

Oracle[®] Process Manufacturing Quality Management

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Oracle® Process Manufacturing Quality Management

Part No. A69850-01

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Primary Authors: R. Persen, C. Pink

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Please send your comments to:

Oracle Corporation
Oracle Process Manufacturing Documentation
500 Oracle Parkway
Redwood City, CA 94065
U.S.A.
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Thank you for helping us improve our documentation.

Quality Management Preface

Quality Management Welcome

Welcome to *Oracle Process Manufacturing Quality Management*.

This user's guide includes the information you need to work with Quality Management effectively.

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

About Quality Management

This guide contains overviews as well as task and reference information about Quality Management. This guide includes the following chapters:

- Quality Control Setup
- Test Specifications Setup
- QC Sampling
- Recording QC Results
- QC Reporting

Audience for Quality Management

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

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*.

Conventions

Bolded Text

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

Additional Menu Options

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

Field References

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

Keyboard Mapping

Some keyboards have an Enter key, while some have Return key. All references to this key appear as Enter.

Required Fields

The word "Required" appears as the last word in the field descriptions 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" is shown. 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 use 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

Each chapter contains a procedure with numbered steps. Any actions which are subordinate to a step are assigned letters.

Note: You can customize your Oracle Application, therefore, all procedures are suggestive only. Navigate to forms and between responsibilities in a way that works best for your particular setup. Also note that fields may appear on your screen in a different order than they are discussed in this guide.

Oracle Process Manufacturing Glossaries

A module-specific glossary is included.

Use of Word "Character"

The word "character" means an alphanumeric character. Characters that are numeric or alphabetic only are referenced specifically.

Note: Depending on your system security profile, you may not have access to all of the forms 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

Because Oracle Applications tables are interrelated, 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 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.

Information Sources Related Quality Management

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

Online Documentation

All Oracle Applications documentation is available online on CD-ROM, except for technical reference manuals.

All user's guides are available in HTML and paper. Technical reference manuals are available in paper only. Other documentation is available in paper and sometimes 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 in 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. The HTML documentation also ships with Oracle Information Navigator (if your national language supports this tool) which enables you to search for words and phrases throughout the documentation set.

Other Information Sources

OPM Quality Management shares business and setup information with other Oracle products. The following Oracle Applications guides might be useful when you are setting up and using OPM Quality Management.

- **Oracle Applications User's Guide**
This guide explains how to enter data, query, run reports, and navigate using the graphical user interface (GUI) available with this release. This guide also includes information on setting user profiles, as well as running and reviewing reports and concurrent processes.
- **Oracle Applications Flexfields Guide**
This guide provides flexfields planning, setup and reference information for the implementation team, as well as for users responsible for the ongoing maintenance of Oracle Applications product data. This manual also provides information on creating custom reports on flexfields data.
- **Oracle Workflow**
This guide provides information about the Oracle Workflow product. It provides guidance and assistance for automating and routing information of any type according to business rules.
- **Oracle Applications System Administrators Guide**
This guide provides planning and reference information for the Oracle Applications System administrator. It contains information on how to define security, customize menus and online help text, and manage processing.

Oracle Process Manufacturing Guides

The following is a list of the documentation in each product group of OPM release 11.0.

System Administration and Technical Reference

- *Oracle Process Manufacturing Implementation Guide*
- *Oracle Process Manufacturing Technical Reference Manuals*

OPM Inventory Control

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

OPM Process Execution

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

OPM 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*

OPM Logistics

- *Oracle Process Manufacturing Order Fulfillment User's Guide*
- *Oracle Process Manufacturing Purchasing User's Guide*

OPM Process Planning

- *Oracle Process Manufacturing Forecasting User's Guide*
- *Oracle Process Manufacturing Capacity Planning User's Guide*
- *Oracle Process Manufacturing MPS/MRP User's Guide*

OPM Financials

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

Other Sources

Training

We offer a complete set of formal training courses to help you and your staff master OPM Quality Management and reach full productivity quickly. We organize these courses into functional learning paths, so you take only those courses appropriate to your job's 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 structure, terminology, and data as examples in a customized training session delivered at your own facility.

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

Quality Control Setup

Quality Control Setup Overview

Initial setup of this module requires that you enter default actions or dispositions to be taken on items and lots. You must also enter your lot grading scheme and hold reasons. Once these are entered, you can configure default attributes (inventory item QC attributes) for lot items and define lot status associated with permissions (inventory item lot status control).

This section describes:

- Setting up QC codes
- Setting up QC grades
- Setting up QC hold reasons
- Setting up inventory item QC attributes
- Setting up inventory item 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.

Note: Setting up QC test specifications is discussed in *Test Specifications Setup*

QC Action Codes Form - Procedure

To set up Action codes:

1. Navigate to the **Actions** form
2. Complete the fields as described in the Fields topic.
3. Save the form.

QC Action Codes Form- Fields

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.

QC Action Codes - What to Do Next

Enter default actions for your item/lot.

Note: Items must be lot and grade controlled in order to enter actions for them

Find Action Codes

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Actions - Procedure

To find item action codes:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Actions - Fields topic.
3. Click **Find**.

Find Actions - Fields

Action Code

Enter the desired action code to find.

Description

Enter an action code description to find.

Interval

Enter the interval to find. This will be either:

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

Marked for Deletion

- Select Yes to find action codes marked for deletion.
- Select No to find action codes not marked for deletion.

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.

Caution: 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.

