cobas® infinity

Short Guide
Software version 1.1.0

Roche

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Information about the document

Revision index

Manual version	Software version	Revision date	Changes
1.0	1.0.0	September 2013	First edition
1.1	1.0.0	September 2013	Format and content extension improvements
1.2	1.0.0	January 2014	Some symbols deleted
2.0	1.1.0	July 2014	Updated for new software version

Table 1

Edition notice

This manual is intended for users of the **cobas** infinity solution.

Every effort has been made to ensure that all the information contained in this document is correct at the time of printing. However, Roche Diagnostics S.L. reserves the right to make any changes necessary without prior notice as part of ongoing product development.

Any changes made to the software by the customer will render the warranty or service agreement null and void.

Software updates may only be performed by Roche technical service representatives.

Intended use

cobas infinity is a laboratory information system that covers work flow and data management with connected preanalytical, analytical, and postanalytical instruments, including processes from order entry to report printing. This management involves order entry and report printing processes, among others.

cobas infinity can be connected to one or several:

1. Roche preanalytical instruments.
2. Roche postanalytical instruments.
3. Roche and non-Roche analytical instruments (biochemistry, immunology, urine analysis, coagulation, hematology, and molecular diagnostics).
4. Laboratory Information Systems (LIS).
5. Hospital Information Systems (HIS).
6. Electronic Health Record Systems (EHRS).
7. Work area solutions for hematology, clinical chemistry, and urinalysis. Roche and non-Roche analytical instruments.
8. Point-of-care devices and software.
9. Export of quality control results to commercial benchmarking tools: QC results are sent to an external QC validation system for validation. The results of the validation can be integrated into the solution.
10. Clinical Decision Support Systems (CDSS) and Risk Calculation Software (e.g. Astraia, Viewpoint, SsdwLab).
11. Billing systems.
12. Intensive care systems.
13. Non-HIS order entry systems.
14. Picture Archiving Systems (PACS).
15. Document Management Systems (DMS).

Connectivity between the solution and the aforementioned instruments or systems enables the exchange of data uni- or bidirectionally via interface.

Uni- and bidirectionally transmitted data contain patient information, order data, and result data.

Patient information includes patient demographics and identifying information. Order information contains test requests.

It is essential that the user reads this manual carefully before using the system, since it contains relevant information for the correct use and configuration of the software, as well as security warnings that should be taken into account to guarantee patient safety.

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Implementation (basic configurations)

The configurations that are essential for the application to operate in its most basic form are described below.

Common configurations for all modules

This section details the necessary configurations that must be carried out in all modules.

Users

Access **Administration > Users**

Configure the users and the access level they will have for screens in the application and the actions that they can perform on them.

Configuring users

1. Configure the profiles (**Administration > Users > Profiles**) to create permission levels to access the application and the task performance menu entry points (order entry, result entry, configurations, etc.).
2. Enter users and associate one or more profiles to them (**Administration > Users > Users**).

Order ID

Access **Administration > Order entry > Order ID**

Configure the order ID format to be assigned to the orders entered in the application.

If you wish to work with shared orders (that incorporate General Lab and Microbiology tests) it is necessary to configure the same order ID format for both applications.

Patient ID1

Access **Administration > Patient management > Patient ID1**

The patient ID (or history number) is a unique code that is assigned to each patient entered in the application. Define whether you wish to assign this ID manually or automatically. In the latter case, specify the format it must have (prefixes, suffixes, number of letters, etc.).

Demographics

Access **Administration > Demographics > Configuration**

By configuring the demographics you are defining the fields (and the names of these fields) relevant to patient data and order data that will be viewed on the **Order entry**, **Patient entry/edition**, **Patient merging**, and **Patient search** work screens. Similarly, you can:

- Configure whether the demographic fields that appear on the screen must be filled in obligatorily.
- Assign values that are shown by default in the demographic fields.
- Configure the type of data accepted by demographic fields (free text, coded text, images, dates, etc.).

Configuring demographics

1. Create demographics (**Administration > Demographics > Configuration**).
2. Assign values for patient demographics (**Administration > Patient management > Demographics**).
3. Assign values for order demographics (**Administration > Order entry > Demographics**).

Reports

Access **Administration > Reports**

After obtaining the results of the tests in a supergroup or an order, you must print them in a report to be delivered to the patient. To do this, you must have prepared a report format and defined its characteristics before printing the results.

Configuring reports

1. Define the report formats by assigning templates and later by personalizing the format (**Administration > Reports > Definition**).
2. Assign the reports to some demographics to apply a specific format and target to each order according to the demographics they include (**Administration > Reports > Demographic assignment**).
3. Specify the demographic values for the types of demographics defined in the application and associate a report format with these values (**Administration > Reports > Report assignment**).
4. Enter the data of the printers available in the system (**Administration > Reports > Printers**).
5. Configure all the print targets available in the system (**Administration > Reports > Print targets**).
6. Select a value for the demographic specified in **Demographic assignment**, select the print targets (fax, printers, or host) and define the demographic value that will trigger the report to be sent to a specific print target (**Administration > Reports > Target assignment**).
7. Configure the conditions that will prevent reports with pending results from being sent (**Administration > Reports > Holding**).

Rule engines

Access **Administration > Rule engine**

The rules configuration specifies the actions that the system will perform if the order or any of its items meet the conditions defined by the application of the rule.

Configuring rule engines

1 Configure the rule activation modes that indicate when the conditions configured for it must be evaluated.

2 Configure the rule conditions where you indicate which premises specific items must meet to launch the action configured in the rule.

