Oracle® Process Manufacturing

Quality Management User's Guide

Release 11*i*

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Oracle® Process Manufacturing Quality Management User's Guide, Release 11*i*

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If you find any errors or have any other suggestions for improvement, please indicate the chapter, section, and page number (if available). You can send comments to us in the following ways:

- FAX: 650-506-7200 Attn: Oracle Process Manufacturing
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If you would like a reply, please give your name, address, and telephone number below.

If you have problems with the software, please contact your local Oracle Support Services.

Preface

Welcome to the Oracle Process Manufacturing *Quality Management User's Guide*. This user's guide includes the information you need to work with the Oracle Process Manufacturing (OPM) application effectively.

This preface explains how this user's guide is organized and introduces other sources of information that can help you.

Intended Audience

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

This guide also assumes that you are familiar with the Oracle Applications graphical user interface. To learn more about Oracle Applications graphical user interface, read the *Oracle Applications User's Guide*.

About This Guide

This guide contains overviews as well as task and reference information. It includes the following:

Name	Description
Quality Control Setup	Explains how to set up action codes, quality control grades, quality control hold reasons, assay classes, inventory item quality control attributes, and lot status control

Test Specifications Setup	Explains basic concepts of test specifications and how to set up quality control assay units of measure, assay types, item / location specifications, customer / vendor specifications, and production specifications
Quality Control Sampling	Explains the fundamentals of quality control sampling, and how to run the Item / Location Required Analysis Report to identify inventory that may need quality control attention. Also explains how to sample materials from inventory, customers or vendors, and production
Recording Quality Control Results	Explains how to enter item / location results, customer / vendor results, and production results, change status and grade, and manage expired lots
Quality Control Reporting	Describes all quality control reports and inquiries
OPM Quality Control Workflows	Explains the OPM Quality Control Workflow including setup, startup, and, how to use the Sample Results Window
Appendix A	Explains typical navigation paths, specific Profile Options that need to be set up and discusses the use of the Graphical Process Navigator

Information Sources

You can choose from many sources of information, including documentation, training, and support services to increase your knowledge and understanding.

Online Documentation

Oracle Applications documentation is available on CD-ROM, except for technical reference manuals. User's guides are available in HTML format and on paper. Technical reference manuals are available on paper only. Other documentation is available on paper and sometimes in PDF format.

The content of the documentation remains the same from format to format. Slight formatting differences could occur due to publication standards, but such differences do not affect content. For example, page numbers are included on paper, but are not included in HTML.

The HTML documentation is available from all Oracle Applications windows. Each window is programmed to start your web browser and open a specific, context-sensitive section. Once any section of the HTML documentation is open, you can navigate freely throughout all Oracle Applications documentation.

Related Documents

Oracle Process Manufacturing shares business and setup information with other Oracle products. You may find the following Oracle Applications user's guides useful:

- *Oracle Applications User's Guide*
- *Oracle Application's Flexfields Guide*
- *Oracle Workflow User Guide*
- *Oracle Applications System Administrator's Guide*
- *Oracle General Ledger User's Guide*
- *Oracle Payables User's Guide*
- *Oracle Receivables User's Guide*
- *Oracle Human Resources North American User's Guide*
- *Oracle Purchasing User's Guide*

Oracle Process Manufacturing Guides

The following is a list of documentation in each product group for OPM:

Financials

- *Oracle Process Manufacturing Accounting Setup User's Guide*
- *Oracle Process Manufacturing Cost Management User's Guide*
- *Oracle Process Manufacturing Manufacturing Accounting Controller User's Guide*
- *Oracle Process Manufacturing and Oracle Financials Integration User's Guide*

Inventory Control

- *Oracle Process Manufacturing Intrastat Reporting User's Guide*
- *Oracle Process Manufacturing Inventory Management User's Guide*
- *Oracle Process Manufacturing Physical Inventory User's Guide*

Logistics

- *Oracle Process Manufacturing Order Fulfillment User's Guide*
- *Oracle Process Manufacturing Purchase Management User's Guide*

Process Execution

- *Oracle Process Manufacturing Process Operation Control User's Guide*
- *Oracle Process Manufacturing Production Management User's Guide*

Process Planning

- *Oracle Process Manufacturing Capacity Planning User's Guide*
- *Oracle Process Manufacturing Integration with Advanced Planning and Scheduling User's Guide*
- *Oracle Process Manufacturing MPS/MRP and Forecasting User's Guide*

Product Development

- *Oracle Process Manufacturing Formula Management User's Guide*
- *Oracle Process Manufacturing Laboratory Management User's Guide*
- *Oracle Process Manufacturing Quality Management User's Guide*

Regulatory

- *Oracle Process Manufacturing Regulatory Management User's Guide*

System Administration and Technical Reference

- *Oracle Process Manufacturing Implementation Guide*
- *Oracle Process Manufacturing System Administration User's Guide*
- Oracle Process Manufacturing Technical Reference Manuals

Training

Oracle offers a complete set of formal training courses to help you master Oracle Process Manufacturing and reach full productivity quickly. We organize these courses into functional learning paths, so you take only those courses appropriate to your area of responsibility.

You have a choice of educational environments. You can attend courses offered by Oracle Education Services at any one of our many Education Centers, or you can arrange for our trainers to teach at your facility. In addition, Oracle Training professionals can tailor standard courses or develop custom courses to meet your

needs. For example, you may want to use your organization's structure, terminology, and data as examples in a customized training session delivered at your own facility.

Conventions

The following conventions are used in this guide:

Bolded Text

Buttons, fields, keys, menus, and selections are bolded in procedures only. For example: To access the next window, click **OK**. Otherwise, references to these features appear in regular type.

Additional Menu Options

Only nonstandard menu options are discussed. Standard menu bar options (such as Save) are not discussed. These standard options are described in the *Oracle Applications User's Guide*. Only menu options unique to the use of the specific window are discussed.

Field References

References to fields within procedures are in bold type. References within the body of this guide appear in regular type.

Required Fields

The word Required appears as the last word in the field description of all required fields. When the field is required contingent on the entry in another field, or only in specific situations, "Required if..." is the last sentence of the field description.

Fields Reserved for Future Use

Fields with no current processing implications are referenced by the statement "This field is not currently used" or "Reserved for future use." Do not use these fields for your own reference data, because there are plans to link future functionality to these fields. Fields intended for informational purposes only are referenced by the statement "This field is for informational purposes only."

Pending/Completed Transactions

Discussions about processing transactions that use the words pending and completed refer to the status of a transaction. Pending and completed do not refer to the database tables that are updated as a result of transactions (for example, some completed transactions are stored in the Pending Transactions table).

Procedures

Most topics contain a procedure with numbered steps. Any actions which are subordinate to a step are assigned letters. You can customize your Oracle Application, therefore, all procedures are suggestive only. Navigate to windows and between responsibilities in a way that works best for your particular setup. Also note that fields may appear in a different order than they are discussed.

Use of the Word Character

The word character means an alphanumeric character. Characters that are numeric or alphabetic only are referenced specifically. Depending on your system security profile, you many not have access to all of the windows and functions described in this guide. If you do not see a menu option described in this guide, and you want access to it, contact your System Administrator.

Do Not Use Database Tools to Modify Oracle Applications Data

Oracle Applications tables are interrelated. As a result, any change you make using Oracle Applications can update many tables at once. If you modify the Oracle Applications data using anything other than Oracle Applications, you could change a row in one table without making corresponding changes in related tables. If your tables are not synchronized with each other, you risk retrieving erroneous information and receiving 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 track who changes information. If you enter information into database tables using database tools, you could 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.

Consequently, we strongly recommend that you never use SQL*Plus or any other tool to modify Oracle Applications data unless otherwise instructed by Oracle Support Services.

About Oracle

Oracle Corporation develops and markets an integrated line of software products for database management, applications development, decision support, and office automation, as well as Oracle Applications, an integrated suite of more than 45 software modules for financial management, supply chain management, manufacturing, project systems, human resources, sales, and service management.

Oracle Products are available for mainframes, minicomputers, personal computers, network computers, and personal digital assistants, allowing organizations to integrate different computers, different operating systems, different networks, and even different database management systems, into a single, unified computing, and information resource.

Oracle is the world's leading supplier of software for information management, and the world's second largest software company. Oracle offers its database, tools, and applications products, along with related consulting, education, and support services in over 140 countries around the world.

Thank You

Thank you for choosing Oracle Process Manufacturing and this user's guide.

We value your comments and feedback. At the beginning of this guide is a Reader's Comment Form that you can use to explain what you like or dislike about this user's guide. Mail your comments to the following address or call us directly at 650-506-7000.

Oracle Applications Documentation Manager
Oracle Corporation
500 Oracle Parkway
Redwood Shores, CA 94065
U.S.A.

Or, send an electronic mail message to appsdoc@us.oracle.com

1

Quality Control Setup

This topic explains how to set up action codes, quality control grades, quality control hold reasons and inventory item quality control attributes. You will also be shown how to set up lot status control. Once you have entered your lot grading scheme and hold reasons you can configure the default quality control attributes for lot items.

The following topics are covered:

- Setting Up Action Codes
- Setting Up Quality Control Grades
- Setting Up Quality Control Hold Reasons
- Setting Up Assay Classes
- Setting Up Inventory Item Quality Control Attributes
- Setting Up Lot Status Control

Setting Up Action Codes

Action codes state what should be done to items that expire or do not meet quality control test specifications. Once established, you assign them as the default actions for items and lots. The action is then displayed for the item on quality control reports.

Setting Up Action Codes Procedure

To set up Action codes:

1. Navigate to the **Actions** window.
2. Complete the fields as described.
3. Save the window.

Action Codes Field Reference

The fields on this window are:

Code

Enter a Code to identify this action. For example, enter DES for Destroy. Required.

Description

Enter a description of the action to be taken. This is displayed for items and lots assigned this action. For example, enter Destroy. Required.

Interval

Depending on how you implement action codes, you can enter one of the following in this field:

- 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 control test date that the action must be taken.

Setting Up Quality Control Grades

Grades represent the quality rating you assign to an item / lot as part of the item's quality control specifications. Grades are usually based on certain criteria, such as color or size.

Grade is a characteristic of an item lot, *never* a location. When you change the quality control grade of an item lot, specifying the warehouse location of that lot does *not* assign a quality control grade to the location. Items must be lot and grade controlled in order to enter grades for them.

Setting Up Quality Control Grades Procedure

To set up quality control grade codes, proceed as follows:

1. Navigate to the **Grades** window.
2. Complete the fields as described.
3. Save the window.

Grades Field Reference

The fields on this window are:

Grade

Enter a code to identify this grade. For example, type A for Grade A or type AAA for Grade AAA. Required.

Description

Enter a description of this grade. For example, type Grade A. Required.

Setting Up Quality Control Hold Reasons

Hold reason codes are used to place a hold on an item or lot that has expired or failed a quality control test. The hold reason description is displayed for the item/lot indicating that it should not be sold or used for production.

You assign a default hold reason to assays (the measurements you plan to take on items and lots). When you enter "out of specification" test results for an item, the hold reason is assigned to the item/lot indicating that it should not be sold or used for production.

Setting Up Quality Control Hold Reasons Procedure

To set up Hold Reasons codes:

1. Navigate to the **Hold Reasons** window.
2. Complete the fields as described.
3. Save the window.

Hold Reasons Field Reference

The fields on this window are:

Reason Code

Enter a code to identify this quality control hold reason. For example, BLW for Below Grade. Required.

Description

Enter a description for this hold reason code. For example, Below Grade. This description will display for items/lots to which it is assigned. Required.

Setting Up Assay Classes

Assay Classes help you group specific assays into meaningful sets for purposes of evaluating them or managing them in workflows. You could set up basic classes for each assay type.

Here are some examples. Please note, these are not actual values.

- CHEMICAL - a class containing measurements of: pH, sweetness, or organic content
- MICROBIOLOGIC - a class containing bacterial-, fungal-, or viral assays
- PHYSICAL - a class containing measurements of: specific gravity, hardness, or visual opacity

Setting Up Assay Classes Procedure

To set up Assay Classes proceed as follows:

1. Navigate to the **Assay Classes** window.
2. Complete the fields as described.
3. Save the window.

Assay Classes Field Reference

The fields on this window are:

Class

Enter the name of the assay class. Required.

Description

Enter a description of the assay class. Required.

Setting Up Inventory Item Quality Control Attributes

Once you have established action, grade, and hold reason codes, you can use them to set default attributes for inventory items. Quality control attributes include grade and lot status control.

Inventory Item Quality Control Attributes Grade Control

An item must be lot controlled in order to establish quality control grade or lot status control. In addition, an item must be grade controlled in order to establish its default quality control attributes. You must verify that Lot and Grade are set to Yes on the Items window. If they have been set to No, and transactions are logged against the item, you cannot change the status to Yes. A new item must be created to reflect new default quality control attributes.

Setting Up Inventory Item Quality Control Attributes Procedure

To set up default quality control attributes for an item:

1. From the **OPM Inventory Control** main menu choose **Setup**.
2. Navigate to the **Items** window.
3. Verify that **Lot** and **Grade** on the **Controls** region have been set to **Yes**.
4. From the **Actions** menu, choose **Additional Information**.
5. Complete the fields as described.
6. Save the window.

Inventory Item Quality Control Attributes Field Reference

The fields on this window are:

Retest Interval

Enter a number (in days) in this field. OPM adds this number to the lot creation date to establish the default retest date for the lot/sublot.

Shelf Life

Enter a number (in days) in this field. OPM adds this number to the lot creation date to establish the expiration date for the lot/sublot.

Hold Reason

This field defaults to the default hold reason code NONE when you are initially setting up Item quality control attributes, but may be changed to any valid hold reason code.

Expiration Interval

Enter a number (in days) in this field. OPM adds this number to the expiration date (calculated from the previous field) to establish the date on which the action (entered in the next field) should be taken.

Action Code

Enter the default action code for this item. This is the action to be taken when this item / lot expires or fails a quality control test.

Setting Up Lot Status Control

Controlling the usability of purchased or produced items is a task often associated with Quality Control. With lot status control, OPM allows you to identify the use of lot-controlled material in production, order processing, or shipping. Once it has been determined that a sample does not meet quality control specifications or has failed quality control tests, you need to change the status of the sample lot for certain purposes in production or shipping.