QC Grades Form - Procedure

To set up QC Grade codes:

1. Navigate to the **Grades** form.
2. Complete the fields as described in the Fields topic.
3. Save the form.

QC Grades Form - Fields

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.

QC Grades - What to Do Next

Enter the QC grade for your item/lot.

Note: Items must be lot and grade controlled in order to enter grades for them.

Find QC Grades

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Grades - Procedure

To find QC grades:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Grades - Fields topic.
3. Click **Find**.

Find Grades - Fields

Grade

Enter the desired grade code to find.

Description

Enter a description of the desired grade code to find.

Marked for Deletion

- Select Yes to find grade codes marked for deletion.
- Select No to find grade codes not marked for deletion.

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.

Note: Setting up assays is described in *Test Specifications Setup*.

QC Hold Reasons Form - Procedure

To set up Hold Reasons codes:

1. Navigate to the **Hold Reasons** form.
2. Complete the fields as described in the Fields topic.
3. Save the form.

QC Hold Reasons Form - Fields

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.

QC Hold Reasons - What to Do Next

See also *Test Specifications Setup* and set up assays with default hold reason codes.

Find Hold Reasons

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Hold Reasons - Procedure

To find hold reasons:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Hold Reasons - Fields topic.
3. Click **Find**.

Find Hold Reasons - Fields

Reason Code

Enter the desired hold reason code to find.

Description

Enter the desired description for the hold reason code to find.

Marked for Deletion

- Select **Yes** to find hold reasons marked for deletion.
- Select **No** to find hold reasons not marked for deletion.

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.

Note: You must verify that Lot and Grade are set to Yes on the Items form. 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.

Inventory Item QC Attributes Form - Procedure

To set up default QC attributes for an item:

1. From the **Inventory Control** main menu choose **Inventory Setup**.
2. Navigate to the **Item Master** form.
3. Verify that Lot and Grade have been set to **Yes**.
4. From the **Special** menu, choose **QC Additional Information**.
5. Complete the fields as described in the Fields topic.
6. Save the form.

Inventory Item QC Attributes Form - Fields

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.

Lot Status Control Form - Procedure

To set up lot status control:

1. From the **Inventory Control** main menu choose **Inventory Setup**.
2. Navigate to the **Lot Status** form.
3. Complete the fields as described in the Fields topic.
4. Save the form.

Lot Status Control Form - Fields

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.

Nettable

This field determines whether a lot/sublot is nettable, meaning whether or not it is included in material requirements planning (MRP). Select Yes if it is included in MRP or select No if it is not 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.

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.

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 be shipped or select No if the lot cannot be shipped. Required.

Test Specifications Setup

Test Specifications Setup Overview

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 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.

This section discusses:

- Setting up assay units of measure
- Setting up assays
- Setting up item/location specifications
- Setting up customer/vendor specifications
- Setting up production specifications

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).

Note: QC units of measure differ from inventory units of measure.

Units Form - Procedure

To set up QC Assay units of measure:

1. Navigate to the **Units** form
2. Complete the fields as described in the Fields topic.
3. Save the form.

Units Form - Fields

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.

Assay Units of Measure - What to Do Next

Define QC assays and assign the QC unit of measure to them.

Find Assay Units of Measure

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Units - Procedure

To find assay units of measure:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Units - Fields topic.
3. Click **Find**.

Find Units - Fields

Unit

Enter the desired unit of measure to find.

Description

Enter the desired description of the unit of measure to find.

Marked for Deletion

- Select **Yes** to find units marked for deletion.
- Select **No** to find units not marked for deletion.

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.

Assay Types

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.

Assays Form - Procedure

To set up assay types:

1. Navigate to the **Assays** form.
2. Complete the fields as described in the Fields topic. Depending on the type of assay selected, the fields displayed in Assays Values alternate region will vary.
3. Save the form.

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

Assays Form - Fields

Organization

Defaults to your default organization. The assay code you enter will be effective only for that organization (a local assay code). The default organization code is assigned to your operator code using the Operator Codes form. If you wish this assay code to apply to all organizations (a global assay code) leave this field blank.

Note: 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

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.

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 form will vary. Refer to the Assay Values alternate region of the Assays form. 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.

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.

Assays - What to Do Next

Read the next topics in this manual, QC item/location, customer/vendor, and production specifications.

Find Assay Types

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Assays - Procedure

To find assay types:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Assays - Fields topic.
3. Click **Find**.

Find Assays - Fields

Local/Global

Select whether the assay type you wish to find is local or global.

Organization

Enter the organization name to find.

Type

Enter the assay type to find.

Assay

Enter the assay code name to find.

Marked for Deletion

- Select Yes to find assay types marked for deletion.
- Select No to find assay types not marked for deletion.

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 subplot controlled) + Warehouse + Location
- (Lot OR Lot + Sublot if item is subplot controlled) + Warehouse + Location
- Organization + (Lot OR Lot + Sublot if item is subplot controlled) + Warehouse
- (Lot or Lot + Sublot if item is subplot controlled) + Warehouse
- Organization + (Lot OR Lot + Sublot if item is subplot controlled)
- (Lot OR Lot + Sublot if item is subplot 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 form, 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 directly from the OPM QC module, or from any of the following OPM forms, available from the Inventory Control module:

- Item Master
- Lot/Sublot
- Warehouses
- Location

Item/Location Specifications Form - Procedure

To enter QC item/location specifications:

1. Navigate to the **Item/Location Specifications** form.
2. 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.
3. Select **Out of Specification** to define the Action to be taken on an item which falls outside the defined assay specification.
4. Complete the fields as described in the Fields topic.
5. Save the form.