3 Define the rule actions, that is, which processes are executed on specific items if the conditions configured in the rule are met.

Specific General Lab and Emergency Lab configurations

Carry out all the procedures detailed in this section in the order specified.

Tests

Access **Administration > Tests**

Using this section, you can configure specific General Lab and Emergency Lab tests and enter the tube-sample type-test relationships, reference ranges, function tests, etc.

Entering tests

1 Configure sample types (**Administration > Tests > Sample types**).

2 Configure tubes (**Administration > Tests > Tubes**).

3 If you are going to enter function tests, configure stimulations (**Administration > Tests > Stimulations**).

4 Configure tests (**Administration > Tests > Tests**). After performing the basic configuration, you can configure:

- Reference ranges (**Test references** button).
- Delta Check (**Test Delta Check** button).
- Function tests (**Function Tests** button)
- Formula tests (**Formula** button).

5 Configure groups and supergroups to create test sets (**Administration > Tests > Groups** and **Administration > Tests > Supergroups**).

These aid test selection and report printing.

Tube IDs

Access **Administration > Order entry > Tube identifiers**

This option allows you to define the identifier format for the tubes available in the system. Before configuring this menu, define the order ID format.

It is recommended that you configure this option since the tubes are actually present in the laboratory (with or without a date, with or without prefixes or suffixes, etc.) and in this way you can:

- Handle the orders on the most important work screens either through tubes or orders.
- Search for tubes using the order IDs.
- Search for orders using the tube ID they belong to.

Validation

Although this is not a mandatory configuration, it is recommended that you perform it as it will make working with the application easier.

Access **Administration > Validation**

Keep in mind that the application allows you to perform two types of validation: automatic and manual.

- There are two types of automatic validation:
  - One validation is performed by the system according to the criteria assigned in the **Automatic validation criterion** general parameter (**Administration > General > General parameters**).

    For this validation to be enabled, you must previously enable the **Enable the automatic validation** general parameter.
  - Another validation is performed by the user according to the validation criteria associated with the user. This validation is developed on the **Order selection** screen, after choosing the **Validate** or **Validation** buttons.
- Manual validation is performed by the user in the **Result entry** screen, where the orders that could not be validated automatically are shown.

Similarly, validation may be only medical, or technical and medical:

- Medical validation is always enabled.
- Technical validation is optional and precedes medical validation in validation processes. It is enabled by entering **No** in the **Use medical validation only** general parameter (**Administration > General > General parameters**).

Configuring validation

1. Configure the criteria that will allow you to automatically validate the orders (**Administration > Validation > Criteria**).
2. Configure the filters and the validation profile available to each user (**Administration > Validation > Filters** and **Administration > Validation > Validation profiles**).
3. Configure the validation screen that each user will use (**Administration > General > Configurable screens**).

For more information, see *Configurable screens* (p. 9).

Configurable screens

Although this is not a mandatory configuration, it is recommended that you perform it as it will make working with the application easier.

Access **Administration > General > Configurable screens**

The application allows you to personalize the format of some work screens. In this configuration option, you can associate a template to the screen you wish to generate and define its format. There are different templates according to the screen you configure.

Configuring screens

1. In **Administration > General > Configurable screens**, choose **Add** to enter a screen.
2. Select the template according to the screen you wish to enter:
   - Validation screens: **Validation by order**, **Validation with charts** (hemograms, protein analyses), **Order selection**, **Validation by serology order**, **Validation with result template**, or **Validation** (validation on a single screen) templates.
   - Result entry screen: **Results by work lists**, **Urinalysis management** templates.
   - Work areas screens: **Monitoring screen by tube**, **Monitoring screen by order**.
3. Choose the **Accept** button.
4. Select the screen you entered in the previous steps.
5. Choose the **Configure** button to access the screen where you can add the fields and other features that your screen must have.

Work areas

Although this is not a mandatory configuration, it is recommended that you perform it as it will make working with the application easier.

Access **Administration > Work areas > Entries**

The work areas allow you to control the status of certain orders in the application for a specific set of tests. Before configuring work areas, you must:

- Define a monitoring screen and a validation screen for the work area (**Administration > General > Configurable screens**).
- Enter groups and supergroups (**Administration > Tests**) to be associated with the work area. In this way, the work area will only show the orders that contain a test belonging to the group or the supergroup it is associated with.

Once these elements have been configured, this menu entry point will allow you to enter different work areas to be associated with monitoring screens and validation screens as well as groups and supergroups.

Specific Microbiology configurations

Carry out all the procedures in this section in the order specified.

Results

Access **Administration > Results**

In this option, you can configure the microorganisms, isolates, and coded results to be assigned to the different items of the order on the result entry screen and that may be numerical or textual. The application allows you to define all the items in one single file.

Entering microbiology results

1. Go to **Administration > Results > Results**.
2. Choose **Add** and configure the following types of result.
   - All types.
   - Tests:
     - Main test
     - Secondary test
   - Culture media.
   - Microorganisms:
     - Isolate description.
     - Microorganism quantification.
     - Microorganism.
   - Antibiotic.
3. Optionally, configure groups of results (**Administration > Results > Result group**) to associate specific results with specific items in the order.
   - In this case, link them to a main test (**Administration > Tests > Tests**, **Results** tab).

     In this way, the result entry process is more efficient since a window opens for you to select the results linked to the main test selected by choosing **Results** in **Work areas**.
4. Optionally, configure coded comments (**Administration > Comments > Coded comments**): they are frequently used as microbiology results.

Antibiograms

Access **Administration > Antibiogram**

This option allows you to configure all the necessary items to work with antibiograms, antibiotics, and the methods for assessing antibiotic sensitivity.

