storage Condition Plans

The Find Storage Condition Plans dialog box helps you find existing storage condition plans by name or by the base test interval plan associated to them. You can also find storage condition plans that are marked for deletion.

### Prerequisite

- Enter and save storage condition plans.

### To find a storage condition plan:

1. Navigate to the Find Storage Condition Plans dialog box.
2. Make no entries to find all storage condition plans. Enter any of the following parameters to narrow the search:
  - **Storage Plan Name** as the name of a storage condition plan to find.
  - **Base Test Interval Plan** as the name of the base test interval plan associated to storage condition plans.
  - **Deleted** as those storage condition plans marked for purge.
3. Click **Find**.

## Defining Storage Packages

The Storage Packages window lists all existing packages and you can define the packages for variants for a specified organization. A storage package is the package material (item) or container closer system (formula) that the material is stored in for stability testing. Each package applies to a single variant. You can select these packages when you create or plan variants. Reuse these package definitions for multiple stability studies.

You can use flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

### Prerequisite

- Enter a packaging formula if there are multiple components to the storage package, or container closure system.

- Define process quality-enabled items for the storage package.

### To define a storage package:

1. Navigate to the **Storage Packages** window.
2. Enter the package **Name**. For example, enter one package as Glass Vial Closure and another package as Plastic Vial Closure. You can define multiple storage packages when the stability study evaluates material in different container closure systems. Required.
3. Select **Organization** as a process-enabled organization.
4. Select one of the following:
  - **Item** as the package material in which stability samples are stored. The item **Description** displays. The item is the container closure system. Select the item **Rev**, if the item is revision-controlled. This field is disabled if the item is not revision-controlled in Oracle Inventory.
  - Enter the packaging **Formula** and its **Version**. This represents the bill of materials for a container closure system. The product of the formula is the packaging configuration for stability sample storage.
5. Enter **Qty** as the quantity of material required for each testing time point sample in its **UOM**. This represents the total quantity of sample in the storage package. If you change the UOM, then the UOM entered must be convertible to the primary UOM for the item. Required.

### To mark a storage package for deletion:

Choose **Mark for Purge** from the **Actions** menu.

### To edit text in the storage packages:

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.
2. Make appropriate text changes.
3. Save the window.

## Finding Storage Packages

The Find Storage Package dialog box lets you find storage packages by name, item, or

formula. You can also find deleted storage packages.

## Prerequisites

- Enter and save storage packages.

### To find a storage package:

1. Navigate to the Find Storage Package dialog box.
2. Make no entries to find all storage packages. Enter any of the following parameters to narrow the search:
  - **Package** is the package name.
  - **Organization** is the process-enabled organization.
  - **Item** is the package material in which stability samples are stored.
  - **Rev** is the item revision, if the item is revision-controlled.
  - **Formula** is the bill of materials for the container closure system. The product of the formula is the packaging configuration for stability sample storage.
3. Select **Yes** to find **Deleted** storage packages that meet the criteria entered, or select **No** to find current storage packages that meet the criteria entered.
4. Click **Find**.

## Creating and Managing a Stability Study

The Stability Study window lets you create and manage a stability study. Refer to the "Managing the Stability Study Lifecycle" topic for an overview of the creation and management of a stability study.

To create a stability study, enter preliminary information about the study including its document number, description, and storage condition plan. Specify the process quality-enabled item, item revision if the item is revision-controlled, and its base item specification to test in a quality laboratory.

Once the study is created, assign material sources to the study and create all the variants to investigate. At least one material source is required to create a stability study. Once the stability study is underway, use this window to view other pertinent information about the study, including its actual and revised start and end dates. This window also serves as a repository for assigned shelf life recommendations.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Set up document numbering for the organization that owns the stability study by selecting the stability study Assignment Type as Manual or Automatic in the Process Quality Parameters window.
- Create a storage condition plan.
- Create a master item specification for stability testing.
- Identify at least one material source for the stability study.
- Identify at least one storage package for the stability study.
- Enable the stability study workflows as described in "Appendix C."

## To create a stability study:

1. Navigate to the **Stability Study** window. The stability study owner organization or the context organization displays in the window title. Select a different context organization using the Organizations window.
2. Enter **Study** as the stability study number if you select the stability study document numbering Assignment Type as Manual in the Process Quality Parameters window. If you select the Assignment Type as Automatic, then this field is protected. The stability study number is automatically assigned and displays when you save the window.
3. Enter a **Description** for the stability study.
4. Choose **Change Status** from the **Actions** menu of the Stability Study window to change the stability study status, after entering all relevant information, and saving the stability study with the default **Status** of **New**. The Status Approval workflow must be enabled for stability study approval. You can request the following actions in the order presented from the **Actions** menu:
  - **Approved Launch** to launch the stability study.
  - **Canceled** to initiate the stability study cancellation process. The response to this change depends on the status of the current stability study. It can be canceled from an approved plan, an approved launch, or an in progress study.Refer to the "OPM Quality Stability Study Change Status Workflow" topic in "Appendix C" for an explanation of the stability study workflow statuses.

- **Stability Study Plan Approved** to approve the planned stability study.

Required.

5. Enter the **Storage Condition Plan** to use for the stability study.

Refer to the "Creating a Storage Condition Plan" topic for more information on how to structure a plan for the storage conditions. Required.

6. Enter the **Item** as the material tested in the stability study. The item can be an engineering item, but it must be active and lot-controlled. The initial sample material tested must be the same as the item entered here. The item must be set up as process quality-enabled in the Item Master. The item **Description** displays as it appears on the Item Master. Required.

7. Enter the item **Revision**, if the item is revision-controlled. Required. This field is disabled if the item is not revision-controlled in Oracle Inventory.

8. Enter the **Master Item Spec** as the item specification containing the list of tests performed throughout the entire stability study. The **Version** displays. The Master Item Spec must be a base specification, and it must have a status of:

- Approved for Lab Use, for a laboratory item such as an engineering item
- Approved for General Use, for a production item

This specification serves as the default item specification when variants are loaded initially.

Required.

9. Enter the inventory organization defined as the **Quality Lab**. Required.

10. Enter the **Owner** of the stability study. This field defaults to the user who creates the stability study. The user must be associated with the stability study lab organization. The individual who creates the stability study can specify the owner. Required.

11. Enter the **Notification Lead Time** as the amount of advance notice you need prior to each scheduled testing time point using the OPM Stability Study Time Point Scheduling Notification workflow. For example, if a testing time point is scheduled for March 15, and you enter a 3-day notification lead time, you are notified of the scheduled time point on March 12. The notification lead time applies to all time points for all variants.

12. Enter **Testing Grace Period** as the lag time that can be added to each scheduled time point to create a window of opportunity for testing the item. If testing is not done within this testing grace period, then the Stability Study Late Time Point Scheduling Notification starts to notify appropriate individuals that testing is late.

The testing grace period applies to all time points for all variants.

#### **Variant**

13. Enter **Material Sources** as the required number of material sources for the stability study. This entry must be a whole positive integer greater than zero. The default for this field is 1 and is updated based on the number of lots or recipes identified as material sources for the stability study. Identify the item, lot, and batches that serve as the basis for the stability study. Required.
14. **Storage Conditions** displays the number of storage conditions required by the stability study. This field defaults from the number of storage conditions defined for the storage condition plan entered for the stability study.
15. Enter **Packages** as the number of packaging configurations that you plan to use to build the stability study. A minimum of one packaging configuration is required. If you plan to study more than one packaging configuration, then enter the total number of packages. For example, if you plan to study an amber vial and clear glass vial closure system, enter 2 because these are two separate packaging configurations.
16. **Count** displays the actual number of variants created.

#### **Dates**

17. Enter the **Scheduled Start** date for the stability study. This date cannot be changed after the stability study has a status of Stability Study Plan Approved. This scheduled start date is used to calculate the scheduled end date. Variants created by the application use the scheduled start date as the variant start date unless the material source has a yield date. Required.
18. **Scheduled End** date is calculated by adding the longest time point identified across all the time intervals in the storage condition plan to the scheduled start date. You can only change this date until the stability study is approved. Required.
19. **Revised Start** date displays a revision to the Scheduled Start date. You can only enter this field after the stability study has reached a status of Stability Study Plan Approved, but does not yet have a status of Approved for Launch. This revised start date is used to calculate the revised end date.
20. **Revised End** date displays the revision to the scheduled end date based on the revised start date.
21. Enter **Actual Start** date when the stability study is changed to a status of In Progress and defaults to the system date. The stability study can only reach this status when the:
  - Required number of initial samples for each material source have a disposition

of Accepted or Accepted with Variance

- Required number of variants are created
- Stability study has a status of Approved for Launch

22. **Actual End** date displays the date the stability study has a status of Completed.

### **Recommendations**

23. Recommended **Shelf Life** displays the recommended shelf life for the item tested in the stability study. Enter this field when the stability study has a status of Completed. Enter a recommended shelf life in years, months, weeks, days, or hours.
24. Recommended **Storage Spec** displays the ideal storage condition for the item tested in the stability study by entering the recommended storage specification and **Version** for the material. Enter this field when the stability study has a status of Completed.
25. Save your work to create a stability study with the status of **New**.
26. Assign material sources as described in the "Assigning Stability Study Material Sources" topic.
27. Choose **Change Status** from the **Actions** menu to select appropriate statuses.
28. Edit variants as described in the "Editing Variants for the Stability Study" topic.

### **To assign material sources to the stability study:**

1. Identify the item, lot, and batches to serve as the basis for the stability study as described in the "Planning a Stability Study" topic.
2. Query the stability study to assign material sources.
3. Click **Material Source**. Refer to the "Assigning Stability Study Material Sources" topic for additional information.

### **To edit variants for the stability study:**

1. Identify the unique combinations of the stability study storage conditions, the test interval plan, and the package.
2. Query the stability study to edit variants.
3. Click **Variants**. Refer to the "Editing Variants for the Stability Study" topic for

additional information.

### To edit text in the stability study:

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.
2. Make appropriate text changes.
3. Save the window.

### To mark the stability study for purge:

Choose **Mark for Purge** from the **Actions** menu. The record is marked for deletion.

### To change the status of the stability study:

1. Choose **Change Status** from the **Actions** menu.
2. Select the desired status.
3. Save the window.

### To display the master item specification:

Choose **View Master Item Specification** from the **Actions** menu. The master item displays in the **Specifications** window.

### To display the storage condition plan:

Choose **View Storage Condition Plan** from the **Actions** menu. The storage condition plan displays in the **Storage Condition Plan** window.

## Finding Stability Studies

The Find Stability Studies dialog box helps you find stability studies by study status, item tested, lab organization, or owner.

### Prerequisites

- Enter and save stability studies.

## To find stability studies:

1. Navigate to the Find Stability Studies dialog box.
2. Make no entries to find all stability studies. Enter any of the following parameters to narrow the search:
  - Enter **Study** as the stability study number.
  - Select **Status** as:
    - **New** to find stability studies created, but not yet approved.
    - **Request Approval of Stability Study Plan** to find stability studies submitted for the stability study plan approval process using the workflow.
    - **Revise Stability Study Plan** to find stability studies under revision for stability study plan approval.
    - **Stability Study Plan Approved** to find stability studies that have an approved stability study plan.
    - **Request Approval to Launch** to find stability studies submitted for stability study launch approval using the workflow.
    - **Revise Launch Request** to find stability studies under revision for stability study launch approval.
    - **Launch Approved** to find stability studies that have an approved stability study launch.
    - **In Progress** to find stability studies in-progress.
    - **Request Approval to Cancel** to find stability studies submitted for stability study cancellation before the stability study plan is approved.
    - **Request Approval to Cancel From Approved Plan** to find stability studies submitted for stability study cancellation when the study has a status of Stability Study Plan Approved.
    - **Request Approval to Cancel From Approved Launch** to find stability studies submitted for the stability study cancellation when the study has a status of Launch Approved.
    - **Request Approval to Cancel From In Progress** to find stability studies submitted for stability study cancellation when the study has a status of In Progress.

- **Canceled** to find stability studies that are canceled.
- **Completed** to find stability studies that are completed.
- **Item** as the material tested in the stability study.
- **Revision** as the item revision.
- **Quality Lab** as the inventory organization defined as a quality laboratory.
- **Owner** as the individual responsible for the stability study.

3. Click **Find**.
4. Press the down arrow to display each study that was found.

## Assigning Stability Study Material Sources

The Material Sources window lets you specify the organization and the material source of sample material for the stability study. This window displays the details for the number of material sources entered on the Stability Study window. The source material can already exist in inventory as lots or it can be selected, or requested as batch. Batches can be initial production batches for a new formulation, or a portion of routine production batches that are pulled for stability testing. This information includes the item, revision, lot, batch number, date of manufacture or manufacturing release date, batch size, recipe, and recipe version used.

The batch that produces the sample material for the stability study is specified in one of the following ways:

- Request batch, if the material needs to be produced. Specify the plant, or plant and recipe, or plant, recipe, and recipe version.
- Select lot if the material is produced and is assigned a specific lot.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Create and save a stability study.
- Identify material sources to use in the stability study.

## To enter material source details:

1. Navigate to the **Material Sources** window. The stability study owner organization and the status display in the window title.
2. Enter **Organization** as the process-enabled material source inventory organization where the sample material is produced. The organization must be defined as either a plant or a research and development laboratory. If the item is an engineering item, then the organization must be defined as a laboratory organization. If the material is not yet produced, then this is the organization that is assigned to produce the material. If you leave this field blank, then specify the recipe and version for the material source.
3. Enter the **Batch** number. Specify the organization before you can enter this field. The batch status must be WIP or Completed. Select a batch that contains a stability study item identified as a product or byproduct.
4. Enter the **Lot** when material already exists in inventory. You can update this field after the source material is produced by the specified recipe and recipe version. Specify the organization before you enter this field. Required if Batch is entered.
5. Enter the **Recipe** as the recipe to use when the source material is planned for the stability study. There must be an active recipe validity rule for the material source organization.
6. Enter the **Recipe Version** as the version of the recipe to use when the source material is planned for the stability study. If you leave this field blank, then indicate any version of the recipe can be used to produce the material.
7. **Yield Date** displays the date that the specified lot is yielded from the specified batch.
8. **Sample Qty** displays the total sample quantity required for stability testing of each material source identified in the item primary **UOM**.
9. **Sample Qty UOM** displays the UOM of the sample quantity.
10. **Initial Sample Group Associated** is selected if a sample group is associated to the material source before launching the stability study.
11. Save the window.

## To update the sample quantity required:

Enter the number of samples per time point and the sample quantity to put into storage package for all study variants:

1. Choose **Calculate Sample Quantity** from the **Actions** menu. The **Sample Qty** field displays an updated sample quantity for the selected material source.
2. Evaluate sample quantity to make certain there is sufficient material to complete the stability study.

### To display all stability study variants:

Click **Study Variants** to open the **Variant** window where all stability study variants for all material sources display.

### To select initial samples:

1. Choose **Select Initial Sample Group** from the **Actions** menu. A list of sample groups with a disposition of Accept or Accept with Variance for the selected material source display.
2. Select the desired initial sample group.
3. Click **OK**.

### To edit text in the material sources:

1. Choose **Edit Text** from the **Actions** menu. The **Select Text Paragraph** window displays.
2. Make appropriate text changes.
3. Save the window.

### To mark the material sources for purge:

Choose **Mark for Purge** from the **Actions** menu. The record is marked for deletion.

## Editing Stability Study Variants

The Variant window lets you edit stability study variants. This window displays all variants the application creates when the stability study is created. The total number of rows displayed on this window depends on the number of unique combinations of:

- A specific batch.
- A specific storage condition in a storage organization such a combination of temperature and humidity. For example, 30 deg C and 60% RH.

- A specific storage package. You can set up a stability study for several storage packages, however at least one package is required.

Delete or add variants until the stability study plan is approved. Resources or locators identified for variant storage conditions can also be replaced if they do not meet environmental monitoring requirements.

## Creating Variants

Each row on the Variant window represents an individual material source, storage condition, and storage package combination. Based on the variant count for a new stability study, the application creates a variant for each of these combinations. It is assumed that stability study sample material from each source is stored in each storage condition and storage package combination for the specified duration. Sample material from a batch is stored at one or several storage conditions in a process-enabled inventory storage organization, depending on the scope of the stability study.

## Planning Variants

Plan or edit variants once material sources are defined. However, changes to the number of acceptable material sources can affect the number of planned variants before a stability study plan is approved. Add, edit, or delete variants until the stability study plan is approved. Once the stability study is in progress, you can only edit the variant end date, or replace the resource or physical location for a storage condition.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Define base and overlay item specifications for stability testing.
- Define the storage organization, resource and resource instance, or storage subinventory and storage locator that provide and maintain the required storage conditions.
- Define at least one storage package.
- Create a stability study.

## To edit variants in a stability study:

1. Navigate to the **Variant** window. The context organization displays in the window title. Select a different context organization using the **Organizations** window.
2. Query the stability **Study** to enter variants.

**Note:** Status must be **New** or **Revise Stability Study Plan** to edit variants.

3. The following fields are display only:
  - **Item** displays the material tested in the stability study. The item description displays as it appears on the Item Master.
  - **Revision** displays the item revision.
  - **Variant Count** displays the total number of variants for the stability study. Each time you add or delete a variant, this number displays the current number of variants saved.

#### **Variant**

4. **Num** displays a unique variant number generated by the application in a series with increments of one. When a new variant is added, a material source is required for the record entered. You cannot delete a numbered row once the stability study plan is approved. The variant number remains, and it is not reused. However, the particular variant is no longer valid. Required.
5. Enter **Default Spec** as the item specification for the variant, and the specification **Default Spec Version**. These fields default from the master item specification entered on the **Stability Study** window. If an overlay specification exists for the master item specification, then you can enter the overlay specification. The default item specification applies to all time points for a variant. You can also configure it more specifically on the **Time Points** window. Required.
6. Enter **Start Date** as the default start date from the material source yield date. This changes to the scheduled start date of the stability study when the stability study has a status of **New**.
7. Enter **End Date** as the default end date of the stability study.
8. Enter **Samples Per Time Point** as the default number of samples for each time point that is associated to the variant selected. The default is one sample per time point.
9. Enter **Retained Samples** as the number of samples retained for a variant in the eventuality that unscheduled testing is required. The default value is zero. You can assign retained samples for a variant at a specific time point on the **Variant Time Points** window.

#### **Material Source**

10. The following fields are display only:

- **Num** displays a unique variant number generated by the application in a series with increments of one. When a new variant is added, a material source is required for the record entered. You cannot delete a numbered row once the stability study plan is approved. The variant number remains, and it is not reused. However, the particular variant is no longer valid. Required.
- **Organization** displays the material source organization where the sample material is produced. This defaults from the Material Sources window and is a process-enabled inventory organization.
- **Batch** displays the batch document number where the stability study item is identified as a product or byproduct.
- **Recipe** displays the recipe to use when the source material is requested for the stability study, and the **Recipe Version**.
- **Lot** displays the lot for a stability study material source.

### **Storage Condition**

11. The following fields are display only:

- **Num** displays a unique variant number generated by the application in a series with increments of one. When a new variant is added, a material source is required for the record entered. You cannot delete a numbered row once the stability study plan is approved. The variant number remains, and it is not reused. However, the particular variant is no longer valid. Required.
- **Storage Spec** displays the monitoring specification and **Storage Spec Version** for a storage condition that defaults from the storage condition plan.
- **Organization** displays the process-enabled inventory organization that stores the sample. This defines the storage subinventory and storage locator or resource and resource instance.
- **Resource** displays the storage resource specified on the storage condition plan. You can override this entry. For example, enter a refrigerator that meets the requirements for the monitoring specification if the default resource cannot meet this requirement. This field defaults from the storage condition plan.
- **Resource Instance** displays a specific resource instance identified for the storage condition specified in the monitoring specification. For example, this field can display a specific environmental chamber.
- **Subinventory** displays a subinventory that meets the storage condition requirements for the variant. This field defaults from the storage condition plan.