Item/Location Specifications Form - Fields

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 operator code using the Operator Codes form. If you wish this specification to apply to all organizations (a global specification) leave this field blank.

Note: 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.

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 form.

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 form.

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 module. 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

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.

Unit

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).

Note: Click on a selection from the Effectivity/Out of Specification alternate region to determine the fields that are displayed on the form.

From Date

(Effectivity only) If you intend this specification to be effective for a limited period of time, enter the beginning date for this specification in DD-MON-YYYY HH:MM:SS format where DD is the numeric day in that month, MON is the 3-character abbreviation for the month, YYYY is the 4-digit year, HH is the numeric hour (based on a 24-hour clock), MM is the numeric minute, and SS is the numeric second. This entry defaults to the current date and time.

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

(Effectivity only) If you intend this specification to be effective for a limited period of time, enter the ending date for this specification in DD-MON-YYYY HH:MM:SS format where DD is the numeric day in that month, MON is the 3-character abbreviation for the month, YYYY is the 4-digit year, HH is the numeric hour (based on a 24-hour clock), MM is the numeric minute, and SS is the numeric second. This field defaults to the maximum system date 31-DEC-2010 00:00:00

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

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

Action

(Out of Specification only) Enter the code representing the action to be taken on this item if the specification is not met.

Description

(Out of Specification only) The default description for the Action code is displayed here. Action codes are set up using the Actions form.

Interval

(Out of Specification only) 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.

Range

A range is entered for a numeric range (validated) assay.

(Left field) If you wish to filter the range values for an assay to target the needs of a particular specification, enter the minimum acceptable

specification value for this item/location. The value defaults from the assay range on the screen. Assay values are specified using the Assays form.

(Right field) If you wish to filter the range values for an assay to target the needs of a particular specification, enter the maximum acceptable specification value for this item/location. The value defaults from the assay range on the screen. Assay values are specified using the Assays form.

Find Item/Location Specifications

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Item/Location Specifications - Procedure

To find Item/Location Specifications:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Item/Location Specifications Fields topic.
3. Click **Find**.

Find Item/Location Specifications - Fields

Local/Global

Select whether the item/location specification is local or global.

Organization

Enter the organization name to find.

Item

Enter the item name to find.

Warehouse

Enter the warehouse code to find.

Marked for Deletion

- Select Yes to find item/location specifications marked for deletion.
- Select No to find item/location specifications not marked for deletion.

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. You can do this for one or all items in a specific lot/sublot/location/warehouse combination, or all lots, sublots, locations, and warehouses.

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 module, or from any of the following OPM forms:

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

Note: The module from which each form may be selected is shown in parentheses.

Customer/Vendor Specifications Form - Procedure

To enter Customer/Vendor specifications:

1. Navigate to the **Customer/Vendor Specifications** form.
2. 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.
3. Select **Out of Specification** to define the Action to be taken on an item which falls outside the defined assay specification.
4. Complete the fields as described in the Fields topic.
5. Save the form.

Customer/Vendor Specifications Form - Fields

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 operator code using the Operator Codes form. If you wish this specification to apply to all organizations (a global specification) leave this field blank.

Note: 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

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

(Effectivity or Out of Specification) 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.

Note: The selection your make for the Effectivity or Out of Specification alternate region will determine the fields that are displayed on the form.

From Date

(Effectivity only) If you intend this specification to be effective for a limited period of time, enter the beginning date for this specification in DD-MON-YYYY HH:MM:SS format where DD is the numeric day in that month, MON is the 3-character abbreviation for the month, YYYY is the 4-digit year, HH is the numeric hour (based on a 24-hour clock), MM is the numeric minute, and SS is the numeric second. This entry defaults to the current date and time. This entry defaults to the current date and time.

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

To Date

(Effectivity only) If you intend this specification to be effective for a limited period of time, enter the ending date for this specification in DD-MON-YYYY HH:MM:SS format where DD is the numeric day in that month, MON is the 3-character abbreviation for the month, YYYY is the 4-digit year, HH is the numeric hour (based on a 24-hour clock), MM is the numeric minute, and SS is the numeric second. This entry defaults to the current date and time. This field defaults to the maximum system date 31-DEC-2010 00:00:00

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

See also *Oracle Process Manufacturing System Administrator's Reference* manual for more information on minimum and maximum system dates.

Action

(Out of Specification only) Enter the code representing the action to be taken on this item if the specification is not met.

Description

(Out of Specification only) The default description for the Action code is displayed here.

Action codes are set up using the Actions form.

Interval

(Out of Specification only) 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.

Range

A range is entered for a numeric range (validated) assay.

(Left field) If you wish to filter the range values for an assay to target the needs of a particular specification, enter the minimum acceptable specification value for this item/location. Otherwise, accept the default minimum value specified for this assay. Assay values are specified using the Assays form.

(Right field) If you wish to filter the range values for an assay to target the needs of a particular specification, enter the maximum acceptable specification value for this item/location. Otherwise, accept the default maximum value specified for this assay. Assay values are specified using the Assays form.

Certificate of Analysis Required

- Select Shipment 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.
- Select Invoice if a Certificate of Analysis is required by the customer when goods are invoiced. This field is informational only.
- Select Vendor Receipt 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.

Customer/Vendor Specifications - What to Do Next

See also QC Sampling.