The first step is to define each Lot Status and its associated permissions (described below). Later, after quality control tests have been performed, you may need to change the status of lots in order to prevent them from being sold or used for production. See also *Changing Lot Status* for more information.

Setting Up Lot Status Control Procedure

To set up lot status control:

1. From the **OPM Inventory Control** main menu choose **Setup**.
2. Navigate to the **Lot Status** window.
3. Complete the fields as described.
4. Save the window.

Lot Status Control Field Reference

The fields on this window are:

Lot Status

Enter a code for a lot status that you wish to assign to an item/lot. For example, enter PEND for Pending quality control approval. Remember that you will ultimately assign these statuses to lots as a default. You should create lots statuses for: holding inventory, the initial status of a lot that was just produced or received, and for any interim production steps. Required.

Description

Enter a description for this lot status. For example, Pending Quality Control Approval. Required.

Hold Reason

If this status is preventing a lot/item from being released, enter the hold reason that defaults for this status.

Indicators

Nettable

This field determines whether a lot is included in material requirements planning (MRP).

- Select Yes if the lot is to be included in MRP.
- Select No if it is not to be included in MRP.

Required.

Order Processing

This field determines if a lot with this status can be used for processing an order. Select Yes if the lot can be used for processing an order or select No if it cannot be used for processing an order. Required.

Rejected

For material that does not meet quality control specifications, you can establish a lot status of Rejected. Required.

- Select Yes if the lot that has been rejected should not be used for anything.
- Select No if the lot has not been rejected.

Required.

Production

This field determines if a lot with this status can be used to produce product. Select Yes if the lot can be used in production or select No if it cannot be used in production. Required.

Shipping

This field determines if a lot with this status can be shipped to a customer. Select Yes if the lot can shipped or select No if the lot cannot be shipped. Required.

2

Test Specifications Setup

This topic explains the basic concepts of test specifications. You are shown how to set up assay types. You are also shown how to set up specifications for item / location, customer / vendor and production.

The following topics are covered:

- Understanding Test Specifications
- Setting Up Quality Control Assay Units of Measure
- Setting Up Assay Types
- Setting Up Quality Control Item / Location Specifications
- Setting Up Customer / Vendor Specifications
- Setting Up Production Specifications

Understanding Test Specifications

Specifications identify the target, or ideal result, of a quality control assay test performed on an item or lot. Once you have completed the initial quality control setup, you can combine the assay codes and item attributes to devise test specifications for specific items and lots.

You can also define specifications for each item / lot in your inventory for each customer or vendor that you sell to or buy from, or for each formula / production batch that you produce. The specifications you enter are used by OPM to compare against actual test results that you enter.

Setting Up Quality Control Assay Units of Measure

Before you can define the quality control tests that can be performed, you must first define the units in which to measure them. For example, if a quality control test (assay) is performed for saturation, you need to establish the unit of measure for saturation such as PPM (parts per million).

Quality control units of measure differ from inventory units of measure.

Setting Up Quality Control Assay Units of Measure Procedure

To set up quality control assay units of measure:

1. Navigate to the **Units** window.
2. Complete the fields as described.
3. Save the window.

Units Field Reference

The fields on this window are:

Unit

Enter a code to identify the quality control unit of measure. For example, enter PPM as the unit code for parts per million. Required.

Description

Enter a description for the quality control unit of measure code. For example, enter Parts per million. Required.

Setting Up Assay Types

Once you have established quality control units of measure, you can define the measurements to be taken for items and lots. These measurements, called assays, define all the attributes or characteristics you plan to measure and record in quality control. For example: concentration, saturation, temperature, viscosity, color, or flavor.

You can set up three assay types:

- Not Validated: You enter an assay code, description, and quality control unit of measure. Test results for this assay type are simply recorded for future evaluation against the assay value. Test results will not cause the item / lot to be rejected. The assay value is a freeform attribute that does not require validation.
- Numeric Range: You enter an assay code, description, and range of acceptable values for the assay. If the item / lot falls outside this range it will be rejected. For example, a glucose assay may have a full functional range of 20 to 300 g / dL. Values outside this assay range would not be acceptable.
- List of Specifications: You enter an assay code, description, and list of valid values for this assay type. For example, Clear or Turbid could be listed here. Test results must match an entry in the list.

Setting Up Assay Types Procedure

To set up assay types:

1. Navigate to the **Assays** window.
2. Complete the fields as described.
3. Save the window.

You can use Attachments with this window. See *Oracle Applications* for detailed information on attachments and folders.

Assays Window Field Reference

Organization

Defaults to your default organization. The assay code you enter will be effective only for that organization (a local assay code). If you wish this assay code to apply to all organizations (a global assay code) leave this field blank.

If an assay is associated with a specific organization it is a local assay. This means it is effective for that organization only. If you delete the organization, the assay is global, making it available to all organizations.

Assay Details

Assay

Enter a code name to represent this assay. For example, you can enter SLV for the assay of percent solvent. You can also enter CLR for a qualitative visual assay of sample clarity. Required.

Description

Enter a description for this assay code. For example, Percent Solvent. Required.

Assay Class

Enter the assay class code for this assay type.

Type

You must select one of the following assay types:

- Select Not Validated if you do not want test results to cause the item / lot to be rejected. You must enter an assay code, description, and quality control unit of measure. Test results are simply recorded for future evaluation against the assay value. Test results will not cause the item / lot to be rejected.
- Select Numeric Range if you want an item / lot falling outside a specified range to be rejected. You enter an assay code, description, and range of acceptable values.
- Select List of Specifications if you want an item / lot to match an entry in a specific list of values. You must enter an assay code, description, and then a list of valid values for the assay specification.

Depending on selection of assay type, the remaining fields on the window will vary. Refer to the Assay Values tabbed region of the Assays window. For example, if you select Numeric Range, the Range fields will be editable. If you select List of Specifications, the Value and Description fields will be editable. Required.

UOM

Enter the quality control unit of measure code for this assay. For example PPM for parts-per-million. Setting up quality control units of measure is described previously in this section. Required.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Assay Values

Range

(For Numeric Range Assay Types only) Enter the lower limit of the range for the test method in the left text box. Enter the upper limit of the range in the right text box. You will define the target value in the specification. For example: pH would have an assay range of 0 to 14, but an item could have a pH specification range of 4.2 to 6.7.

Value

(For List of Specifications Assay Types only) Enter a list of values to match for item / lot acceptability. You will define the target value in the specification. Enter only 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.

Description

(For List of Specifications Assay Types only) Enter a brief value description.

Setting Up Quality Control Item/Location Specifications

You can define the specifications required for a particular inventory item / lot / sublot. Specifications can be for a particular item location in a warehouse or for all items / lots / sublots in all warehouses and locations. There is a hierarchy of specifications for item / location:

- Item is always required.
- Organization + (Lot OR Lot + Sublot if item is sublot controlled) + Warehouse + Location
- (Lot OR Lot + Sublot if item is sublot controlled) + Warehouse + Location
- Organization + (Lot OR Lot + Sublot if item is sublot controlled) + Warehouse
- (Lot or Lot + Sublot if item is sublot controlled) + Warehouse
- Organization + (Lot OR Lot + Sublot if item is sublot controlled)
- (Lot OR Lot + Sublot if item is sublot controlled)
- Organization + Warehouse + Location
- Warehouse + Location
- Organization + Warehouse
- Warehouse

You can establish multiple specifications for an item. For each assay you can establish the target specification (most desired result) and the preference or priority for the assay with respect to all other quality control specifications defined for an item. You must specify a date range within which the specification is effective. For range-validated assays (see also the discussion of Assay Types) you can further define the minimum and maximum acceptable range values for the assay on the specification window, as well as the "out-of-specification" action to be performed for items that fail assay tests or become expired.

You can enter quality control item / location specifications from this application, or from any of the following OPM windows, available from the Inventory Control application:

- Item Master
- Lot / Sublot
- Warehouses
- Location

Setting Up Quality Control Item/Location Specifications Procedure

To enter quality control item / location specifications:

1. Navigate to the **Item/Location Specifications** window.
2. Select one of the following:
    1. Select **Effectivity** to specify a From Date and a To Date for the Assay and Specification you define. You will need to enter the Assay code (which can be Global or Local), Specification, From Date, and To Date.
    2. Select **Out of Specification** to define the Action to be taken on an item which falls outside the defined assay specification.
3. Complete the fields as described.
4. Save the window.

Item/Location Specifications Field Reference

The fields on this window are:

Item/Location Specifications

Organization

Defaults to your default organization. The inventory specifications you enter will be effective only for that organization (a local specification code). The default organization code is assigned to your user code using the User Codes window. If you wish this specification to apply to all organizations (a global specification) leave this field blank.

If an specification is associated with a specific organization it is a local specification. This means it is effective for that organization only. If you delete the organization, the specification is global, making it available to all organizations.

Item

Enter the item code for which you are assigning quality control test specifications. Required.

Lot

If this field is dimmed, the item is not lot controlled. If the item is lot controlled, the field will be editable. To enter specifications for an item in a specific lot, enter the lot code in this field. Otherwise leave the field blank to indicate all lots.

Inventory item lot control is set up on the Items window.

Sublot

This field is editable only if the item you entered is lot controlled, otherwise it will be dimmed and blank. To enter specifications for an item in a specific sublot, enter the sublot code in this field. Inventory item lot control is set up on the Items window.

Warehouse

If you want to enter specifications for an item in a particular warehouse, enter the warehouse code in this field. Otherwise, leave the field blank to indicate all warehouses.

Location

Locations are created in the Inventory Management application. If the item and warehouse have location control, and you want this specification to be for a specific location, you can enter the location in this field. Otherwise leave this field blank for all locations.

Assay Details

Effectivity Region

Assay

Enter a predefined assay code for this item specification. The assay code identifies the characteristics of the item that will be tested. You can set up multiple assays for this item by entering multiple lines of assays. For a local specification, you can enter either a local or a global assay. Required.

Specification

Enter the target specification for the assay code in this line. Depending on the assay type entered, the specification may vary. For example:

- For nonvalidated assays, any entry is accepted in this field, including a blank.
- For range validated assays, you must enter a value within the range specified for the assay. The assay minimum/maximum range is the default. If you wish to tailor the range specifically for the assay as it relates to your particular specification, navigate to the Range fields and type over the default values.

- For value list assays, you must enter a valid value from the list of values for the assay.

UOM

This field automatically displays the quality control unit of measure set up for this assay.

Preference

(Effectivity or Out of Specification) This field is used to prioritize the assay test results you enter for this item. For example, you can establish up to four different types of specifications for an item:

- Customer specifications
- Vendor specifications
- Item / location specifications
- Production specifications

You can specify multiple assay tests for the item. The entry you make in this field (1 - 9999) determines the priority level of the assay and specification shown on this line in relation to other specifications established for this item. This field defaults to 1 (which is the highest priority).

Click on a selection from the Effectivity / Out of Specification tabbed region to determine the fields that are displayed on the window.

From Date

If you intend this specification to be effective for a limited period of time, enter the beginning date for this specification. Use this field and the next field (To Date) together to set up several specifications for one item with or without overlapping dates. Required.

To Date

If you intend this specification to be effective for a limited period of time, enter the ending date for this specification.

Use this field and the previous field (From Date) together to set up several specifications for one item without overlapping dates.

See the *Oracle Process Manufacturing System Implementation User's Guide* for more information on minimum and maximum system dates.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Range

Enter a range for a numeric range (validated) assay if you wish to filter the range values for an assay to target the needs of a particular specification:

- (Left field) Enter the minimum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.
- (Right field) Enter the maximum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.

Assay Description

Displays a description of the Assay selected in either the Effectivity or the Out of Spec panel.

Out of Spec(ification) Region

Assay

Enter a predefined assay code for this item specification. The assay code identifies the characteristics of the item that will be tested. You can set up multiple assays for this item by entering multiple lines of assays. For a local specification, you can enter either a local or a global assay. Required.

Specification

Enter the target specification for the assay code in this line. Depending on the assay type entered, the specification may vary. For example:

- For nonvalidated assays, any entry is accepted in this field, including a blank.
- For range validated assays, you must enter a value within the range specified for the assay. The assay minimum / maximum range is the default. If you wish to tailor the range specifically for the assay as it relates to your particular specification, navigate to the Range fields and type over the default values.
- For value list assays, you must enter a valid value from the list of values for the assay.

UOM

This field automatically displays the quality control unit of measure set up for this assay.

Preference

This field is used to prioritize the assay test results you enter for this item. For example, you can establish up to four different types of specifications for an item:

- Customer specifications
- Vendor specifications
- Item / location specifications
- Production specifications

You can specify multiple assay tests for the item. The entry you make in this field (1 - 9999) determines the priority level of the assay and specification shown on this line in relation to other specifications established for this item. This field defaults to 1 (which is the highest priority).

Action

Enter the code representing the action to be taken on this item if the specification is not met.

Description

The default description for the Action code is displayed here. Action codes are set up using the Actions window.

Interval

If you specified an action to be taken for this item in the Out of Specification Action field, the Interval value defaults from the Action Code data input. It represents the number of days after the date the result was entered that the indicated action must be taken.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Range

Enter a range for a numeric range (validated) assay if you wish to filter the range values for an assay to target the needs of a particular specification:

- (Left field) Enter the minimum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.
- (Right field) Enter the maximum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.

Assay Description

Displays a description of the Assay selected in either the Effectivity or the Out of Spec panel.

Setting Up Customer/Vendor Specifications

You can define the specifications to be taken for a particular customer's products or for a particular vendor's supplies.

There is a hierarchy for customer or vendor specification setup:

- Item is always required.
- Organization + Customer OR Organization + Vendor
- Customer OR Vendor

You can establish multiple specifications for an item, and for each assay you can establish the target specification (most desired result) and the preference for the assay with respect to all other quality control specifications defined for the item. In addition, you can specify a date range within which the specification is effective.

For range-validated assays (see the discussion of Assay) you can define the minimum and maximum acceptable range values for the assay, as well as the "out-of-specification" action to be performed for items that fail assay tests or becomes expired. If no Customer / Vendor Specification is defined and you obtain a Customer / Vendor sample, you will be asked if you wish to use the Item / Location Specification.