- **Locator** displays the subinventory locator if the subinventory exists for the locator. This field defaults from the storage condition plan.

12. Enter the **Storage Date** that samples are placed in the variant storage condition. This date can also represent the date the resource or locator for a storage condition is modified after the start of the stability study. You can reenter this field after the stability study plan is approved and launched until samples are put in the variant storage condition.

### Package

13. **Num** displays a unique variant number generated by the application in a series with increments of one. When a new variant is added, a material source is required for the record entered. You cannot delete a numbered row once the stability study plan is approved. The variant number remains, and it is not reused. However, the particular variant is no longer valid. Required.

14. Enter a valid **Package** as the selected storage package used to store the variant of the item in the stability study organization.

15. **Formula** displays the formula and **Formula Version** if a formula is defined for the storage package.

16. **Item** displays the item for the storage package.

17. **Revision** displays the item revision, if the item is revision-controlled.

18. Enter **Sample Quantity** as the quantity of sample for each variant and the **Sample Quantity UOM**. These fields default from the **Storage Packages** window. You can reenter them for each variant. Required.

19. Save the window.

### To add a variant:

1. Query the **Study**. Status must be **New** or **Revise Stability Study Plan** to edit variants.
2. Select a row to add a variant. Variants insert below the row selected.
3. Choose **New** from the **File** menu.
4. Select the material source from the Material Source dialog box. Required.
5. Click **OK**.

## To delete a variant:

1. Query the **Study**. Status must be **New** or **Revise Stability Study Plan** to edit variants.
2. Select the variant to delete.
3. Choose **Delete** from the **Edit** menu. All time points associated to the selected variant are deleted.
4. Save the window.

## To display the item specification associated to the variant:

Click **Item Spec**. The **Specifications** window displays the default item specification for the selected variant.

## To display the storage specification associated to the variant:

Click **Item Spec**. The **Specifications** window displays the default item specification for the selected variant.

## To display time points associated to the variant:

1. Select the variant.
2. Click **Time Points**. Refer to the "Editing Variant Time Points" topic for more information.

## To display the stability study samples associated to a variant:

1. Select the variant.
2. Click **Samples**.

## To display monitoring samples for a storage specification:

1. Select the variant.
2. Choose **View Storage Spec Samples** from the **Actions** menu.

## To modify the resource or locator for a storage condition:

1. Choose **Modify Storage Condition** from the **Actions** menu.

2. **From Storage Conditions** display the current:

- Process-enabled **Storage Organization**, which is the inventory organization of the stability study variant.
- **Resource** that meets the requirements for the storage condition. This defaults initially from the storage condition plan, but you can override it.
- **Instance** of a specific resource identified for the storage condition specified in the monitoring specification.
- **Subinventory** that meets the requirements for the storage condition. This defaults initially from the storage condition plan, but you can override it.
- **Locator** in the subinventory that meets the requirements for the storage condition, if the subinventory exists for the locator.
- **Start Date** as the date when samples are placed in the variant storage condition, resource, or locator. This date reflects modifications to the start of the stability study.
- **End Date** as the date when samples are removed from the variant storage condition, resource, or locator. When you save the window, this field updates to reflect the start date entered for the To Storage Condition.

3. Enter a **To Storage Condition** for a resource and resource instance, or for a subinventory and locator to change the current value displayed. Following is a list of conditions you can enter:

- **Storage Organization** as the process-enabled inventory organization of the stability study variant. Required.
- **Resource** that meets the requirements for the storage condition. When you enter a new resource, the resource instance field is cleared if an instance was entered previously.
- **Instance** that meets the storage condition specified in the monitoring specification.
- **Subinventory** that meets the requirements for the storage condition.
- **Locator** that meets the requirements for the storage condition, if the subinventory exists for the locator.
- **Start Date** when samples are placed in the variant storage condition.

4. Click **OK** to modify the resource or locator storage conditions.

## To display the history of storage condition resource and locator changes:

1. Choose **View Storage History** from the **Actions** menu. The **View Storage History** dialog box displays the history of the **Storage Organization, Resource, Instance, Subinventory, Locator, Start Date, and End Date** replacements or the variant.
2. Review the history.

## To assign a retained sample from the variant to a testing time point:

1. Select the variant.
2. Choose **Assign Sample to Time Point** from the **Actions** menu
3. **Variant Num** defaults from the **Variant** window.
4. **Source Time Point** displays the current time interval of the retained sample. This field is blank when selecting a retained sample from the variant.
5. Enter the **Sample No** to assign to the target time point. The organization code for the sample defaults to the sample organization identified for the material source.
6. **Target Time Point** displays the time interval the retained sample is assigned to.
7. Click **OK**.

## Finding Stability Study Variants

The Find Variants dialog box lets you find stability study variants.

### To find a stability study variant:

1. Navigate to the Find Variants dialog box.
2. Make no entries to find all variants. Enter any of the following parameters to narrow the search:
  - **Study** as the name of the stability study.
  - **Status** as the status of the stability study.  
Refer to the "Finding Stability Studies" topic for a complete explanation of stability study status.
  - **Item** as the material tested in the stability study. The item can be an engineering item, but it must be active. The item **Description** displays as it appears on the

Item Master.

- **Revision** as the item revision.

3. Click **Find**.

## Editing Variant Time Points

The Variant Time Points window displays all time intervals defined in the test interval plan assigned to the storage condition for each variant in the stability study. The time intervals display in chronological order starting with the earliest time point to test.

The number and frequency of the time points are defined by the test interval plan assigned to the variant storage condition in the storage condition plan. You can add or remove time points from the variant at the time the variant is created, or during the revised stability study approval phase, if rework is required. After the stability study begins, you can add additional time points. You can assign retained samples to a time point, or move retained samples between time points.

You can use folders and flexfields with this window.

See: *Oracle Applications User's Guide* and *Oracle Applications Flexfields Guide*

## Prerequisites

- Define base and overlay item specifications for stability testing.
- Create a stability study and variants.

## To edit variant time points:

1. Navigate to the **Time Point** window.
2. **Time Interval** displays the time interval from the variant's test interval plan that defines a testing time point.
3. Enter **SpecName** as the item specification number and **Spec Version** used to test sample material at the testing time point. This field displays the default item specification for the variant. You can select an overlay specification.
4. The following fields are display only:
  - **Scheduled Date** displays the date the testing for the time point needs to be scheduled. This date calculated by adding the time point interval to the variant start date.

- **Actual Date** displays the actual date the testing for the time point was done. You can enter and modify this field when the stability study is in progress.

5. Enter **Samples Per Time Point** as the required number of samples for the testing time point. This field defaults from the **Samples Per Time Point** field entered on the **Variants** window.
6. **Disposition** displays the disposition of the testing time point sample group.

### To add a time point to a stability study before it is approved:

1. Select the time interval to insert the new time point. **Status** must be **New** or **Revise Stability Study Plan**.
2. Choose **New** from the **File** menu.
3. Enter the **Time Interval name**, **Spec Name**, **Version**, **Scheduled Date**, and **Samples Per Time Point** for testing the new time point.
4. Save the window.

### To add a time point to a stability study after it is approved:

1. Select the time interval to insert the new time point. **Status** must be **Revise Stability Study Plan**.
2. Choose **New** from the **File** menu.
3. Enter the **Time Interval name**, **Spec Name**, **Version**, **Scheduled Date**, and **Samples Per Time Point** for testing the new time point.
4. Assign the sample to the time point.
5. Save the window.

### To display the item specification associated to the variant:

Click **Item Spec**. The default item **Specification** displays.

### To display the sample associated to a variant:

1. Select the variant time point.
2. Click **Samples**.

3. Drill down to individual item samples to view information about each one of them.

### To assign a retained sample to a new testing time point:

1. Select the new testing time point.
2. Choose **Assign Sample to Time Point** from the **Actions** menu.
3. **Variant** defaults from the **Variants** window.
4. Enter a **Source Time Point**, or leave this field blank for the application to select a retained sample from the variant.
5. Enter the **Sample** to assign to the new testing time point. The organization code for the sample defaults to the same organization identified for the material source.
6. **Target Time Point** displays the time interval for the new testing time point created, and cannot be edited.
7. Click **OK**.

### To move a retained sample to a specific time point:

Move a retained sample from one time point to another specific time point in order to replace a sample that was damaged in transit to the laboratory, or to complete testing.

1. Select the testing time point to move the sample to.
2. Choose **Assign Sample to Time Point** from the **Actions** menu.
3. **Variant** defaults from the **Variant** window.
4. Enter **Source Time Point** as the testing time point to move the sample from.
5. Enter the **Sample** assigned to the new testing time point. The organization code for the sample defaults to the same organization identified for the material source.
6. **Target Time Point** displays testing time point selected and cannot be edited.
7. Click **OK**.



# A

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## Quality Management Navigator Paths

### Quality Management Navigator Paths

Although your System Administrator may have customized your Navigator, typical navigation paths are described in the following tables. In some cases, there is more than one way to navigate to a window. These tables provide the most typical default path.

Window	Path
Add Tests	Quality Manager:Samples:Sample Groups:click Composite Results:click Add Test
	Quality Manager:Results:Results:Actions:Add Tests
Certificate of Analysis Report	Quality Manager:Reports:Certificate of Analysis/Conformance
Composite Results	Quality Manager:Results:Actions:Composite Results
	Quality Manager:Samples:Sample Groups:click Composite Results
Copy Specification	Quality Manager:Specifications:Specifications:select desired specification:Actions:Copy Specification
Customer Display	Quality Manager:Setup:Tests:click Customer Display

Window	Path
Customer/Supplier Test Results Report	Quality Manager:Reports:Other Reports:Run
Experimental Error	Quality Manager:Setup:Tests:click Experimental Error
Experimental Errors	Quality Manager:Samples:Sample Groups:select desired sample group:click Mass Results:Mass Results Entry Test Selection:select appropriate tests:click Mass Results Entry:click Experimental Errors
Find Actions	Quality Manager:Setup:Actions:View:Find...
Find Grades	Quality Manager:Setup:Grades:View:Find...
Find Sample Groups	Quality Manager:Samples:Sample Groups:View:Find...
Find Samples (from Item Samples window)	Quality Manager:Samples:Item Samples:View:Find...
Find Samples (from Results window)	Quality Manager:Results:Results:View:Find
Find Samples (from Specification Comparison window)	Quality Manager:Results: Specification Comparison:View:Find
Find Samples (from the Quality Workbench navigator)	Quality Manager:Quality Workbench:click the Samples tab:View:Find
Find Sampling Plans	Quality Manager:Setup:Sampling Plans:View:Find
Find Sample Storage Summary	Quality Manager:Inquiries:Sample Storage:View:Find
Find Specifications (from Specifications window)	Quality Manager:Specifications:Specifications:View:Fi nd
Find Specifications (from the Quality Workbench navigator)	Quality Manager:Quality Workbench:click the Specifications tab:View:Find

Window	Path
Find Stability Studies	Quality Manager:Stability Study:Stability Study:View:Find...
Find Variants	Quality Manager:Stability Study:Stability Study:View:Find:find the desired stability study:click Variants:View:Find
Find Status Codes	Quality Manager:Setup:Status Codes:View:Find
Find Storage Condition Plans	Quality Manager:Stability Study:Setup:Storage Condition Plan:View:Find
Find Storage Package	Quality Manager:Stability Study:Setup:Storage Package:View:Find...
Find Process Quality Parameters	Quality Manager:Setup:Process Quality Parameters:View:Find
Find Test Classes	Quality Manager:Setup:Test Classes:View:Find
Find Test Interval Plans	Quality Manager:Stability Study:Setup:Test Interval Plan:View:Find
Find Test Methods	Quality Manager:Setup:Test Methods:View:Find...
Find Test Units	Quality Manager:Setup:Test Units:View:Find...
Find Tests	Quality Manager:Setup:Tests:View:Find...
Find Variants	Quality Manager:Stability Study:Stability Study:click Variants:View:Find...
Item Samples	Quality Manager:Samples:Item Samples
Item/Location Required Analysis Report	Quality Manager:Reports:Other Reports:Run
Item/Location Test Results Report	Quality Manager:Reports:Other Reports:Run

<b>Window</b>	<b>Path</b>
Item Lots	Quality Manager:Inquiries:Lot Genealogy
Maintain Actions	Quality Manager:Setup:Actions
Maintain Grades	Quality Manager:Setup:Grades
Mass Results Entry	Quality Manager:Samples:Sample Groups:select desired sample group:click Mass Results Entry:Mass Results Entry Test Selection:select appropriate tests:click Mass Results Entry
	Quality Manager: Samples:Sample Groups:click View Samples:Samples Summary:click Mass Results Entry:Mass Results Entry Test Selection:select appropriate tests:click Mass Results Entry
Mass Results Entry Test Selection	Quality Manager:Samples:Sample Groups:select desired sample group:click Mass Results Entry
	Quality Manager:Quality Workbench:select Show Active Samples:select appropriate View By...:expand Samples By...:select desired sample group:Samples By...:click Mass Results Entry
	Quality Manager: Samples:Sample Groups:click View Samples:Samples Summary:click Mass Results Entry
Material Sources	Quality Manager:Stability Study:Stability Study:query the desired stability study:click Material Sources
Monitoring Samples	Quality Manager:Samples:Monitoring Samples
Organizations	Quality Manager:Other:Change Organization
Process Quality Parameters	Quality Manager:Setup:Process Quality Parameters

Window	Path
Production Test Results Report	Quality Manager:Reports:Other Reports:Run
Quality Change Disposition	Quality Manager:Samples:Item Samples:query a sample:Actions:Change Disposition
	Quality Manager:Results:Results:query a result:Actions:Change Disposition
	Quality Manager:Results:Results:query a result:Actions:Composite
	Results:Actions:Change Disposition
Quality Workbench	Quality Manager:Quality Workbench
Results	Quality Manager:Results:Results
Result Association	Quality Manager:Results:Results:Find Samples:Actions:Result Association
Sample Groups	Quality Manager:Samples:Sample Groups
Sample Label Generation	Quality Manager:Reports:Other Reports:Run
Sample Storage Summary	Quality Manager:Inquiries:Sample Storage
Samples By...	Quality Manager:Quality Workbench:click Samples tab:select View By...:expand Samples By... node:expand desired node:click desired object
Samples Summary	Quality Manager:Samples:Sample Groups:click View Samples
Sampling Plan	Quality Manager:Setup:Sampling Plans
Specification Comparison	Quality Manager:Results:Specification Comparison
Specification Summary	Quality Manager:Quality Workbench:select View By Specifications:expand Specifications node:click specification
Specifications	Quality Manager:Specifications:Specifications

Window	Path
Setup Test Interval	Quality Manager:Stability Study:Setup:Test Interval Plan:Actions:Generate Mass Intervals
Stability Study	Quality Manager:Stability Study:Stability Study
Status Codes	Quality Manager:Setup:Status Codes
Status Details	Quality Manager:Setup:Status Codes:click Details
Storage Condition Plan	Quality Manager:Stability Study:Setup:Storage Condition Plan
Storage Packages	Quality Manager:Stability Study:Setup:Storage Package
Test Classes	Quality Manager:Setup:Test Classes
Test Interval Plan	Quality Manager:Stability Study:Setup:Test Interval Plan
Test Methods	Quality Manager:Setup:Test Methods
Test Units	Quality Manager:Setup:Test Units
Tests	Quality Manager:Setup:Tests
Time Point	Quality Manager:Stability Study:Variants and Time Points:click Time Points
Item Spec Validity Rule Details	Quality Manager:Specifications:View:Find...:select Spec Type as Item:click Find:select the desired specification:click Validity Rules:select a validity rule:click Edit
Monitoring Spec Validity Rule Details	Quality Manager:Specifications:View:Find...:select Spec Type as Monitor:click Find:select the desired monitoring specification:click Validity Rules:select a validity rule:click Edit

<b>Window</b>	<b>Path</b>
Item Spec Validity Rules Summary	Quality Manager:Specifications:query specification:click Validity Rules
Monitoring Spec Validity Rules Summary	Quality Manager:Specifications:View:Find...:select Spec Type as Monitor:click Find:select the desired monitoring specification:click Validity Rules. Edit to edit an existing monitoring specification, or click New to enter a new monitoring specification
Variant	Quality Manager:Stability Study:Variants and Time Points
Time Point	Quality Manager:Stability Study:Variants and Time Points:select the desired variant:click Time Points
View Samples for Test (from Composite Results window)	Quality Manager:Samples:Sample Groups:click Composite Results:click View Samples



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## Quality Management Responsibilities

### Quality Management Responsibilities

The application offers the following responsibilities:

- **Quality Manager** with unlimited access to the entire application
- **Quality Technician** with privileges to view specifications, access the Item Samples window, Monitoring Samples window, Sample Groups window, the Entry, Internal, and External tabs on the Results window, and all reports and inquiries

Refer to the *Oracle Applications System Administrator's Guide* and *Oracle Common Application Components Implementation Guide* for detailed information on setting up responsibilities.



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# Quality Management Business Rules

## Specification Matching Business Rules

These topics summarize the business rules used to find the appropriate specification version and specification validity rule in effect for quality inspection of material. This specification matching logic is performed when associating a specification to a sample in OPM Quality Management, and when running the Customer Specification Matching inquiry in Oracle Order Management. There are two sets of business rules for:

- Item Specification Matching
- Monitoring Specification Matching

### Item Specification Matching

The following discussions pertain to item specification matching:

#### Local and Global Specification Searches

To match a specification with a specific sample, the Samples window uses the base hierarchy. Local specifications are searched before global specifications at each level of the specification matching hierarchy.

#### Item and Item Revision in Specification Matching

Item and item revision are considered in customer, inventory, supplier, and WIP specification matching.

#### Grade Control in Specification Matching

Specifications with no grade specified are searched for items that are not grade-controlled. For grade-controlled items, specification matching searches for a given grade.

If the grade is specified, then it is used in the search, otherwise item specifications with no grade are used.

If the grade is not specified, then the lot-specific grade is used first, followed by item default grade, and finally the global grade is used.

If a grade is not found, then the application searches for a specification with no grade specified for the closest match. These rules apply to all specification matching hierarchies for inventory, WIP, customer, and supplier.

### **Customer Specification Matching**

To match a specification with a customer sample, the Samples window uses the base hierarchy and considers local versus global specifications. While matching a customer sample, if the customer specification is not found based on the following hierarchical criteria, then the application searches for an inventory specification. If the grade is specified, then it is used in the search, otherwise item specifications with no grade are used. If grade is not specified, then item specifications with no grade are used in the search. Item and Item Revision are considered. The search hierarchy is:

1. Local Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line ID
2. Global Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line ID
3. Local Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line
4. Global Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line
5. Local Organization + Customer + Operating Unit + Ship-To + Order Number
6. Global Organization + Customer + Operating Unit + Ship-To + Order Number
7. Local Organization + Customer + Operating Unit + Order Number
8. Global Organization + Customer + Operating Unit + Order Number
9. Local Organization + Customer + Operating Unit + Ship-To Location
10. Global Organization + Customer + Operating Unit + Ship-To Location
11. Local Organization + Customer
12. Global Organization + Customer

### **Specification Matching from the Pick Lots Window**

To find a customer specification from the Select Available Inventory window, the specification matching feature uses the base hierarchy and considers local versus global

versus other organization-specific specifications. The Select Available Inventory window searches only for a customer specification. It does not search for an inventory specification if the customer specification is not found. If the grade is specified, then it is used in the search, otherwise item specifications with no grade are used. Item and Item Revision are considered. The search hierarchy is:

1. Local Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line ID
2. Global Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line ID
3. Other Organizations + Customer + Operating Unit + Ship-To + Order Number + Order Line ID
4. Local Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line
5. Global Organization + Customer + Operating Unit + Ship-To + Order Number + Order Line
6. Other Organizations + Customer + Operating Unit + Ship-To + Order Number + Order Line
7. Local Organization + Customer + Operating Unit + Ship-To + Order Number
8. Global Organization + Customer + Operating Unit + Ship-To + Order Number
9. Other Organizations + Customer + Operating Unit + Ship-To + Order Number
10. Local Organization + Customer + Operating Unit + Order Number
11. Global Organization + Customer + Operating Unit + Order Number
12. Other Organizations + Customer + Operating Unit + Order Number
13. Local Organization + Customer + Operating Unit + Ship-To Location
14. Global Organization + Customer + Operating Unit + Ship-To Location
15. Other Organizations + Customer + Operating Unit + Ship-To Location
16. Local Organization + Customer
17. Global Organization + Customer
18. Other Organizations + Customer

## **Inventory Specification Matching**

To find an inventory specification, the specification matching feature uses the base hierarchy and considers local versus global versus other plant-specific specifications. Item and Item Revision are considered.