Find Customer/Vendor Specifications

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Customer/Vendor Specifications- Procedure

To find QC grades:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Customer Vendor Specifications -Fields topic.
3. Click **Find**.

Find Customer/Vendor Specifications - Fields

Local/Global

Select whether the customer/vendor specification is local or global.

Organization

Enter the customer/vendor organization name to find.

Customer

Enter the customer name to find.

Vendor

Enter the vendor name to find.

Item

Enter the item name to find.

Marked for Deletion

- Select **Yes** to find customer/vendor specifications marked for deletion.
- Select **No** to find customer/vendor specifications not marked for deletion.

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 module, or from any of the following OPM forms:

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

- Batches (Production)

Note: The module from which each form may be selected is shown in parentheses.

Production Specifications Form - Procedure

To enter Production specifications:

1. Navigate to the **Production Specifications** form.
2. 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.
3. Select **Out of Specification** to define the Action to be taken on an item which falls outside the defined assay specification.
4. Complete the fields as described in the Fields topic.
5. Save the form.

Production Specifications Form - Fields

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 operator code using the Operator Codes form. If you wish this specification to apply to all organizations (a global specification) leave this field blank.

Note: 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.

Note: Of the following four fields (Batch, Formula Number, Routing Number, or Operation) that display on the production Specifications form, 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.

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

(Effectivity or Out of Specification) 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).

Note: The selection your make for Effectivity or Out of Specification alternate region will determine the fields that are displayed on the form.

From Date

(Effectivity only) If you intend this specification to be effective for a limited period of time, enter the beginning date for this specification in DD-MON-YYYY HH:MM:SS format where DD is the numeric day in that month, MON is the 3-character abbreviation for the month, YYYY is the 4-digit year, HH is the numeric hour (based on a 24-hour clock), MM is the numeric minute, and SS is the numeric second. This entry defaults to the current date and time.

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

To Date

(Effectivity only) If you intend this specification to be effective for a limited period of time, enter the ending date for this specification in DD-MON-YYYY HH:MM:SS format where DD is the numeric day in that month, MON is the 3-character abbreviation for the month, YYYY is the 4-digit year, HH is the numeric hour (based on a 24-hour clock), MM is the numeric minute, and SS is the numeric second. This field defaults to the maximum system date 31-DEC-2010 00:00:00

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

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

Action

(Out of Specification only) Enter the code representing the action to be taken on this item if the specification is not met.

Description

(Out of Specification only) The default description for the Action code is displayed here.

Action codes are set up using the Actions form.

Interval

(Out of Specification only) 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.

Range

A range is entered for a numeric range (validated) assay.

(Left field) If you wish to filter the range values for an assay to target the needs of a particular specification, enter the minimum acceptable specification value for this item/location. The value defaults from the assay range on the screen. Assay values are specified using the Assays form.

(Right field) If you wish to filter the range values for an assay to target the needs of a particular specification, enter the maximum acceptable specification value for this item/location. The value defaults from the assay range on the screen. Assay values are specified using the Assays form.

Find Production Specifications

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Production Specifications - Procedure

To find Production Specifications:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Production Specifications - Fields topic.
3. Click **Find**.

Find Production Specifications - Fields

Local/Global

Select whether the production specification you wish to find is local or global.

Organization

Enter the production specification organization name to find.

Batch

Enter the batch name for which you wish to find production specifications.

Formula Number

Enter the formula number for which you wish to find production specifications.

Formula Version

Enter the formula version for which you wish to find production specifications.

Routing Number

Enter the routing number for which you wish to find production specifications.

Routing Version

Enter the routing version for which you wish to find production specifications.

Routing Step

Enter the routing step for which you wish to find production specifications.

Operation

Enter the operation for which you wish to find production specifications.

Item

Enter the item name for which you wish to find production specifications.

Marked for Deletion

- Select Yes to find production specifications marked for deletion.
- Select No to find production specifications not marked for deletion.

QC Sampling Overview

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 chapter discusses the sampling functions of the OPM QC module 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

Note: See the *Oracle Applications* user's guide for detailed information on submitting a report.

To submit the Item/Location Required Analysis Report:

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

Item/Location Analysis Report Form - Fields

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 subplot 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.

Note: Taking samples from inventory does not decrease inventory quantities.

You can record inventory sampling directly from the OPM QC module or from any of the following OPM forms, available from the Inventory Setup menu:

- Item Master
- Warehouses
- Location

Item/Location Samples Form - Procedure

To record inventory samples:

1. Navigate to **Item/Location Samples** form.

Note: You can also navigate to this form from the **Inventory Item Master**, **Lot/Sublots**, **Warehouses** or **Location** forms by selecting **Samples** from the **Special** menu.

2. Complete the fields as described in the Fields topic.
3. Save the form.

Item/Location Samples Form - Fields

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. Required.

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.

User

Enter the user code of the person who withdrew the sample. Leave this field blank to default to the current user code. 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.

Item/Location Samples - What to Do Next

Perform QC testing on the sample.

Enter QC Results for the sample.

Find Item/Location Samples

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Item/Location Sample - Procedure

To find Item/Location Samples:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Item/Location Sample - Fields topic.
3. Click **Find**.

Find Item/Location Sample - Fields

Sample

Enter the sample name you need to find.

Item

Enter the item code you need to find for sampling.

Lot

Enter the lot from which you want to find a sample.

Sublot

Enter the subplot from which you want to select a sample.