You can enter quality control customer / vendor specifications directly from the OPM quality control application, or from any of the following OPM windows:

- Customers (Order Fulfillment)
- Generic Items (Order Fulfillment)
- Vendors (Purchase Management)

Vendor Items (Purchase Management)

The application from which each window may be selected is shown in parentheses.

Setting Up Customer/Vendor Specifications Procedure

To enter Customer / Vendor specifications:

1. Navigate to the **Customer/Vendor Specifications** window.
2. Select one of the following:
    1. Select **Effectivity** to specify a From Date and a To Date for the Assay and Specification you define. You will need to enter the Assay code (which can be Global or Local), Specification, From Date, and To Date.

2. Select **Out of Specification** to define the Action to be taken on an item which falls outside the defined assay specification.

3. Complete the fields as described.

4. Save the window.

Customer/Vendor Specifications Field Reference

The fields on this window are:

Organization

Defaults to your default organization. The customer / vendor specifications you enter will be effective only for that organization (a local specification code). The default organization code is assigned to your user code using the User Codes window. If you wish this specification to apply to all organizations (a global specification) leave this field blank.

If an customer / vendor specification is associated with a specific organization it is a local specification. This means it is effective for that organization only. If you delete the organization, the specification is global, making it available to all organizations.

Customer

If you are setting up customer specifications, enter the customer code for whom this specification is effective. Otherwise leave this field blank if you are establishing a Vendor specification. This field is inaccessible if you entered a vendor code in the Vendor field.

Vendor

If you are setting up vendor specifications, enter the vendor code for whom this specification is effective. Otherwise leave this field blank if you are establishing a Customer specification. This field is inaccessible if you entered a customer code in the Customer field.

Item

Enter the item for which this specification is effective. Required.

Assay Details

Effectivity Region

Assay

Enter an assay code for this customer / vendor item specification. The assay code identifies the characteristics of the item that will be tested. For a local specification, you can enter either a local or global assay. You can set up multiple assays for this item by entering multiple lines of assays. Required.

See also Assays for more information.

Specification

Enter the target specification for the assay code entered on this line. Depending on the assay type entered, the specification may vary. For example:

- For nonvalidated assays, any entry is accepted in this field, including a blank.
- For range validated assays, you must enter a value within the range specified for the assay. The assay minimum / maximum range is the default. If you wish to tailor the range specifically for the assay as it relates to your particular specification, navigate to the Range fields and type over the default values.
- For value list assays, you must enter a valid value from the list of values for the assay.

UOM (Unit of Measure)

This field automatically displays the quality control unit of measure set up for this assay.

Preference

This field is used to prioritize (on quality control reports) the assay test results you enter for this item. For example, you can establish up to four different types of specifications for an item:

- Customer specifications
- Vendor specifications
- Item / location specifications
- Production specifications

Within each type, you can specify multiple assay tests for the item. The entry you make in this field (1 - 9999) determines the priority level of the assay and specification shown on this line in relation to other specifications established for this item. This field defaults to 1 (highest priority). Required.

From Date

If you intend this specification to be effective for a limited period of time, enter the beginning date for this specification. Use this field and the next field (To Date) together to set up several specifications for one item without overlapping dates. Required.

To Date

If you intend this specification to be effective for a limited period of time, enter the ending date for this specification. Use this field and the previous field (From Date) together to set up several specifications for one item without overlapping dates.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Range

Enter a range for a numeric range (validated) assay if you wish to filter the range values for an assay to target the needs of a particular specification:

- (Left field) Enter the minimum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.
- (Right field) Enter the maximum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.

Assay Description

Displays a description of the Assay selected in either the Effectivity or the Out of Spec panel.

Certificate of Analysis Required

- Shipment is selected if a Certificate of Analysis is required by the customer when goods are shipped. This field is informational only and is accessible if this is a customer specification.

- Invoice is selected if a Certificate of Analysis is required by the customer when goods are invoiced. This field is informational only.
- Vendor Receipt is selected if a Certificate of Analysis is required from the vendor. This field is informational only and is accessible only when this is a vendor specification.

Out of Specification Region

Assay

Enter an assay code for this customer / vendor item specification. The assay code identifies the characteristics of the item that will be tested. For a local specification, you can enter either a local or global assay. You can set up multiple assays for this item by entering multiple lines of assays. Required.

See also Assays for more information.

Specification

Enter the target specification for the assay code entered on this line. Depending on the assay type entered, the specification may vary. For example:

- For nonvalidated assays, any entry is accepted in this field, including a blank.
- For range validated assays, you must enter a value within the range specified for the assay. The assay minimum / maximum range is the default. If you wish to tailor the range specifically for the assay as it relates to your particular specification, navigate to the Range fields and type over the default values.
- For value list assays, you must enter a valid value from the list of values for the assay.

UOM (Unit of Measure)

This field automatically displays the quality control unit of measure set up for this assay.

Preference

This field is used to prioritize (on quality control reports) the assay test results you enter for this item. For example, you can establish up to four different types of specifications for an item:

- Customer specifications
- Vendor specifications

- Item / location specifications
- Production specifications

Within each type, you can specify multiple assay tests for the item. The entry you make in this field (1 - 9999) determines the priority level of the assay and specification shown on this line in relation to other specifications established for this item. This field defaults to 1 (highest priority). Required.

Action

Enter the code representing the action to be taken on this item if the specification is not met.

Description

The default description for the Action code is displayed here.

Action codes are set up using the Actions window.

Interval

If you specified an action to be taken for this item in the Out of Specification Action field, the Interval value defaults from the Action Code data input. It represents the number of days after the date the result was entered that the indicated action must be taken.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Range

Enter a range for a numeric range (validated) assay if you wish to filter the range values for an assay to target the needs of a particular specification:

- (Left field) Enter the minimum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.
- (Right field) Enter the maximum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.

Assay Description

Displays a description of the Assay selected in either the Effectivity or the Out of Spec panel.

Certificate of Analysis Required

- Shipment is selected if a Certificate of Analysis is required by the customer when goods are shipped. This field is informational only and is accessible if this is a customer specification.
- Invoice is selected if a Certificate of Analysis is required by the customer when goods are invoiced. This field is informational only.
- Vendor Receipt is selected if a Certificate of Analysis is required from the vendor. This field is informational only and is accessible only when this is a vendor specification.

Setting Up Production Specifications

You can define the production test specifications for any item that you produce or consume during production. You can establish the specifications for any combination of production batch, formula, routing, routing step or operation.

There is a hierarchy for setting up production specifications:

- Organization + Batch + Formula + Routing + (Routing Step OR Operation)
- Batch + Formula + Routing + (Routing Step OR Operation)
- Organization + Batch + Formula + Routing
- Batch + Formula + Routing
- Organization + Batch + Formula
- Batch + Formula
- Organization + Formula + Routing + (Routing Step OR Operation)
- Formula + Routing + (Routing Step OR Operation)
- Organization + Formula + Routing
- Formula + Routing
- Organization + Formula + Operation OR Organization + Routing + (Routing Step OR Operation) (Depending Upon Preference)
- Formula + Operation OR Routing + (Routing Step OR Operation) (Depending Upon Preference)
- Formula OR Routing (Depending Upon Preference)
- Operation

You can establish multiple specifications for an item. For each assay you can establish the target specification (most desired result) as well as the preference for the assay with respect to all other quality control specifications defined for the item. In addition, you can specify a date range within which the specification is effective.

For range-validated assays (see also the discussion of Assay Types) you can define the minimum and maximum acceptable range values for the assay, as well as the "out-of-specification" action to be performed for items that fail assay tests or become expired.

You can enter quality control production specifications directly from the OPM quality control application, or from any of the following OPM windows:

- Formulas (Formulas)
- View Effectivities (Formulas)
- Routings (Formulas)
- Operations (Formulas)
- Batches (Production)

Setting Up Production Specifications Procedure

To enter Production specifications:

1. Navigate to the **Production Specifications** window.
2. Select one of the following:
    1. Select **Effectivity** to specify a From Date and a To Date for the Assay and Specification you define. You will need to enter the Assay code (which can be Global or Local), Specification, From Date, and To Date.
    2. Select **Out of Specification** to define the Action to be taken on an item which falls outside the defined assay specification.
3. Complete the fields as described.
4. Save the window.

Production Specifications Field Reference

The fields on this window are:

Organization

Defaults to your default organization. The production specifications you enter will be effective only for that organization (a local specification code). The default organization code is assigned to your user code using the User Codes window. If you wish this specification to apply to all organizations (a global specification) leave this field blank.

If a specification is associated with a specific organization it is a local specification. This means it is effective for that organization only. If you delete the organization, the specification is global, making it available to all organizations.

Of the following four fields (Batch, Formula Number, Routing Number, or Operation) that display on the production Specifications window, at least one is required to create a production specification.

Batch

Enter the batch number for which this specification is effective. Otherwise, leave the field blank indicate all batches.

Formula Number

Enter the formula number for which this specification is effective. Otherwise, leave the field blank to indicate all formulas.

Version (Formula)

If you enter a formula number for this specification, enter the applicable formula version number in this field. This field defaults to 1.

Routing Number

Enter the formula routing number for which this specification is effective. Otherwise, leave the field blank to indicate all routings. Required.

Version (Routing)

If you enter a routing number for this specification, enter the applicable routing version number in this field. This field defaults to 1.

Routing Step

If you enter a routing number, you can also enter a specific step in that routing to which you want to the test to apply.

Operation

Enter the Operation for which this specification is effective. Otherwise, leave the field blank to indicate all operations. Required.

Item

Enter the Item for which this specification is effective. The item must be a valid component of the Formula. Required.

Description

The item description displays in this field. It is informational only.

Effectivity Region

Assay

Enter an assay code for this production specification. The assay code identifies the characteristics of the item that will be tested. For a local specification, you can enter either a local or global assay. You can set up multiple assays for this item by entering multiple lines of assays. Required.

See also Assays for more information.

Specification

Enter the target specification for the assay code in this line. Depending on the assay type entered, the specification may vary. For example:

- For nonvalidated assays, any entry is accepted in this field, including a blank.
- For range validated assays, you must enter a value within the range specified for the assay. The assay minimum / maximum range is the default. If you wish to tailor the range specifically for the assay as it relates to your particular specification, navigate to the Range fields and type over the default values.
- For value list assays, you must enter a valid value from the list of values for the assay.

Unit

This field automatically displays the quality control unit of measure set up for this assay.

Preference

This field is used to prioritize (on quality control reports) the assay test results you enter for this item. For example, you can establish up to four different types of specifications for an item:

- Customer specifications
- Vendor specifications
- Item / location specifications
- Production specifications

Within each type, you can specify multiple assay tests for the item. The entry you make in this field (1 - 9999) determines the priority level of the assay and specification shown on this line in relation to other specifications established for this item. This field defaults to 1 (highest priority).

The selection your make for Effectivity or Out of Specification tabbed region will determine the fields that are displayed on the window.

From Date

If you intend this specification to be effective for a limited period of time, enter the beginning date for this specification. Use this field and the next field (To Date) together to set up several specifications for one item without overlapping dates. Required.

To Date

If you intend this specification to be effective for a limited period of time, enter the ending date for this specification. Use this field and the previous field (From Date) together to set up several effective specifications for one item without overlapping dates.

See *Oracle Process Manufacturing System Administration* for more information on minimum and maximum system dates.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Range

Enter a range for a numeric range (validated) assay if you wish to filter the range values for an assay to target the needs of a particular specification:

- (Left field) Enter the minimum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.
- (Right field) Enter the maximum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.

Assay Description

Displays a description of the Assay selected in either the Effectivity or the Out of Spec panel.

Out of Spec(ification) Region

Assay

Enter an assay code for this production specification. The assay code identifies the characteristics of the item that will be tested. For a local specification, you can enter either a local or global assay. You can set up multiple assays for this item by entering multiple lines of assays. Required.

See also Assays for more information.

Specification

Enter the target specification for the assay code in this line. Depending on the assay type entered, the specification may vary. For example:

- For nonvalidated assays, any entry is accepted in this field, including a blank.
- For range validated assays, you must enter a value within the range specified for the assay. The assay minimum / maximum range is the default. If you wish to tailor the range specifically for the assay as it relates to your particular specification, navigate to the Range fields and type over the default values.
- For value list assays, you must enter a valid value from the list of values for the assay.

Unit

This field automatically displays the quality control unit of measure set up for this assay.

Preference

This field is used to prioritize (on quality control reports) the assay test results you enter for this item. For example, you can establish up to four different types of specifications for an item:

- Customer specifications
- Vendor specifications
- Item / location specifications

- Production specifications

Within each type, you can specify multiple assay tests for the item. The entry you make in this field (1 - 9999) determines the priority level of the assay and specification shown on this line in relation to other specifications established for this item. This field defaults to 1 (highest priority).

The selection your make for Effectivity or Out of Specification tabbed region will determine the fields that are displayed on the window.

Action

Enter the code representing the action to be taken on this item if the specification is not met.

Description

The default description for the Action code is displayed here.

Action codes are set up using the Actions window.

Interval

If you specified an action to be taken for this item in the Out of Specification Action field, the Interval value defaults from the Action Code data input. It represents the number of days after the date the result was entered that the indicated action must be taken.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Range

Enter a range for a numeric range (validated) assay if you wish to filter the range values for an assay to target the needs of a particular specification:

- (Left field) Enter the minimum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.
- (Right field) Enter the maximum acceptable specification value. The value defaults from the assay range on the screen. Assay values are specified using the Assays window.

Assay Description

Displays a description of the Assay selected in either the Effectivity or the Out of Spec panel.

3

Quality Control Sampling

This topic explains the fundamentals of quality control sampling. You are shown how to run the Item / Location Required Analysis Report to identify inventory that may need quality control attention. You are also shown how to sample materials from inventory, customers or vendors, and production.

The following topics are covered:

- Understanding Quality Control Sampling
- Running the Item / Location Required Analysis Report
- Sampling Materials from Inventory
- Sampling Customer / Vendor Materials
- Sampling Production Materials

Understanding Quality Control Sampling

The materials you will need to sample are identified within OPM as follows:

- Materials drawn directly from inventory
- Materials associated with a customer or vendor
- Materials associated with a formula or production batch

Before you sample any of the types of materials mentioned above, you could generate a report that specifically tells you the inventory and locations from which to sample.