If the grade is specified, then it is used in the search, otherwise item specifications with no grade are searched. If the grade is not specified and the item is grade-controlled, then the item with no grade is used in the search. The following is the hierarchy used by the inventory specification matching program:

1. Local Organization + Parent Lot + Lot + Subinventory + Locator
2. Local Organization + Parent Lot + Lot + Subinventory
3. Local Organization + Parent Lot + Lot
4. Global Organization + Parent Lot + Lot
5. Local Organization + Parent Lot + Lot + Subinventory + Locator
6. Local Organization + Parent Lot + Lot + Subinventory
7. Local Organization + Parent Lot + Lot
8. Global Organization + Parent Lot + Lot
9. Local Organization + Subinventory + Locator
10. Local Organization + Subinventory
11. Local Organization + Item
12. Global Organization + Item

## **Supplier Specification Matching**

To find a supplier specification, the specification matching feature uses the base hierarchy and considers local versus global versus other plant-specific specifications. If no supplier specification is found that matches a supplier sample, then the application searches for a matching inventory specification. Item and Item Revision are considered. If the grade is specified, then it is used in the search, otherwise item specifications with no grade are used. If grade is not specified, then item specifications with no grade are searched. The following is the hierarchy used by the supplier specification matching program.

1. Local Organization + Supplier + Supplier Site + PO Number + PO Line Number
2. Global Organization + Supplier + Supplier Site + PO Number + PO Line Number

3. Local Organization + Supplier + Supplier Site + PO Number
4. Global Organization + Supplier + Supplier Site + PO Number
5. Local Organization + Supplier + Supplier Site
6. Global Organization + Supplier + Supplier Site
7. Local Organization + Supplier
8. Global Organization + Supplier

#### **WIP Specification Matching**

To find a WIP specification, the specification matching feature uses the base hierarchy and considers local versus global versus other plant-specific specifications. If no WIP specification is found that matches a WIP sample, then the application searches for a matching inventory specification. WIP specifications are searched using the following priorities:

1. Charge
2. Step
3. Routing + Version
4. Routing
5. Formula Line
6. Formula + Version
7. Formula
8. Recipe + Version
9. Recipe
10. Batch
11. Operation + Version
12. Operation

Based on the previous search priorities, a routing takes precedence over a formula, recipe, batch, or operation. When a recipe is defined, the formula and optional routing are associated to it. When a batch is defined from a recipe, a formula and optional routing are associated to it.

If the grade is specified, then it is used in the search, otherwise item specifications with no grade are used. If the grade is not specified and the item is grade-controlled, then the item with no grade is used in the search. Item and Item Revision are considered. The WIP specification matching program uses the inventory specification matching program as the base hierarchy and searches based on the previous priorities as follows:

1. Local Organization + Lot + Subinventory + Locator
2. Global Organization + Lot + Subinventory + Locator
3. Local Organization + Lot + Subinventory + Locator
4. Global Organization + Lot + Subinventory + Locator
5. Local Organization + Lot + Subinventory
6. Global Organization + Lot + Subinventory
7. Local Organization + Lot + Subinventory
8. Global Organization + Lot + Subinventory
9. Local Organization + Lot
10. Global Organization + Lot
11. Local Organization + Lot
12. Global Organization + Lot
13. Local Organization + Subinventory + Locator
14. Global Organization + Subinventory + Locator
15. Local Organization + Subinventory
16. Global Organization + Subinventory
17. Local Organization + Item
18. Global Organization + Item

#### **Monitoring Specification Matching**

Monitoring specifications are created for resources or locators that you need to assess as part of your quality operations in the supply chain. The following is the hierarchy used by the monitoring specification matching program.

**Locator**

The search hierarchy is:

1. Organization + Subinventory + Locator
2. Organization + Subinventory
3. Organization

**Resource**

The search hierarchy is:

1. Resource + Resource Organization + Resource Instance
2. Resource + Resource Organization
3. Resource



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## Quality Management Workflows

This topic introduces you to the concept of a workflow process and refers you to the documentation that fully explains Oracle workflows. It presents an understanding of the OPM Quality Management workflows, how to set them up, how to start them, and how to use the Quality windows.

This appendix covers the following topics:

- Basic Business Needs
- Technical Overview
- Understanding Workflow Processes
- Understanding OPM Quality Management Workflows
- Setting Up OPM Quality Management Workflows
- Using OPM Quality Management Workflows
- OPM Quality Sample Creation Workflow
- OPM Quality Test Workflow
- OPM Quality Sample Disposition Workflow
- OPM Quality Composite Results Workflow
- OPM Quality Sample Group Disposition Workflow
- OPM Quality Spec Status Change Approval Workflow
- OPM Quality Spec Customer Validity Rule Status Change Approval Workflow
- OPM Quality Spec Inventory Validity Rule Status Change Approval Workflow
- OPM Quality Spec Supplier Validity Rule Status Change Approval Workflow
- OPM Quality Spec WIP Validity Rule Status Change Approval Workflow
- OPM Quality Spec Monitoring Validity Rule Status Change Approval Workflow
- OPM Quality Sample Group Rejection Workflow
- OPM Quality Stability Study Change Status Workflow

- OPM Quality Stability Study Lot Sample Workflow
- OPM Quality Stability Study Batch Creation Workflow
- OPM Quality Stability Study Testing Workflow
- OPM Quality Stability Study Time Point Test Workflow
- OPM Quality UOM Conversion Workflow
- Approval Management Engine (AME) Approval Matrix

## Basic Business Needs

The Quality Management application in Oracle Process Manufacturing (OPM) supports quality inspection on the raw materials, intermediates, or finished goods at any stage during inventory transaction, receiving, production, or sales cycle, from within the corresponding applications.

Using the Quality Management application, you can set up specifications, draw samples, enter test results, and perform stability studies. The following business events are supported:

- Oracle Inventory
  - Inventory Increase
  - Receiving into Inventory
  - Receiving into a Receiving Locator
  - Lot Expiration
- Process Execution
  - Batch Creation
  - Batch Step Creation
  - Batch Step Release
- Quality Management
  - Sample Creation
  - Sample Disposition and Sample Group Disposition
  - Testing Request
  - Compositing Results

- Specification Status Change Approval
- Specification Validity Rule Status Change Approval
- Customer, Inventory, Supplier, WIP, and Monitoring Validity Rule Status Change Approval
- Stability Study
- Status Change
- Lot Sampling
- Batch Creation
- Testing
- Time Point Testing
- Lot Retesting
- Item UOM Conversion

## Technical Overview

OPM Quality Management workflows use two major components:

- Oracle Workflow
- Oracle Workflow Business Event Systems

The design uses the Oracle Workflow Business Event System to define an event and associate it with a subscription to the business event. The subscription initiates a workflow to perform any needed database changes, notifications, or other requirements. Events and subscriptions can be enabled or disabled by the customer as needed using the business event system. A customer can add a new subscription to an event to perform customized functionality or features.

## Understanding Workflow Processes

Oracle Workflow lets you automate and continuously improve business processes by routing information according to a set of business rules. You can transmit this information to individuals both inside and outside your enterprise on an individual basis.

Refer to the *Oracle Workflow Guide* and the *Oracle E-Records Implementation Guide* for additional information on:

- Workflow Business Event System
- XML Gateway
- Oracle Approval Management Engine (AME)
- Workflow Notification Subsystem
- Workflow Automatic Notification Processing

## Understanding OPM Quality Management Workflows

### Sample Creation Notification

The Sample Creation Notification workflow sends a notification to draw a material sample as required by the associated sampling plan for the item specification and specification validity rule in effect. This workflow can be triggered by an inventory quantity increase, receiving transaction, batch step release, or lot expiration or retest. The notification lists the sampling plan information and includes a link to the Item Samples window, where information about the sampling event is populated.

### Testing Notification

The Testing Notification workflow sends a notification to prompt you to perform a test and enter its result against a particular sample. It is initiated by the creation of a sample that is already associated to a specification or selection of the result action for retesting a certain test. Each tester for a given sample in process receives a notification for the expected test result.

### Sample Disposition Notification

The Sample Disposition Notification workflow prompts for assignment of the final disposition for a sample once testing is complete. The sample disposition can be changed to accepted, accepted with variance, or rejected when all tests (if required by the associated specification) have recorded results that have been evaluated and finalized.

### Sample Group Disposition Notification

The Sample Group Disposition Notification workflow notifies you that the sampling event requires a final disposition, based on the number of samples required by the sampling plan. This workflow is launched when all the samples within a sampling event have a final disposition of accept, accept with variance, reject, or cancel.

### Composite Results Notification

The Composite Results Notification workflow asks you whether to composite the results across a set of samples within the same sampling event. This workflow is

initiated when testing of all the samples in a sampling event (based on the number of samples required by the sampling plan) is complete and each sample has a final sample disposition. The notification provides a link to the Composite Results window, where information about the sampling event is populated.

#### **Spec Status Change Approval Notification**

The Spec Status Change Approval Notification workflow notifies the contact person when the specification status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

#### **Spec Customer Validity Rule Status Change Approval Notification**

The Spec Customer Validity Rule Status Change Approval Notification workflow notifies the contact person when the customer specification validity rule status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

#### **Spec Inventory Validity Rule Status Change Approval Notification**

The Spec Inventory Validity Rule Status Change Approval Notification workflow notifies the contact person when the inventory specification validity rule status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

#### **Spec Supplier Validity Rule Status Change Approval Notification**

The Spec Supplier Validity Rule Status Change Approval Notification workflow notifies the contact person when the supplier specification validity rule status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

#### **Spec WIP Validity Rule Status Change Approval Notification**

The Spec WIP Validity Rule Status Change Approval Notification workflow notifies the contact person when the WIP specification validity rule status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

#### **Spec Monitoring Validity Rule Status Change Approval Workflow**

The Spec Monitoring Validity Rule Status Change Approval Notification workflow

notifies the contact person when the monitoring specification validity rule status has changed. The workflow is activated for processing the status change. Typically, workflow approval is activated for status changes to Approved for Lab Use and Approved for General Use. The other statuses can be processed without requiring workflow approval.

#### **Sample Group Rejection Notification**

The Sample Group Rejection Notification workflow notifies the contact person that either a monitoring sample group, or a stability study time point sample group is rejected.

#### **Stability Study Change Status Notification**

The Stability Study Change Status Notification workflow notifies the study owner of status changes in the stability study. The process of changing status from New to a status of Completed involves a series of workflow notifications. Oracle E-Records operates with this workflow to enforce the stability study status control business rules. The cancellation of a stability study is also controlled by the workflow.

#### **Stability Study Lot Sample Notification**

When the stability study is approved, and specific lots of the item to be tested exist, then the Stability Study Lot Sample Notification workflow notifies the stability study contact person to obtain samples for all required material sources. In the notification, the contact person is designated to draw and store the specified samples, and to update the sample records accordingly.

#### **Stability Study Batch Creation Notification**

When the stability study is approved, and specific lots of the item to be tested do not exist, then the Stability Study Batch Creation Notification workflow notifies the stability study contact person to request that a batch be created for the study. The notification is sent only if the batch is a material source.

#### **Stability Study Testing**

The Stability Study Testing workflow is a master workflow that governs the Stability Study Time Point Scheduling Notification workflow, and the Stability Study Late Time Point Scheduling Notification workflow. This workflow runs as a background process to monitor for any time point test that requires a workflow notification, or a late workflow notification. The workflow raises the appropriate event for either scheduled or late time point tests.

If the stability study is canceled or the scheduled time point testing date changes, then a workflow API manages the situation. The sample group disposition is changed from a status of retained to a status of pending, and the sample pull dates are updated.

#### **Stability Study Time Point Scheduling Notification**

The Stability Study Time Point Scheduling Notification workflow notifies you to pull

samples for time point testing. The notification considers the required lead time, and it requests you to change the disposition of a time point sample from Retained to Pending. When the sample disposition is changed to Pending, tests are scheduled. If the test is not performed within the grace period, then the OPM Quality Stability Study Testing master workflow raises a separate event that indicates the test is overdue.

#### **Stability Study Late Time Point Scheduling Notification**

The Stability Study Late Time Point Scheduling Notification workflow notifies you that a test is overdue. The notification considers the required grace period, and uses the OPM Quality Stability Study Testing master workflow to raise a separate event to indicate the test is late.

#### **Quality UOM Conversion Notification**

The Quality UOM Conversion Notification workflow notifies the contact person that a recommended UOM conversion exists. A link to the Item Lot Inter-class Unit of Measure Conversion window in the Oracle Inventory application is provided. This link does not operate unless a lot number is assigned.

## **Setting Up OPM Quality Management Workflows**

For the proper functioning of the workflows, a few administrative steps must be handled. These include setting up notification contacts for the workflow and starting the workflow engine.

In Oracle Applications, choose the Oracle Workflow responsibility and invoke the Workflow Process Activation. Enable the following workflow notifications:

- OPM Quality Sample Creation
- OPM Quality Test
- OPM Quality Sample Disposition
- OPM Quality Sample Group Disposition
- OPM Quality Composite Results
- OPM Quality Spec Status Change Approval
- OPM Quality Spec Customer Validity Rule Status Change Approval
- OPM Quality Spec Inventory Validity Rule Status Change Approval
- OPM Quality Spec Supplier Validity Rule Status Change Approval
- OPM Quality Spec WIP Validity Rule Status Change Approval

- OPM Quality Spec Monitoring Validity Rule Status Change Approval
- OPM Quality Sample Group Rejection
- OPM Quality Stability Study Change Status
- OPM Quality Stability Study Lot Sample
- OPM Quality Stability Study Batch Creation
- OPM Quality Stability Study Testing
- OPM Quality Stability Study Time Point Scheduling
- OPM Quality Stability Study Late Time Point Scheduling
- OPM Quality UOM Conversion

### Raising an Event from PL/SQL

Raising an event can be done from PL/SQL code or within a workflow. Raising events must be done before commit statements or when something has occurred. When raising an event, parameters can be sent to the event for use by the workflow. The parameters are defined as a set of name/value pairs. These name/values are used as the attribute name/values of the workflow associated with the subscription for the specific event being raised.

### Events

Use the Workflow Administrator to configure the seeded event subscription for the prebuilt inbound message if necessary.

Using the Workflow Administrator, add an event that can be raised from the PL/SQL code. This event can be due to an inventory transaction, item receiving or production, shipment picklot, etc.

Each business event is identified by a short name followed by a description. The event is referenced by the event short name across the framework and outside the framework. You need to know the event short name in order to call the API. The event is defined using the SSWA responsibility Workflow Administrator Web Applications. The owner tag of the business event is the application short name, such as GMD.

Refer to the *Oracle Workflow Guide* for details on configuring a workflow event.

### Subscriptions

Use the Workflow Administrator to add a subscription that subscribes to the event as defined earlier. This subscription is associated with a specific workflow. For example, an inventory transaction can raise an event where a subscriber to that event initiates the Sample Creation workflow.

A subscription can be added to a defined local business event. The phase of the subscription determines if the subscription is synchronous or not. Phase values less than 100 are synchronous; all others asynchronous. There can be multiple subscriptions to the same business event with different functionality. A workflow can be associated with a subscription.

The Workflow Quality Manager events should have the second subscriber disabled. This enables the Quality workflow notifications to function as expected with respect to samples and sample dispositions.

## Workflow

Workflows can be associated with a subscription. In the case of OPM Quality Management, a subscription for an event initiates a workflow execution.

Workflows control notifications for sample creation, sample disposition, and sample rejection. Workflows also control notifications for specification status and specification validity rule status. Workflows monitor and execute all aspects of the stability study including notifications for study status change, lot sampling, batch creation, time point testing. If time point testing is not performed within a scheduled grace period, then workflow issues a late time point test notification.

## Using OPM Quality Management Workflows

Following are the OPM Quality Management workflows:

- OPM Quality Sample Creation
- OPM Quality Test
- OPM Quality Sample Disposition
- OPM Quality Composite Results
- OPM Quality Sample Group Disposition
- OPM Quality Spec Status Change Approval
- OPM Quality Spec Customer Validity Rule Status Change Approval
- OPM Quality Spec Inventory Validity Rule Status Change Approval
- OPM Quality Spec Supplier Validity Rule Status Change Approval
- OPM Quality Spec WIP Validity Rule Status Change Approval
- OPM Quality Spec Monitoring Validity Rule Status Change Approval
- OPM Quality Sample Group Rejection

- OPM Quality Stability Study Change Status
- OPM Quality Stability Study Lot Sample
- OPM Quality Stability Study Batch Creation
- OPM Quality Stability Study Testing
- OPM Quality Stability Study Time Point Test
- OPM Quality UOM Conversion

## OPM Quality Sample Creation Workflow

The OPM Quality Sample Creation workflow notifies the workflow recipient that a sample or samples need to be taken for the item transaction.

The workflow that notifies a user about creating a sample can be instantiated by multiple applications, each with its own set of attributes and parameters. These applications include Receiving, Inventory, Production, and the resample quality action.

### Oracle Inventory Created Event

This business event is triggered when adjusting, updating, or creating items.

#### Event Name

oracle.apps.gmd.inventory.created

#### Event Key and Attribute

IC\_TRANS\_CMP.TRANS\_ID

#### Subscriber

Subscriber Workflow:

OPM Quality Sample Creation

Oracle Approval Management Transaction Name:

Process Quality Inventory Transaction Sample Creation

#### Recommended Attributes for Approval Configuration

Parameter	Description
ORG	Inventory Organization

Parameter	Description
ITEM_ID	Item ID
ITEM_NO	Item
TRANS_QTY1	Quantity1
TRANS_QTY2	Quantity2
TRANS_QTY_UOM1	UOM1
TRANS_QTY_UOM2	UOM2
LOT_ID2	Lot ID
LOT_NO	Lot Number
LPN	License Plate Number
SUBINVENTORY	Subinventory
LOCATOR	Locator
GRADE	Grade
TRANSACTION_TYPE	Trans Type

### Request Notification

The workflow sends a notification to the contact person, requesting that a sample be taken. The body of the notification for inventory transaction follows:

You have been designated to create a sample or samples based on the inventory transaction described below:

Transaction Details

Document Type: &DOC\_TYPE

Document Description: &DOC\_DESC

Document No: &DOCUMENT\_NO

Organization Code: &ORGN\_CODE

Item: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Parent Lot Number: &PARENT\_LOT\_NUMBER

Lot Number: &LOT\_NO

LPN: LPN\_No.

Quantity: &TRANS\_QTY

UOM: &TRANS\_UOM

Dual Quantity: &ITEM\_QTY2

Dual UOM: &ITEM\_UOM2

Sampling Plan: &SAMPLING\_PLAN

Click Forms to launch the Samples window. Enter the sample and save. The Notifications window is displayed again and you can click OK to respond to the notice.