Warehouse

Enter the warehouse from which you want to select a sample.

Location

Enter the location from which you want to select a sample.

Date Drawn

Enter the date the sample you wish to find was drawn.

External ID

Enter an alternate or cross-reference code for the sample you wish to find.

Marked for Deletion

- Select **Yes** to find item/location samples marked for deletion.
- Select **No** to find item/location samples not marked for deletion.

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.

Note: Taking customer/vendor samples does *not* decrease inventory.

You can record customer/vendor sampling directly from the OPM QC module or from any of the following OPM forms:

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

Note: The module from which each of these forms may be selected is shown in parentheses.

Customer/Vendor Samples Form - Procedure

To sample customer/vendor materials:

1. Navigate to **Customer/Vendor Samples** form.

Note: You can also navigate to this form from the Purchase Management module Generic Items, Vendors, or Vendor Items forms by selecting **Samples** from the **Special** menu.

2. Complete the fields as described in the Fields topic.
3. Save the form.

Customer/Vendor Samples Form - Fields

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.

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. If left blank, the system defaults to today's date, but you can type the desired date in this field. Required.

User

Enter the user code of the person who withdrew the sample, or leave the field blank to default to the current user. 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 in another system, enter the sample ID as recorded on the external system.

Customer/Vendor Samples - What to Do Next

Perform QC testing on the sample.

Enter QC Results for the sample.

Find Customer/Vendor Samples

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Customer/Vendor Samples - Procedure

To find Customer/Vendor Samples:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Customer/Vendor Samples Fields topic.
3. Click **Find**.

Find Customer/Vendor Samples - Fields

Sample

Enter the sample name you need to find.

Customer

Enter the customer code you need to find for sampling.

Vendor

Enter the vendor code you need to find for sampling.

Item

Enter the item code you need to find for sampling.

Date Drawn

Enter the date the customer/vendor sample you wish to find was drawn.

External ID

Enter an alternate or cross-reference code for the customer/vendor sample you wish to find.

Marked for Deletion

- Select **Yes** to find customer/vendor samples marked for deletion.
- Select **No** to find customer/vendor samples not marked for deletion.

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 module or from any of the following OPM forms:

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

Note: The module from which each of the above forms may be selected is shown in parentheses.

Production Samples Form - Procedure

To record production samples:

1. Navigate to the **Production Samples** form.

Note: You can also navigate to this form from the Formula Management module **Formulas**, **Effectivities**, **Routings**, and **Operations** forms by selecting **Samples** from the **Special** menu. It is also available from the Production Management module **Batches** form by selecting **Samples** from the **Special** menu at the Product detail line.

2. Complete the fields as described in the Fields topic.
3. Save the form.

Production Samples Form - Fields

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.

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.

Routing Desc

This field 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).

Description

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 date, but you can type the desired date in this field. Required.

User

Enter the user code of the person who withdrew the sample, or leave the field blank to default to the current user code. Required.

External ID

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

Production Samples - What to Do Next

Perform QC testing on the sample.

Enter QC Results for the sample.

Find Production Samples

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Production Samples - Procedure

To find Production Samples:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Production Samples Fields topic.
3. Click **Find**.

Find Production Samples - Fields

Sample

Enter a sample code you need to find.

Batch

Enter the batch code you need to find.

Formula Number

Enter the formula number you need to find for production sampling.

Formula Version

Enter the formula version you need to find for production sampling.

Routing Number

Enter the routing number you need to find for production sampling.

Routing Version

Enter the routing version you need to find for production sampling.

Routing Step

Enter the routing step number you need to find for production sampling.

Operation

Enter the operation code for the operation performed in the routing you need to find for production sampling.

Item

Enter the item code to find for production sampling.

Date Drawn

Enter the date the sample was taken that you need to find for production sampling.

External ID

Enter an alternate or cross-reference code for the sample you need to find for production sampling.

Marked for Deletion

- Select Yes to find production samples marked for deletion.
- Select No to find production samples not marked for deletion.

Recording QC Results

Results Overview

Once you have recorded the samples and performed QC tests you need to enter the results into OPM.

QC Sampling discussed taking samples from the following three groups:

- Samples taken directly from inventory
- Samples for a customer or vendor order
- Samples for a formula or production batch

This chapter discusses entering testing results for these three groups.

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 subplot controlled) + Warehouse + Location
- (Lot OR Lot + Sublot if item is subplot controlled) + Warehouse + Location
- Organization + (Lot OR Lot + Sublot if item is subplot controlled) + Warehouse
- (Lot or Lot + Sublot if item is subplot controlled) + Warehouse
- Organization + (Lot OR Lot + Sublot if item is subplot controlled)
- (Lot OR Lot + Sublot if item is subplot controlled)
- Organization + Warehouse + Location
- Warehouse + Location
- Organization + Warehouse
- Warehouse

Note: 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 module or from any of the following OPM forms available from the Inventory module:

- Item Master
- Lot/Sublot
- Warehouses
- Location

Entering Item/Location Results - Procedure

To enter item/location results:

1. Navigate to the **Item/Location Results** form.
2. Complete the fields as described in the Fields topic.
3. Save the form.

Item/Location Results Form - Fields

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 sample.

Sublot

This field displays the subplot number associated with this item sample. Sublot data is only displayed if you entered a subplot 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.

Location

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

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 form. 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 form.

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.

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 Inventory Results - What to Do Next

Print the Assay Results report.

Change the status of any items that fail assay tests. See also [Changing Lot Status](#).