This topic discusses the sampling functions of the OPM Quality Control application as well as the report required to perform sampling.

Running the Item/Location Required Analysis Report

The Item / Location Required Analysis Report allows you to identify inventory that may need quality control attention. The report prints the items (and their location) that need attention, the date that attention is required, and the action to be taken.

The report allows you to select inventory from specific warehouses by lot status. You can include currently expired and retest required items. In addition you can include items that will expire or require retest in the future by specifying the number of days out that you want the report to include.

Submitting the Report

To submit the Item / Location Required Analysis Report:

1. Navigate to the **Submit Request** window.
2. In the **Name** field, enter **Item/Location Required Analysis Report**. The Parameters box is displayed.
3. Complete the **fields** as described, and click **OK**. The Submit Request window is displayed.
4. Complete the **fields** in the Submit Request window and click **Submit**. You can then view or print the report.

Selected Report Parameters

The report parameters are:

From Warehouse

Enter the starting or From warehouse to include on the report. This is the warehouse that is the starting point for your report.

To Warehouse

Initially defaults to the starting warehouse displayed in the From Warehouse field. This warehouse selection is the ending point or "Through" warehouse for your report.

From Status

Enter the starting status code to include on the report.

To Status

Initially defaults to the starting status code displayed in the From Status field. Type over it to change to another status.

Expired Items

Inventory items that are currently expired.

Retest Items

Inventory items that currently require retesting.

Future Expire

- Select Yes if you want to specify a time in the future that the items will expire. If you select Yes, you must make an entry in the Expire Within field.
- Select No (or leave blank) if you do not want to specify a time in the future that the items will expire. You do not have to make an entry in the Expire Within field.

Expire Within

Inventory with future expiration dates. Enter the number of days (from today) for which to include an inventory expiration range.

Future Retest

- Select Yes if you want to specify a time in the future that the items will require retest. If you select Yes, you must make an entry in the Retest Within field.
- Select No (or leave blank) if you do not want to specify a time in the future that the items will expire. You do not have to make an entry in the Retest Within field.

Retest Within

Inventory that has retesting scheduled for the future. Enter the number of days (from today) for which to include inventory in the Within (Days) field

Exclusive Test

- Select Yes if you want to exclude inventory for which quality control tests have already been performed. If you select Yes, you must make an entry in the Exclusive Within field.

- Select No if you do not want exclude inventory for which quality control tests have already been performed. You do not have to make an entry in the Exclusive Within field.

Exclusive Within

Indicates that you want to exclude inventory for which quality control tests have already been performed over a defined interval. Enter the number of days (from today) that you want to exclude pretested inventory.

Item/Location Analysis Report - Report Description

The following are descriptions of the fields displayed on the Item/Location Analysis Report.

Item

This report field displays the item from which the sample will be taken.

Lot

This report field displays the lot from which the sample will be taken.

Sublot

This report field displays the sublot from which the sample will be taken.

Warehouse

This report field displays the warehouse from which the sample will be taken.

Location

This report field displays the location from which the sample will be taken.

Lot Status

This report field displays the current lot status.

Retest Date

This report field displays the scheduled retest date for this item.

Expire Date

This report field displays the current expiration date for this item.

Assay
This report field displays the test defined for this item.

Specification
This report field displays the specification defined for this assay.

Minimum
This report field displays the minimum specification defined for this item.

Maximum
This report field displays the maximum specification defined for this item.

UOM
This report field displays the unit of measure for the assay.

Description
This report field displays the Action code for the assay.

Sampling Materials from Inventory

You may need to sample material directly from inventory for quality control testing. That is, material not associated with a particular vendor purchase order, customer sale order, or production batch. You will need to record the quantity of material taken from inventory and the date and time the sample was drawn and the lot/sublot from which it was taken.

Taking samples from inventory does not decrease inventory quantities.

You can record inventory sampling directly from the OPM quality control application or from any of the following OPM windows, available from the Inventory Setup menu:

- Item Master
- Warehouses
- Location

Sampling Materials from Inventory Procedure

To record inventory samples:

1. Navigate to **Item/Location Samples** window. You can also navigate to this window from the **Inventory Item Master**, **Lot/Sublots**, **Warehouses** or **Location** windows by selecting **Samples** from the **Actions** menu.
2. Complete the fields as described.
3. Save the window.

Item/Location Samples Field Reference

The fields on this window are:

Organization

Your default organization code is displayed.

Sample

Enter a code to identify this sample. Required.

Description

Enter a description of this sample. Required.

Disposition

Displays the current state of the sample in its testing process. For example, PENDING could indicate that the sample is being tested.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Sample Details

Item

Specify the item you need to sample. Required.

Lot

You must specify the lot number from which you want to select the sample. This field is only editable if the item you entered is lot controlled. If you did not indicate a lot number at the specification level, OPM will make this field mandatory.

Sublot

Specify the sublot from which you want to select the sample item. This field is only editable if the item you specified is lot/sublot controlled.

Warehouse

Specify the warehouse from which you want to select the sample item.

Location

Specify the location from which you want to select the sample item. This field is only editable if the item you specified is lot/location controlled.

Quantity

Enter the quantity of the sample item. Required.

UOM

Enter the unit of the sample. The default unit of measure is displayed. You can enter another unit of measure. Required.

Date Drawn

Enter the date the sample was taken. The system defaults to today's date, but you can type the desired date in this field. Required.

External ID

This field is for informational purposes only. You can enter an alternate or cross-reference code for this sample. For example, if the sample is recorded on another system, enter the sample ID as recorded on the external system.

Sampler

Enter the code for the person who withdrew the sample. The individual's name appears in the field to the right of this entry. Leave this field blank to default to the current user. Required.

Sample Approver

Displays the individual who can approve the sample in the OPM Quality Control Workflow.

Inventory Approver

Displays the individual who can approve the item to be released to production in the OPM Quality Control Workflow.

Sampling Customer/Vendor Materials

You may need to sample material for a customer sales order or a vendor purchase order. You will need to record the quantity of material taken and the date and time the sample was drawn. Taking customer / vendor samples does *not* decrease inventory.

You can record customer / vendor sampling directly from the OPM quality control application or from any of the following OPM windows:

- Generic Items (Purchase Management)
- Vendors (Purchase Management)
- Vendor Items (Purchase Management)

The application from which each of the these windows may be selected is shown in parentheses.

Sampling Customer/Vendor Materials Procedure

To sample customer / vendor materials:

1. Navigate to **Customer/Vendor Samples** window. You can also navigate to this window from the Purchase Management application Generic Items, Vendors, or Vendor Items windows by selecting **Samples** from the **Actions** menu.
2. Complete the fields as described.
3. Save the window.

Customer/Vendor Samples Field Reference

The fields on this window are:

Organization

Your default organization code is displayed.

Sample

Enter a code to identify this sample. You can enter any alphanumeric code up to 32 characters in length. Required.

Description

Enter a description of this sample. You can enter any alphanumeric code up to 32 characters in length. Required.

Disposition

Displays the current state of the sample in its testing process. For example, PENDING could indicate that the sample is being tested.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Sample Details

Customer

If you are selecting inventory for a customer sales order, enter the customer code. Either the Customer or Vendor field must be entered.

Vendor

If you are selecting inventory for a vendor purchase order, enter the vendor code. Either the Customer or Vendor field must be entered.

Item

Enter the item code to be sampled. Required.

Lot

Enter the lot to be sampled (if the item is lot controlled).

Sublot

Enter the sublot to be sampled (if the item is sublot controlled)

Quantity

Enter the quantity of the sample item. Required.

UOM

Enter the unit of measure of the sample. The default unit of measure is displayed. You can enter another unit of measure. Required.

Date Drawn

Enter the date the sample was taken. The system defaults to today's date, but you can type the desired date in this field. Required.

External ID

This field is for informational purposes only. You can enter an alternate or cross-reference code for this sample. For example, if the sample is recorded on another system, enter the sample ID as recorded on the external system.

Sampler

Enter the code for the person who withdrew the sample. The individual's name appears in the field to the right of this entry. Leave this field blank to default to the current user. Required.

Sample Approver

Displays the individual who can approve the sample in the OPM Quality Control Workflow.

Inventory Approver

Displays the individual who can approve the item to be released to production in the OPM Quality Control Workflow.

Sampling Production Materials

You may need to sample material for a particular production batch. You will need to record the quantity of material taken and the date and time the sample was drawn.

You can record production batch sampling directly from the OPM quality control application or from any of the following OPM windows:

- Formulas (Formulas)
- View Effectivities (Formulas)
- Routings (Formulas)
- Operations (Formulas)
- Batches (Production)

  The application from which each of the above windows may be selected is shown in parentheses.

Sampling Production Materials Procedure

To record production samples:

1. Navigate to the **Production Samples** window. You can also navigate to this window from the Formula Management application **Formulas**, **Effectivities**, **Routings**, and **Operations** windows by selecting **Samples** from the **Actions** menu. It is also available from the Production Management application **Batches** window by selecting **Samples** from the **Actions** menu at the Product detail line.
2. Complete the fields as described.
3. Save the window.

Production Samples Field Reference

The fields on this window are:

Organization

Your default organization code is displayed.

Sample

Enter a code to identify this sample. You may enter any alphanumeric code up to 32 characters. Required.

Description

Enter a description of this sample. For example, indicate the purpose of this quality control test. Required.

Disposition

Displays the current state of the sample in its testing process. For example, PENDING could indicate that the sample is being tested.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Sample Details

Batch

If you want to sample a production batch, enter the batch number from which to draw the sample, or navigate past this field to enter a formula number in the Formula field.

Formula Number

If you want to sample materials produced using a particular formula, specify the formula number.

Version

If you specified a formula number for this batch, you must specify the version of the formula.

Formula Desc

This field displays the description of the formula/version. This field defaults from the Formula Header and is shown here for informational purposes only.

Routing Number

If you want to sample materials produced using a particular routing, specify the routing number.

Version

If you specified a routing number, also specify the routing version number. The field to the right of Version displays the description of the Routing and is shown here for informational purposes only.

Routing Step

You can enter a sample for a specific routing step.

Operation

If you want to sample materials for a particular operation, enter the code for the operation performed in the routing.

Item

Indicate the item you are sampling. Required

Two description fields are displayed:

- The field to the right of the item displays the item description from inventory.
- The second field displays the formula line item description (ingredient, product, or by-product).

The field to the right of Item displays a description of this sample. For example, indicate the purpose of this quality control test.

Lot

Enter the lot to be sampled (if the item is lot controlled).

Sublot

Enter the sublot to be sampled (if the item is sublot controlled).

Quantity

Indicate the quantity of the sample. Required.

UOM

Enter the unit of measure of the sample. Required.

Date Drawn

Enter the date the sample was taken. If left blank, the system defaults to today's

External ID

This field is for informational purposes only. You can enter an alternate or cross-reference code for this sample.

Sampler

Enter the code for the person who withdrew the sample. The individual's name appears in the field to the right of this entry. Leave this field blank to default to the current user. Required.

Sample Approver

Displays the individual who can approve the sample in the OPM Quality Control Workflow.

Inventory Approver

Displays the individual who can approve the item to be released to production in the OPM Quality Control Workflow.

4

Recording Quality Control Results

This topic explains how to enter assay results into OPM. You will be shown how to enter item / location results, customer / vendor results, and production results. You will also be shown how to change lot status and quality control grade in single or multiple items. A topic on expired lot management shows you how to change the lot status of all, one, or a range of expired items, in all, one, or a range of lots, sublots, warehouses, or locations.

The following topics are covered:

- Entering Item / Location Results
- Entering Customer / Vendor Results
- Entering Production Results
- Changing Lot Status / Quality Control Grade
- Performing Single Item Quality Control Status / Grade Changes
- Performing Multiple Items Quality Control Status / Grade Changes
- Managing Expired Lots

Entering Item/Location Results

If you sampled and tested materials directly from inventory (that is, materials not associated with a particular vendor/customer order or formula/production batch) you will need to record the results of the quality control tests. When you record results, all of the assays associated with the most recent specification that you defined for the material are automatically retrieved hierarchically from the OPM database. For each assay you will enter the result of quality control tests done, the date of each test, and whether to accept or reject the material.

There is a hierarchy of item/location:

- Item is always required.
- Organization + (Lot OR Lot + Sublot if item is sublot controlled) + Warehouse + Location
- (Lot OR Lot + Sublot if item is sublot controlled) + Warehouse + Location
- Organization + (Lot OR Lot + Sublot if item is sublot controlled) + Warehouse
- (Lot or Lot + Sublot if item is sublot controlled) + Warehouse
- Organization + (Lot OR Lot + Sublot if item is sublot controlled)
- (Lot OR Lot + Sublot if item is sublot controlled)
- Organization + Warehouse + Location
- Warehouse + Location
- Organization + Warehouse
- Warehouse

If you reject the material, you need to change the inventory status in order to prevent it from being used for an operation whose requirements it does not meet.

You can add additional assay tests at this point if you performed additional quality control tests on the material other than those set up for the item on the specification. The target specifications for the assays are displayed. You are able to see whether or not the results are within the target specifications range. The status of your results entries of results can be printed on quality control reports.

You can record inventory results directly from the quality control application or from any of the following OPM windows available from the Inventory application:

- Item Master
- Lot / Sublot
- Warehouses
- Location

Entering Item/Location Results Procedure

To enter item / location results:

1. Navigate to the **Item/Location Results** window.
2. Complete the fields as described.
3. Save the window.

Item/Location Results Field Reference

The fields on this window are:

Organization

Your default organization code is displayed.

Sample

Enter the sample number for which you are entering results. Required.

Item

This field displays the item number associated with this sample number.

Lot

This field displays the lot number associated with this item's sample.

Sublot

This field displays the sublot number associated with this item's sample. Sublot data is only displayed if you entered a sublot for this item at the sample level.

Warehouse

This field displays the warehouse associated with this item if you entered a warehouse at the sample level. The warehouse description appears in the field to the right of the warehouse.

Location

This field displays the location associated with this item if you entered a location at the sample level.

Sample Disposition

Displays the current state of the sample in its testing process. For example, PENDING could indicate that the sample is being tested.

Assay Details

Assay

This field displays the assay or assays established for this item at the specification level.