#### **OPM Purchase Order Receipt Created Event**

This business event is triggered from the receipt transaction for an item that has the inspection required indicator enabled on the item master. The receiving transaction process flow is:

1. Receive against a purchase order line.
2. Receive material into a receiving locator.
3. Quality Receiving event is raised.
4. An applicable specification is retrieved.

5. Send a notification to create a sample.
6. Sample is created.
7. Send a notification to perform tests.
8. Testing is performed and completed.
9. Sample Disposition is assigned.
10. Sample Group Disposition is assigned.
11. Go to the Receiving Transaction window to record accepted or rejected quantities and deliver material to inventory.

**Event Name**

oracle.apps.gml.po.receipt.created

**Event Key and Attribute**

rcv\_transactions.transaction\_id

**Subscriber**

Subscriber Workflow:

OPM Quality Sample Creation

Oracle Approval Management Transaction Name:

Process Quality Receiving Transaction Sample Creation

**Recommended Attributes for Approval Configuration**

Parameter	Description
ORG	Inventory Organization
SUB_ORG	Sub inventory
ITEM_ID	Item ID
ITEM_NO	Item
TRANS_QTY1	Quantity1
TRANS_QTY_UOM1	UOM1

Parameter	Description
TRANS_QTY2	Quantity2
TRANS_QTY_UOM2	UOM2
LINE_TYPE	Only products and byproducts
RECEIPT_ID	Receipt ID
RECEIPT_LINE_ID	Receipt Line ID
PO_HEADER_ID	PO Header ID
PO_LINE_ID	PO Line ID
SUPPLIER_ID	Supplier ID

### Request Notification

The workflow sends a notification to the contact person, requesting that a sample be taken. The body of the notification for receiving transaction follows:

You are designated to create a sample or samples based on the receiving transaction described below:

Transaction Details

Organization Code: &ORGN\_CODE

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Receipt: &RECEIPT\_NO

Purchase Order No: &PURCHASE\_NO

Supplier Number: &SUPPLIER\_NO

Item Number: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC  
Parent Lot Number: &PARENT\_LOT\_NUMBER  
Lot Number: &LOT\_NO  
Qty: &TRANS\_QTY  
UOM: &TRANS\_UOM  
Sampling Plan: &SAMPLING\_PLAN

### **OPM Receiving into Inventory Event**

This business event is triggered from the receipt transaction into a specific lot for an item that has the inspection required indicator enabled on the item master. The receiving transaction process flow is:

1. Receive against a purchase order line.
2. Receive material into a lot inventory locator.
3. Quality Receiving event is raised.
4. An applicable specification is retrieved.
5. Send a notification to create a sample.
6. Sample is created.
7. Send a notification to perform tests.
8. Testing is performed and completed.
9. Sample Disposition is assigned.
10. Sample Group Disposition is assigned.
11. Go to the Receiving Transaction window to record accepted or rejected quantities and deliver material to inventory.

#### **Event Name**

oracle.apps.gmi.po.receipt

#### **Event Key and Attribute**

rcv\_transaction\_interface.transaction\_id

## Subscriber

Subscriber Workflow:

OPM Quality Sample Creation

Oracle Approval Management Transaction Name:

Process Quality Receiving into Inventory

## Recommended Attributes for Approval Configuration

Parameter	Description
ORG	Inventory Organization
SUB_ORG	Sub inventory
ITEM_ID	Item ID
ITEM_NO	Item
TRANS_QTY1	Quantity1
TRANS_QTY_UOM1	UOM1
TRANS_QTY2	Quantity2
TRANS_QTY_UOM2	UOM2
LINE_TYPE	Only products and byproducts
RECEIPT_ID	Receipt ID
RECEIPT_LINE_ID	Receipt Line ID
PO_HEADER_ID	PO Header ID
PO_LINE_ID	PO Line ID
SUPPLIER_ID	Supplier ID

## Request Notification

The workflow sends a notification to the contact person, requesting that a sample be taken. The body of the notification for receiving transaction follows:

You are designated to create a sample for the receiving transaction described below:

**Transaction Details**

Organization Code: &ORGN\_CODE - &ORGN\_NAME

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Receipt: &RECEIPT\_NO

Purchase Order No: &PO\_NUMBER

Supplier Number: &SUPPLIER

Item Number: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC1

Parent Lot Number: &PARENT\_LOT\_NUMBER

Lot Number: &LOT\_NO

Qty: &TRANS\_QTY

UOM: &TRANS\_UOM

Sampling Plan: &SAMPLING\_PLAN

Click Forms to launch the Samples window. Enter the sample and save. The Notifications window is displayed again and you can click OK to respond to the notice.

### **OPM Batch Created and OPM Batch Step Created Events**

When a batch or batch step is created, an event is raised to initiate the OPM Quality Sample Creation workflow. This workflow sends a notification to a contact person informing that a new batch or batch step is created and sampling is required. This includes the samples required for the batch or batch step.

At the release of each step (operation), when the batch step quality status is Sample Required, the OPM Quality Sample Creation workflow is initiated to inform the contact person to take a sample of the production item. This notification includes a link to the Samples window.

#### **Event Name**

- oracle.apps.gme.batch.created

- oracle.apps.gme.batchstep.created
- oracle.apps.gme.bstep.rel.wf

#### Event Key and Attribute

- GME\_BATCH\_HEADER.BATCH\_ID
- GME\_BATCH\_STEPS.BATCHSTEP\_ID

#### Subscriber

Type	Subscriber Workflow	Oracle Approval Management Transaction Name
Batch	OPM Quality Sample Creation	Process Quality Production Transaction Sample Creation
Batch Step	OPM Quality Sample Creation	Process Quality Production Transaction Sample Creation

#### Recommended Attributes for Approval Configuration

Parameter	Description
BATCH_ID	Batch ID
BATCH_STEP_ID	Batch Step ID

#### Request Notification

The workflow sends a notification to the contact person, requesting that a Sample be taken. The body of the notification for the production transaction follows:

You have been designated to create a sample or samples based on the production transaction described below:

Transaction Details

Organization Code: &ORGN\_CODE - &ORGN\_NAME

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Batch No: &BATCH\_NO  
 Batch Step: &BATCH\_STEP\_NO  
 Recipe: &RECIPE\_NO  
 Formula: &FORMULA\_NO  
 Item: &ITEM\_NO  
 Item Revision: &ITEM\_LOCATOR  
 Item Description: &ITEM\_DESC  
 Sampling Plan: &SAMPLING\_PLAN  
 Click Forms to launch the Samples window. Enter the sample and save. The Notifications window is displayed again and you can click OK to respond to the notice.

### Oracle Inventory Lot Expiry Date Changed Event

This business event is initiated by reaching the expiration date for an item lot.

#### Event Name

oracle.apps.gmd.lotexpiry

#### Event Key and Attribute

IC\_LOTS\_MST.ITEM\_ID || '-' || IC\_LOTS\_MST.LOT\_ID  
 ORGANIZATION\_ID - INVENTORY\_ITEM\_ID - LOT\_NUMBER

#### Subscriber

Subscriber Workflow:  
 OPM Quality Sample Creation  
 Oracle Approval Management Transaction Name:  
 Process Quality Lot Expiry Sample Creation

#### Recommended Attributes for Approval Configuration

Parameter	Description
ITEM_ID	Item ID
LOT_ID	Lot ID

Parameter	Description
LOT_NO	Lot Number
GRADE	Grade
EXPIRE_DATE	Expiration Date

### Request Notification

The workflow sends a notification to the contact person, requesting that a Sample be taken. The body of the notification for Lot expiration transaction follows:

You are designated to create a sample for the lot expiry transaction described below Transaction Details:

Transaction Details

Organization: &ORGN\_CODE - &ORGN\_NAME

Subinventory: &SUBINVENTORY

Item Number: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC1

Parent Lot Number: &PARENT\_LOT\_NUMBER

Lot Number: &LOT\_NO

UOM: &TRANS\_UOM

Dual UOM: &ITEM\_UOM2

Expiry Date: &EXPIRY\_DATE

Sampling Plan: &SAMPLING\_PLAN

Run the Inventory Date Notification concurrent program in Oracle Inventory to either send a notification to manually or automatically create samples based on lot retest or lot expiry. The concurrent request can launch the Lot and Serial Date Notification workflow, which raises the business events for reaching the lot retest or expiry date. The Inventory Date Notification concurrent request searches for item lots that are process quality-enabled in a process-enabled inventory organization. Refer to the *Oracle Inventory User's Guide* for detailed information on the concurrent request parameters.

## Oracle Inventory Lot Retest Date Change Event

This business event is initiated by reaching the retest date for an item lot.

### Event Name

oracle.apps.gmd.lotretest

### Event Key and Attribute

IC\_LOTS\_MST.ITEM\_ID || '-' || IC\_LOTS\_MST.LOT\_ID

### Subscriber

Subscriber Workflow:

OPM Quality Sample Creation

Oracle Approval Management Transaction Name:

Process Quality Lot Retest Sample Creation

### Recommended Attributes for Approval Configuration

Parameter	Description
ITEM_ID	Item ID
LOT_ID	Lot ID
LOT_NO	Lot Number
GRADE	Grade
RETEST_DATE	Retest Date

### Request Notification

The workflow sends a notification to the contact person, requesting that a Sample be taken. The body of the notification for lot retest transaction follows:

You are designated to create a sample for the lotretest transaction described below Transaction Details:

Transaction Details

Organization Code: &ORG

```

Item Number: &ITEM_NO

Item Revision: &ITEM_REVISION
Item Description: &ITEM_DESC1

Parent Lot Number: &PARENT_LOT_NUMBER

Lot Number: &LOT_NO

UOM: &TRANS_UOM

Dual UOM: &ITEM_UOM2

Retest Date: &RETEST_DATE

Sampling Plan: &SAMPLING_PLAN

Click Forms to launch the Samples window. Enter the sample and save. The Notifications window is displayed again and you can click OK to respond to the notice.

```

Run the Inventory Date Notification concurrent program in Oracle Inventory to either send a notification to manually or automatically create samples based on lot retest or lot expiry. The concurrent request can launch the Lot and Serial Date Notification workflow, which raises the business events for reaching the lot retest or expiry date. The Inventory Date Notification concurrent request searches for item lots that are process quality-enabled in a process-enabled inventory organization. Refer to the *Oracle Inventory User's Guide* for detailed information on the concurrent request parameters.

### Subscriber Workflow

There is a fork in the workflow. The notification is sent to the person defined in AME for the workflow's contact. The control parameter list is:

- Event Type
- Inventory Organization
- Inventory Item
- Subinventory
- Locator

A contact person can be defined using at least one of the control parameters. The workflow resolves the role to at least a single user.

## OPM Quality Test Workflow

This workflow is initiated by creating a sample or retesting. When a sample is created and associated to a specification, each workflow recipient receives a notification for the scheduled tests. The quality testing process is:

1. Sample is created.
2. The tester defined for each test is retrieved from AME.
3. The tests are grouped by the tester defined in AME.
4. Sends a notification to each tester with the list of the tests they need to conduct. The notification includes a link to the Forms window where the results can be entered.

The purpose of this workflow is to find the testers and send notification for testing a particular sample. In the case of a sample creation, the sample information is identified. In the retest or additional testing scenarios, the test is known.

### Event Name

oracle.apps.gmd.qm.performtest

### Event Key and Attribute

GMD\_SAMPLES.SAMPLE\_ID

### Subscriber

Subscriber Workflow:

OPM Perform Quality Test

Oracle Approval Management Transaction Name:

Process Quality Perform Test

### Recommended Attributes for Approval Configuration

Parameter	Description
SAMPLE_ID	Sample ID
SAMPLING_NO	Sample Number
TEST_ID	Test ID

## Subscriber Workflow

This workflow is spawned through the creation of sample and a specific specification for an item. This function finds the notifier associated with the test from AME. The control parameters are:

- Lab
- Item
- Test Class
- Test
- Test Method

A contact person can be defined using at least one of the control parameters. The role associated with this test is resolved to at least a single user.

## Test Request Notification

The workflow sends a notification soliciting a response about the result of the tests.

You have been designated to perform the following test on the sample.

Sample Details

Laboratory Organization: &QC\_LAB\_ORGN\_CODE

Sample Number: &SAMPLE\_NO

Sample Description: &SAMPLE\_DESC

Item Number: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC

Item UOM: &ITEM\_UOM

Parent Lot: &PARENT\_LOT\_NUMBER

Lot Number: &LOT\_NO

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Test Details

-----

Test Code: &TEST\_CODE

```

Test Description: &TEST_DESC
Test Class: &TEST_CLASS

Test Method: TEST_METHOD_CODE

Test Method Description: &TEST_METHOD_DESC

Test Replication: &TEST_REPLICATE
Test Equipment: &RESOURCES
Planned Resource: &PLANNED_RESOURCE

Planned Result Date: &PLANNED_RESULT_DATE
Test By Date: &TEST_BY_DATE
Click on the form to launch the Results window and enter the results.
After saving the result, in the Notification screen, click OK to respond
to the notice.

```

## OPM Quality Sample Disposition Workflow

When sample testing is complete, the OPM Quality Sample Disposition workflow is initiated to prompt for a sample disposition as Accept, Accept with Variance, or Reject.

The basic process for initiating the OPM Quality Sample Disposition workflow is:

1. All required tests have results.
2. An event for the sample disposition is raised.
3. Subscriber for the event initiates the workflow.
4. Workflow sends notification to the contact person as defined in AME, along with the sample information.

### Event Name

oracle.apps.gmd.qm.sample.disposition

### Event Key and Attribute

GMD\_SAMPLES.SAMPLE\_ID

### Subscriber

Subscriber Workflow:

OPM Sample, Sample Group Disposition, and Composite Results Creation

Oracle Approval Management Transaction Name:

Process Quality Sample Disposition

## Recommended Attributes for Approval Configuration

Parameter	Description
SAMPLE_ID	Sample ID
SAMPLING_EVENT_ID	Sampling Event ID
RECOMMENDED_DISP	Recommended Target Disposition

## Subscriber Workflow

This function finds the approver associated with the sample from AME. The control parameters are:

- QC Lab Org
- Item

A contact person can be defined using at least one of the control parameters. The role associated with this test is resolved to at least a single user.

## Sample Approval Notifications

You receive a notification soliciting a response about sample approval.

You have been designated to assign a disposition to the sample as described below.

Item Details

Item Number: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC

Parent Lot Number: &PARENT\_LOT\_NUMBER

Lot Number: &LOT\_NO

LPN: LPN\_No

Sample Details

---

-----  
Sample Number: &SAMPLE\_NO

```
Sample Source: &SAMPLE_SOURCE  
Sample Description: &SAMPLE_DESC  
Specification: &SPECIFICATION  
Sample Plan: &SAMPLE_PLAN  
  
Sample Disposition: &SAMPLE_DISPOSITION
```

Click Forms to launch the Samples window. After saving the result you will come back to the Notification screen where you may Click the OK button to respond to the notice.

## OPM Quality Composite Results Workflow

When testing is complete for a sampling event, the OPM Quality Composite Results workflow lets you composite the results across the samples.

The process for initiating the OPM Quality Composite Results workflow is:

1. All samples of a sampling event have a final sample disposition.
2. An event for the composite results is raised.
3. Subscriber for the event initiates the workflow.
4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

### Event Name

oracle.apps.gmd.qm.compositeresults

### Event Key and Attribute

GMD\_SAMPLES.SAMPLE\_EVENT\_ID

### Subscriber

Subscriber Workflow:

OPM Sample, Sample Group Disposition, and Composite Results Creation

Oracle Approval Management Transaction Name:

Process Quality Sample Composite Results

### Recommended Attributes for Approval Configuration

Parameter	Description
SAMPLING_EVENT_ID	Sampling Event ID

### Subscriber Workflow

This function finds the notifier associated with the composite result from AME. The control parameters list is:

- Org
- Item

A contact person can be defined using at least one of the control parameters. The role associated with this test is resolved to at least a single user.

### Composite Results Notifications

You receive a notification soliciting a response about sample composite.

You have been designated to composite results for the sample described below.

Organization: &ORG

Item: &ITEM\_NO

Description: &ITEM\_DESC1

Parent Lot: &PARENT\_LOT\_NUMBER

Lot: &LOT\_NO

LPN: LPN\_No

Sample Plan Name: &SAMPLE\_PLAN

Samples Taken: &SAMPLES\_TAKEN

Spec Name: &SPEC\_NAME

Click Forms to launch the Composite Results window. After saving the result you will come back to the Notification screen where you may Click the OK button to respond to the notice.

## OPM Quality Sample Group Disposition Workflow

When all the samples in the sampling event have dispositions of accept, reject, accept with variance, or cancel, the OPM Quality Sample Group Disposition workflow is initiated to prompt for a sampling event disposition.

The basic process for initiating the OPM Quality Sample Group Disposition workflow is:

1. All sample dispositions have been changed from testing to accept, accept with variance, reject, or cancel.
2. An event for the sampling disposition is raised.
3. Subscriber for the event initiates the workflow.
4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

### Event Name

oracle.apps.gmd.qm.samplingevent.disposition

### Event Key and Attribute

GMD\_SAMPLES.SAMPLE\_EVENT\_ID

### Subscriber

Subscriber Workflow:

OPM Sample, Sample Group Disposition, and Composite Results Creation

Oracle Approval Management Transaction Name:

Process Quality Sample Group Disposition

### Recommended Attributes for Approval Configuration

Parameter	Description
SAMPLING_EVENT_ID	Sampling Event ID
RECOMMENDED_DISP	Recommended Target Disposition
CURRENT_DISP	Current Target Disposition

## Subscriber Workflow

This function finds the notifier associated with the sampling event approval from AME. The control parameters list is:

- Org
- Item

A contact person can be defined using at least one of the control parameters. The role associated with this test is resolved to at least a single user.

## Sample Group Disposition Notification

You receive a notification soliciting a response about sample event disposition.

You have been designated to assign a disposition to the sampling event as described below.

Recommended Disposition:

Item: &ITEM\_NO

Description: &ITEM\_DESC1

Parent Lot: &PARENT\_LOT\_NUMBER

Lot: &LOT\_NO

LPN: LPN\_No

Sample Plan: &SAMPLE\_PLAN

Spec Name: &SPEC\_NAME

Click Forms to launch the Sample Groups window. After saving the result you will come back to the Notification screen where you may Click the OK button to respond to the notice.

## OPM Quality Spec Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specifications. The basic process for initiating the OPM Quality Spec Status Change Approval workflow is:

1. A specification status is changed.
2. An event for the specification status change is raised.
3. Subscriber for the event initiates the workflow.

- Workflow sends notification to contact person as defined in AME, along with the sampling event information.

**Event Name**

oracle.apps.gmd.qm.spec.sts

**Event Key and Attribute**

GMD\_SPECIFICATIONS.SPEC\_ID

**Subscriber**

Subscriber Workflow:

OPM Quality Spec Status Change Approval

Oracle Approval Management Transaction Name:

Process Quality Spec Status Change Approval

**Recommended Attributes for Approval Configuration**

Parameter	Description
ITEM_NO	Item Name
ORGN_CODE	Organization Code

**Request Notification**

The workflow sends a notification to the contact person indicating that a specification needs approval.

&REQUESTER has requested a spec status change

Spec Name: &SPEC\_NAME

Spec Version: &SPEC\_VRS

Spec Description: &DESCRIPTION

Spec Status: &SPEC\_STATUS

Spec Type: &SPEC\_TYPE

Overlay: &OVERLAY

Base Spec: &BASE\_SPEC

Item: &ITEM\_NO  
Item Revision: &ITEM\_REVISION  
Item Description: &DESCRIPTION  
Grade: &GRADE  
Owner Organization: &OWNER\_ORGN\_CODE  
Owner Organization Name: &OWNER\_NAME  
Current Status: &SPEC\_STATUS  
Change Status To: &TARGET\_STATUS\_DESC  
Please click Approve to approve or Reject to reject.