Entering antibiograms

1. Create antibiotic families (**Administration > Antibiogram > Antibiotic families**).
2. Create the antibiotic methods (**Administration > Antibiogram > Antibiotic methods**).
3. Create the antibiotics (**Administration > Antibiogram > Antibiotics**).
4. Create the antibiograms (**Administration > Antibiogram > Antibiogram**).

Tests

Access **Administration > Tests**

This option allows you to configure the sample types, culture media, main and secondary tests, and, optionally, the necessary anatomic locations to enter Microbiology tests.

Configuring tests

1. Configure culture media (**Administration > Tests > Culture media**).
2. Configure the main and secondary tests (**Administration > Tests > Tests**).
3. Configure the anatomic locations to signal where the sample has been collected from (**Administration > Tests > Anatomic location**).
4. Configure the sample types (**Administration > Tests > Sample types**).
5. Configure groups and supergroups to create test sets (**Administration > Tests > Groups** and **Administration > Tests > Supergroups**).

   These aid test selection and report printing.

Work areas

Access **Administration > Work Areas**

This option allows you to configure the Microbiology areas or work area groupings that you will work with from the **Main > Work Areas** menu entry. These areas access the different order processing screens which include: **Seeding**, **Results** or **Validation**.

Sample identifier

Although this is not a mandatory configuration, it is recommended that you perform it as it will make working with the application easier.

Access **Administration > Order entry > Sample identifiers**

Through this option you can configure a unique identifier for each sample type-test relation in the order generated. Before configuring this option, configure the order ID. The sample identifier is viewed on several screens in the application, such as **Results** and **Order entry**.

Profiles

Although this is not a mandatory configuration, it is recommended that you perform it as it will make working with the application easier.

Access **Administration > Profiles**

Entering profiles

1 Go to **Administration > Profiles > Profiles** to configure the sample type-test relationships.

2 Go to **Administration > Profiles > Isolate profiles** to configure antibiogram and secondary test relationships for an isolate.

3 Go to **Administration > Profiles > Filters** to configure the filters for validating the selector items that appear in **Order entry** and in **Results**.

Labels

Although this is not a mandatory configuration, it is recommended that you perform it as it will make working with the application easier.

Access **Administration > Labels**

This option allows you to configure the labels used in a center and that are printed using the **Labels** and Print labels buttons located in **Order entry** or on the Microbiology, **Seeding**, and **Results** screens.

Configuring labels

1 Create label formats or templates (**Administration > Labels > Labels**).

2 Create a real label using a format or template (**Administration > Labels > Labels**).

3 Enter the label printers (**Administration > Labels > Printers**).

4 Assign the labels to the different items (levels) in the order (**Administration > Labels > Label assignment**).

5 Using Print labels, assign a label printer to the user.

General parameters

Access **Administration > General > General parameters**

These parameters are a series of system options that allow you to define given configurations or enable and disable certain functions in the application.

Specific Lab Flow configurations

This option allows you to enter drivers and associate them with their instruments. In this way, you can configure communication between the instruments that distribute the tubes that reach the laboratory and the application that manages their distribution and incoming results.

Configuring the work screens

Configuring work screens

1 In **Administration > Tests > Tubes**

- with regard to tube distribution, check that the configurations are the most appropriate for the organization of your laboratory.
- indicate the tests that will be processed by the tubes that have not been scanned or entered.
- define the type of tubes that will be sent to an archive type target.

2 In **Administration > ICA > Instrument definition**: enter the instruments with which the application will communicate:

- Add the driver with which you wish to work and configure the tab related with the type of communication it must have.
- It is recommended that you use the **Information** button to obtain more data about the useful configurations of the driver being entered.
- Choose **Accept** to enter the driver and incorporate it into the upper table of drivers registered in the system.
- If the driver is analytical or preanalytical, select it. The drop-down button shows the buttons applicable to these kinds of drivers as enabled:
  - Place the pointer on the relevant driver in the table of drivers registered in the system and choose **Tests** to associate tests with the driver.
  - Choose **Work conditions** to configure the basic performance of the driver.
  - Choose **Default values**, this button allows you to specify the ranges of the items appearing on the **Manual prepar.** and **Reset** screens.
- If the driver is for Microbiology tests, select it. The drop-down button shows the buttons applicable to these kinds of drivers as enabled:
  - Choose the buttons to perform mapping between the items in the application and those of the instrument: antibiotic codes, antibiograms, and other items belonging to Microbiology.
  - Choose **Sample types/tests** to associate the application sample types-tests relationships with the driver.
  - Choose **Settings** to configure the rest of the options.

3 In **Administration > Distribution > Target configuration**:

- configure all the instrument type targets that have previously been entered.
- configure the manual aliquot targets you wish to use in the distribution.
- configure the archive type targets. Define the expiry date of the tubes in this target and specify whether you wish them to be eliminated automatically.
- configure the virtual targets with which you wish to work. Associate the corresponding tests to these targets.

4 In **Administration > Distribution > Target sorting**:

- Define the areas and distribution groups to organize the instruments.
- Sort the targets according to the laboratory work flows.

5 In **Administration > Distribution > Workplace definition**: define a workplace.

6 In **Administration > Users > Profiles**: associate access permissions to the module areas. To do this, select the **Work with Lab Flow areas** permission.

7 In **Administration > Users > Users**: associate the workplaces and distribution areas that users can work with to users to assign them distribution permissions in the related targets.

8 In **Administration > General > General parameters** review the parameter configurations to adapt their work screens as you wish.