Result

Depending on this assay type, you can enter one of the following in this field:

- For nonvalidated assays, enter your comments or observations. For example, if a mixture was supposed to crystallize, you could enter CRYSTALLIZED. The result entry for this type of assay is freeform and does not require validation with the specification.
- For range validated assays, enter the numeric result. Take note of the minimum and maximum values established at the specification level default in the lower part of the window. You may enter a numeric result that is outside of the range of the specification, but the value must be within the assay range.
- For specification list assays enter the result selection based on the value list set up for this assay. Note the specification value shown in the Specification field at the bottom of this window.

UOM

This field displays the quality control Unit of Measure (UOM) established at the assay level.

Date

Enter the date and time for this result entry. If left blank, the system defaults to today's date and time, but you can type the desired date and time in this field. Required.

Accept

There are two valid entries for this field:

- Select the Accept check box to accept the result.
- Clear the Accept check box to reject the result.

For nonvalidated assays you must manually enter this field.

For range validated and specification list validated assays this field is automatically updated based on the result you entered and validated against the specifications established for this assay. You can manually override this field to accept or reject material.

Certificate of Analysis

If you enter multiple results for the same assay, you can specify which one or ones are for final use for Certificates of Analysis established for item / location specifications.

- Select the Certificate of Analysis check box to use the result for a Certificate of Analysis.
- Clear the Certificate of Analysis check box if you do not want to use the result for a Certificate of Analysis.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Assay Description

This field displays a description of the highlighted assay.

Specification

This field displays the target specification for this item / assay combination.

Range

This field is shown for numeric range assays.

- The lower or minimum limit of the range is indicated in the left field.
- The upper or maximum limit of the range is indicated in the right field.

Entering Customer/Vendor Results

If you sampled and tested materials for a particular vendor or customer order, you will need to record the results of the quality control tests. These results may be needed for a Certificate of Analysis (COA) for the customer or vendor.

Certificates of Analysis are typically based on company criteria and are therefore not provided by OPM reports.

When you begin to record results, all assays associated with the most recent specifications that you defined for the sample material are automatically retrieved hierarchically from the OPM database. For each assay you will enter the result of each quality control test, the date of the test, and whether to accept or reject the material.

There is a hierarchy of specifications:

- Item is always required.
- Organization + Customer OR Organization + Vendor

If you reject the material, you need to change its inventory status in order to prevent it from being sold or used for production.

You can add additional assay tests and results at this point if you performed additional quality control tests on the materials other than those set up for the item or the specification. The target specifications for the assays are displayed. You are able to see whether or not the results are within the target specifications range. The status of your results entries can be printed on quality control reports.

You can record customer / vendor results directly from the quality control application or from any of the following OPM windows:

- Customers (Order Fulfillment)
- Generic Customer Items (Order Fulfillment)
- Vendors (Purchase Management)
- Vendor Item (Purchase Management)

Entering Customer/Vendor Results Procedure

To enter inventory results:

1. Navigate to **Customer/Vendor Results** window. You can also navigate to this window from the Order Fulfillment **Customers** and **Generic Customer Items** windows or the Purchase Management **Vendors** and **Vendor Item** windows by selecting **Results** from the **Special** menu.
2. Complete the fields as described.
3. Save the window.

Customer/Vendor Results Field Reference

The fields on this window are:

Organization

Your default organization code is displayed.

Sample

Enter the sample number for which you are entering results. Required.

Customer

If you are creating a quality control sample for a customer sales order, the customer code is displayed, otherwise the vendor code is displayed. Either a Customer or Vendor field must be entered.

Vendor

If you are creating a quality control sample for a vendor purchase order, enter the vendor code. Either the Customer or Vendor field must be entered.

Item

This field displays the item number associated with the sample.

Lot

This field displays the lot associated with the sample (if the item is lot controlled).

Sublot

This field displays the sublot associated with the sample (if the item is sublot controlled).

Sample Disposition

Displays the current state of the sample in its testing process. For example, PENDING could indicate that the sample is being tested.

Assay Details

Assay

This field displays the assay or assays established for this item at the specification level.

Result

Depending on this assay type, you can enter one of the following in this field:

- For nonvalidated assays, enter your comments or observations. For example, if a mixture was supposed to crystallize, you could enter CRYSTALLIZED. The result entry for this type of assay is freeform and does not require validation with the specification.
- For range validated assays, enter the result noting the minimum and maximum Range displayed at the bottom of the window. You may enter a numeric result that is outside of the range of the specification, but the value must be within the assay range.
- For specification list assays the result selection is based on the value list set up for this assay. Note the specification value shown in the Specification field at the bottom of this window.

UOM

This field displays the quality control unit of measure established at the assay level.

Date

Enter the date and time for this result entry. If left blank, the system defaults to today's date, but you can type the desired date in this field Required.

Accept

There are two valid entries for this field:

- Select the Accept check box to accept the result.
- Clear the Accept check box to reject the result.

For nonvalidated assays you must manually enter this field.

For range validated and specification list validated assays this field is automatically updated based on the result you entered and validated against the specifications established for this assay. You can manually override this field to accept or reject material.

Certificate of Analysis

If you enter multiple results for the same assay, you can specify which one or ones are for final use for Certificates of Analysis established for customer / vendor specifications.

- Select the Certificate of Analysis check box you want to use the result for a Certificate of Analysis.
- Clear the Certificate of Analysis check box if you do not want to use the result for a Certificate of Analysis.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Assay Description

This field displays a description of the highlighted assay.

Specification

This field displays the target specification for this item / assay combination.

Range

(Numeric Range only) The lower or minimum limit of the range is indicated in the left field. The upper or maximum limit of the range is indicated in the right field.

Entering Production Results

If you sampled and tested materials for a particular formula or production batch, you will need to record the results of the quality control tests.

When you begin to record results, all assays associated with the most recent specifications that you defined for the sample material are automatically retrieved hierarchically from the OPM database. For each assay you will enter the result of each quality control test, the date of the test, and whether to accept or reject the material.

There is a hierarchy of specifications:

- Organization + Batch + Formula + Routing + (Routing Step OR Operation)
- Batch + Formula + Routing + (Routing Step OR Operation)
- Organization + Batch + Formula + Routing
- Batch + Formula + Routing
- Organization + Batch + Formula
- Batch + Formula
- Organization + Formula + Routing + (Routing Step OR Operation)
- Formula + Routing + (Routing Step OR Operation)
- Organization + Formula + Routing
- Formula + Routing
- Organization + Formula + Operation OR Organization + Routing + (Routing Step OR Operation) (Depending Upon Preference)
- Formula + Operation OR Routing + (Routing Step OR Operation) (Depending Upon Preference)
- Formula OR Routing (Depending Upon Preference)
- Operation

If you reject the material, you need to change the inventory status in order to prevent it from being sold or used for production.

You can add additional assay tests and results at this point if you performed additional quality control tests on the materials other than those previously defined for the item on the specification. The target specifications for the assays are displayed. You are able to see, at a glance, whether or not the results are within the

target specifications range. The status of your results entries can be printed on quality control reports.

You can perform production results entry directly from the quality control application or from any of the following OPM windows:

- Formulas (Formulas)
- View Effectivities (Formulas)
- Routings (Formulas)
- Operations (Formulas)
- Batches (Production)

Entering Production Results Procedure

To enter production results:

1. Navigate to the **Production Results** window. You can also navigate to this window from the Formula Management application's **Formulas**, **View Effectivities**, **Routings**, and **Operations** windows by selecting **Results** from the **Special** menu. It is also available from the Production Management application **Batches** window by selecting **Results** from the **Special** menu.
2. Complete the fields as described.
3. Save the window.

Production Results Field Reference

The fields on this window are:

Organization

Your default organization code is displayed.

Sample

Enter the inventory sample number for which you are entering results. Required.

Batch

This field displays the batch number associated with this sample (if applicable).

Formula Number

This field displays the formula number associated with this sample (if applicable).

Version (Formula)

If this is a formula sample, this field displays the formula version number for the sample (if applicable).

Routing Number

This field displays the formula routing number (if applicable).

Version (Routing)

This field displays the formula routing version number (if applicable).

Routing Step

This field displays the routing step to which the test applies (if applicable).

Operation

This field displays the formula operation name/code and description (if applicable).

Item

This field displays the item name and description associated with this sample (if applicable).

Lot

This field displays the lot associated with the sample (if the item is lot controlled).

Sublot

This field displays the sublot associated with the sample (if the item is sublot controlled).

Description

This field displays the function of the line item in the formula, for example, by-product, product, or ingredient.

Sample Disposition

Displays the current state of the sample in its testing process. For example, PENDING could indicate that the sample is being tested.

Assay Details

Assay

This field displays each assay established for this item.

Result

Depending on this assay type, you can enter one of the following in this field:

- For nonvalidated assays, enter your comments or observations. For example, if a mixture was supposed to crystallize, you could enter CRYSTALLIZED. The result entry for this type of assay is freeform and does not require validation with the specification.
- For range validated assays, enter the numeric result noting the minimum and maximum Range displayed at the bottom of the window. You may enter a numeric result that is outside of the range of the specification, but the value must be within the assay range.
- For specification list assays enter the result selection based on the value list set up for this assay. Note the specification value shown in the Specification field at the bottom of this window.

UOM

This field displays the quality control unit of measure established at the assay level.

Date

Enter the date and time for this result entry. If left blank, the system defaults to today's date, but you can type the desired date in this field. Required.

Accept

There are two valid entries for this field:

- Select the Accept check box to accept the result.
- Clear the Accept check box to reject the result.

For nonvalidated assays you must manually enter this field.

For range validated and specification list validated assays this field is automatically updated based on the result you entered and validated against the specifications established for this assay. You can manually override this field to accept or reject material.

Certificate of Analysis

If you enter multiple results for the same assay, you can specify which one or ones are for final use for Certificates of Analysis established for production specifications.

- Select the Certificate of Analysis check box you want to use the result for a Certificate of Analysis.
- Clear the Certificate of Analysis check box if you do not want to use the result for a Certificate of Analysis.

[ ]

The double brackets ([ ]) identify a descriptive flexfield that you can use to add data fields to this window without programming.

Assay Description

This field displays a description of the assay on the highlighted line.

Specification

This field displays the target specification for this item / assay combination.

Range

(Numeric Range only) The lower or minimum limit of the range is indicated in the left field, and the upper or maximum limit of the range is indicated in the right field.

Changing Lot Status/Grade

Once it has been determined that a sample does not meet quality control specifications or has failed quality control tests, you may need to change either the lot status or the quality control grade of the sample lot. Lot status is used to prevent failed lots from being sold or shipped from production depending on your definition of the status.

You can select one of the following options for changing either the lot status or the quality control grade of the lot that failed a quality control test. Three methods for changing lot status or quality control grade are available:

Changing Lot Status

- Status Change Immediate: Changes the lot status of one item in one warehouse. Status for the item is updated as soon as the changes are saved.
- Status Change Journaled: Changes the lot status of one item in one warehouse. Status for the item is written to the Inventory Adjustment Journal and assigned an edit journal log number. Status is not updated until the journal is posted using the Inventory Post Journals option. (See also *Oracle Process Management Inventory Control* for more information on the Inventory Post Journals option.)
- Multiple Items Status Change Immediate: Changes the lot status for one or many items in all, one, or a range of lots, sublots, warehouses, locations or grades. Lot statuses are updated as soon as the changes are saved.
- Multiple Items Status Change Journaled: Changes the lot status of multiple items. Status is written to the Inventory Adjustment Journal and assigned an edit journal log number. Status is not updated until the journal is posted using the Inventory Post Journals option. (See also *Oracle Process Management Inventory Control* for more information on the Inventory Post Journals option.)

Changing Grade

- Grade Change Immediate: Changes the quality control grade of the item lot. quality control grade for the item is updated as soon as the changes are saved. If the item lot exists in several warehouses, the Grade Immediate command will change it for all warehouses.
- Grade Change Journaled: Changes the quality control grade of one item lot in one warehouse. quality control grade for the item is written to the Inventory Adjustment Journal and assigned an edit journal log number. Quality control grade is not updated until the journal is posted using the Inventory Post

Journals Option. (See also *Oracle Process Management Inventory Control* for more information on the Inventory Post Journals option.)

- Multiple Items Grade Change Immediate: Changes the quality control grade for one or many items in all, one, or a range of lots, sublots, warehouses, or locations. quality control grades are updated as soon as the changes are saved.
- Multiple Items Grade Change Journaled: Changes the quality control grade of multiple items. Status is written to the Inventory Adjustment Journal and assigned an edit journal log number. Status is not updated until the journal is posted using the Inventory Post Journals option. (See also *Oracle Process Management Inventory Control* for more information on the Inventory Post Journals option.)

Quality control grade is a characteristic of an item lot, *never* a location. When you change the quality control grade of an item lot, specifying the warehouse location of that lot does *not* assign a quality control grade to the location.

Performing Single Item Status/Grade Changes

Quality control grade is a characteristic of an item lot, never a location. When you change the quality control grade of an item lot, specifying the warehouse location of that lot does not assign a quality control grade to the location.

The Status/Grade Change Immediate and Status/Grade Change Journaled options both use the same OPM window and are described together.

Performing Single Item Status/Grade Changes Procedure

Refer to the Inventory Control Application to perform an immediate or journaled status or quality control grade change.

Quantities Field Reference

Refer to the Inventory Control application for a complete description of the fields on the Quantities window.

Performing Multiple Items Status/Grade Changes

The Multiple Items Immediate quality control grade and status option changes the status or quality control grade for one or many items in all, one, or a range of lots, sublots, warehouses, locations or grades. Statuses are updated as soon as the changes are saved.

Quality control grade is a characteristic of an item lot, never a location. When you change the quality control grade of an item lot, specifying the warehouse location of that lot does not assign a quality control grade to the location.

Performing Multiple Items Status/Grade Changes Procedure

Refer to the Inventory Control Application to perform an immediate or journaled status or quality control grade change changes on multiple items.

Quantities Field Reference

Refer to the Inventory Control application for a complete description of the fields on the Quantities window.

Managing Expired Lots

When a lot of materials expires, it may require retesting, a grade change (for example to EXPIRED), or other action to be taken. The auto-allocation features of the OPM Inventory Control application incorporate lot expiration criteria, however expired lots are still considered available for manual allocation since the availability of material is controlled by its lot status. It is therefore necessary to change the status of expired lots so that they are not used.

