Oracle® Process Manufacturing

Quality Management User's Guide

Release 11*i*

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Part No. A77220-02

ORACLE®

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

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Oracle Corporation welcomes your comments and suggestions on the quality and usefulness of this publication. Your input is an important part of the information used for revision.

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- Is the information clearly presented?
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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
- Postal service:
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  Oracle Process Manufacturing
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- Electronic mail message to appsdoc@us.oracle.com

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 Quality Control, 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, QC grades, QC hold reasons, inventory item QC attributes, and lot status control

Test Specifications Setup	Explains basic concepts of test specifications and how to set up assay types
QC Sampling	Explains the fundamentals of QC sampling, and how to run the Item/Location Required Analysis Report to identify inventory that may need QC attention
Recording QC Results	Explains how to enter item/location results, customer/vendor results, and production results, change status and QC grade, and manage expired lots
QC Reporting	Describes all QC 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 and specific Profile Options that need to be set up

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 Release 11i*
- *Oracle Application's Flexfields Guide Release 11i*
- *Oracle Workflow User Guide*
- *Oracle Applications System Administrator's Guide Release 11i*
- *Oracle General Ledger User's Guide Release 11i*
- *Oracle Payables User's Guide Release 11i*
- *Oracle Receivables User's Guide Release 11i*
- *Oracle Human Resources North American User's Guide Release 11i*
- *Oracle Purchasing User's Guide Release 11i*

Oracle Process Manufacturing Guides

The following is a list of documentation in each product group for OPM Release 11*i*.

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 EC 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 Capacity Planning with RHYTHM Factory Planner 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 Release 11i*. 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, QC grades, QC hold reasons and inventory item QC 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 QC attributes for lot items.

The following topics are covered:

- Setting Up Action Codes
- Setting Up QC Grades
- Setting Up QC Hold Reasons
- Setting Up Assay Classes
- Setting Up Inventory Item QC 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 QC test specifications. Once established, you assign them as the default actions for items and lots. The action is then displayed for the item on QC 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 QC test date that the action must be taken.

Setting Up QC Grades

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

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

Setting Up QC Grades Procedure

To set up QC Grade codes:

1. Navigate to the **Grades** window.

2. Complete the fields as described.

3. Save the window.

QC 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 QC Hold Reasons

Hold reason codes are used to place a hold on an item or lot that has expired or failed a QC 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 QC 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.

QC Hold Reasons Field Reference

The fields on this window are:

Reason Code

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

Description

Enter a description for this QC 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 QC Attributes

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

Inventory Item QC Attributes Grade Control

An item must be lot controlled in order to establish QC grade or lot status control. In addition, an item must be grade controlled in order to establish its default QC 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 QC attributes.

Setting Up Inventory Item QC Attributes Procedure

To set up default QC 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 **QC Additional Information**.

5. Complete the fields as described.

6. Save the window.

Inventory Item QC 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 QC 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 QC 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 QC specifications or has failed QC 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 QC 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 QC 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 QC 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 QC 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 QC Assay Units of Measure

- Setting Up Assay Types

- Setting Up QC Item/Location Specifications

- Setting Up Customer/Vendor Specifications

- Setting Up Production Specifications

Understanding Test Specifications

Specifications identify the target, or ideal result, of a QC assay test performed on an item or lot. Once you have completed the initial QC 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 QC Assay Units of Measure

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

QC units of measure differ from inventory units of measure.

Setting Up QC Assay Units of Measure Procedure

To set up QC 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 QC unit of measure. For example, enter PPM as the unit code for parts per million. Required.

Description

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

Setting Up Assay Types

Once you have established QC 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 QC 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 QC 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 QC unit of measure code for this assay. For example PPM for parts-per-million. Setting up QC 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 QC 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 QC 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 QC 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 QC Item/Location Specifications Procedure

To enter QC 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 QC 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 QC 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 QC 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 QC 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 QC customer/vendor specifications directly from the OPM QC 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 QC unit of measure set up for this assay.

Preference

This field is used to prioritize (on QC 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 Spec(ification) 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 QC unit of measure set up for this assay.

Preference

This field is used to prioritize (on QC 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

Setting Up Customer/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.

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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 QC 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 QC production specifications directly from the OPM QC 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 QC unit of measure set up for this assay.