Basic flows

The most frequent and basic processes that take place in a center are shown below.

Processing orders – by roles

These procedures describe the necessary steps for the roles involved in order processing to open orders, enter results, validate them, and print them.

How to register orders if I am a secretary

1 Go to **Main > Order entry > Order entry**

2 If no automatic order ID has been configured, enter the order ID in the [**Order ID**] field.

3 Enter the patient associated with the order. Perform one of the following actions:

- If you know the patient ID1, enter it directly in the [**Patient ID1**] field and press Enter to load the data on the screen.
- If you wish to use a patient ID1 that does not exist in the system:
  - Enter it directly in the [**Patient ID1**] field.
  - Press Enter to access the **Patient entry/edition** screen. Fill in the mandatory fields on this screen and choose the **Accept** button to save the information in the database and return to the **Order entry** screen, which displays the patient ID1 entered.
- If the patient already exists in the database:
  - Enter their first surname or the surname root in the [**Patient ID1**] field, or
  - Leave the [**Patient ID1**] field empty and choose the button to access the **Patient search** screen.
  - Once on this screen, use the filter fields to search for the patient. Once the patient has been found, double-click on it to load its data on the **Order entry** screen.
- If you wish to create a new patient:
  - Leave the [**Patient ID1**] field empty and choose the adjacent button.
  - From the **Patient search** screen, choose the **Add** button to create the patient from the **Patient entry/edition** screen.

4 Fill in at least the mandatory demographic fields (marked in bold and with an asterisk).

5 For General Lab and Emergency Lab orders, in the **Test selection** area, assign tests to the order:

- Choose an option from the drop-down menu in the **Supergroup**, **Sample type**, or **Tube/container type** fields. These fields cannot be used at the same time.
- Next, you can see the tests associated with the **Supergroup**, **Sample type** or **Tube/container type** field option selected. They are displayed in the lower left table.

Only if you have used the **Supergroup** field in the previous step, the **Tests**, **Test groups**, and **Tests/Groups** view options are enabled to monitor the type of data to be displayed in the table.

6 For Microbiology orders, in the **Test selection** area, assign tests to the order. Tests can be entered in two ways:

- Using the **Sample types** field:

  Select a sample type in the drop-down menu of the **Sample types** field to view the list of associated tests in the lower field.
- If you wish to specify the anatomic location where the sample was taken from, select it in the **Locations** field.
- Double-click on the tests or profiles displayed below the selected sample. The selected tests are added to the table displaying the sample types-tests entered.
- Select a new sample type for each associated test that you wish to enter in the order. Each sample type and its associated tests are displayed in a different column in the table.
- Using the **Profiles** field:
  - Optionally, you can specify the anatomic location the sample was taken from through the **Locations** field.
  - Select a profile in the drop-down menu of the **Profiles** field to add the test-sample type relation of the selected profile to the table below. Each sample type and its associated tests are displayed in a different column in the table.

7 Double-click on the tests or groups that you wish to enter in the order: they are added to the lower table of selected items.

8 Choose the **Save** button to store the information in the database and exit this screen.

How to enter routine and emergency results if I am a laboratory technician

1 Go to **Main > Validation > Result entry**.

2 Enter the number of the order in which you wish to enter results in the [**Order ID**] field.

3 The order then appears on the screen. Enter the results of the tests in the corresponding cells.

4 To add comments:

- Choose the **Comment** button.
- Once on the corresponding screen, select whether the comment affects the order, test, or patient.

- Enter the comment:
  - If you wish to add a comment that was pre-saved in the application, select it in the **Available comments** panel to move it to the **Selected comments** area.
  - To add a comment directly, place the cursor in the **Selected comments** area and type the text.
  - Choose **Accept** to save them.

5 To repeat tests:

- Select the adjacent check box of the test you wish to repeat.
- Choose the **Repeat** button. The field where you had entered the result will become empty. As soon as you fill it in, the repeated result icon will appear.

6 Choose **Accept** to save them in the database.

■

How to seed microbiology sample types

1 Go to **Main > Work Areas** > [**Work area that you wish to access**].

2 Select one or more work areas to show their tests. If you are working with work area groups, you can select just one of them.

3 Choose the **Seeding** button to access the associated screen (**Seeding** screen).

4 Enter the number of the order for which you wish to perform seeding in the **Order ID** field.

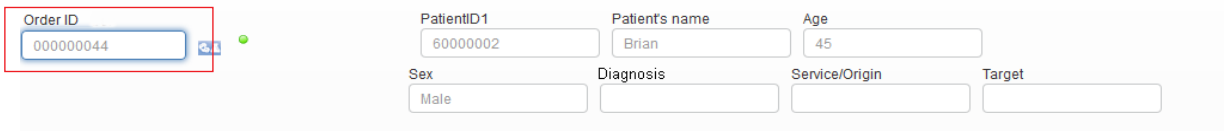


Figure 1 Registering the Order ID on the **Seeding** screen

5 Next, the corresponding order appears on the screen and you can perform any of the following actions:

- Enter culture media and new main tests. To do this:
  - Choose the tree level to which you wish to add any items belonging to the level immediately below.
  - Choose the **Add** button to open the test or culture media selector.
- Remove any item from the order, except sample types. To do this:
  - Choose the tree level to be deleted.
  - Choose the **Delete** button.
- Label all the items configured as labelable (marked with the **Pending labelling** icon). To do this:
  - Choose the tree level to be labeled.
  - Choose the **Labels** button.
- Enter results for main tests and culture media. To do this:
  - Enter the coded result or the free-text result in the box adjacent to the relevant item, or
  - Enter a comment through the **Comment** button.
- Mark a culture medium as seeded by printing the corresponding label. To do this, select the culture medium to be seeded and choose the **Labels** button.