See the *OPM Inventory Management User's Guide* or a complete discussion of automatic allocation and manual allocation.

The Expired Lot Status Change window allows you to change the lot status of all, one, or a range of expired items, in all, one, or a range of lots, sublots, warehouses, or locations. Status changes are made immediately upon accepting the selections on the Expired Lot Status Change selection window.

Managing Expired Lots Procedure

To change expired lot statuses:

1. Navigate to the **Expired Lot Status Change** window.
2. Complete the fields as described.
3. Click on **Accept**.

Expired Lot Status Change Field Reference

The fields on this window are:

Organization

The default organization is displayed in this field.

Journal

The default journal is displayed in this field.

Item

Enter the beginning item in the From field. Enter the ending item in the To field. The To field defaults to the same item entered in the From field. Leave this default to change expired lot status for only one item, or enter the item number for the last item in a range of items.

Lot

Enter the beginning lot to expire in the From field. Enter the ending lot to expire in the To field.

Sublot

Enter the beginning sublot to expire in the From field. Enter the ending lot to expire in the To field.

Warehouse

Enter the beginning warehouse containing the lot / sublot to expire in the From field. Enter the ending lot containing the lot / sublot to expire in the To field.

Location

Enter the beginning location containing the lot / sublots to expire in the From field. Enter the ending location containing the lot / sublots to expire in the To field.

Transaction Date

Enter the date that the expiration is to be effective. The field defaults to today's date. Required.

Reason

Indicate the reason for this status change. Reason codes are set up using the Reason Codes window. Required.

Inventory Status

Indicate the new quality control status to which you are changing the selected expired items. Lot status is set up using the Lot Status window in Inventory Setup in Inventory Control. Required.

5

Quality Control Reporting

There are several quality control reports and online inquiries that can help you manage your quality control activity. One of these reports, the Item / Location Required Analysis Report, was discussed in *Quality Control Sampling*, since it is an essential part of the Sampling process.

This topic describes all OPM quality control reports and inquiries, including:

- Running the Item / Location Required Analysis Report
- Running the Item / Location Assay Results Report
- Running the Customer / Vendor Assay Results Report
- Running the Production Assay Results Report
- Running the Certificate of Analysis / Certificate of Conformance Report
- Making a Single Level Lot Source Inquiry, now Lot Genealogy Inquiry
- Making a Single Level Where Used Inquiry, now Lot Genealogy Inquiry

Running the Item/Location Required Analysis Report

The Item / Location Required Analysis Report (Required Specifications) identifies inventory that may need quality control attention. Quality control attention may include the retesting of materials or expiration actions needed to be taken on materials.

The report prints the items and locations that need attention, that date the attention is required, and the action to be taken (if any).

The report allows you to select inventory from specific warehouses by lot status. You can include currently expired and retest required items. In addition, you can include items that will expire or require retest in the future.

This quality control report identifies inventory that may need quality control attention since it is about to expire. In order to identify assays that need to be run, items must have item / location specifications. An expired lot must contain inventory in order to appear on the report. This report does not advise the user about which lots are expiring (per the item master).

See Quality Control Sampling for an explanation of this report.

Running the Item/Location Assay Results Report

The Item / Location Assay Results Report displays all of the results obtained from quality control test samples that have been entered into the system.

Submitting the Report

To submit the Item / Location Assay Results Report:

1. Navigate to the **Submit Request** window.
2. In the **Name** field, **Item/Location Assay Results Report** . The Parameters dialog box is displayed.
3. Complete the **fields** as described, and click **OK**. The Submit Request window is displayed.
4. Complete the **fields** in the Submit Request window and click **Submit**. You can then view or print the report.

Selected Report Parameters

The report parameters are:

From Sample

Enter the beginning sample number for your report in this field.

To Sample

Enter the ending sample number for your report in this field.

From Item

Enter the beginning item for your report in this field.

To Item

Enter the ending item for your report in this field

From Lot

Enter the beginning lot for your report in this field.

To Lot

Enter the ending lot for your report in this field.

From Sublot

Enter the beginning sublot for your report in this field.

To Sublot

Enter the ending sublot for your report in this field.

From Warehouse

Enter the beginning warehouse for your report in this field.

To Warehouse

Enter the ending warehouse for your report in this field.

From Location

Enter the beginning location for your report in this field.

To Location

Enter the ending location for your report in this field.

From Result Date

Enter the beginning result date for your report in this field.

To Result Date

Enter the ending result date for your report in this field.

Include

- Select All Results to include all results on the report, even those that are not accepted.
- Select Certificate of Analysis to eliminate any results that are not accepted from appearing on the report.

Print Condition

- Select None to stop the printing of Specification Text and Result Text on the report.
- Select Result Text to print Result Text on the report. Specification Text will not be printed.

- Select Spec Text to print Specification Text on the report. Result Text will not be printed.
- Select Spec Text / Result Text to print both Specification Text and Result Text on the report.

Both the From Result Date and The To Result Date fields display Today's Date as the default. If you choose to enter additional selection criteria such as From Sample, To Sample, From Item, or To Item, the selection criteria must coincide with the From Result Date and To Result Date in order to generate a meaningful report.

Item/Location Assay Results Report – Report Description

The following are descriptions of the fields displayed on the Assay Results Report:

Item

This report field displays the item from which the sample was taken.

Lot

This report field displays the lot from which the sample was taken.

Sublot

This report field displays the sublot from which the sample was taken.

Warehouse

This report field displays the warehouse from which the sample was taken.

Location

This report field displays the location from which the sample was taken.

Assay

This report field displays the test defined for this item.

Specification

This report field displays the specification defined for this assay.

Minimum

This report field displays the minimum specification defined for this item.

Maximum

This report field displays the maximum specification defined for this item.

Effective From

This report field displays the beginning effectivity for the specification.

Effective Through

This report field displays the ending effectivity for the specification.

Spec Text

This report field displays any specification text entered when the sample was recorded.

Result

This report field lists the test result for the assay test shown on this line.

UOM

This report field lists the assay unit of measure for the test result shown on this line.

Result Date

This report field displays the date the sample for this assay test was drawn.

Accept

This report field indicates whether or not this sample was accepted or rejected.

Yes means it was accepted. No means it was not accepted.

Certificate Of Analysis

This report field indicates whether or not this result will appear on the Certificate of Analysis.

- Yes means it will appear.
- No means it will not appear.

Sample Number

This report field indicates the sample number used for this assay test results displayed on this line.

Quantity

This report field displays the quantity of the sample used.

UOM

This report field displays the inventory Unit of Measure for this sample.

Sample Date

This report field displays the date this result was recorded.

Result Text

This report field displays any text associated with the results entered.

Running the Customer/Vendor Assay Results Report

The Customer / Vendor Assay Results Report displays all of the results obtained from quality control test samples that have been entered into the system.

Submitting the Report

To submit the Customer / Vendor Assay Results Report:

1. Navigate to the **Submit Request** window.
2. In the **Name** field, enter **Customer/Vendor Assay Results Report**. The Parameters dialog box is displayed.
3. Complete the **fields** as described, and click **OK**. The Submit Request window is displayed.
4. Complete the **fields** in the Submit Request window and click **Submit**. You can then view or print the report.

Selected Report Parameters

From Customer

Enter the beginning customer for your report in this field.

To Customer

Enter the ending customer for your report in this field.

From Item

Enter the beginning item for your report in this field.

To Item

Enter the ending item for your report in this field.

From Lot

Enter the beginning lot for assay results (if the item is lot controlled).

To Lot

Enter the ending lot for assay results (if the item is lot controlled).

From Sublot

Enter the beginning sublot for assay results (if the item is sublot controlled).

To Sublot

Enter the ending sublot for assay results (if the item is sublot controlled).

From Result Date

Enter the beginning date for assay results.

To Result Date

Enter the ending date for assay results.

From Customer

Enter the beginning customer in this field.

To Customer

Enter the ending customer in this field.

From Vendor

Enter the beginning vendor in this field.

To Vendor

Enter the ending vendor in this field.

From Sample

Enter the beginning sample in this field.

To Sample

Enter the ending sample in this field.

Include

- Select All Results to include all results on the report, even those that are not accepted.
- Select Certificate of Analysis to print only those results that were selected for Certificate of Analysis on the Results window.

Print Condition

- Select None to stop the printing of Specification Text and Result Text on the report.
- Select Result Text to print Result Text on the report. Specification Text will not be printed.
- Select Spec Text to print Specification Text on the report. Result Text will not be printed.
- Select Spec Text / Result Text to print both Specification Text and Result Text on the report.

Customer/Vendor Assay Results Report - Report Description

The following are descriptions of the fields displayed on the Assay Results Report:

Item

This report field displays the item from which the sample was taken.

Lot

This report field displays the lot from which the sample was taken (if the item is lot controlled).

Sublot

This report field displays the sublot from which the sample was taken (if the item is sublot controlled).

Assay

This report field displays the test defined for this item.

Specification

This report field displays the specification defined for this assay.

Minimum

This report field displays the minimum specification defined for this item.

Maximum

This report field displays the maximum specification defined for this item.

Effective From

This report field displays the beginning effectivity for the specification.

Effective Through

This report field displays the ending effectivity for the specification.

Spec Text

This report field displays any specification text entered when the sample was recorded.

Result

This report field lists the test result for the assay test shown on this line.

UOM

This report field lists the assay unit of measure for the test result shown on this line.

Result Date

This report field displays the date the sample for this assay test was drawn.

Accept

This report field indicates whether or not this sample was accepted or rejected.

Yes means it was accepted. No means it was not accepted.

Certificate Of Analysis

This report field indicates whether or not this result will appear on the Certificate of Analysis. Yes means it will appear. No means it will not appear.

Sample Number

This report field indicates the sample number used for this assay test results displayed on this line.

Quantity

This report field displays the quantity of the sample used.

UOM

This report field displays the inventory Unit of Measure for this sample.

Sample Date

This report field displays the date this result was recorded.

Result Text

This report field displays any text associated with the results entered.

Running the Production Assay Results Report

The Production Assay Results Report displays all of the results obtained from quality control test samples that have been entered into the system.

Submitting the Report

To submit the Production Assay Results Report:

1. Navigate to the **Submit Request** window.
2. In the **Name** field, enter **Production Assay Results Report**. The Parameters dialog box is displayed.
3. Complete the **fields** as described, and click **OK**. The Submit Request window is displayed.
4. Complete the **fields** in the Submit Request window and click **Submit**. You can then view or print the report.

Selected Report Parameters

The report parameters are:

From Sample

Enter the beginning sample for your report in this field.

To Sample

Enter the ending sample for your report in this field.

From Batch

Enter the beginning batch for your report in this field.

To Batch

Enter the ending batch for your report in this field.

From Formula

Enter the beginning formula for your report in this field.

To Formula

Enter the ending formula for your report in this field.

From Formula Version
Enter the beginning formula version for your report in this field.

To Formula Version
Enter the ending formula version for your report in this field.

From Routing
Enter the beginning routing for your report in this field.

To Routing
Enter the ending routing for your report in this field.

From Routing Version
Enter the beginning routing version for your report in this field.

To Routing Version
Enter the ending routing version for your report in this field.

From Routing Step Number
Enter the beginning routing step number for your report in this field.

To Routing Step Number
Enter the ending routing step number for your report in this field.

From Operation
Enter the beginning operation for your report in this field.

To Operation
Enter the ending operation for your report in this field.

From Item
Enter the beginning item for your report in this field.

To Item
Enter the ending item for your report in this field.

From Lot

Enter the beginning lot for your report in this field (if the item is lot controlled).

To Lot

Enter the ending lot for your report in this field (if the item is lot controlled).

From Sublot

Enter the beginning sublot for your report in this field (if the item is sublot controlled).

To Sublot

Enter the ending sublot for your report in this field (if the item is sublot controlled).

From Result Date

Enter the beginning result date for your report in this field.

To Result Date

Enter the ending result date for your report in this field.

Include

- Select ALL to include all results on the report, even those that are not accepted.
- Select Certificate of Analysis to eliminate any results that are not accepted from appearing on the report.

Print Condition

- Select None to stop the printing of Specification Text and Result Text on the report.
- Select Result Text to print Result Text on the report. Specification Text will not be printed.
- Select Spec Text to print Specification Text on the report. Result Text will not be printed.
- Select Spec Text / Result Text to print both Specification Text and Result Text on the report.

Production Assay Results Report - Report Description

The following are descriptions of the fields displayed on the Production Assay Results Report:

Item

This report field displays the item from which the sample was taken.

Lot

This report field displays the lot from which the sample was taken (if the item is lot controlled).

Sublot

This report field displays the sublot from which the sample was taken (if the item is sublot controlled).

Assay

This report field displays the test defined for this item.

Specification

This report field displays the specification defined for this assay.

Minimum

This report field displays the minimum specification defined for this item.

Maximum

This report field displays the maximum specification defined for this item.

Effective From

This report field displays the beginning effectivity for the specification.

Effective Through

This report field displays the ending effectivity for the specification.

Spec Text

This report field displays any specification text entered when the sample was recorded.

Result

This report field lists the test result for the assay test shown on this line.

UOM

This report field lists the assay unit of measure for the test result shown on this line.

Result Date

This report field displays the date the sample for this assay test was drawn.

Accept

This report field indicates whether or not this sample was accepted or rejected.

Yes means it was accepted. No means it was not accepted.

Certificate Of Analysis

This report field indicates whether or not this result will appear on the Certificate of Analysis. Yes means it will appear. No means it will not appear.

Sample Number

This report field indicates the sample number used for this assay test results displayed on this line.

Quantity

This report field displays the quantity of the sample used.

UOM

This report field displays the inventory Unit of Measure for this sample.

Sample Date

This report field displays the date this result was recorded.

Result Text

This report field displays any text associated with the results entered.

Running the Certificate of Analysis/Conformance Report

The Certificate of Analysis (CoA) / Certificate of Conformance (CoC) verifies that the items produced or shipped comply with test procedures (assays) and quality specifications as prescribed by the customer. A process manufacturer authorizes a CoC / CoA for shipment of supplies that would normally require inspection upon receipt. The Certificate of Analysis and Certificate of Conformance reports present data derived from quality management information. These certificates are created primarily for items that are included on sales orders and shipped to customers. An OPM user's customer may require certification of assays that have been performed, and results generated on specific products sold to them. Potential customers may want to review results certification before actually ordering products.