Find Item/Location Results

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Item/Location Results - Procedure

To find Item/Location Results:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Item/Location Results - Fields topic.
3. Click **Find**.

Find Item/Location Results - Fields

Organization

Enter the organization code for which you wish to find item/location results.

Sample

Enter the sample code for which you wish to find item/location results.

Item

Enter the item code for which you wish to find item/location results.

Warehouse

Enter the warehouse code for which you wish to find item/location results.

Marked for Deletion

- Select Yes to find item/location results marked for deletion.
- Select No to find item/location results not marked for deletion.

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.

Note: 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
- Customer OR Vendor

Note: 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 module or from any of the following OPM forms:

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

Customer/Vendor Results Form - Procedure

To enter inventory results:

1. Navigate to **Customer/Vendor Results** form.

Note: You can also navigate to this form from the Order Fulfillment **Customers** and **Generic Customer Items** forms or the Purchase Management **Vendors** and **Vendor Item** forms by selecting **Results** from the **Special** menu.

2. Complete the fields as described in the Fields topic.
3. Save the form.

Customer/Vendor Results Form - Fields

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.

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 form. 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 form.

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.

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.

Customer/Vendor Results - What Do Next

Print the Assay Results report.

Change that status of any items that fail assay tests. See also Changing Lot Status.

Find Customer/Vendor Results

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Customer/Vendor Results - Procedure

To find Customer/Vendor Results:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Customer/Vendor Results - Fields topic.
3. Click **Find**.

Find Customer/Vendor Results - Fields

Organization

Enter the organization code for which you wish to find customer/vendor results.

Sample

Enter the sample code for which you wish to find customer/vendor results.

Vendor

Enter the vendor code for which you wish to find customer/vendor results.

Item

Enter the item code for which you wish to find customer/vendor results.

Marked for Deletion

- Select **Yes** to find customer/vendor results marked for deletion.
- Select **No** to find customer/vendor results not marked for deletion.

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

Note: 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 module or from any of the following OPM forms:

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

Production Results Form - Procedure

To enter production results:

1. Navigate to the **Production Results** form.

Note: You can also navigate to this form from the Formula Management module's **Formulas**, **View Effectivities**, **Routings**, and **Operations** forms by selecting **Results** from the **Special** menu. It is also available from the Production Management module **Batches** form by selecting **Results** from the **Special** menu.

2. Complete the fields as described in the Fields topic.
3. Save the form.

Production Results Form - Fields

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.

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 form. 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 form.

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.

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.

Entering Production Results - What to Do Next

Print the Assay Results report.

Change that status of any items that fail assay tests. See also Changing Lot Status.

Find Production Results

There are several options for locating a record and populating a form. The List of Values option displays a dialog box with the appropriate records. The Query Find option displays a separate block called the Find form, where you enter search criteria.

Find Production Results - Procedure

To find Production Results:

1. Choose **Find** from the **Query** menu.
2. Complete the fields as described in the Find Production Results Fields topic.
3. Click **Find**.

Find Production Results - Fields

Organization

Enter the organization code for which you need for find production results.

Sample

Enter a sample number for which you need to find production results.

Batch

Enter the batch code for which you need to find production results.

Formula Number

Enter the formula number you need to find for production results.

Formula Version

Enter the formula version you need to find for production results.

Routing Number

Enter the routing number you need to find for production results.

Routing Version

Enter the routing version you need to find for production results.

Operation

Enter the operation code for the operation performed in the routing you need to find for production results.

Item

Enter the item code to find for production results.

Marked for Deletion

- Select Yes to find production results marked for deletion.
- Select No to find production results not marked for deletion.

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 Journalized:** 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 Journalized:** 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 Journalized:** 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 Journalized: 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.)

Caution: 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

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

Immediate and Journalled Status/Grade Changes Form - Procedure

To perform an immediate or journalled status or QC grade change:

1. Navigate to the Inventory Control **Inventory Quantities** form.
2. Select the **Journalled** check box to make a journalled change, or clear the **Journalled** check box to make an immediate status change. The fields appearing on the form will differ depending on which selection you make.
3. Select **Single Item** to make changes to a single item.
4. Select **Change Lot Status** to change the status of the lot/sublot, or select **Change QC Grade** to change the status of a QC grade. The fields appearing on the form will differ depending on which selection you make.
5. Complete the fields as described in the Fields topic.
6. Save the form.

Inventory Quantities Form - Fields

Organization

Your default organization code is displayed.

Journal

(Journalled only) If this is a journalled status or grade change. Required (if journalled)

Line

(Journalled only) If this is a journalled status or grade change, leave this field blank to let the system assign the next edit journal line number. Otherwise, enter an existing journal line number to make changes to it.

Date

Enter the date and time for this lot status or QC grade change. If left blank, the system defaults to today's date. Required.

Reason Code

Enter a valid code to indicate the reason why the lot status or grade change is required. Required.

Item

Enter the Item for which status or grade changes are being made.
Required.

Lot Status

This field displays the current lot status for this item.

Lot

If this item is lot controlled, enter the lot for which status or grade changes are being made.

QC Grade

This field displays the current QC Grade.

Sublot

If this item is lot/sublot controlled, enter the subplot for which status or grade changes are being made.

On Hand Qty

This field displays the on hand quantities of this item in this location.

Warehouse

Enter the warehouse within which status or grade changes for this item are being made. Required.

Location

Enter the location within which status or grade changes for this item are being made.