6 After completing this procedure, choose the **Accept** button to save the information in the database.

■

How to seed microbiology sample types

1 Go to **Main > Work Areas > [Work area that you wish to access]**

2 Select one or more work areas to show their tests. If you are working with work area groups, you can select just one of them.

3 Choose the **Results** button to access the corresponding screen.

4 Enter the number of the order for which you wish to enter results.

5 If necessary, add new items to the order (main tests, culture media, isolates, antibiograms, or secondary tests). To do this:

- Choose the hierarchical level placed above the items you wish to add.
- Choose the **Add** button to open the selector of the items to be added.

6 Enter a result or comment for each item.

- To enter results:
  - Choose the item for which you wish to enter a result.
  - Enter the result in the box adjacent to the item, except for antibiograms. The result can be entered manually. If it is coded result, enter the corresponding code or choose the **Results** button, in which case a selector appears.
- For antibiograms, you must select them. In the table displayed, you have to manually enter the result and the type of method used for at least one antibiotic.
- To enter comments, choose the **Comment** button to open the corresponding screen.

7 Once the results have been entered, choose the **Save** button to save the results.

■

How to validate results if I am a routine or emergency laboratory doctor

1 Go to **Main > Validation > Order selection**.

2 If the **Validation profile** field is empty, select the profile to be applied to the order range defined in the rest of the fields.

3 Define the order range to be validated by filling in the following fields:

- **Date**, **Date from**, **Date to**: enter the time interval in which the order IDs to be validated should be comprised.
- **Initial sequence num.**, **Final sequence num.**: enter the range of orders to be validated.
- **Validate medically**, **Validate technically** options: select the types of validation to be performed at this stage.
- **Validated by**: select the desired levels of validation (order, group, or test).
- **Applications**: choose the modules that include the orders whose tests are to be validated.

4 Perform one of the following actions:

- Choose the **Search** button to view the orders matching the filters. Then, choose the **Validation** button to go to the validation screen.
- Choose the **Validate** button to go to the validation screen.

5 The validation screen shows the orders that must be validated manually (since they did not meet the system or user automatic validation requirements). Perform one of the following actions:

- In order to validate all the results of an order at the same time, choose the **Validate** button. Next, the following order to be validated is displayed.
- In order to validate only some tests, select the left check box of the tests to be validated and choose the **Test val.** button.

How to validate results if I am a microbiology doctor

1 Go to **Main > Work Areas > > [Work area that you wish to access]**.

2 Select one or more work areas to show their tests. If you are working with work area groups, you can select just one of them.

3 Choose the **Validation** button to access the screen displaying the orders pending to be validated.

4 Choose the **Detail** button to access the result validation screen.

5 Perform one of the following actions:

- If you wish to validate the complete order shown on the screen, choose the **Validate** button.
- If you only wish to validate the test you have chosen, choose the **Test val.** button.

How to print result reports if I am a secretary

1 Go to **Main > Reports > Report print**.

2 Indicate the type of report you wish to print:

- **Pre-report** option: it is only allowed for those orders or test groups whose final report has not been printed yet.
- **Final report** option: it is only allowed if all the order or the supergroup tests have results, they have been clinically validated, and they have not been printed yet in a final report.
- **Result reprint** option: it is only allowed for those orders or test groups whose final report has already been printed.

3 Define the range of orders to be printed by filling in the following fields:

- **Date**, **Date from**, **Date to**: enter the time interval in which the order IDs to be printed should be comprised.
- **Initial sequence num.**, **Final sequence num.**: enter the range of orders to be printed.

4 Fill in the **Test groups** field if the validation is performed by test groups and not by orders. To do this, choose the button to open the selector and specify the group of tests to be printed.

5 In the **Application** table, select the module containing the orders that you wish to print.

6 In the **Sorting** area, select the items that determine how orders are sorted in the report:

- **Criterion no. 1** field: in this field, select the demographic determining the datum by which the orders are sorted.
- **Value no. 1** field: select the demographic values determining the way orders are sorted in the report. The orders whose demographic value does not match the one specified in this field are not printed.
- **Criterion no. 2** and **Value no. 2** fields: It is possible to set a second sorting criterion and another value for limiting the orders to be printed. In this case, the orders are sorted first according to **Criterion no. 1** and then to **Criterion no. 2** and finally by date and order ID.

7 Choose the **Preselection** button to view a list of the orders to be printed.

8 Choose the **Print** button to launch the printing process.

9 Once the order has been printed, close it through the end-of-day process.

- If the general parameter triggering the automatic process has been enabled, the system closes the order at the specified time.
- If you wish to perform the process manually, access **Monitoring > End-of-day process**. Once on this screen, press the **Launch process** button. Next, a list pops up indicating, among other details, the number of orders that have been closed.

Querying order statuses: applying filters and reading the information on the screen

This screen only displays Microbiology open orders, that is, those that have not been closed by the end-of-day process or because they have exceeded the value specified in the **No. of days after which a complete or incomplete order is closed** general parameter and identifies what is missing in order to finalize them (validate, print, seed, etc.).