Preference

This field is used to prioritize (on QC 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 QC unit of measure set up for this assay.

Preference

This field is used to prioritize (on QC 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

QC Sampling

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

The following topics are covered:

- Understanding QC Sampling

- Running the Item/Location Required Analysis Report

- Sampling Materials from Inventory

- Sampling Customer/Vendor Materials

- Sampling Production Materials

Understanding QC 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 QC 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 QC 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 Whse

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

To Whse

Initially defaults to the starting warehouse displayed in the From Whse 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 QC 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 QC 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 QC 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 QC 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 QC 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 QC 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.

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 QC 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 QC 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 QC test.

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 QC 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 QC 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/QC Grade
- Performing Single Item QC Status/Grade Changes
- Performing Multiple Items QC 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 QC 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 QC 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. See also Changing Lot Status/QC Grade.

You can add additional assay tests at this point if you performed additional QC 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 QC reports.

You can record inventory results directly from the QC 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 QC 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 (COAs) established for item/location specifications.

- Select the Certificate of Analysis check box to use the result for a COA.

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

[ ]

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 QC 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 QC 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. See also Changing Lot Status/QC Grade.

You can add additional assay tests and results at this point if you performed additional QC 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 QC reports.

You can record customer/vendor results directly from the QC 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 QC 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 QC 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.

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 QC 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 (COAs) established for customer/vendor specifications.

- Select the Certificate of Analysis check box you want to use the result for a COA.

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

[ ]

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 QC 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 QC 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. See also Changing Lot Status/QC Grade.

You can add additional assay tests and results at this point if you performed additional QC 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 QC reports.

You can perform production results entry directly from the QC 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).

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 QC 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 (COAs) established for production specifications.

- Select the Certificate of Analysis check box you want to use the result for a COA.

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

[ ]

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/QC Grade

Once it has been determined that a sample does not meet QC specifications or has failed QC tests, you may need to change either the lot status or the QC 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 QC grade of the lot that failed a QC test. Three methods for changing lot status or QC 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 QC Grade

- Grade Change Immediate: Changes the QC grade of one item lot in one warehouse. QC grade for the item is updated as soon as the changes are saved.

- Grade Change Journaled: Changes the QC grade of one item lot in one warehouse. QC grade for the item is written to the Inventory Adjustment Journal and assigned an edit journal log number. QC 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 QC grade for one or many items in all, one, or a range of lots, sublots, warehouses, or locations. QC grades are updated as soon as the changes are saved.

- Multiple Items Grade Change Journaled: Changes the QC 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.)

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

Performing Single Item QC Status/Grade Changes

QC grade is a characteristic of an item lot, never a location. When you change the QC grade of an item lot, specifying the warehouse location of that lot does not assign a QC 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 QC Status/Grade Changes Procedure

Refer to the Inventory Control Application to perform an immediate or journaled status or QC 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 QC Status/Grade Changes

The Multiple Items Immediate QC grade and status option changes the status or QC 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.

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

Performing Multiple Items QC Status/Grade Changes Procedure

Refer to the Inventory Control Application to perform an immediate or journaled status or QC 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 QC 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

QC Reporting

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

This topic describes all OPM QC 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

- 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 QC attention. QC 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 QC Report identifies inventory that may need QC 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 QC 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 QC 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 Whse

Enter the beginning warehouse for your report in this field.

To Whse

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 Thru

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.

COA

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 QC 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 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.

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 Thru
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.

COA

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 QC 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 No

Enter the beginning routing step number for your report in this field.

To Routing Step No

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 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.

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 Thru

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.

COA

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.

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 QC 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 QC 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:**   QC 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 QC 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 QC 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 QC 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 QC 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 QC 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 QC 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 QC 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

QC 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 QC sample for a customer sales order, the customer code is displayed.

Vendor

If this is a vendor QC 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 QC 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 (COA).

- The Certificate of Analysis check box is selected when the result should be used for the COA.

- The Certificate of Analysis check box is cleared when the result should not be used for the COA 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

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:Cust/Vend
Customer/Vendor Samples	OPM Product Development:Quality Control:Samples:Cust/Vend
Customer/Vendor Specifications	OPM Product Development:Quality Control:Specifications:Cust/Vend
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.

Glossary

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.

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.

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.

QC 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).

QC 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.

QC 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.

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.

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.

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