## OPM Quality Spec Customer Validity Rule Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specification validity rules. The basic process for initiating the OPM Quality Spec Validity Rule Status Change Approval workflow is:

1. A specification validity rule status is changed.
2. An event for the specification validity rule status change is raised.
3. Subscriber for the event initiates the workflow.
4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

### Event Name

oracle.apps.gmd.qm.svr.cus.sts

### Event Key and Attribute

GMD\_CUSTOMER\_SPEC\_VRS. SPEC\_VR\_ID

### Subscriber

Subscriber Workflow:

OPM Quality Customer Spec Validity Rule Status Change

Oracle Approval Management Transaction Name:

## Process Quality Customer Validity Rule Status Change Approval

### Recommended Attributes for Approval Configuration

Parameter	Description
CUST_NAME	Customer Name
ITEM_NO	Item

### Request Notification

The workflow sends a notification to the contact person indicating a request to approve a customer validity rule.

&REQUESTER has requested a spec validity rule status change

Spec Name: &SPEC\_NAME

Spec Version: &SPEC\_VRS

Spec Description: &DESCRIPTION

Spec Status: &SPEC\_STATUS

Spec Type: &SPEC\_TYPE

Overlay: &OVERLAY

Item No: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC

Grade: &GRADE

Owner Organization: &OWNER\_ORGN\_CODE

Owner Organization Name: &OWNER\_ORGN\_NAME

Spec Validity Rule Status: &SPEC\_VR\_STATUS

Parent Lot: &PARENT\_LOT\_NUMBER

Lot: &LOT\_NUMBER

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Resource: &RESOURCE

Requestor: &REQUESTOR  
 Current Status: &START\_STATUS\_DESC  
 Change Status To: &TARGET\_STATUS\_DESC  
 Please click Approve to approve or click Reject to reject.

## OPM Quality Spec Inventory Validity Rule Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specification validity rules. The basic process for initiating the OPM Quality Spec Validity Rule Status Change Approval workflow is:

1. A specification validity rule status is changed.
2. An event for the specification validity rule status change is raised.
3. Subscriber for the event initiates the workflow.
4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

### Event Name

oracle.apps.gmd.qm.svr.inv.sts

### Event Key and Attribute

GMD\_INVENTORY\_SPEC\_VRS.SPEC\_VR\_ID

### Subscriber

Subscriber Workflow:

OPM Quality Inventory Spec Validity Rule Status Change

Oracle Approval Management Transaction Name:

Process Quality Inventory Validity Rule Status Change Approval

### Recommended Attributes for Approval Configuration

Parameter	Description
ITEM_NO	Item

### Request Notification

The workflow sends a notification to the contact person indicating a request to approve an inventory validity rule.

&REQUESTER has requested a spec validity rule status change

Spec Name: &SPEC\_NAME

Spec Version: &SPEC\_VRS

Spec Status: &SPEC\_STATUS

Source Type: &SOURCE\_TYPE

Item No: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC

Grade: &GRADE

Owner Organization: &OWNER\_ORGN\_CODE

Owner Organization Name: &OWNER\_ORGN\_NAME

Spec Validity Rule Status: &SPEC\_VR\_STATUS

Parent Lot: &PARENT\_LOT\_NUMBER

Lot: &LOT\_NUMBER

Delayed LPN Entry: delayed\_lpn\_entry (Yes/No).

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Resource: &RESOURCE

Requester: &REQUESTER

Current Status: &START\_STATUS\_DESC

Change Status To: &TARGET\_STATUS\_DESC

Please click Approve to approve or click Reject to reject.

## OPM Quality Spec Supplier Validity Rule Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specification validity rules. The basic process for initiating the OPM Quality Spec Validity Rule Status Change Approval workflow is:

1. A specification validity rule status is changed.

2. An event for the specification validity rule status change is raised.
3. Subscriber for the event initiates the workflow.
4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

**Event Name**

oracle.apps.gmd.qm.svr.sup.sts

**Event Key and Attribute**

GMD\_SUPPLIER\_SPEC\_VRS.SPEC\_VR\_ID

**Subscriber**

Subscriber Workflow:

OPM Quality Supplier Spec Validity Rule Status Change

Oracle Approval Management Transaction Name:

Process Quality Supplier Validity Rule Status Change Approval

**Recommended Attributes for Approval Configuration**

Parameter	Description
SUPP_NAME	Supplier Name
ITEM_NO	Item

**Request Notification**

The workflow sends a notification to the contact person indicating a request to approve a supplier validity rule.

&REQUESTER has requested a spec validity rule status change

Spec Name: &SPEC\_NAME

Spec Version: &SPEC\_VRS

Spec Status: &SPEC\_STATUS

Source Type: &SOURCE\_TYPE

Item No: &ITEM\_NO

```

Item Revision: &ITEM_REVISION

Item Description: &ITEM_DESC

Grade: &GRADE

Owner Organization: &OWNER_ORGN_CODE

Owner Organization Name: &OWNER_ORGN_NAME
Spec Validity Rule Status: &SPEC_VR_STATUS

Parent Lot: &PARENT_LOT_NUMBER
Lot: &LOT_NUMBER
Delayed LPN Entry: delayed_lpn_entry (Yes/No).
Subinventory: &SUBINVENTORY
Locator: &LOCATOR
Resource: &RESOURCE
Requester: &REQUESTER
Current Status: &START_STATUS_DESC
Change Status To: &TARGET_STATUS_DESC
Please click Approve to approve or click Reject to reject.

```

## OPM Quality Spec WIP Validity Rule Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specification validity rules. The basic process for initiating the OPM Quality Spec Validity Rule Status Change Approval workflow is:

1. A specification validity rule status is changed.
2. An event for the specification validity rule status change is raised.
3. Subscriber for the event initiates the workflow.
4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

### Event Name

oracle.apps.gmd.qm.svr.wip.sts

### Event Key and Attribute

GMD\_WIP\_SPEC\_VRS. SPEC\_VR\_ID

## Subscriber

Subscriber Workflow:

OPM Quality WIP Spec Validity Rule Status Change

Oracle Approval Management Transaction Name:

Process Quality WIP Validity Rule Status Change Approval

## Recommended Attributes for Approval Configuration

Parameter	Description
RECIPE	Recipe
ITEM_NO	Item

## Request Notification

The workflow sends a notification to the contact person indicating a request to approve a WIP validity rule.

&REQUESTER has requested a spec validity rule status change

Spec Name: &SPEC\_NAME

Spec Version: &SPEC\_VRS

Spec Status: &SPEC\_STATUS

Source Type: &SOURCE\_TYPE

Item No: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC

Grade: &GRADE

Owner Organization: &OWNER\_ORGN\_CODE

Owner Organization Name: &OWNER\_ORGN\_NAME

Spec Validity Rule Status: &SPEC\_VR\_STATUS

Parent Lot: &PARENT\_LOT\_NUMBER

Lot: &LOT\_NUMBER

Delayed LPN Entry: delayed\_lpn\_entry (Yes/No).

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Resource: &RESOURCE

```

Requester: &REQUESTER
Current Status: &START_STATUS_DESC
Change Status To: &TARGET_STATUS_DESC
Please click Approve to approve or click Reject to reject.

```

## OPM Quality Spec Monitoring Validity Rule Status Change Approval Workflow

Refer to the "Understanding the Status Approval Workflow" topic for a complete discussion of changing status of specification validity rules. The basic process for initiating the OPM Quality Spec Validity Rule Status Change Approval workflow is:

1. A specification validity rule status is changed.
2. An event for the specification validity rule status change is raised.
3. Subscriber for the event initiates the workflow.
4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

### Event Name

oracle.apps.gmd.qm.svr.mon.sts

### Event Key and Attribute

GMD\_MONITORING\_SPEC\_VRS. SPEC\_VR\_ID

### Subscriber

Subscriber Workflow:

OPM Quality Monitoring Spec Validity Rule Status Change

Oracle Approval Management Transaction Name:

Process Quality Monitoring Validity Rule Status Change Approval

### Recommended Attributes for Approval Configuration

Parameter	Description
ORG	Organization

### Request Notification

The workflow sends a notification to the contact person indicating a request to approve a WIP validity rule.

```
&REQUESTER has requested a spec validity rule status change

Spec Name: &SPEC_NAME

Spec Version: &SPEC_VRS

Spec Status: &SPEC_STATUS

Source Type: &SOURCE_TYPE

Item Number: &ITEM_NO

Item Revision: &ITEM_REVISION

Item Description: &ITEM_DESC

Grade: &GRADE

Owner Organization: &OWNER_ORGN_CODE

Owner Organization Name: &OWNER_ORGN_NAME

Spec Validity Rule Status: &SPEC_VR_STATUS

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Resource: &RESOURCE

Requestor: &REQUESTOR

Current Status: &START_STATUS_DESC

Change Status To: &TARGET_STATUS_DESC

Please click Approve to approve or click Reject to reject.
```

## OPM Quality Sample Group Rejection Workflow

The Sample Group Rejection Notification notifies you that either a monitoring sample group, or a stability study time point sample group is rejected.

The basic process for initiating the OPM Quality Sample Group Rejection workflow is:

1. Sample group dispositions are changed from complete to reject.
2. An event for the sampling disposition is raised.
3. Subscriber for the event initiates the workflow.
4. Workflow sends notification to contact person as defined in AME, along with the sampling event information.

### **OPM Quality Sample Group Rejection**

The Sample Group Rejection Notification notifies the contact person that either a monitoring sample group, or a stability study time point sample group is rejected.

#### **Event Name**

oracle.apps.gmd.qm.smpl.rej

#### **Event Key and Attribute**

SAMPLING\_EVENT\_ID

#### **Subscriber**

Subscriber Workflow:

OPM Quality Sample Group Rejection Workflow

Oracle Approval Management Transaction Name:

Process Quality Sample Rejection

#### **Recommended Attributes for Approval Configuration**

<b>Parameter</b>	<b>Description</b>
SUBINVENTORY	Subinventory
RESOURCE	Resource

#### **Request Notification**

The workflow sends a notification to the contact person indicating that a sample group is rejected.

In the case of Resource/Locator:

The following sample disposition has been rejected

Resource Details

Resource: &RESOURCE  
Resource Instance: &RESOURCE\_INST  
Description: &RESOURCE\_DESC  
Subinventory: &SUBINVENTORY  
Locator: &LOCATOR

Click on the form to open the Sample Groups window.

In the case of Stability Studies:

The following sample disposition has been rejected

Study: &STUDY\_NAME  
Study Description: &STUDY\_DESC  
Item: &ITEM\_NO  
Item Description: &ITEM\_DESC

Click on the form to open the Sample Groups window.

## OPM Quality Stability Study Change Status Workflow

The Stability Study Change Status Notification notifies the study owner of status changes in the stability study. The process of changing the stability study status from New to a status of Complete involves a series of workflow notifications. This workflow can work in conjunction with Oracle E-Records if it is enabled.

The basic process for initiating the OPM Quality Stability Study Change Status workflow is:

1. A stability study is created with an initial status of New, depending on the default value assigned to GMA: New for the STBL document type.
2. An event for change status is raised.
3. Subscriber for the event initiates the workflow.
4. Workflow sends notification to contact person as defined in AME, along with the change status event information.

## OPM Quality Stability Study Change Status Event

This business event is triggered from the Change Status dialog box accessed from the Actions menu on the Stability Study window.

### Event Name

oracle.apps.gmd.qm.ss.csts

### Event Key and Attribute

SS\_ID

### Subscriber

Subscriber Workflow:

Quality Stability Study Change Status

Oracle Approval Management Transaction Name:

GMDQM\_STABILITY\_CSTS

Process Quality Stability Study Status Change

### Recommended Attributes for Approval Configuration

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

### Request Notification

You receive a notification about the requested change of status for the stability study.

The body of that request is:

&REQUESTER has requested a change status for the following Stability Study

Owner Organization: &ORG

Stability Study Name: &SS\_NAME

Stability Study Description: &SS\_DESC

Start Status Description: &START\_STATUS\_DESC

Target Status Description: &TARGET\_STATUS\_DESC

Storage Plan: &STORAGE\_PLAN  
 Item No: &ITEM\_NO  
 Item Description: &ITEM\_DESC  
 Item Revision: &ITEM\_REVISION  
 Base Spec: &BASE\_SPEC  
 Lab Org: &LAB\_ORGN  
 Notification Time: &NOTIFY\_TIME  
 Grace Time: &GRACE\_TIME  
 Sched Start Date: &SCHED\_START\_DATE  
 Sched End Date: &SCHED\_END\_DATE  
 Revised Start Date: &REVISED\_START\_DATE  
 Revised End Date: &REVISED\_END\_DATE  
 Actual Start Date: &ACTUAL\_START\_DATE  
 Actual End Date: &ACTUAL\_END\_DATE  
 Owner: &OWNER

### Preseeded Stability Study Statuses

The following table lists each of the preseeded stability study statuses, a description of the status as it appears in the workflow notification process, whether status can be updated, and the listed status type:

Status	Description	Updateable?	Status Type
100	New	Yes	100
200	Request Approval of Stability Study Plan	No	200
300	Revise Stability Study Plan	Yes	300

Status	Description	Updateable?	Status Type
400	Stability Study Plan Approved	Yes	400
500	Request Approval to Launch	No	500
600	Revise Launch Request	Yes	600
700	Launch Approved	Yes	700
800	In Progress	No	800
900	Request Approval to Cancel	No	900
940	Request Approval to Cancel From Approved Plan	Yes	940
970	Request Approval to Cancel From Approved Launch	No	970
980	Request Approval to Cancel from In Progress	No	980
1000	Canceled	No	1000
1100	Completed	No	1100

## OPM Quality Stability Study Lot Sample Workflow

The Stability Study Lot Sample Notification notifies a workflow recipient to take samples from the specified lot material source when a stability study is approved.

### OPM Quality Stability Study Sample Creation

This business event is triggered by a stability study status change to Stability Study Plan Approved.

**Event Name**

oracle.apps.gmd.qm.ss.lot

**Event Key and Attribute**

SOURCE\_ID

**Subscriber**

Subscriber Workflow:

OPM Quality Stability Study Sample Creation

Oracle Approval Management Transaction Name:

GMD\_STABILITY\_LOT

Process Quality Stability Study Lot Sample

**Recommended Attributes for Approval Configuration**

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

**Request Notification**

The workflow sends a notification to the contact person designating them to draw and store the listed samples, and to update the sample records accordingly. The body of the notification follows:

The following sample records have been created after the approval of the Sample Source Stability Study. You are designated to take an initial sample to qualify as a material source from this Stability Study:

Study: &STUDY

Study Description: &STUDY\_DESC

Status: &STATUS

Organization: &ORG

Item Number: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC

Parent Lot: &PARENT\_LOT\_NUMBER  
Lot Number: &LOT\_NO  
Variant Material Source  
Batch: &BATCH\_NO  
Recipe: &RECIPE\_NO  
Recipe Version: &RECIPE\_VERSION  
Variant Storage condition  
Storage Spec: &STORAGE\_SPEC  
Storage Spec Version: &STGE\_SPEC\_VER  
Resource: &RESOURCE  
Storage Subinventory: &STORAGE\_SUBINVENTORY  
Storage Locator: &STORAGE\_LOCATOR  
Variant Package  
Package: &PACKAGE  
Formula: &FORMULA\_NO  
Formula Version: &FORMULA\_VERSION  
Sample Quantity/UOM: &SAMPLE\_QTY/&SAMPLE\_UOM  
Click Forms to open the Source Variants window. The notification window is displayed again and you can click OK to respond to the notice.

## OPM Quality Stability Study Batch Creation Workflow

The Stability Study Batch Creation Notification notifies a workflow recipient to create a batch as a material source when no specific lots are entered as material sources for the stability study. The workflow is triggered when a stability study is approved.

### OPM Quality Stability Study Sample Creation

This business event is triggered by a stability study status change to Stability Study Plan Approved.

**Event Name**

oracle.apps.gmd.qm.ss.batch.cr

**Event Key and Attribute**

SOURCE\_ID

**Subscriber**

Subscriber Workflow:

OPM Quality Stability Study Sample Creation

Oracle Approval Management Transaction Name:

GMDQM\_STABILITY\_BATCH

Process Quality Stability Study Batch

**Recommended Attributes for Approval Configuration**

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

**Request Notification**

The workflow sends a notification to the contact person designating them to create a batch. The body of the notification follows:

You are designated for creation of a batch as material source of a stability study. The details are as follows:

Organization: &ORG

Study: &STUDY

Study Description: &STUDY\_DESC

Status: &STATUS

Study Date: &STUDY\_DATE

Item Number: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC

```
Plant: &PLANT
Recipe: &RECIPE
Recipe Version: &RECIPE VERSION
Sample Qty: &SAMPLE_QTY
Sample UOM: &SAMPLE_UOM
Please enter the Batch Number in the Material Sources Screen
```

## OPM Quality Stability Study Testing Workflow

The OPM Quality Stability Study Testing workflow is the master workflow for two related workflows:

- OPM Quality Stability Study Time Point Scheduling Workflow
- OPM Quality Stability Study Late Time Point Scheduling Workflow

The workflow is the background process for the stability study, and it checks continuously for any time point test requiring a workflow notification (oracle.apps.gmd.qm.ss.tp) or a late workflow notification (oracle.apps.gmd.qm.ss.tplt). In each instance, it raises an appropriate event.

### Scheduling the Workflow Background Process

Schedule the Workflow Background Process concurrent program to run hourly, or at an interval that is compatible with your stability study time point testing design.

1. Navigate to the **Submit Request** window.
2. Enter **Name as Workflow Background Process**. The Parameters dialog box displays.
3. Select **Item Type** as **OPM Quality Stability Study Testing**.
4. Select **Process Deferred** as **Yes**.
5. Select **Process Timeout** as **Yes**.
6. Click **OK**.
7. Click **Schedule...** in the **At these Times...** region. The Schedule dialog box displays.
8. Select **Periodically** in the **Run the Job...** region.
9. Enter **Start At** as the date and time to begin the stability study testing. This field defaults to the system date and time.
10. Leave **End At** blank to run the process indefinitely, or enter an appropriate time

and date to end the workflow background process.

11. Enter **1** and select **Hour(s)** to check for time point testing hourly.
12. Click **OK**.
13. Click **Submit** on the **Submit Request** window to submit the request.

The time point testing workflow is triggered so that a notification is sent to a user at a time set by the stability study lead time. If the test is not performed within the grace period, then a late notification is raised as a separate event.

If the stability study is canceled or a date changes, then the `wf_engine.abort` workflow API is called using the combination of `item_type`, the eight character name of the workflow, and `item_key` the key used for identifying the workflow.

Sample group disposition is changed from a status of Retained to a status of Pending. Sample pull dates on the are updated.

**Event Name**

`oracle.apps.gmd.qm.ss.test`

**Event Key and Attribute**

`SS_ID`

**Subscriber**

Subscriber Workflow:

OPM Quality Stability Study Testing

Oracle Approval Management Transaction Name:

`GMDQM_STABILITY_PARENTTEST`

**Recommended Attributes for Approval Configuration**

Parameter	Description
<code>OWNER_ORGN_CODE</code>	Lab Organization Code
<code>ITEM_NO</code>	Item

## OPM Quality Stability Study Time Point Test Workflow

The Stability Study Time Point Test notification manages notifications for future testing and for late time point testing.

The Stability Study Time Point Test Notification notifies you that a future test is required. The notification considers the required lead time. If the test is not performed within the grace period, then the OPM Quality Stability Study Testing master workflow raises a separate event that indicates the test is overdue.