Viewing the status of orders and applying filters

1 Select the Microbiology module to access its work areas.

2 Choose the desired work areas or work area groups whose corresponding orders you wish to view.

3 Choose the **Queries** button to access the corresponding screen.

4 At this stage, this screen does not show any data. Choose the **Filter** button and apply the desired filter:

- Single filter: this is the usual operating mode of the button.
- Multiple filter mode: This filter allows you to select more than one value within the same item to perform a search. To do this:

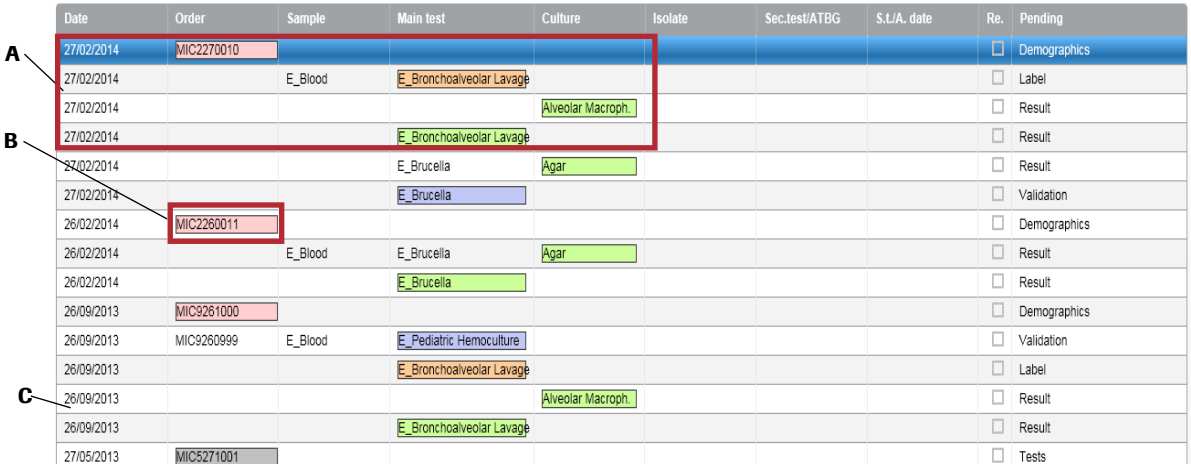
  - Select the **Customized...** option in the drop-down menu of the column to which you wish to apply different filter values.

  - Next, select the search values from the window appearing on the screen.

  - Then, the area above the multi-filter button chosen shows the values selected via the selector used for the search.

  - Choose the **Apply** button to start the search.

5 The results are shown on the screen. They must be read as:



A Items belonging to the order.

B Each order ID indicates the beginning of a new list of items.

C The microbiology hierarchy tree is represented on this screen: each item in the order is moved one place to the right with respect to the item it depends on. The higher level is the order; the lower level includes, in this order: samples, main tests, cultures, isolates, secondary tests and antibiograms.

Figure 2 Representation of the order items hierarchy

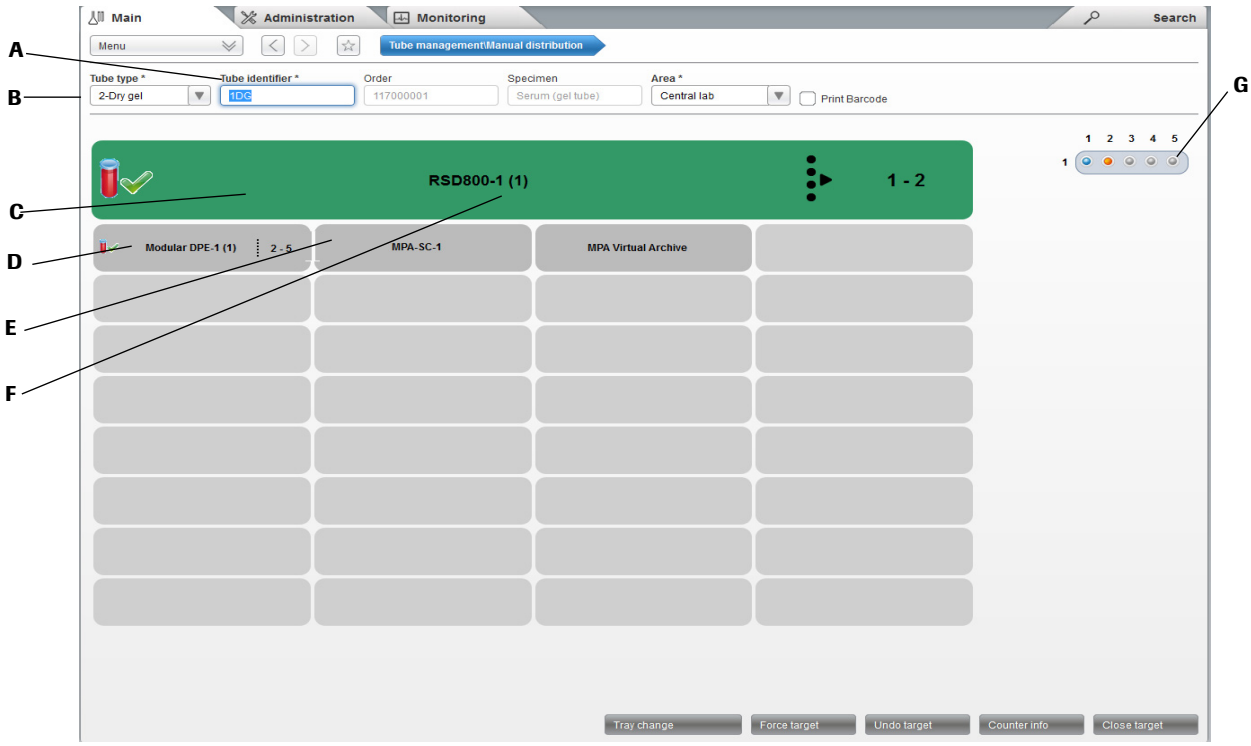
Distributing tubes and consulting traces in Lab Flow

Distributing tubes manually

1 Enter the orders (manually or electronically from the relevant module).

2 Enter the tubes associated to the orders in the rack or on the tray.

3 Go to **Main** > **Tube management** > **Manual distribution**, scan the tube and distribute it to the corresponding target.