A Certificate of Analysis or a Certificate of Conformance can be generated depending on item disposition and availability of information about the item as described in the following:

The Certificate of Analysis Report

This report satisfies the need to show that certain assays have been performed on an item, what target results are expected, what the results are, and the date each result was entered. A Certificate of Analysis Report can only be generated when:

- The item is active and lot controlled.
- Specifications and results exist for the item and lot selected.
- Sample Disposition is APPROVED.
- Results are ACCEPTED.
- Sales Order shipment status is not VOID (if a Sales Order, Bill of Lading or shipping information are given as parameters).
- Items selected are not scheduled for deletion.
- Appropriate selection criteria have been entered on the Certificate of Analysis Report window.

Specification and result text will appear only if the appropriate Print Text Options have been selected on the Certificate of Analysis Report window.

Make certain that the Certificate of Analysis check boxes have been selected on any appropriate windows:

- Item / Location Results
- Customer / Vendor Results

- Production Results

The Certificate of Conformance Report

This report satisfies the need to show the assays that will be performed on a specific item and what target results are expected. A Certificate of Conformance Report can be generated when:

- The item is active.
- Specifications exist for the item (and lot) selected.
- Appropriate Selection criteria have been entered on the Certificate of Analysis Report window.

Specification text will appear only if the appropriate Print Text Options on the Certificate of Analysis Report window have been selected.

Submitting the Report

Run the report as follows:

1. Navigate to the **Certificate of Analysis Report** window.
2. Complete the fields as described.
3. Click **OK**.

Viewing the Certificate of Analysis Report Online

1. From the **View** menu select **Requests**.
2. Select **All My Requests**, and click **Find**.
3. Highlight the current record indicator next to the requested **Certificate of Analysis** report that you want to view. Make sure that the report phase is completed.
4. Click **View Output**. The report you selected is displayed on the window. The output defaults to a *.pdf file, but can be changed by your System Administrator.

Selected Report Parameters

In addition to Organization, you must enter at least one other parameter. The report parameters are:

Selection

As you enter data in the following fields, some of them will fill automatically. This occurs in cases where a specific order, shipment, item or lot can be identified from the data supplied.

Organization

Enter the abbreviated name of the Organization. A brief description of the Organization appears to the right of this entry. Required.

Ship Date

Enter the Ship date as follows:

- From Ship Date (if known) in the left field
- To Ship Date in the right field.

Both From Ship Date and To Ship Date default to the current System Date. If you know the Actual Ship Date, enter it in both fields. If the Actual Ship Date is not available, the Scheduled Ship Date will be displayed on the Report.

Customer

Enter the Customer Number, if available. The name entered on the sales order detail line is displayed, if it is available.

Sales Order Number

Enter the Sales Order Number, if available.

Shipment Number

Enter the Shipment Number, if available.

Item

Enter the Item number if available. A brief description of the Item appears to the right of this entry.

Lot

Enter the Lot number, if available. A brief description of the Lot appears to the right of this entry.

Sublot

Enter the Sublot number, if available.

Warehouse

Enter the Warehouse code, if available. A brief description of the Warehouse appears to the right of the entry.

Print Text Options

Select one of the following buttons:

- No Text - to suppress printing Edit Text on the report
- All Text - to include Specification and Result Text on the report
- Specification Text Only - to include only Specification Text on the report
- Result Text Only - to include only Result Text on the report

Print Options

Copies

Enter the number of copies desired, if you wish to print the report. If you wish only to view the report, enter 0, and no hard copy will be generated. You can use the View command to see the report output.

Printer

Displays the name of the Printer to which you wish to direct the printed report.

Style

Displays the default Style for the report.

Certificate of Analysis Report - Report Description

Report fields are blank when information is not available for the field. The following are descriptions of the fields displayed:

Report Title

One of the following report titles prints on the report:

Certificate of Analysis

Prints when a Result and Result Date are available for an Assay.

Certificate of Conformance

Prints when a Result and Result Date are *not* available for an Assay.

Report Body

Organization

Displays the name of the Organization running the report.

Customer

Displays the shipped-to Customer number and name chosen from the sales order detail line.

Customer PO

Displays the Purchase Order number from the Sales Order header.

Order Number

Displays the customer sales Order Number from the Sales Order header.

Shipment Number

Displays the bill of lading number from the Shipment header.

Shipment Date

Displays the Actual Shipment Date if it is available. If this date is not available, this field displays the Scheduled Shipment Date.

Item

Displays the Item number and a brief description of it.

Warehouse

Displays the "From" Warehouse abbreviation and its description.

Lot

Displays lot number and its description (if lot controlled).

Sublot
Displays the sublot number and its description (if the item is sublot controlled).

Quantity Ordered (Qty1)
Displays the quantity and unit of measure ordered.

UOM
Displays the primary unit of measure for the quantity ordered.

Qty2
Displays the number of items ordered in the secondary unit of measure.

UOM2
Displays the secondary unit of measure for the quantity ordered.

Quantity Shipped (Qty1)
Displays the quantity and unit of measure shipped.

UOM
Displays the primary unit of measure for the quantity shipped.

Qty2
Displays the number of items shipped in the secondary unit of measure.

UOM2
Displays the secondary unit of measure for the quantity shipped.

Assay
Displays the assay number and description on which the result or specification is based.

Target
Displays the specification target.

UOM
Displays the unit of measure for the result or specification.

Result

Displays the numeric, text or unformatted result. This information appears only on the Certificate of Analysis.

Result Date

Displays the date of the Result.

(Specifications Text)

Displays any Edit Text associated with the current Specification if Specification Text Only or All Text have been indicated in the Print Text Options.

(Result Text)

Displays any Edit Text associated with the current Result if Result Text Only or All Text have been indicated in the Print Text Options.

Making a Single Level Lot Source Inquiry

This inquiry is now managed by the Lot Genealogy Inquiry. Please refer to *Oracle Process Manufacturing Inventory Management User's Guide* for additional information on the Lot Genealogy Inquiry.

Making a Single Level Where Used Inquiry

This inquiry is now managed by the Lot Genealogy Inquiry. Please refer to *Oracle Process Manufacturing Inventory Management User's Guide* for additional information on the Lot Genealogy Inquiry.

6

OPM Quality Control Workflows

This topic introduces you to the concept of a workflow process and refers you to the documentation that fully explains Oracle Workflow. It presents an understanding of the OPM Quality Control Workflow, how to set it up, how to start it, and how to use the Quality Control Workflow Sample Results Window.

The following topics are covered:

- Understanding Workflow Processes
- Setting Up the OPM Quality Control Workflow
- Understanding the OPM Quality Control Workflow
- Starting the OPM Quality Control Workflow
- Using the Quality Control Workflow Sample Results Window

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 a need-to-know basis.

Setting Up Roles

Oracle Workflow routes information to a role. A role can be an individual user or a group of users. Any user associated with that role can act on the notification. Each notification includes a message associated with all the information a user needs to make a decision. Some possible responses are also included. Oracle Workflow interprets each response and moves on to the next workflow activity.

Setting Up Workflow Processes

In order for a workflow to operate properly, you must make certain that the Oracle Workflow product has been set up as described in the *Oracle Workflow Guide*.

A workflow process starts when an application calls a set of Oracle Workflow Engine Application Program Interfaces (APIs). The workflow itself is depicted as a process diagram containing icons that represent activities. The process contains several workflow steps that include roles, activities, and decision trees that are needed to complete the workflow.

Delivering Electronic Notifications

Oracle Workflow enables you to let people receive notifications of items awaiting their attention through electronic mail (E-mail), by using a web browser, or on a Notification Summary window in Oracle Applications.

Setting Up the OPM Quality Control Workflow

Make certain that the OPM Quality Control Workflow has been set up in the OPM System Administration application. Contact your System Administrator if you are not sure that this has been done.

Setting Up the OPM Quality Control Workflow in System Administration

Your OPM System Administrator should set up:

- Workflow Activation - to activate the workflow. For more information on this please refer to *OPM System Administration Installation User Guide*.
- Workflow Activity Definition - predefined (seed data)
- Column Definition - predefined (seed data)
- Role Association - to associate each role to a set of data

If the workflow does not start, the Workflow Activation window may be set to Deactivate. Contact your OPM System Administrator to determine if this window and all appropriate triggers have been set properly.

Note: Quality Control Workflows will not function if this seed data is disturbed.

Note: The workflow will be activated only for lot controlled and grade controlled items. Therefore, the activation trigger only fires for items which are lot controlled and grade controlled.

Understanding the OPM Quality Control Workflow

The OPM Quality Control workflow has the capability to meet various quality assurance tests on:

- Raw materials
- Intermediates
- Finished goods

These tests can be viewed at any stage during the purchasing, production or sales cycle. You can set up specifications, draw samples and enter the results of tests at the following levels:

- Item / Lot
- Production
- Customer / Vendor

The OPM Quality Control Workflow is composed of three subordinate workflows:

- Sample Creation Notification Workflow
- Sample Approval Process Workflow
- Assay Testing Process Workflow

Initiating the OPM Quality Control Workflow

An inventory transaction triggers the Sample Creation Notification Workflow if a valid specification exists and the transaction increments inventory. OPM sends a message to the owner of the inventory item to advise that a transaction has been created and that a sample needs to be drawn.

Processing OPM Quality Control Samples

Whenever the user creates a sample, the Sample Approval Process Workflow finds appropriate assays and specifications for that sample and initiates the Assay Testing Process Workflow. The Workflow then sends notifications to individuals who perform the required quality control assays for the sample. The samples are drawn and sent for testing. Each assay is monitored within the Assay Testing Process Workflow.

Resolving Assay Hierarchies

During the search for specifications, the workflow examines the specifications' hierarchies. Hierarchies searched are:

- Customer / Vendor Specifications hierarchy - if the sample is associated with either a customer or a vendor
- Production Specifications hierarchy - if the sample is associated with a batch, a formula, a routing, an operation or any combination of these
- Item / Location Specifications hierarchy - if neither of the previous two hierarchies apply to the sample

Communicating Sample Status

When the prescribed assays have been completed, the user who owns the quality control sample (Sample Approver) evaluates the test results and indicates:

- Accept - to accept the assay or assays and release the material to production
- Partial Retest - to indicate that partial retesting is in-progress.
- Complete Retest - to indicate that complete retesting is in-progress
- Reject - to indicate that the assays were outside the limits of the specification, and the material should not be released to production
- Allow More Time - to indicate that more time is required for determining the assay sample disposition

Reporting OPM Quality Control Results

Once the quality control sample owner indicates that the sample has been accepted, the Sample Approval Process Workflow sends notification to the inventory approver to indicate the final status of the material tested.

Starting the OPM Quality Control Workflow

Without the implementation of the OPM Quality Control Workflow the scheduling and monitoring of assay tests are major responsibilities that require careful coordination and follow-up for all materials that require quality control assay.

The OPM Quality Control Workflow changes this by allowing you to set up an electronic notification system. This system allows you to coordinate the selective identification, active gathering, and reporting of assay results so that inventory can be released to manufacturing.

Starting the OPM Quality Control Workflow Procedure

To start the OPM Quality Control Workflow, proceed as follows:

1. Begin with the OPM Quality Control Workflow installed and operational.
2. Complete an inventory transaction that increments inventory and has a valid specification.
3. The OPM Quality Control Workflow initiates as described in the OPM Quality Control Workflow Steps topic.

OPM Quality Control Workflow Steps

The workflow proceeds as three subordinate workflows:

- Sample Creation Notification Workflow
- Sample Approval Process Workflow
- Assay Testing Process Workflow

Sample Creation Notification Workflow

The Sample Creation Notification Workflow proceeds as follows:

1. The workflow starts when OPM transacts inventory requiring an assay.
2. The Notifier is found and notification is sent.
3. The Sample Approval Process Workflow is initiated if the notifier creates a sample from the notification or creates a sample independent of the workflow.
4. The workflow ends.

Sample Approval Process Workflow

The Sample Approval Process Workflow proceeds as follows:

1. The workflow starts when a sample is created either from the Sample Creation Notification Workflow or in the Quality Control application.
2. The workflow finds the assay specifications and initiates the Assay Testing Process Workflow.
3. The workflow waits for all assays included in the Assay Testing Process Workflow to be completed or timed out.
4. If the workflow detects a manual termination, it ends.
5. The workflow finds the Sample Approver, and sends notification to this user that testing of all assays related to a sample has been completed.
6. The Sample Approver can open the Sample Results window to verify the assay results. See the Using the Quality Control Workflow Sample Results Window topic.
7. The workflow continually checks assay test disposition as follows:
   - If Snooze is detected it initiates the Assay Testing Process Workflow for Timed-out Assays, and repeats steps 2 through 4.
   - If Partial Retest is detected, it initiates the Assay Testing Process Workflow for selected assays, and repeats steps 2 through 4.
   - If Complete Retest is detected, it initiates the Assay Testing Process Workflow for all assays, and repeats steps 2 through 4.
   - If Accept or Reject is detected, it proceeds to step 8.
8. The workflow finds the Inventory Approver, and sends notification to this user that the inventory has been accepted or rejected. The Inventory Approver can open the Quantities window (in the Inventory application) to assign a Grade to the material tested.
9. The workflow ends.

Assay Testing Process Workflow

The Assay Testing Process Workflow proceeds as follows:

1. The workflow starts when an assay is required for new material. It is initiated from the Sample Approval Process Workflow.
2. The Notifier is found and notification is sent.

3. The status of the Assay is updated to "Notified."
4. When the assay is completed, the assay status is updated to "Completed," otherwise the status is "Time-out."
5. Assay results are accumulated for the Sample Approval Process Workflow.
6. The workflow ends.

Using the Quality Control Workflow Sample Results Window

The Sample Approver uses this window to monitor the disposition of assays in progress. By selecting the final disposition of the assays and saving this form, the Sample Approver enables the workflow to find the Inventory Approver, and send notification to this user that the inventory has been accepted or rejected. The Inventory Approver can then open the Quantities window (in the Inventory application) to assign a Grade to the material tested.