Caution: 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.

To Status

(Change Lot Status only) Enter the new status for this item/lot. That is, the status to which you are changing this item. Required.

To Grade

(Change QC Grade only) Enter the grade for this item/lot. That is, the grade to which you are changing this item/lot.

Description

(Lot Status or QC Grade) The defined description for the status or grade is displayed.

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.

Caution: 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.

Multiple Items Immediate QC Grade/Status Changes Form - Procedure

To perform an immediate or Journalled status or QC grade change on multiple items:

1. Navigate to the Inventory Control **Inventory Quantities** form.
2. Select the **Journalled** check box to make a journalled change, or clear the **Journalled** check box to make an immediate status change. The fields appearing on the form will differ depending on which selection you make.
3. Select **Multiple Items** to make changes to make changes to several items.
4. Select **Change Lot Status** to change the status of the lot/sublot, or select **Change QC Grade** to change the status of a QC grade. The fields appearing on the form will differ depending on which selection you make.
5. Complete the fields as described in the Fields topic.
6. Save the form.

Inventory Quantities Form - Fields

Organization

Your default organization code is displayed. You can only retrieve samples that were entered for this organization. The default organization code is assigned to your operator code using the Operator Codes form.

Journal

(Journalled only) This field shows the journal name to which this transaction will be saved.

Line

(Journaled only) If this is a journaled status or grade change, leave this field blank to let the system assign the next edit journal line number. Otherwise, enter an existing journal line number to make changes to it.

Date

Enter the date and time for this lot status or QC grade change. If left blank, the system defaults to today's date. Required.

Reason Code

Enter a valid code to indicate the reason why the lot status or grade change is required. Required.

Item

Enter the beginning item for which status or grade changes are being made in the From field. Enter the ending item for which status or grade changes are being made in the Through field.

Lot

Enter the beginning lot for which status or grade changes are being made in the From field. Enter the ending lot for which status or grade changes are being made in the Through field.

Sublot

Enter the beginning sublot for which status or grade changes are being made in the From field. Enter the ending sublot for which status or grade changes are being made in the Through field.

Warehouse

Enter the warehouse within which status or grade changes for this item are being made. Required.

Location

Enter the beginning location for which status or grade changes for this item are being made in the From field. Enter the ending location for which status or grade changes for this items are being made in the Through field.

Caution: 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.

QC Grade

Enter the starting QC grade for which grade changes for this item are being made. Enter the ending QC grade for which grade changes are being made.

Lot Status

Enter the starting lot status for which status changes for this item are being made. Enter the ending lot status for which status changes are being made.

To Status

(Change Lot Status only) Enter the new status for this item/lot. That is, the status to which you are changing this item/lot. Required.

To Grade

(Change QC Grade only) Enter the grade for this item/lot. That is, the grade to which you are changing this item/lot.

Description

(Lot Status or QC Grade) The defined description for the status or grade is displayed.

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 module 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.

Note: See also the *OPM Inventory Management user's guide* for a complete discussion of automatic allocation and manual allocation.

The Expired Lot Status Change form 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 form.

Expired Lot Status Change Form - Procedure

To change expired lot statuses:

1. Navigate to the **Expired Lot Status Change** form.
2. Complete the fields as described in the Fields topic.
3. Save the form.

Expired Lot Status Change Form - Fields

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.

Reason

Indicate the reason for this status change. Reason codes are set up using the Reason Codes form. 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 form in Inventory Setup in Inventory Control. Required.

QC Reporting Overview

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 chapter describes all OPM QC reports and inquiries, including:

- Item/Location Required Analysis Report
- Item/Location Assay Results Report
- Customer/Vendor Assay Results Report
- Production Assay Results Report
- Lot Source and Where Used Inquiries

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.

See also *QC Sampling* for a complete description of the Item/Location Required Analysis 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

Note: See the *Oracle Applications* for detailed information on submitting a report.

To submit the Item/Location Assay Results Report:

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

Item/Location Assay Results Report - Parameter Fields

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 subplot for your report in this field.

To Sublot

Enter the ending subplot 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.

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 subplot 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

Note: See the *Oracle Applications* for detailed information on submitting a report.

To submit the Customer/Vendor Assay Results Report:

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

Customer/Vendor Assay Results Report - Parameter Fields

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 form.

Print Condition

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

Customer/Vendor Assay Results Report - Report Description

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

Item

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

Lot

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

Sublot

This report field displays the subplot 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 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

Note: See the *Oracle Applications* for detailed information on submitting a report.

To submit the Production Assay Results Report:

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

Production Assay Results Report - Parameter Fields

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.

Lot

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

Sublot

This report field displays the subplot 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.

Finding Single Level Lot Source

There are many reasons why you may want to know where a particular lot came from or where it went. Probably the most serious and most critical reason is to track down a source of contamination and to determine what has been affected.

The Lot Source inquiry displays each ingredient that went into a particular product. If a customer has a problem with a lot that you shipped, you can use this utility to trace the components of the lot level by level back to the purchased raw material that went into the lot, and to the vendors from whom you purchased the raw materials.

Single Level Lot Source Form - Procedure

To perform a Lot Source inquiry:

1. From the **Inventory Control** main menu, navigate to the **Lot/Sublot** form.
2. Enter the Item and Lot/Sublot for which you want to determine the Lot/Source. (See also *Oracle Process Manufacturing Inventory Control* for more information on the Lot/Sublot form).
3. From the **Special** menu select **Lot/Source**.
4. Complete the fields as described in the Fields topic. The form displays the results of the Single Level Lot Source inquiry.