A Field showing the scanned tube or where the ID is entered manually.

B Selection field for the tube type that you wish to distribute.

C Proposed target where the tube is sent to.

D Target that the tube has already passed through (the relevant icon and position are displayed).

E Target that the tube has not yet passed through (it displays no icon or position).

F Current tube target. The figures show the following (starting from the left): tray ID, rack where the tube is located, and the position it occupies in the rack.

G This chart displays:
- tray positions occupied by other tubes: blue circles;
- the position that the system suggests for the tube when a target is newly assigned: orange circle;
- free positions: gray circles.

Figure 3 **Manual distribution** screen

4 Carry out the previous step each time you retrieve the tube to distribute it to the next target until it reaches the end.

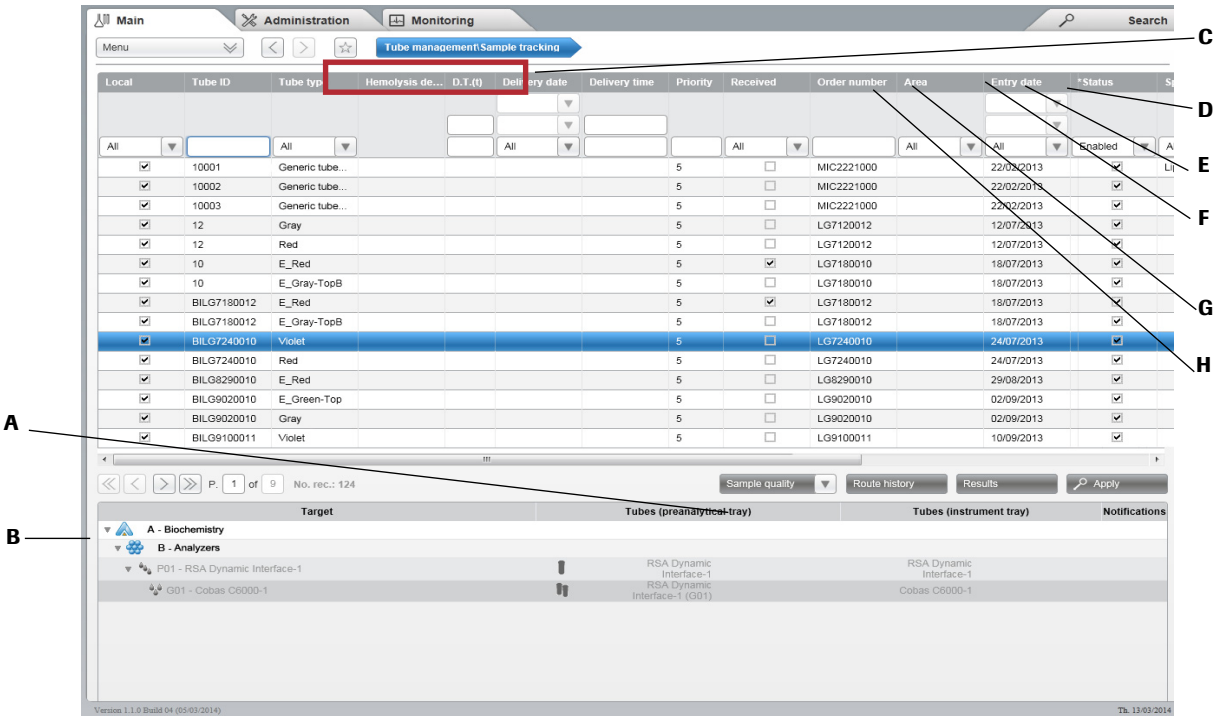
5 Enter the results obtained to process the sample in the system manually or automatically (the analyzer sends the results to the application).

■

Checking the tube trace

1 Go to **Main** > **Tube management** > **Sample tracking**.

2 Choose **Route history** to access the traces screen.



A This button allows you to close the targets related to the tube ID and consider them completed in order for the tube to be able to continue to be processed in the rest of pending targets and stages.

B This area shows the areas and targets that make up the full path of the selected tube.

C This area displays the route the tube has undergone, the current location, and the remaining route to complete.

D The cells that are selected indicate that there has been a distribution action (distribution, aliquot, and so on) on the corresponding tube.

E This column shows the level of degradation of the hemolyzed sample.

F This column shows the quality of the sample in the tube (unknown, hemolyzed, icteric, and so on).

G This column shows the hours until the results of the tube tests must be delivered (information transmitted by HCA).

H This column shows the tube's distribution area starting from the moment it was scanned.

Figure 4 **Sample tracking** screen

Performing manual preparations

This section describes how to send tests (and samples) to the selected instrument. The different procedures are described depending on the type of driver (Microbiology, routine, preanalytical, or postanalytical).

Generating and sending manual preparations in microbiology, general laboratory, and preanalytical drivers

Previous requirements To define whether the drivers work with:

- Barcodes. Configure the driver to work with them (**Administration > ICA > Instrument definition**, **Work conditions** button, **Work with barcode** option).
- General load sheets. Configure the driver to work with them (**Administration > ICA > Instrument definition**, **Work conditions** button, **Work with load sheet** option).
- Load sheets for trays. In this case:
  - configure the driver to work with them (**Administration > Distribution > Target configuration**, **Instrument load sheet** option).
  - perform the corresponding manual distribution in Lab Flow (**Main > Tube management > Manual distribution**).