**Event Name**

oracle.apps.gmd.qm.ss.tp

**Event Key and Attribute**

TIMEPOINT\_ID

**Subscriber**

Subscriber Workflow:

OPM Quality Stability Study Time Point Test

Oracle Approval Management Transaction Name:

GMDQM\_STABILITY\_TEST

Process Quality Stability Study Testing Timepoint

**Recommended Attributes for Approval Configuration**

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

**Request Notification**

You are designated to draw and store these samples and update the sample records accordingly:

Organization: &ORG

Study: &STUDY

Study Description: &STUDY\_DESC

Status: &STATUS

Study Date: &STUDY\_DATE

Time Name: &TIME\_NAME

Item Number: &ITEM\_NO

Item Revision: &ITEM\_REVISION  
Item Description: &ITEM\_DESC  
Variant No: &VARIANT\_NO  
Storage Spec: &STORAGE\_SPEC  
Storage Spec Version: &STGE\_SPEC\_VER  
Sample Qty: &SAMPLE\_QTY  
Resource: &RESOURCE  
Subinventory: &SUBINVENTORY  
Locator: &LOCATOR  
Sample Number: &SAMPLE\_NO  
Sample Qty: &SAMPLE\_QTY  
Click Forms to launch the MultiRow Samples window. After saving the result you will come back to the Notification screen where you may Click the OK button to respond to the notice.

The Stability Study Late Time Point Test Notification notifies you that a test is overdue. The notification considers the required grace period, and uses the OPM Quality Stability Study Testing master workflow to raise a separate event to indicate the test is late.

**Event Name**

oracle.apps.gmd.qm.ss.tplt

**Event Key and Attribute**

TIMEPOINT\_ID

**Subscriber**

Subscriber Workflow:  
OPM Quality Stability Study Late Time Point Test  
Oracle Approval Management Transaction Name:  
GMDQM\_STABILITY\_LATETEST  
Process Quality Stability Study Testing Timepoint Late

**Recommended Attributes for Approval Configuration**

Parameter	Description
OWNER_ORGN_CODE	Lab Organization Code
ITEM_NO	Item

### Request Notification

Late Time Point Testing of a Stability Study

You have been designated to pull the stability study variant time point testing as described below.

Organization: &ORG

Study: &STUDY

Study Description: &STUDY\_DESC

Status: &STATUS

Study Date: &STUDY\_DATE

Time Name: &TIME\_NAME

Item Number: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Item Description: &ITEM\_DESC

Variant No: &VARIANT\_NO

Storage Spec: &STORAGE\_SPEC

Storage Spec Version: &STGE\_SPEC\_VER

Sample Qty: &SAMPLE\_QTY

Resource: &RESOURCE

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Sample Number: &SAMPLE\_NO

Sample Qty: &SAMPLE\_QTY

Click Forms to launch the MultiRow Samples window. After saving the result you will come back to the Notification screen where you may click the OK button to respond to the notice.

## OPM Quality UOM Conversion Workflow

The Quality UOM Conversion Notification notifies the workflow recipient of a recommended UOM conversion. One workflow notification is issued for each recommended UOM conversion listed on the Change Disposition window UOM Conversions tab. Click the link to the Oracle Inventory Lot Inter-class Unit of Measure Conversion window. The item, lot, and conversion information displays on that window. The window fields are all protected from update. A lot number must be entered if it is not available for the sample group.

You can keep the workflow notification open, reenter the item lot conversion link, and enter another lot number for the same conversion. When the conversions are established for all the desired item lots, then you can close out the notification.

The basic process for initiating the OPM Quality UOM Conversion workflow is:

1. Record samples and results for all tests saved on the specification created in setting up for the unit of measure conversion process. Refer to the "Using Lot UOM Conversions Based on Quality Results" topic for a complete discussion of this process.
2. Change the sample group disposition to Accept, Accept with Variance, or Reject.
3. An event for change status is raised.
4. Workflow sends notification to contact person as defined in AME, along with the UOM conversion event information.
5. Select the UOM Conversion tab on the Change Disposition window. The application enters all data displayed on this tab:
  - If at least one test on the specification has the Calculate UOM indicator selected
  - If the Change Disposition To field displays Accept, Accept with Variance, or Reject
  - If the sample group source is Inventory or SupplierData appears on this tab even when test results are out-of-specification.  
If a lot UOM conversion already exists for the lot, then the current conversion between the UOM class of the base UOM and the UOM class of the To UOM is displayed below the new proposed conversion.
6. Select the **Recommend** indicator next to the desired UOM conversions. If this indicator is not selected, then the proposed conversion is not used in inventory.

7. Click **OK** to change the disposition of the sample group.
8. Subscriber for the event initiates the workflow.
9. Provide an eSignature for the disposition change if one is required.
10. Receive the OPM Quality UOM Conversion workflow notification.
11. Click the UOM Conversion link to the Oracle Inventory **Lot Inter-class Unit of Measure Conversion** window, and save to create the conversions.
12. Close the workflow notification.

### **OPM Quality UOM Conversion**

This business event is triggered from the Change Disposition window.

#### **Event Name**

oracle.apps.gmd.qm.uomconv.csts

#### **Event Key and Attribute**

EVENT\_SPEC\_DISP\_ID

#### **Subscriber**

Subscriber Workflow:

Quality UOM Conversion

Oracle Approval Management Transaction Name:

Process Quality UOM Conversion

#### **Recommended Attributes for Approval Configuration**

<b>Parameter</b>	<b>Description</b>
ORGN_CODE	Organization

#### **Request Notification**

You receive a notification about the UOM conversion. The body of that request is:

There has been a recommendation for Item Lot UOM Conversion.

Source: &SOURCE

Samples Taken: &SAMPLES\_TAKEN

Samples Group Disposition: &SAMPLE\_GRP\_DISP

Item Number: &ITEM\_NO

Item Revision: &ITEM\_REVISION

Parent Lot: &PARENT\_LOT\_NUMBER

Lot Number: &LOT\_NO

Organization: &ORG

Subinventory: &SUBINVENTORY

Locator: &LOCATOR

Supplier: &SUPPLIER

Supplier Lot: &SUPPLIER\_LOT

PO Number: &PO\_NUMBER

PO Line Num: &PO\_LINE\_NO

Receipt Num: &RECEIPT\_NO

Receipt Line No: &RECEIPT\_LINE\_NO

Spec: &SPEC

Spec Version: &SPEC\_VERSION

Test Name: &TEST\_NAME

Conversion: &CONVERSION

Please open the Lot Inter-class Unit of Measure Conversion window Link in order to approve the Lot UOM Conversions, form Link: ICCNVED

Your responsibility must have access to the Lot Inter-class Unit of Measure Conversion window in order to approve the Lot UOM Conversions.

## Approval Management Engine (AME) Approval Matrix

The Oracle Approval Management framework defines the approval matrix and approval groups. AME lets you define transaction and associate attributes that control

the approvers of the transaction. It also lets you define approval groups based on FND users and let these groups be associated to rules. Approval Management production rules represent business rules that determine who must approve a transaction.

The process flow for creating an e-record and e-signature approval matrix is accomplished through the AME responsibility available in Oracle Applications.

Refer to the *Oracle Approvals Management Implementation Guide* and the *Oracle E-Records Implementation Guide* for details.

### **Defining Transaction, Attributes, and Approval Groups**

Each business event is associated with a set of control parameter lists. The business event is the transaction in AME while the control parameter list becomes the list of attributes. In the case of the test business event, the attributes are Lab, Item, Test Class, Test, and Test Method.

A transaction type is defined in AME, and corresponds to an Oracle workflow business event. The name of the transaction type is the same as the name of the business event. Attributes are defined for the transaction along with the associated SQL statement, which derives the values of the attributes for a given transaction.

You define approval groups that are associated to the rule in AME.

### **Defining AME Conditions**

Define conditions in AME using the attributes. For example, the Lab is OPME.

### **Defining eSignature Rules**

Define rules in AME using the conditions. For example, the Rule for Plant Code is used with a specific approval list. If the plant code is OPME, then the approval list defined in AME is used.



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# Oracle E-Record Events in Quality Management

OPM Quality Management supports the acquisition of electronic signatures on electronic records. Electronic documentation replaces paper with a seamless interface of business activities that improves manufacturing throughput and enhances the overall quality of operations in the supply chain. The following provides information for online and deferred events that are e-record and e-signature enabled in the OPM Quality Management application. A brief discussion of each event is provided. Refer to the Oracle E-Records Implementation Guide for details on setting up the events and approvals

This appendix covers the following topics:

- Events
- Subscriptions
- Approval Matrix
- Approval of Quality Specification
- Samples Creation
- Results
- Sample and Sample Group Disposition
- Stability Study Change Status

## Events

The following table lists the events that are e-record and e-signature enabled for OPM Quality Management:

<b>Event</b>	<b>Online or Deferred</b>
Process Quality Specifications Event	Deferred
Process Quality Inventory Validity Rule Specifications Event	Deferred
Process Quality WIP Validity Rule Specifications Event	Deferred
Process Quality Customer Validity Rule Specifications Event	Deferred
Process Quality Supplier Validity Rule Specifications Event	Deferred
Process Quality Monitoring Validity Rule Specifications Event	Deferred
Process Quality Sample Creation Event	Online
Process Quality Results Entry Event	Online
Process Quality Results Evaluation	Online
Process Quality Sample Disposition	Online
Process Quality Sample Event Disposition	Online
Process Quality Sample Event Disposition Composite	Online
Process Quality Stability Study Change Status	Online

## Events

Name	Display Name	Description	Status	Owner Name	Owner Tag
oracle.apps.g md.qm.spec	GMD ERES Specifications Event	ERES Event for Specifications in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.spec.v r.inv	GMD ERES Inventory Validity Rule Specifications Event	ERES Event for Inventory Specifications Validity Rule in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.spec.v r.wip	GMD ERES WIP Validity Rule Specifications Event	ERES Event for WIP Specifications Validity Rule in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.spec.v r.cus	GMD ERES Customer Validity Rule Specifications Event	ERES Event for Customer Specifications Validity Rule in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.spec.v r.sup	GMD ERES Supplier Validity Rule Specifications Event	ERES Event for Supplier Specifications Validity Rule in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.spec.v r.mon	GMD ERES Monitoring Validity Rule	ERES Event for Monitoring Validity Rule	Enabled	Oracle Process Manufacturin g Product Development	GMD

Name	Display Name	Description	Status	Owner Name	Owner Tag
oracle.apps.g md.qm.smpl. crea	GMD ERES Sample Creation Event	ERES Event for Sample Creation in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.rslt.en try	GMD ERES Results Event	ERES Event for Results Entry in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.rslt.m entry	GMD ERES Mass Results Event	ERES Event for Mass Results Entry in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.rslt.ev al	GMD ERES Results Evaluation	ERES Event for Results Evaluation in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.smpl. disp	GMD ERES Sample Disposition	ERES Event for Sample Disposition in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.evt.di sp	GMD ERES Sample Group Disposition	ERES Event for Sample Disposition in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD
oracle.apps.g md.qm.evt.di spcom	GMD ERES Sample Group Disposition Composite	ERES Event for Sample Composite Disposition in OPM Quality	Enabled	Oracle Process Manufacturin g Product Development	GMD

Name	Display Name	Description	Status	Owner Name	Owner Tag
oracle.apps.g md.qm.ss.ecst s	GMD ERES Stability Study Change Status	ERES Event for Stability Study Change Status	Enabled	Oracle Process Manufacturing Product Development	GMD

**Note:** It is recommended that the user entering the mass results data be the one signing for the event. In order to accomplish this, the following AME attributes must have the appropriate values:

**Note:** ALLOW\_REQUESTOR\_APPROVAL : true

**Note:** ALLOW\_EMPTY\_APPROVAL\_GROUPS: true

**Note:** TRANSACTION\_REQUESTOR\_USER\_ID : select  
fnd\_global.user\_id from fnd\_dual

**Note:** Create a rule without any constraints attached to a empty  
approval Group.

## Event Key

Event Name	Event Key
oracle.apps.gmd.qm.spec	Spec_id
oracle.apps.gmd.qm.spec.vr.inv	Spec_vr_id
oracle.apps.gmd.qm.spec.vr.wip	Spec_vr_id
oracle.apps.gmd.qm.spec.vr.cus	Spec_vr_id
oracle.apps.gmd.qm.spec.vr.sup	Spec_vr_id

Event Name	Event Key
oracle.apps.gmd.qm.spec.vr.mon	Spec_vr_id
oracle.apps.gmd.qm.rslt.entry	Sample_id-update_instance_id-spec_id
oracle.apps.gmd.qm.rslt.mentry	Sample_id-update_instance_id-spec_id
oracle.apps.gmd.qm.rslt.eval	Sample_id-update_instance_id-spec_id
oracle.apps.gmd.qm.evt.disp	Event_spec_disp_id
oracle.apps.gmd.qm.evt.dispcom	Event_spec_disp_id
oracle.apps.gmd.qm.smpl.crea	Sample_id
oracle.apps.gmd.qm.smpl.disp	Event_spec_disp_id-sample_id
oracle.apps.gmd.qm.ss.ecsts	SS_Id

## Subscriptions

Source Type	Event Filter	Phase	Status	Rule Data	Rule Function	Priority
Local	oracle.apps.gmd.qm.spec	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps.gmd.qm.spec.vr.inv	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps.gmd.qm.spec.vr.wip	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal

Source Type	Event Filter	Phase	Status	Rule Data	Rule Function	Priority
Local	oracle.apps .gmd.qm.s pec.vr.cus	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps .gmd.qm.s pec.vr.sup	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps .gmd.qm.s pec.vr.mon	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps .gmd.qm.rs lt.entry	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps .gmd.qm.rs lt.mentry	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps .gmd.qm.rs lt.eval	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps .gmd.qm.s mpl.disp	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps .gmd.qm.s mpl.crea	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal

Source Type	Event Filter	Phase	Status	Rule Data	Rule Function	Priority
Local	oracle.apps.gmd.qm.e vt.disp	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps.gmd.qm.e vt.dispcom	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal
Local	oracle.apps.gmd.qm.ss .ecsts	0	Disabled	Key	EDR_UTIL. WF_RULE _FUNCTION	Normal

## Approval Matrix

### Transaction Type

Oracle Application	Transaction Type ID	Transaction Type Description	Line Item Id Query String
Oracle Process Manufacturing	oracle.apps.gmd.qm.spec	GMD ERES Specifications Event	N/A
Oracle Process Manufacturing	oracle.apps.gmd.qm.spec.vr.inv	GMD ERES Inventory Validity Rule	N/A
Oracle Process Manufacturing	oracle.apps.gmd.qm.spec.vr.wip	GMD ERES WIP Validity Rule	N/A
Oracle Process Manufacturing	oracle.apps.gmd.qm.spec.vr.cus	GMD ERES Customer Validity Rule	N/A

<b>Oracle Application</b>	<b>Transaction Type ID</b>	<b>Transaction Type Description</b>	<b>Line Item Id Query String</b>
Oracle Process Manufacturing Product Development	oracle.apps.gmd.qm.s pec.vr.sup	GMD ERES Supplier Validity Rule Specifications Event	N/A
Oracle Process Manufacturing Product Development	oracle.apps.gmd.qm.s pec.vr.mon	GMD ERES Monitoring Validity Rule Specifications Event	N/A
Oracle Process Manufacturing Product Development	oracle.apps.gmd.qm.s mpl.crea	GMD ERES Sample Creation Event	N/A
Oracle Process Manufacturing Product Development	oracle.apps.gmd.qm.r slt.mentry	GMD ERES Mass Results Event	N/A
Oracle Process Manufacturing Product Development	oracle.apps.gmd.qm.r slt.entry	GMD ERES Results Event	N/A
Oracle Process Manufacturing Product Development	oracle.apps.gmd.qm.r slt.eval	GMD ERES Results Evaluation	N/A
Oracle Process Manufacturing Product Development	oracle.apps.gmd.qm.s mpl.disp	GMD ERES Sample Disposition	N/A
Oracle Process Manufacturing Product Development	oracle.apps.gmd.qm.e vt.disp	GMD ERES Sample Group Disposition	N/A
Oracle Process Manufacturing Product Development	oracle.apps.gmd.qm.e vt.dispcom	GMD ERES Sample Group Disposition Composite	N/A
Oracle Process Manufacturing Product Development	oracle.apps.gmd.qm.s s.ecsts	GMD ERES Stability Study Change Status	N/A

## Transaction Attributes

Approval attributes are seeded for these events. You can define the attributes and use them in the rules as per the implementation instructions.

## Define Rules/Associate Approvers/Associate E-Record Output XSL

The rules basing the status on Approved For Laboratory Use and Approved For General Use are seeded.

As part of the implementation, you must complete these activities. The following mandatory and non mandatory attributes must be added for all transaction types. Substitute the values shown with appropriate transaction specific values or data:

## Mandatory Attributes

Name	Attribute Type	Description	Static Usage	Usage
ALLOW_DELETE	boolean	Whether to let the calling application (or its end users) delete approvers generated by the rules.	Yes	False
ALLOW_REQUESTOR_APPROVAL	boolean	Whether to allow requestors to approve their own transactions (when the rules do so).	Yes	False
AT_LEAST_ONE_RULE_MUST_APPLY	boolean	Whether to require that at least one rule apply to each transaction.	Yes	False
EFFECTIVE_RULE_DATE	date	The date that determines which rules are active.	Yes	(blank)

Name	Attribute Type	Description	Static Usage	Usage
TRANSACTION_DATE	date	Date transaction occurred.	No	Select ame_util.version DateToString(CR EATION_DATE)  from gme_batch_header  where batch_id=:transactionId
TRANSACTION_GROUP_ID	number	Business-group ID in which transaction occurred.	Yes	(blank)
TRANSACTION_ORG_ID	number	Org ID in which transaction occurred.	Yes	(blank)
TRANSACTION_REQUESTOR_PERSON_ID	number	Person ID of person initiating transaction.	Yes	(blank)
TRANSACTION_REQUESTOR_USER_ID	number	User ID of person initiating transaction.	No	Select Last_updated_by  from gme_batch_header  where batch_id=:transactionId
TRANSACTION_SET_OF_BOOKS_ID	number	Set of books ID in which transaction occurred.	No	(blank)

Name	Attribute Type	Description	Static Usage	Usage
USE_RESTRICTIVE_LINE_ITEM_EVALUATION	boolean	Whether to require that the same line item satisfy all line-item conditions in a given rule.	Yes	False
WORKFLOW_IT_EM_KEY	string	The transaction's workflow item key.	No	(blank)
WORKFLOW_IT_EM_TYPE	string	The transaction's Workflow item type.	No	(blank)
ALLOW_DELETE_GENERATED_APPROVERS	boolean	Whether to let the calling application (or its end users) delete approvers generated by the rules.	Yes	False

## Approval of Quality Specification

Making a Quality Specification active consists of two separate events: the approval of a specification and the approval of the specification validity rule. Process Quality Inventory, WIP, Customer, and Supplier Specification Validity Rule Events apply to item specifications. The Process Quality Monitoring Validity Rule Specifications Event only applies to the monitoring specification. Both events require the capture of e-records and e-signatures.

A specification status can be controlled through a workflow. Therefore, signatures for both creation and updates of specifications are captured deferred (electronic notifications are sent).