Single Level Lot Source Form - Fields

Item

Enter the item for which you want to view source information or leave this field blank to accept the item that was specified on the Lot/Sublot form. The item description is displayed. Required.

Lot

Enter the lot for which you want to view source information or leave this field blank to accept the lot that was specified on the Lot/Sublot form. Required if lot controlled.

Sublot

Enter the subplot for which you want to view source information or leave this field blank to accept the subplot that was specified on the Lot/Sublot form. Required if subplot controlled.

Date

This field displays the date and time the transaction on this line occurred. For batch transactions, this is the date and time the batch was consumed.

Item

This field displays the item consumed by: the item/lot/sublot entered.

Lot

This field displays the lot consumed by: the item/lot/sublot entered.

Sublot

This field displays the sublot consumed by the item/lot/sublot entered.

Quantity

This field displays the quantity of this lot that was consumed by the item/lot/sublot entered.

UOM

This field displays the Unit of Measure (UOM) for the lot/sublot quantity.

Type

This field displays transaction type for the transaction displayed on this line.

Note: The following fields are shown at the bottom of this form, for the highlighted Transaction Detail.

Organization

This field displays the default organization code. The default organization code is assigned to your operator code using the Operator Codes form.

Document Number

This field displays the document number for the highlighted line.

Document Line

This field displays the line number of this transaction within this document.

Line Status

This field displays the status of this transaction. For example, COMPLETED or PENDING.

Item Description

This field displays the description of the item on the highlighted line.

Lot Description

This field displays the description of the lot on the highlighted line.

Finding Single Level Where Used

There are many reasons why you may want to know where a particular lot came from or where it went. Probably the most serious and most critical reason is to track down a source of contamination and to determine what has been affected. OPM allows you to do this through the Where-Used inquiry.

The Where-Used inquiry displays each lot that consumed a portion of the lot in question. If you traced a customer complaint all the way back to a contaminated lot of raw material, you can then use this utility to determine all other product lots that could be affected.

Single Level Where Used Form - Procedure

To perform a Where-Used inquiry:

1. From the **Inventory Control** main menu, navigate to the **Lot/Sublot** form.
2. Enter the Item and Lot/Sublot that you want to determine Where Used. (See also *Oracle Process Manufacturing Inventory Control* for more information on the Lot/Sublot form).
3. From the **Special** menu, select **Where Used**. The Single Level Where Used form is displayed.
4. Complete the fields as described in the Fields topic. The form displays the results of the Single Level Where Used inquiry.

Single Level Where Used Form - Fields

Item

Enter the item for which you want to view source or where-used information or leave this field blank to accept the item that was specified on the Lot/Sublot form. The item description is displayed. Required.

Lot

Enter the lot for which you want to view source or where-used information or leave this field blank to accept the lot that was specified on the Lot/Sublot form. Required, if lot controlled.

Sublot

Enter the subplot for which you want to view source or where-used information or leave this field blank to accept the subplot that was specified on the Lot/Sublot form. Required if subplot controlled.

Date

This field displays the date and time the transaction on this line occurred. For batch transactions, this is the date and time the batch was consumed.

Item

This field displays the item in which the item/lot/sublot entered is used.

Lot

This field displays the lot in which the item/lot/sublot entered is used.

Sublot

This field displays the subplot in which the item/lot/sublot entered is used.

Quantity

This field displays the quantity of the lot in which the item/lot/sublot entered is used.

UOM

This field displays the Unit of Measure (UOM) for the lot/sublot quantity.

Type

This field displays transaction type for the transaction displayed on this line.

Note: The following fields are shown at the bottom of this form, for the highlighted Transaction Detail.

Organization

This field displays the default organization code. The default organization code is assigned to your operator code using the Operator Codes form.

Document Number

This field displays the document number for the highlighted line.

Document Line

This field displays the line number of this transaction within this document.

Line Status

This field displays the status of this transaction. For example, COMPLETED or PENDING.

Item Description

This field displays the description of the item on the highlighted line.

Lot Description

This field displays the description of the lot on the highlighted line.

Appendixes

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 form. These tables provide the most typical default path.

Form	Path
Actions	OPM Product Development > Quality Control > Setup > Actions
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

Form	Path
ItemLocation Results	OPM Product Development > Quality Control > Results > ItemLocation
ItemLocation Samples	OPM Product Development > Quality Control > Samples > ItemLocation
ItemLocation Specifications	OPM Product Development > Quality Control > Specifications > ItemLocation
Production Assay Results Report	OPM Product Development > Quality Control > Reports > Run
Production Results	OPM Product Development > Quality Control > Results > Production
Single Level Lot Source	OPM Inventory > OPM Inventory Control > Setup > LotSublot > Special > Lot Source
Single Level Where Used	OPM Inventory > OPM Inventory Control > Setup > LotSublot > Special > Where Used
Production Samples	OPM Product Development > Quality Control > Samples > Production
Production Specifications	OPM Product Development > Quality Control > Specifications > Production
Single Level Lot Source	OPM Product Development > Quality Control > Inquires > Lot Source
Single Level Where Used	OPM Product Development > Quality Control > Inquires > Where Used
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:

- QC\$DISPLAYSPEC
- QC\$EXACTSPECMATCH
- SYSQC_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 of Terms

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 QC status is user-defined in OPM and is informational only. A QC 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 QC 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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