Using the Quality Control Workflow Sample Results Window Procedure

To view results proceed as follows:

1. From the Sample Approval Notification, navigate to the **Sample Results** window.
2. Complete the fields as described.
3. Save the window

Quality Control Workflow Sample Results Field Reference

The fields on this window are:

Organization

Displays your default organization code.

Sample

Displays the sample number for which results were reported.

Item

Displays the item number associated with the sample number displayed.

Disposition

The sample disposition is selected by the Sample Approver, who can select one of the following:

- Accept - to accept the assay or assays and release the material to production
- Partial Retest - to indicate that partial retesting is in-progress
- Complete Retest - to indicate that complete retesting is in-progress

- Reject - to indicate that the assays were outside the limits of the specification, and the material should not be released to production
- Allow More Time - to indicate that more time is required for determining the assay sample disposition.

Production Region

Batch
This field displays the batch number associated with this sample (if applicable).

Formula Number
This field displays the formula number associated with this sample (if applicable).

Version
If this is a formula sample, this field displays the formula version number for the sample (if applicable).

Routing Number
This field displays the formula routing number (if applicable).

Version
This field displays the formula routing version number (if applicable).

Routing Step
This field displays the routing step to which the test applies (if applicable).

Operation
This field displays the formula operation name/code and description (if applicable).

Item/Lot Region

Warehouse
This field displays the warehouse associated with this item if you entered a warehouse at the sample level.

Lot

This field displays the lot number associated with the item's sample.

Sublot

This field displays the sublot number associated with this item's sample. Sublot data is only displayed if a sublot for this item was entered at the sample level.

Location

This field displays the location associated with this item if a location was entered at the sample level.

Customer/Vendor Region

Customer

If you are creating a quality control sample for a customer sales order, the customer code is displayed.

Vendor

If this is a vendor quality control sample, the vendor code is displayed.

Assay Details

Assay

Each field displays the assay or assays established for the listed item at the specification level. Results for the listed assay are read from left to right on a single line.

Description

This field displays a brief description of the assay.

Result

Depending on this assay type, you one of the following will be entered in this field:

- For nonvalidated assays, comments or observations are displayed. The result entry for this type of assay is free form and does not require validation with the specification.

- For range validated assays, numeric results are displayed. Take note of the minimum and maximum Range values established at the specification level default in the lower part of the window.
- For specification list assays results are based on the value list set up for this assay. Note the specification value shown in the Specification field at the bottom of this window.

UOM

This field displays the quality control unit established at the assay level.

Date

This field displays the date and time for the assay result entry.

Analyst

This field displays the analyst who performs the assay.

Workflow Status

This field displays one of the following assay status messages:

- Timed Out - when the assay is in-progress
- Complete - when the assay is completed

Accept

This field displays assay results:

- The Accept check box is selected when the result is accepted.
- The Accept check box is cleared when the result is pending or rejected.

Certificate of Analysis

This field displays whether the result is for final use for the Certificate of Analysis.

- The Certificate of Analysis check box is selected when the result should be used for the Certificate of Analysis.
- The Certificate of Analysis check box is cleared when the result should not be used for the Certificate of Analysis or is pending or rejected.

Retest

This field displays the assay retest status.

- The Retest check box is selected when the result should be retested.
- The Retest check box is cleared when the result is accepted, pending or rejected.

Specification

This field displays the target specification for the item / assay combination selected.

Range

This field is shown for numeric range assays.

- The lower or minimum limit of the range is indicated in the left field.
- The upper or maximum limit of the range is indicated in the right field.

A

Appendixes

This topic explains typical navigation paths and specific Profile Options that need to be set up.

The following topics are covered:

- Quality Management Navigator Paths
- Setting Up Quality Management Profile Options
- Using the Graphical Process Navigator

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
Actions	OPM Product Development:Quality Control:Setup:Actions
Assay Classes	OPM Product Development:Quality Control:Setup:Assay Classes
Assays	OPM Product Development:Quality Control:Setup:Assays
Customer / Vendor Assay Results Report	OPM Product Development:Quality Control:Reports:Run
Customer / Vendor Results	OPM Product Development:Quality Control:Results:Customer / Vendor
Customer / Vendor Samples	OPM Product Development:Quality Control:Samples:Customer / Vendor
Customer / Vendor Specifications	OPM Product Development:Quality Control:Specifications:Customer / Vendor
Expired Lot Status Change	OPM Product Development:Quality Control:Expired Lots
Grades	OPM Product Development:Quality Control:Setup:Grades
Hold Reasons	OPM Product Development:Quality Control:Setup:Hold Reasons
Item / Location Assay Results Report	OPM Product Development:Quality Control:Reports:Run
Item / Location Required Analysis Report	OPM Product Development:Quality Control:Reports:Run
Item / Location Results	OPM Product Development:Quality Control:Results:Item / Location
Item / Location Samples	OPM Product Development:Quality Control:Samples:Item / Location

Window	Path
Item / Location Specifications	OPM Product Development:Quality Control:Specifications:Item / Location
Lot Genealogy	OPM Product Development:Quality Control:Inquiries:Lot Genealogy
Production Assay Results Report	OPM Product Development:Quality Control:Reports:Run
Production Results	OPM Product Development:Quality Control:Results:Production
Production Samples	OPM Product Development:Quality Control:Samples:Production
Production Specifications	OPM Product Development:Quality Control:Specifications:Production
Single Level Lot Source	This is now managed by the Lot Genealogy Inquiry. See also: *Oracle Process Manufacturing Inventory Management*
Single Level Where Used	This is now managed by the Lot Genealogy Inquiry See also: *Oracle Process Manufacturing Inventory Management*
Units	OPM Product Development:Quality Control:Setup:Units

Setting Quality Management Profile Options

During your implementation, you set a value for selected profile options to specify how your Quality Management application controls access to and processes data. Quality Management uses the listed profile options:

- GMD:Display Specifications
- GMD: Exact Specification Match
- GMD:QC Grade

You can set up these profile options when you set up other applications prior to your Quality Management implementation. Refer to the other product user's guides for more details on how these products use these profile options.

Your System Administrator sets user profile options at one or more of the following levels: Site, Application, Responsibility, and User. Use the Personal Profile Options window to view or set your profile options at the user level. You can consult the *Oracle Process Manufacturing Implementation Guide* for a complete description of the profile options listed. Consult your *Oracle Applications System Administrator's Guide* for a list of profile options common to all Oracle Applications.

Using the Graphical Process Navigator

A Graphical Process Navigator (GPN) is available for New Product Development. The Graphical Process Navigator offers an alternative to the traditional menu structure. For more information please refer to the *Oracle Applications User's Guide*.

You can access the Graphical Process Navigator from the Processes tab on Navigator - OPM New Product Development.

- Click an icon to display its related process.
- Double click an icon to navigate to the window described under Process in the following table.

Step	Action	Process
1. Create Item	Navigates to the Items window	Using the OPM Inventory responsibility, define the Item and its default attributes which will be used throughout the Process Manufacturing application to record Inventory transactions.
2. Create Assays	Navigates to the Assays window	Within the OPM Product Development responsibility you can define measurements to be taken for items and lots. These measurements, called Assays, define all the attributes or characteristics you plan to measure and record in quality control. For example: concentration, saturation, temperature, viscosity, color, or flavor. Assays will be used to help define quality control Specifications.
3. Create Item / Location Specification	Navigates to the Item / Location Specifications window	Quality specifications can be defined for a particular inventory item / lot / sublot, (which can be used per warehouse or application wide). One or more Assays are required to define a Specification. Target values or ranges, date ranges and preferences can be associated with each Assay.
4. Create Item / Location Sample	Navigates to the Item / Location Samples window	Use the Item / Location Sample window when sampling material directly from inventory for quality control testing is required. Specify the organization, warehouse, location, lot / sublot, quantity, UOM, and date drawn for each sample.

Step	Action	Process
5. Enter Results for Item / Location Sample	Navigates to the Item / Location Results window	Enter the result of quality control tests performed against each Assay for the materials you sampled from Inventory. You can add additional assay tests at this point if you performed additional quality control tests on the material other than those set up for the item on the specification.
6. Verify / Set Laboratory Type	Navigates to the Personal Profile Values window	The Profile window is used to set default values at different levels (application, site, responsibility, user) which the application uses to populate fields. The default Lab Type is used to determine under which Laboratory a user will be creating Technical Specifications or Lab Formulas.
7. Create Technical Parameters	Navigates to the Technical Parameters window	Technical parameters are those characteristics of items which you want to measure and calculate. There are several types of technical parameters, each type determines what kind of data will be entered or calculated for the Technical Parameter. For example, a technical parameter for percent solids by weight would be of the type "weight percent." For each type of technical parameter, you specify certain constraints on the data that can be entered, such as the minimum and maximum values.
8. Sequence Technical Parameters	Navigates to the Technical Parameter Sequences window	After you have entered the technical parameters for a lab type, you must specify the order in which they will be displayed on other windows using the Tech Parameter Sequences window. Note that any expression type technical parameters (type 4) which refer to other technical parameters must come after the technical parameters they reference in the sequence. By default, the DENSITY technical parameter is 1. You should not change this.
9. Assign Values for Technical Parameters	Navigates to the Item Technical Data window	You can create a Lab Formula by manually entering the information on the Lab Formula window or you can download a formula from Formula Management by selecting Download Formula from the Action menu on the Lab Formulas window.

Step	Action	Process
10. Create Laboratory Formula	Navigates to the Laboratory Formulas window	The Lab Spreadsheet displays each ingredient, product, and by-product in a formula, and the quantity and technical parameter values for each. You can manipulate ingredients and by-products, and the quantities and technical parameter values for each ingredient and by-product. For technical parameters of types 5 through 10, you can see how this affects the technical parameter values of the products. Product technical parameter values are only calculated for one product in a formula.
11. Display Laboratory Spreadsheet	Navigates to the Laboratory Spreadsheet window	The Laboratory Spreadsheet displays each ingredient, product, and by-product in a formula, and the quantity and technical parameter values for each. You can manipulate ingredients and by-products, and the quantities and technical parameter values for each ingredient and by-product. For technical parameters of types 5 through 10, you can see how this affects the technical parameter values of the products. Product technical parameter values are only calculated for one product in a formula.
12. Enable GMD:Effectivity on Upload to 1	Navigates to the Personal Profile Values window	This profile option will indicate to the Lab and Formula modules that when a Lab Formula is uploaded for production use, that an Effectivity for that Formula should be created.
13. Make Laboratory Formula a Production Formula with effectivity	Navigates to the to the Laboratory Formulas window where you can upload the formula	Use the Upload Lab Formula to Production dialog box to copy a formula from the Laboratory Management module to the Formula Management module. An existing formula cannot be overwritten, rather a new version of the formula will be created if a duplicate is found. If the profile option "GMD: Effectivity on upload" is set to "1", you may be prompted to enter an effectivity record when you upload the formula.

Step	Action	Process
14. Verify Quantities for Ingredient Items	Navigates to the Unallocated Inventory Summary window	This inquiry lists nettable, allocated, and unallocated quantities for the specified item and warehouse. Inventory availability is listed based on the nettable indicators for Production, Order Processing, Shipping, and P/MRP. The only enterable fields are Item, Warehouse and Nettable.
15. Create Production Specification	Navigates to the Production Specifications window	Quality specifications can be defined for a particular Batch, formula, effectivity, routing or operation. One or more Assays are required to define a Specification. Target values or ranges, date ranges and preferences can be associated with each Assay.
16. Create Production Batch	Navigates to the Batches window	Choose either an Item or Formula to base this Batch upon, and if you're using a Formula then an Effectivity must also be chosen. Assuming a Formula is used, the Products, Ingredients and their quantities will display automatically. Make any changes and do any necessary scaling. The Batch will go through multiple phases, any of which a sample can be drawn from.
17. Create Production Sample	Navigates to the Production Samples window	Use the Production Sample window when sampling material created by a Batch for quality control testing. Specify at least the Batch Number and item fields. You can alternatively specify a formula, routing or operation that you want to base a sample on. The quantity, UOM, and date drawn for each sample is also required.
18. Enter Results for Production Sample	Navigates to the Production Results window	Enter the result of quality control tests performed against each Assay for the materials you sampled from the Batch. You can add additional assay tests at this point if you performed additional quality control tests on the material other than those set up for the Batch on the specification.

Glossary

Action

User defined message displayed for expired or out-of-specification lots to identify the need for and type of action to be taken on the lot (for example, INCINERATE or RETURN TO VENDOR).

Assay

Test of the physical and chemical properties of a sample.

Assay Unit of Measure

Unit of measure in which assay tests are measured, for example, pH or percent composition (gravimetric or volumetric). Assay units of measure differ from inventory units of measure.

Cust

Refer to Customer.

Customer

Customer may previously have been referred to as Cust.

Expiration Date

Date or time window beyond which an item or lot becomes unusable. This is defined as part of the lot test specification record in OPM.

Grade

Quality grade of an item that identifies its particular composition. Used to separate one lot from other production lots. Defined in the required specifications record for a lot.

Hold Reason

User-defined code denoting the reason a lot has been designated as unusable.

Item Attributes

Characteristics of an item or lot listed in the test specification record. These characteristics are then assayed and test results are recorded.

Lot Source

History record of the composition of a lot.

No

Refer to Num.

Num

An abbreviation for number. Num may previously have been referred to as No.

QC

Refer to Quality Control.

QC Action

Refer to Action.

QC Grade

Refer to Grade.

QC Status

Refer to Status.

Quality Control

Quality Control may previously have been referred to as QC.

Result

Outcome of a quality control test performed on a lot. The results may not be the expected results (as defined in the test specification) therefore, causing the lot to be out-of-specification and unsuitable to be sold or used in production batches.

Sample

Portion of a lot selected to be assay tested, the results of which are used to estimate the characteristics of the entire lot.

Status

Status assigned to an item or lot before, during, and after assay testing denoting the item or lots usability. The quality control status is user-defined in OPM and is informational only. A quality control status of unusable does not prevent the item or lot from being sold or used for production, rather the inventory status must be changed to prevent its use.

Spec

Refer to Specification.

Specification

Specification may previously have been referred to as Spec.

Test Specification

Record of the physical and chemical requirements for an item or lot, which is compared against the results of assay tests to determine whether the item or lot is suitable to be sold or used in production batches.

Vend

Refer to Vendor.

Vendor

Vendor may previously have been referred to as Vend.

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