### E-record for Specification Status Change Approval

Data on the signoff for specifications can include:

- Spec, Description, Spec Version, Spec Status, Spec Type, Overlay, Base Spec, Base Spec Version, Owner Organization, Owner

- Item, Item Revision, Item Description, Grade
- Tests Summary  
Seq, Test, Test Method, Replicate, Unit, Target, Min, Max
- Tests Details  
Test Seq, Test Class, Test, Test Description, Test Method, Test Data Type, From Base, Exclude, Modify, Spec Target, Spec Min, Spec Max, Test Min, Test Max, Test Unit, Expression, Test Qty, Test Qty UOM, Test Replicate, Test Priority, Optional Test, Lot Retest/Expiry Test, Out-of-Spec Action, Out-of-Spec Action Description, Out-of-Spec Action Interval, Calculate UOM Conversion, From UOM, To UOM, Experimental Error Type, Below Min, Below Min Action, Above Min, Above Min Action, Below Max, Below Max Action, Above Max, Above Max Action, Test Alias, Print Specification, Print Result, Display Decimal Precision, Report Decimal Precision
- Spec Descriptions  
Language, Description

#### **E-record for Customer Validity Rule Status Change Approval**

Data on the signoff can include:

- Spec, Spec Version, Spec Status, Organization
- Item, Item Revision, Item Description, Grade
- Validity Rule Status, Customer, Operating Unit, Ship To Location  
Order Number, Order Type, Order Line
- Effective From Date, Effective To Date, Certificate Type, Required at Shipment, Required at Invoice, Required at Supplier, Lot Optional on Sample

#### **E-record for Supplier Validity Rule Status Change Approval**

Data on the signoff can include:

- Spec, Spec Version, Spec Status
- Item, Item Revision, Item Description, Grade
- Organization, Supplier, Supplier Name, Operating Unit, Validity Rule Status
- Site, PO Number, PO Line, Effective From Date, Effective To Date, Certificate Type, Required from Shipment, Required at Invoice, Required from Supplier, Lot Optional on Sample, Delayed Lot Entry
- Create Samples Automatically, Update Inventory Quantity, Control Lot Attributes,

In-Spec, Out-of-Spec

#### **E-record for Inventory Validity Rule Status Change Approval**

Data on the signoff can include:

- Spec, Spec Version, Spec Status
- Item, Item Revision, Item Description, Grade
- Organization, Validity Rule Status, Parent Lot, Lot, Subinventory, Locator
- Effective From Date, Effective To Date, Certificate Type, Required at Shipment, Required at Invoice, Required from Supplier, Lot Optional on Sample, Delayed Lot Entry
- Create Samples Automatically, Update Inventory Qty, Control Lot Attributes, In-Spec, Out-of-Spec

#### **E-record for WIP Validity Rule Status Change Approval**

Data on the signoff can include:

- Spec, Spec Version, Spec Status
- Item, Item Revision, Item Description, Grade
- Organization, Validity Rule Status, Batch, Recipe, Formula, Formula Line, Routing, Step, Operation
- Effective From Date, Effective To Date, Certificate Type, Required at Shipment, Required at Invoice, Required from Supplier, Lot Optional on Sample, Delayed Lot Entry
- Create Samples Automatically, Update Inventory Qty, Control Batch Step Status, Control Lot Attributes, In-Spec, Out-of-Spec

#### **E-record for Monitoring Specification Validity Rule Status Change Approval**

Data on the signoff can include:

- Spec Name, Spec Version, Spec Status, Rule Type
- Validity Rule Status, Organization, Resource, Resource Instance,
- Subinventory, Locator
- Effective From Date, Effective To Date

## Samples Creation

The Samples Creation e-record is sent when you try to approve a sample. The e-record provides all information about sample identification, including its priority, source, quality laboratory, sample dates, the specification tied to it, and any sampling plan information.

### E-record for Sample Creation

Data on the signoff for samples creation can include:

- Sample Number, Description, Disposition, Retain As, Priority
- Item, Item Revision, Item Description, Source, Source Comments
- Parent Lot, Lot, Subinventory, Locator
- Customer, Operating Unit, Ship To Location, Order Number, Order Type, Order Line
- Batch, Recipe, Version, Formula, Version Formula Line, Routing, Version, Step, Charge, Operation Version
- Supplier, Supplier Name, Site, PO Number, PO Line, Receipt Number, Receipt Line
- Quality Laboratory, Date Drawn, Expiration Date, Lot Retest Sample, Update Inventory Quantity, Sample Qty, Sample Qty UOM, Storage Subinventory, Storage Locator, Samples Occurrence, Specification Count, Spec Name, Spec Version, Grade

## Results

Quality results entry and evaluation can also require e-signature and e-record support. After results are entered and evaluation during a session, upon saving the results, the e-signature event is raised by the window and the appropriate signoffs take place online. If all the necessary signatures cannot be fulfilled at this time, then the results cannot be committed to the database. Results for all listed tests do not have to be entered in order for the e-signature event to be raised; if one or more test results are entered and saved, then e-signature is required. If more results are entered and evaluated in subsequent sessions, then e-signature is required at that time.

### E-record for Results Entry

Data on the signoff for results entry includes:

- Organization, Sample Number, Description, Sample Disposition, Item, Item Revision, Item Description, Grade, Parent Lot, Lot
- Spec Name, Spec Version

- Results Summary  
Seq, Test, Replicate, Result, Unit, Result Date, Deleted
- Results Details  
Test Sequence, Test, Test Description, Test Class, Test Method, Test Replicate, Result, Test Data Type, Test unit, Result Date, Test Min, Test Max, Test Priority, Display Label, Expression, Lot Optional, Lot Retest, Quality Laboratory, Tester, Reserve Sample, Planned Test Qty, Actual Test Qty, Actual Test UOM, Test Kit Item, Test Kit Lot, Test Provider, Deleted, Spec Target, Spec Min, Spec Max

#### **E-record for Mass Results Entry**

Data on the signoff for mass results entry includes:

- Test, Test Description, Test Class, Test Method, Test Data Type, Expression
- Samples Used  
Organization, Sample Number, Replicate, Result, Test Unit, Result Date, Tester

#### **E-record for Results Evaluation**

Data on the signoff for results evaluation includes:

- Organization, Sample Number, Description, Sample Disposition, Item, Item Revision, Item Description, Grade, Parent Lot, Lot, Spec Name, Spec Version
- Results Summary  
Seq, Test, Replicate, Result, Unit, Result Date, Deleted
- Results Details  
Test Sequence, Test, Test Description, Test Alias, Test Class, Test Method, Test Replicate, Result, Test unit, Test Data Type, Result Date, Parent Sample, Test Min, Test Max, Test Priority, Display Label, Expression, Lot Optional, Lot Retest, In-Spec, Evaluation, Action, Quality Laboratory, Tester, Reserve Sample, Planned Test Qty, Actual Test Qty, Acual Test UOM, Test Kit Item, Test Kit Lot, Test Provider, Deleted, Spec Target, Spec Min, Spec Max

## **Sample and Sample Group Disposition**

The Process Quality Sample Disposition event represents the final review and approval or rejection of all of the results logged against a sample. After the sample disposition is accepted, accepted with variance, or rejected, the lot status is changed to reflect this disposition. Changing to a final sample group disposition can also control the generation of recommended item lot interclass UOM conversions.

The Certificate of Analysis report and Specification Matching feature both depend on a

sample group disposition being accepted. If a sample group is not accepted, then these programs do not consider the sample group. Therefore, it is important that the sample group Disposition field is updated.

### **E-record for Sample Disposition**

Data on the signoff for sample disposition change includes:

- Organization, Sample Number, Sample Description, Disposition, Priority
- Item, Item Revision, Item Description, Source, Source Comments
- Parent Lot, Lot, Subinventory, Locator
- License Plate Number (LPN)
- Customer, Operating Unit, Ship To Location, Order, Order Type, Order Line
- Batch, Step, Charge, Recipe, Version, Formula, Version, Formula Line, Routing, Version, Operation, Version
- Supplier, Supplier Name, Operating Unit, Site, PO Number, PO Line, Receipt Number, Receipt Line
- Quality Laboratory, Update Inventory Qty, Sample Qty, Sample Qty UOM
- Date Drawn, Expiration Date, Samples Instance, Lot Retest Sample, Samples Taken, Storage Subinventory, Storage Locator
- Spec Name, Spec Version
- Results Summary  
Seq, Test, Replicate, Result, Unit, Result Date, Evaluation
- Results Details  
Test Sequence, Test, Test Description, Test Class, Test Method, Test Replicate, Test Data Type, Result, Test Unit, Result Date, Test Target, Test Min, Test Max, Display Label, Expression, Test Priority, Lot Optional, Lot Retest, LPN, Spec Target, Spec Min, Spec Max, In-Spec, Evaluation, Action, Quality Laboratory, Tester, Planned Test Qty, Actual Test Qty, Test Qty UOM, Test Kit Item, Test Kit Lot, Test Provider

### **E-record for Sample Group Disposition**

Data on the signoff for sample group disposition change includes:

- From Disposition, To Disposition, Item, Item Revision, Item Description, From Grade, To Grade
- Parent Lot, Lot, Subinventory, Locator

- License Plate Number (LPN)
- Customer, Operating Unit, Ship To Location, Order, Order Type, Order Line
- Batch, Recipe, Version, Formula, Version, Formula Line, Routing, Version, Step, Charge, Operation, Version
- Supplier, Supplier Name, Operating Unit, Site, PO Number, PO Line, Receipt Number, Receipt Line
- Samples Taken, Samples Required, Samples Type
- Samples Summary
  - Sample Number, Disposition, Date Drawn
- Results Summary
  - Sample, Seq, Test, Replicate, Result, Unit, Result Date, Evaluation
- Results Details
  - Sample, Test Sequence, Test, Test Description, Test Class, Test Method, Test Replicate, Test Priority, Test Data Type, Result, Test Unit, Result Date, Display Label, Expression, In-Spec, Evaluation, Action, Quality Laboratory, Tester, Test Kit Item, Test Kit Lot, Test LPN, Test Provider, Spec Target, Spec Min, Spec Max

#### **E-record for Sample Disposition Composite Change Disposition**

Data on the signoff for sample disposition composite change disposition includes:

- From Disposition, To Disposition, Item, Item Revision, Item Description, From Grade, To Grade
- Parent Lot, Lot, Subinventory, Locator
- Customer, Operating Unit, Ship To Location, Order, Order Type, Order Line
- Batch, Recipe, Version, Formula, Version, Formula Line, Routing, Version, Step, Charge, Operation, Version
- Supplier, Supplier Name, Operating Unit, Site, PO Number, PO Line, Receipt Number, Receipt Line
- Update Inventory Qty, Control Batch Step Status, Control Lot Attributes, In-Spec Lot Status, Out-of-Spec Lot Status, Hold Date
- Samples Taken, Samples Required
- Samples Summary

## Stability Study Change Status

The stability change status functionality allows you to change stability study status from new to approved, approved to launch, and launch to completion.

Data on the signoff for Stability Study Change Status can include:

- Organization, Stability Study, Study Description, From Current Status, To Status
- Item, Item Revision, Item Description, Master Spec, Quality Laboratory, Owner, Notification Lead Time, Testing Grace Period
- Material Source Count, Storage Condition Count, Package Count
- Scheduled Start Date, Scheduled End Date, Revised Start Date, Revised End Date, Actual Start Date, Actual End Date
- Variant Summary
  - Variant Number, Default Item Spec, Default Item Spec Version, Retained Samples
- Variant Material Source
  - Organization, Batch, Recipe, Lot
- Variant Storage Condition
  - Organization, Storage Spec, Storage Spec Version, Resource, Subinventory, Locator, Storage Date
- Variant Package
  - Package, Formula, Formula Version, Sample Quantity/UOM
- Variant Timepoints
  - Time Interval, Spec, Spec Version, Scheduled Date, Actual Date, Samples Required, Disposition, Time Interval, Spec, Spec Version, Scheduled Date, Actual Date, Samples Required, Disposition



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# Glossary

**Action**

User defined message displayed to identify the need for and type of quality related action to be taken when a lot expires, or its results are not in conformance with quality requirements. Examples of actions are: quarantine, retest, resample, and hold.

**Assay**

See Test.

**Assay Type**

See Test Data Type.

**Assay Units**

See Test Units.

**Business Event**

An event that is of interest to customers or business teams. For example, the movement of inventory to a subinventory is a business event.

**Certificate of Analysis**

Also, COA. Documentation issued to a customer, or for internal records, indicating the quality tests performed and results reported for item lots shipped.

**Certificate of Conformance**

Also, CoC. Documentation provided by a supplier or manufacturer that indicates the supplies or services meet the specified requirements. In this application, the Certificate of Conformance lets the process manufacturer to certify shipments that meet certain quality specifications where results are not printed in the document.

**Charge**

One full load that can be accommodated in a single pass through the equipment. In a process manufacturing plant, the capacity of a step may be predetermined by the capacity of the equipment used in that step. For example, a mixing tank that has a

maximum capacity of 1000 gallons overflows if more is added. The maximum capacity determines the total number of charges that are required to process the ingredients required for a batch. A batch size of 5000 gallons requires five charges at 1000 gallons each when the maximum capacity of the mixing tank is 1000 gallons.

### **CoA**

See Certificate of Analysis.

### **CoC**

See Certificate of Conformance.

### **Decimal Precision**

The number of decimal places that are displayed for numeric data. This ranges from zero to nine decimal places, and it determines how the application manages the rounding of significant figures. A decimal number that is five or higher rounds up, while decimal numbers below five round down.

### **Disposition**

The status of a sample or sample group with respect to analysis.

### **Context Organization**

The inventory organization that serves as the framework for the data entered or displayed.

### **E-Records and e-signatures**

To satisfy signoff requirements in regulated industries, electronic signatures are obtained before changes to records become accessible throughout the supply chain. Management configures where and when these signatures are collected by using an electronic record framework. If a signature is required, then an e-signature window displays. Application users are restricted from moving on to the next logical step or status until all required e-signatures are entered.

### **Event Subscription**

Typically perform any or all of the following:

- Run custom PL/SQL code.
- Send the business event to a predefined workflow.
- Use Oracle Advanced Queuing for asynchronous messaging.

Refer to the *Oracle Workflow Guide* for details on subscribing to a workflow event.

### **Experimental Error**

The error observed defines a region of uncertainty around specification limits for a test that usually requires an action. These action zones can be defined for numeric-based tests.

### **Expiration Date**

Date or time window beyond which an item or lot expires and becomes unusable. This is defined as part of the item master and lot master in OPM.

### **Frequency Period**

Defines the basis of frequency for a sampling plan in terms of hours, batches, lots, and kilograms produced. This corresponds to the frequency count.

### **Frequency Type**

Identifies the type of sampling plan frequency as:

- Time-based
- Quantity-based
- Fixed Number
- Percent

### **Grade**

Combinations of quality attributes that are defined for lot-controlled items. Also, the fitness of an item to preset attributes. For example, diamonds have color and clarity grades as measures of their quality.

### **ICH**

In stability studies. International Conference on Harmonisation.

### **Instrument**

A resource that is linked to a test method so that test results can be traced to the equipment used in the analysis.

### **Inventory Organization**

The plant where batches are produced. Also, the organization that holds the inventory at specified locations. Contains subinventories and locators.

### **Item Revision**

A particular version of an item.

**Item Sample**

See Sample.

**Locator**

A specific physical area within a subinventory such as a row, aisle, bin, or shelf where the item is stored.

**Locator Control**

A technique for enforcing the use of locators during a material transaction that is set at the inventory organization, subinventory, or item level.

**Lot**

A unit used to group quantities of a specific item when subquantities have slightly different characteristics.

**Lot Status**

Defined in the Oracle Inventory application. Assigned to one or more lots to indicate if the lots are nettable for planning, or usable for sales, production, or shipping.

**Monitoring Sample**

See Sample.

**Oracle Workflow**

A complete workflow management system that supports business process definition, automation, and integration. This technology routes information based on user defined business rules. Notification activities deliver messages to you through e-mail or a notification web page that is accessible using any browser.

**Parent Lot**

A quantity of an item that shares the same specifications or contains one or more receipts from the same vendor. Genealogically, each parent lot can be divided into child lots, previously sublots, which reflect the characteristics selected for the items within the parent lot.

**Process Quality Parameters**

A default set of organization-specific controls or options that determines how OPM Quality Management functions.

**Quality Laboratory**

Process-enabled inventory organization where a sample is tested. Represented as a process-enabled lab inventory organization.

## **Quality Workbench**

A navigator with nodes that you can expand to display groups of individual database objects. Lower level nodes, and the objects they contain, are indented to indicate that they belong to these higher level nodes. The terminal node in a branch is called a leaf node. The workbench has a data organizer that groups objects on separate tabs. Each tab has a unique icon and its own hierarchy. The Quality Management application uses tabs to group specifications and samples. When you select an unexpanded, higher level node on the data organizer, a summary view lists the contents of the container.

## **Result**

Outcome of a quality test performed on an item or lot. Results may not be the expected results as defined in the specification. This can be used to determine that an item or lot is unsuitable to be sold or used.

## **Retest Date**

In stability studies. The date after which samples of the drug substance must be examined to ensure that the material is still in compliance with the specification and thus suitable for use in the manufacture of a given drug product.

## **Retest Period**

In stability studies. The period of time during which the drug substance is expected to remain within its specification and, therefore, can be used in the manufacture of a given drug product, provided that the drug substance has been stored under the defined conditions. After this period, a batch of drug substance destined for use in the manufacture of a drug product must be retested for compliance with the specification and then used immediately. A batch of drug substance can be retested multiple times and a different portion of the batch used after each retest, as long as it continues to comply with the specification. For most biotechnological or biological substances known to be labile, it is more appropriate to establish a shelf life than a retest period. The same may be true for certain antibiotics.

## **RH**

Relative humidity.

## **Sample**

Portion of a lot selected to be tested. Results of tests are used to estimate the characteristics of the entire lot. The application distinguishes between an item sample and a monitoring sample. The item sample can be a physical sample with a source from inventory, WIP, a customer, or a supplier. The monitoring sample is typically a virtual sample from an instrument or other measurement device that monitors equipment such as an environmental chamber. For example, temperature and humidity readings can be monitoring samples.

**Sample Group**

Also, Sampling Event. Comprised of one or more samples that share a common sample source, item, and lot are tied to the same business event such as receiving, inventory transfer, batch, and expired lot.

**Sample Quantity**

Total amount of material drawn for inspection, and required for all anticipated tests. It is measured in the inventory unit of measure for the item sampled. The sample quantity can include sufficient material for possible retesting.

**Sample Source**

Identified as the origin of the sample. For example, the material, resource, locator, or stability study.

**Sampling Event**

See Sample Group.

**Sampling Plan**

Identifies how much and how often sampling must occur.

**Shelf Life**

In stability studies. The time period during which a product is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label.

**Specification, Item**

A clear, complete, and accurate statement of the quality acceptance criteria for a material, and of the procedure to determine if the requirements are met. A quality specification includes a set of tests.

In stability studies. Limits of acceptability derived from the profile of the material as used in the preclinical and clinical batches.

**Specification, Monitoring**

In stability studies. A specification that defines the details of the storage condition for one of the variants of a stability study. These conditions can include, but are not limited to, the temperature, humidity, and pressure of the storage condition.

**Specification Validity Rule**

Includes specific information on how and when an item or monitoring specification version applies to inventory, process execution, order management, receiving operations, resources, or locators.

**Stability Study**

Stability Studies analyze a predefined set of tests at prescribed intervals for various parameters. These may include testing of the active ingredient, measurement of known degradation products, dissolution time, appearance, and other physicochemical criteria.

Long term, accelerated, and intermediate studies undertaken on batches according to a prescribed stability protocol to establish or confirm the retest period of a drug substance or the shelf life of a drug product.

**Storage Condition**

In stability studies. A set of environmental conditions to maintain a climate-controlled storage facility. The length of the studies and the storage conditions are required to cover the conditions of the item's storage, shipment, and subsequent use.

**Storage Locator**

A restricted or non-restricted subinventory locator where samples are stored.

**Storage Organization**

Process-enabled inventory organization where a sample is stored.

**Storage Package**

In stability studies. Refers to the containers in which sample material is stored for stability testing. The packages must be the same as, or it must simulate the actual packaging used for storage and distribution of the finished product.

**Storage Subinventory**

A validated or non-validated subinventory where samples are stored.

**Subinventory**

A subdivision of an inventory organization that represents either a physical area or a logical grouping of items, such as a storeroom, damaged inventory, or receiving dock.

**Test**

Previously, Assay. A generic term for the analysis of the physical and chemical properties of a sample. For example, you can perform a test for chloride using commercially available titrimetric or amperometric test methods.

**Test Class**

A grouping of tests based on a common set of meaningful characteristics.

**Test Data Type**

Previously, Assay Type. Categorizes the type of data expected for a test. Numeric and

text based data types are available in the application.

### **Test Kit**

Material used in preparing or running a test. For example, a reagent used in a chemical test.

### **Test Method**

Identifies how a test is performed. For example, a test method refers to a standard American Society for Testing and Materials, or ASTM protocol for measuring the property of a material.

### **Test Procedures and Test Criteria**

In stability studies. The testing covers those features susceptible to change during storage and likely to influence quality, safety, and efficacy.

### **Test Quantity**

The amount of material required for a particular test method and instrument, expressed in the inventory unit of measure.

### **Test Replicate**

An iteration of a test that is repeated on the same sample.

### **Test Units**

Previously Assay Units. Unit of measure for quality tests. For example, pH. Test units of measure often differ from inventory units of measure.

### **Testing Frequency**

In stability studies. Frequency of testing sufficient to establish the stability characteristics of the item. Testing under long term conditions typically is every three months, over the first year, every six months over the second year and then annually.

### **Validity Rule**

See Specification Validity Rule.

### **Variant**

In stability studies. The storage condition for a time point sample defined by a unique combination of the material source, stability study storage condition, test interval plan, and optional storage package.

### **WIP**

See Work in Process.

**Work in Process**

Also, WIP. Batches released to production.



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# Index

## A

---

accelerated stability testing, 8-4  
acceptable values, 3-6  
acceptance sampling, 5-3  
account, 2-16  
action codes, 2-4  
action codes , 2-2  
action codes setup, 2-2  
active specifications, 1-16  
actual test quantity, 6-20  
Add Tests window, 6-39  
ADJI, 2-13  
aliquots, in sampling, 5-11  
application setup, 1-7  
Approval Matrix, E-8  
archive samples, 5-11  
arithmetic operators, in Expression test, 3-8, 3-9  
audit trail, in version control, 4-21  
available inventory, in Oracle Order Management, 4-9

## B

---

base specification, 4-5, 4-23  
batch creation, sampling in, 5-4  
batch step, preventing completion of, 6-9  
batch step completion and quality test results, 1-12  
batch step release, 1-4  
batch step release, and quality sampling, 1-12  
batch termination, 5-4  
batch update, using sample quantity, 1-12

## C

---

certificate formatting, 4-23  
Certificate of Analysis, 4-4, 6-3, 6-8, 7  
Certificate of Analysis Report window, 7-16  
Certificate of Conformance, 4-4, 7  
certification  
certificate of analysis, 7-14  
certificate of conformanceCertificate of AnalysisCertificate of Conformance, 7-14  
certification of tests, 7-14  
cGMP, 8-5  
classes, in test data type, 2-4  
code, status, 4-17  
collaborative analysis, in test grouping, 2-6  
components, navigation, 1-13  
Composite Results Notification, D-4  
Composite Results window, 6-15, 6-34  
conditions, specifying in search and replace, 1-23, 1-26  
conformance to specification, 1-3  
consider optional tests results, 2-16  
Consider Optional Tests Results, 4-2, 4-3  
Consider Optional Tests Results , 4-27  
control batch step status, 2-15  
control batch step status, use of WIP specification validity rule, 6-9  
Control lot attributes, 2-15  
control lot attributes , 4-41  
Control Lot Attributes indicator, 6-11  
converting UOMs, 4-9

convert test units, 2-7  
copy a specification, 4-33  
copy specification, 4-5  
count, in sampling plan, 2-9  
Create Samples Automatically, 2-15  
Customer Display dialog box, 3-14  
Customer Test Results report, 2-4  
Customer Validity Rules node, 1-16

## D

---

data types, in tests, 3-6  
delayed lot entry, 2-15  
Delayed Lot Entry indicator, 5-13  
detail views, 1-14  
display, hierarchical, 1-13  
document types, 2-13

## E

---

editing results, 6-23  
electronic results, 1-4  
electronic signatures, 1-4  
environmental conditions, 4-8  
environmental monitoring, 8-8  
environmental variables, in stability testing, 8-2  
exact specification match, 2-15  
Exact Spec Match, 5-20  
experimental error, 4-7  
    region, 3-18  
    rules, 3-16  
Experimental Errors window, 6-32  
expiration date, 2-2, 5-8  
expiration dating, 8-4  
expired lots, managing, 1-13  
expressions, evaluating partial, 6-7  
expressions, in quality testing, 3-2  
Expression test, 3-8  
    example of entering, 3-10  
    test unit conversion, 2-7  
Expression test type, 3-2

## F

---

failures, in process behavior, 1-3  
FDA, 8-5  
find a sample storage summary, 7-20  
Find Samples dialog box, 5-41, 6-33, 6-46

Find Sample Storage Summary window, 7-20  
Find Samples window, 1-20  
Find Sampling Plans dialog box, 2-12  
Find Specifications dialog box, 4-34  
Find Specifications window, 1-20  
Find Stability Studies dialog box, 8-31  
Find Status Codes dialog box, 4-20  
Find Storage Condition Plans dialog box, 8-24  
Find Test Classes dialog box, 2-5  
Find Test Interval Plans dialog box, 8-21  
Find Test Methods dialog box, 3-5  
Find Tests dialog box, 3-19  
Find Test Units dialog box, 2-8  
Find Variants dialog box, 8-42  
fixed number sampling, 2-9  
frequency of sampling, 2-9  
frequency type, in sampling plan, 2-9

## G

---

Generate Test Intervals dialog box, 8-20  
generic resources, 3-2  
Glossary, Glossary-1  
GMD  
    Include Optional Tests in Sample Disposition, 6-15  
Good Manufacturing Practice, 8-5  
grade, 2-2  
grade, updating, 1-12  
grades, 2-4  
grades setup, 2-2  
GRDI, 2-13  
Group Enabled indicator, 2-7  
grouping tests, 2-6

## H

---

hierarchical display, 1-13  
hierarchy, of navigator, 1-14

## I

---

inquiries, B-1  
In-Spec status, 2-15  
inspection, receiving, 1-13  
inspection points, 1-4  
instruments, used in quality testing, 3-3  
instrument scheduling, 3-3

inventory adjustment, 1-12  
inventory organization, 5-3  
Inventory Validity Rules node, 1-16  
item, 4-36  
Item/Location Required Analysis report, 7-3  
item attributes, 2-1  
item revision, 4-25  
items, 2-1  
item samples, system-generated, 5-13  
Item Samples window, 1-18, 5-15  
Item Specifications, 4-4  
item substitution, 4-8, 5-3  
item units of measure, 2-10

## L

---

laboratory, 2-14  
leaf node, 1-13  
List of Test Values test, 3-6  
locator, 5-19  
locator, in monitoring specification, 4-8  
lot attributes, 4-7  
lot expiration, management of, 1-13  
lot expiration date, 5-8  
Lot Optional, 2-15  
Lot Retest/Expiry indicator, 4-3  
lot-specific unit of measure conversion, 4-9

## M

---

managing results, 2-4  
Manual Allocate, 2-3  
Manual Spec Selection, 2-16  
Mass Results Entry Test Selection window, 6-27  
Mass Results Entry window, 6-30  
material attribute, 4-6  
material source organization, 8-12  
Material Sources window, 8-33  
material status, updating, 1-12  
mathematical expressions, in quality testing, 3-2  
mathematical functions, in Expression test, 3-8  
Mode statistic, 6-3  
Monitoring Samples window, 5-36  
monitoring specification, 4-7, 4-23  
Monitoring Specifications, 4-5

## N

---

navigation components, 1-13  
navigator, 1-13  
nodes, 1-13  
nonconforming material, 1-3  
Non-Validated test, 3-6  
notification window, in workflow, 5-4  
Numeric Range test, 3-6  
Numeric Range with Display Text test, 3-7

## O

---

open-ended ranges, in numeric range tests, 3-7  
operating unit, 4-45, 5-28  
OPM Product Analysis Workbook, 4-9  
OPM Quality Management, 6-13  
OPM Quality Sample Creation workflow, D-10  
OPM Quality Spec Customer Validity Rule  
Status Change approval workflow, D-32  
OPM Quality Spec Inventory Validity Rule  
Status Change approval workflow, D-34  
OPM Quality Spec Monitoring Validity Rule  
Status Change approval workflow, D-39  
OPM Quality Spec Supplier Validity Rule Status  
Change approval workflow, D-35  
OPM Quality Spec Validity Rule Status Change  
Approval workflow, 4-12  
OPM Quality Spec WIP Validity Rule Status  
Change approval workflow, D-37  
OPM Quality Stability Study Change Status  
workflow, 8-14  
OPM Quality Stability Study Lot Sample  
workflow, D-45  
OPM Quality UOM Conversion workflow, 4-10  
Oracle Approval Management Engine (AME), D-  
4  
Oracle Business Intelligence System, in Order  
Fulfillment specification matching, 4-9  
Oracle E-Records, 1-9  
Oracle Inventory, related to quality, D-2  
Oracle Inventory application, 1-8  
Oracle Order Management, 1-9  
Oracle Order Management, in specification  
matching, 4-8  
Oracle Purchasing, 1-9, 6-13  
Oracle Quality, 1-9, 6-12  
Oracle Receivables, 1-8  
Oracle Workflow, D-3

Oracle Workflow Business Event Systems, D-3  
organization, 5-44  
organization, quality laboratory, 5-3  
organization type, 2-14  
Other applications setup, 2-1  
Out-of-spec status, 2-15  
overlay specification, 4-5, 4-23  
owner organization , 4-25

## P

---

parent lot, 4-37, 5-15, 5-25, 5-31, 6-47  
percentage-based sampling, 2-10  
period, in sampling plan, 2-9  
Personal folder, 1-14  
PL/SQL NVL function, 6-7  
planned test quantity, 6-20  
plant, 2-14  
potency, 4-6  
precision, in reports, 3-15  
preventing batch step completion, 6-9  
Print Additional Test on COA, option, 6-23  
Process Execution, related to quality, D-2  
Process Execution application, 1-8  
process flow, in quality management, 1-7  
process loss, 1-12  
Process Quality Parameters window, 2-13, 4-24, 5-6, 5-13  
Process Quality Parameters window , 2-3  
Product Development application, 1-8  
Public folder, 1-14

## Q

---

quality attributes for items setup, 2-2  
quality certificate, 4-8  
Quality Change Disposition dialog box, 6-47  
Quality Change Disposition window , 2-3  
Quality composite results workflow, D-27  
quality grade, 1-4  
quality improvement, 1-3  
quality inspection, 5-3  
quality laboratory, 2-14, 5-3  
quality laboratory organization, 5-3  
Quality Management Responsibilities, B-1  
Quality Manager, B-1  
quality requirements, 1-3  
Quality sample disposition workflow, D-25

quality sampling, 1-12  
quality specifications status change approval workflow, D-30  
Quality Technician, B-1  
quality testing, 1-4  
Quality tests setup, 2-4  
quality test units, 2-7  
quality test workflow, D-23  
Quality UOM Conversion Notification, D-7  
Quality Workbench, 1-14  
quantity-based sampling, 2-9

## R

---

reason code, 2-2  
reason code , 2-15  
reason code access setup, 2-3  
receiving inspection, 1-13  
receiving inspection result, 6-12  
referential integrity, 3-3  
report precision, 3-15  
reports, B-1  
    Certificate of Analysis, 7-14  
    Certificate of Conformance, 7-14  
    Customer/Vendor Test Results, 7-7  
    Item/Location Test Results, 7-4  
    Production Test Results, 7-10  
    Sample Label Generation, 7-21  
resample action, 2-15  
reserve sample, 5-12  
resource, in monitoring specification, 4-8  
responsibilities, B-1  
Result Association window, 6-54  
results, managing, 2-4  
result statistics, 6-3  
Results window, 6-14, 6-33, B-1  
retained sample, 5-11, 5-12  
retest action, 2-15  
retest date , 2-2  
retest interval, 2-2  
retest process, 6-3  
revision, 5-18, 5-24  
Revision, 4-36, 5-30

## S

---

sample  
    collection, 5-3

inspection, 5-3  
supplier, 5-3  
sample approval management engine, D-57  
Sample Creation Notification, D-4  
Sample Creation Notification Workflow, 2-9, 5-4  
sample disposition, 1-21, 5-11, 5-11  
Sample Disposition Notification, D-4  
sample expiration date, 5-8  
sample group disposition, 5-9  
Sample Group Disposition Notification, D-4  
Sample group disposition workflow, D-29  
Sample Group Rejection Notification, D-6  
sample group rejection workflow, D-40  
Sample Groups window, 5-45, B-1  
Sample Label Generation report, 7-21  
samples, impact of batch termination, 5-4  
Samples By... windows, 5-49  
Samples Summary window, 1-18, 5-53  
Samples tab, 1-15  
Sample Storage Summary window, 7-19  
Samples window, 5-5  
sampling  
    fixed number, 2-9  
    percentage-based, 2-10  
    quantity-based, 2-9  
    time-based, 2-9  
sampling frequency, 2-9  
sampling methodologies, 5-4  
sampling plan, 1-12  
sampling plan, definition, 2-10  
Sampling Plan window, 2-9  
sampling process, 1-4  
scheduling tests, 3-3  
security profile access setup, 2-3  
Select Available Inventory window, 2-3  
sequencing tests, 2-6  
Setting Up Quality Responsibilities, B-1  
setup, in other applications, 1-7  
set up material status, 2-3  
shelf life, in stability testing, 8-4, 8-5  
Show Active Samples indicator, 1-17  
Show Active Specs indicator, 1-15  
Spec Customer Validity Rule Status Change  
Approval Notification, D-5  
specification, 3-7  
    stability studies, 8-9  
    updating inventory quantity, 5-16  
Specification Comparison window, 6-41  
specification limits, 3-15  
specification matching, 1-4, 4-2  
specification matching procedure, 4-8  
specification matching setup, 2-4  
specification maximum, 3-16  
specification minimum, 3-16  
Specifications tab, 1-15  
Specification Summary window, 4-54  
Specifications window, 3-19, 4-23  
specification validity rules, 1-4, 2-10, 4-7, 4-12, 5-4  
, 8-14  
specification validity rule status, 1-16  
Specification Validity Rules window, 4-23  
Spec Inventory Validity Rule Status Change  
Approval Notification, D-5  
Spec Monitoring Validity Rule Status Change  
Approval Workflow, D-5  
Spec Status Change Approval Notification, D-5  
Spec Supplier Validity Rule Status Change  
Approval Notification, D-5  
Spec WIP Validity Rule Status Change Approval  
Notification, D-5  
stability studies, 1-11, 8-4  
    accelerated testing, 8-4  
    additional testing, 8-14  
    attachment usage, 8-2  
    completion, 8-14  
    concluding the study, 8-14  
    container closure systems, 8-3  
    expiration dating, 8-3  
    FDA, 8-5  
    guidelines from FDA, 8-5  
    ICH conditions, 8-7  
    initial sampling material, 8-11  
    inventory organization, 8-9  
    item, 8-9  
    item revision, 8-9  
    launch, 8-13  
    lifecycle, 8-7  
    master item specification, 8-9  
    monitoring specification, 8-13  
    owner, 8-10  
    packaging, 8-12  
    pull samples for testing, 8-13  
    relative humidity, 8-8  
    results, communication of, 8-14

sample protocols, 8-6  
sample size, 8-5  
scheduled dates, 8-12  
setup, 8-8  
storage condition plan, 8-10  
storage condition recommendation, 8-4  
storage conditions, 8-5  
storage package, 8-12  
temperature, 8-8  
test accuracy, 8-3  
testing grace period, 8-10  
testing program, 8-2  
testing time points, 8-13  
test interval plan, 8-16  
test linearity, 8-3  
test methods, 8-5  
test reliability, 8-3  
test sensitivity, 8-3  
test specificity, 8-3  
workflow, 8-13

Stability Study Batch Creation Notification, D-6  
stability study batch creation workflow, D-47  
Stability Study Change Status Notification, D-6  
Stability Study Late Time Point Scheduling Notification, D-7  
Stability Study Lot Sample Notification, D-6  
stability study sample records, 5-13  
stability study status change workflow, D-42  
Stability Study Testing, D-6  
stability study testing workflow, D-49  
Stability Study Time Point Scheduling Notification, D-6  
stability study time point test workflow, D-50  
Stability Study window, 8-2, 8-26  
status, 2-2  
Status Approval Workflow, 4-12  
    disabling, 4-15  
    understanding, 4-13  
status codes, 4-13  
status codes, in status control, 4-17  
Status Codes window, 4-16  
Status Details window, 4-19  
storage condition, 8-8  
storage condition parameters, 8-8  
storage condition plan, 8-8, 8-10  
Storage Condition Plans window, 8-22  
storage conditions, 8-8

storage organization, 8-23  
Storage Packages window, 8-24  
storage requirements, in stability studies, 8-4  
STSI, 2-13  
subinventory, 4-37  
Subscriptions, E-6  
summary views, 1-14  
supplier samples, 5-3  
supply chain, sampling, 5-3  
system security profile, 1-2

---

**T**

targetexperimental errorregionexperimental error region., 3-15  
terminated batch, impact on samples taken, 5-4  
terminated batches, 5-35  
terminating batches, 5-8  
test  
    dependencies, 3-3  
test, certification, 7-14  
test class  
    creating test groups, 2-6  
Test Classes window, 2-4  
test data type, 3-6  
test definition, 3-2  
Test Details window, 6-31  
testing, quality, 1-4  
testing, stability, 8-4  
testing instruments, 3-3  
Testing Notification, D-4  
Testing Time Point Label Generation report, 8-12  
testing time points, 8-8  
test interval plan, 8-8, 8-10  
Test Interval Plan window, 8-16  
test method  
    adding edit text, 3-5  
    duplication, 3-4  
    purging, 3-5  
test method, attributes of, 3-3  
Test Methods window, 3-3  
test range, 3-6  
test result, interpreting, 3-3  
tests  
    Expression, 3-8  
    List of Test Values, 3-6  
    Non-Validated, 3-6

Numeric Range, 3-6  
Numeric Range with Display Text, 3-7  
scheduling, 3-3  
Text Range, 3-6  
Tests node, 1-15  
test-specific attributes, 3-3  
Tests window, 3-10, 3-15  
test unit, 2-8, 3-6  
test units, converting, 2-7  
test units, quality, 2-7  
Test Units window, 2-7, 2-8  
Text Range test, 3-6  
time-based sampling, 2-9  
time points, 8-8  
tolerance, in experimental error, 3-16  
tool palette, 1-13  
Transact Move Orders , 2-3

## **U**

---

U.S. Food & Drug Administration, 8-5  
Understanding License Plate Numbers for  
Containerization , 4-22  
unit of measure conversions, 2-1  
UOM conversion, 4-9  
UOM conversion workflow, D-54  
update inventory quantity, 2-15, 4-7

## **V**

---

validity rule, 1-4  
validity rules, 1-16  
validity rules, specification, 4-12, 8-14  
Validity Rules for Item Specifications window, 5-  
6, 5-13  
Validity Rules for Item Spec window, 2-9  
Validity Rules for Monitoring Spec window, 4-50  
Validity Rules Summary for Item Spec window,  
4-46  
Validity Rules Summary for Monitoring Spec  
window, 4-53  
variants, 8-8  
Variant Time Points window, 8-43  
Variant window, 8-35  
version control, 2-14  
Version Control, 4-18  
    Specification Version Control, 4-21  
version control, specifications, 4-21

View By functionality, 1-14  
View Samples For Test window, 6-37

## **W**

---

wildcard, use in search and replace, 1-24, 1-27  
WIP specification validity rule, use of, 6-9  
WIP Validity Rules, 1-16  
workflow  
    Status Approval, 4-12  
Workflow Automatic Notification Processing, D-  
4  
Workflow Notification Subsystem, D-4

## **X**

---

XML Gateway, D-4