Generating and sending manual preparations in microbiology drivers

1. Go to **Monitoring > ICA > Connections status**.
2. Select the instrument for which you wish to perform the manual preparation.
3. Choose the **Manual prepar.** button.
4. If you wish, modify the filters defined in **Administration > ICA > Instrument definition**.
   - In **Order range**, enter the range of sequence numbers whose tests (and sample types) must be displayed in the **Order ID from** and **Order ID to** fields.
   - In **Dates**, fill in the **Dates**, **Date from**, and **Date to** fields with the time interval (entry date) comprising the previously specified sequence numbers whose tests (and sample types) must be displayed.
   - In **Selection result**, use the button to open the window where you can select the result values configured in the system that cause tests including them to be displayed.
   - In **Enable/Disable by test or profile** select the tests that must be kept in mind when choosing one of the two buttons **Send** or **Send again**. To do this:
     - **Test** field: Select the tests associated with the instrument and displayed on the screen so as to enable/disable their adjacent check box.
     - **Profile** field: Select the profiles of tests associated with the instrument and displayed on the screen so as to enable/disable their adjacent check box.
5. Perform one of the following actions:
   - Choose the **Send** button if the selected tests have not been sent in that preparation.
   - Choose the **Send again** button if the selected tests have already been sent in that preparation.
6. Next, a preview screen opens to show the order IDs to be sent/resent depending on the filters applied.

7 Perform one of the following actions:

- Deselect the check box adjacent to the orders not to be sent (if applicable) and choose **Accept** to confirm the sending/resending of tests to the instrument.
- Choose to include a change in the filters so that other tests may also be displayed.

Performing and sending manual preparations in General Lab and preanalytical drivers (with barcodes, general load sheets, or tray load sheets)

1 Go to **Monitoring > ICA > Connections status**.

2 Select the driver for which you wish to perform the manual preparation.

3 Choose the **Manual prepar.** button to access the corresponding screen.

4 Perform one of the following actions:

- For drivers that work with general load sheets or barcodes:
  - If you wish, you can modify the filters defined in **Administration > ICA > Instrument definition**.
  - In **Order**, enter the range of sequence numbers whose tests (and sample types) must be displayed in the **Initial** and **End** fields.
  - In **Order entry date**, fill in the **Date**, **Date from**, and **Date to** fields with the time interval (entry date) comprising the previously specified sequence numbers whose tests must be displayed.
  - In **Demographics**, choose adjacent to each of the demographic fields to open the selector and define the demographics that must be included in the orders. The fields displayed vary according to the driver.
  - The field appearing in **Master** will depend on the driver being configured. Choose the button to assign a value to the field displayed.
  - Choose the **Send** button if the selected tests have not been sent in that preparation, or the **Send again** button if the selected tests have already been sent in that preparation.
- For drivers that work with load sheets for trays:
  - Choose the button next to the **Tray** field to select the tray whose tubes, already distributed manually, you wish to prepare.
  - Next, choose the **Accept** button.

5 Next, a preview screen opens to show the tests to be sent/resent according to the filters applied.

6 If you wish to set priorities within the orders in the group to be sent to the instrument, choose the orders to be sent first and then choose the **With priority** button.

7 Perform one of the following actions:

- Deselect the check box adjacent to the orders that are not sent and choose the **Accept** button to confirm the sending/resending of tests to the instrument.
- Choose to include a change in the filters so that other tests may also be displayed.

Generating and sending manual preparations in postanalytical drivers

This procedure applies to those cases in which the tubes archived in a tray must be sent manually to an automatic location. Using this screen you can use filters to select the trays distributed in a given period of time and whose tubes must be sent to the desired automatic location.

Previous requirements

- Define a path with an archive-type target in Lab Flow (**Administration > Distribution > Target configuration**).
- Enter the driver in the system (**Administration > ICA > Instrument definition**).
- Enter the driver as archive in Lab Flow (**Administration > Archive > Archive location**).
- In Lab Flow, determine to which manual archive the different tubes of the system are sent (**Administration > Distribution > Target configuration**, **Archive definition** tab).

Performing and sending manual preparations in postanalytical drivers

1. Go to **Monitoring > ICA > Connections status**.
2. Select the driver for which you wish to perform the manual preparation.
3. Choose the **Manual prepar.** button to access the corresponding screen.
4. Choose the button next to the **Targets** field to select the archive-type targets where the distributed tubes must be sent to.
5. Choose the button next to the **Types of tube** field, to select whether there are tubes distributed that must be sent to any of the archives selected in the previous step.
6. If desired, you can restrict the information depending on the distributed trays. To do this, in the **Tray** area:
   - If you wish to select a range, place the cursor on the **From tray** and **To tray** fields to enter the interval of the tray identifiers for which the distributed tubes are considered.
   - If you wish to select single tray identifiers, use the **Tray** field and choose the adjacent button to pass it to the **Selected trays:** field.
7. Restrict the information depending on the date on which the tray interval was distributed. To do this, use the fields in the **Date range** area.
8. Choose the **Accept** button so that the screen shows the trays according to the filters applied.
9. Once the tray list is viewed on screen, select the adjacent check boxes of the trays that you wish to take to the automatic archive.
10. Choose the **Send** button to start the process of creating the message to be sent to the instrument with the information about the tubes of the selected trays.

Quality management flows in Total Quality Management

The three work flows that can be carried out via the Total Quality Management module are described below.

Managing documents

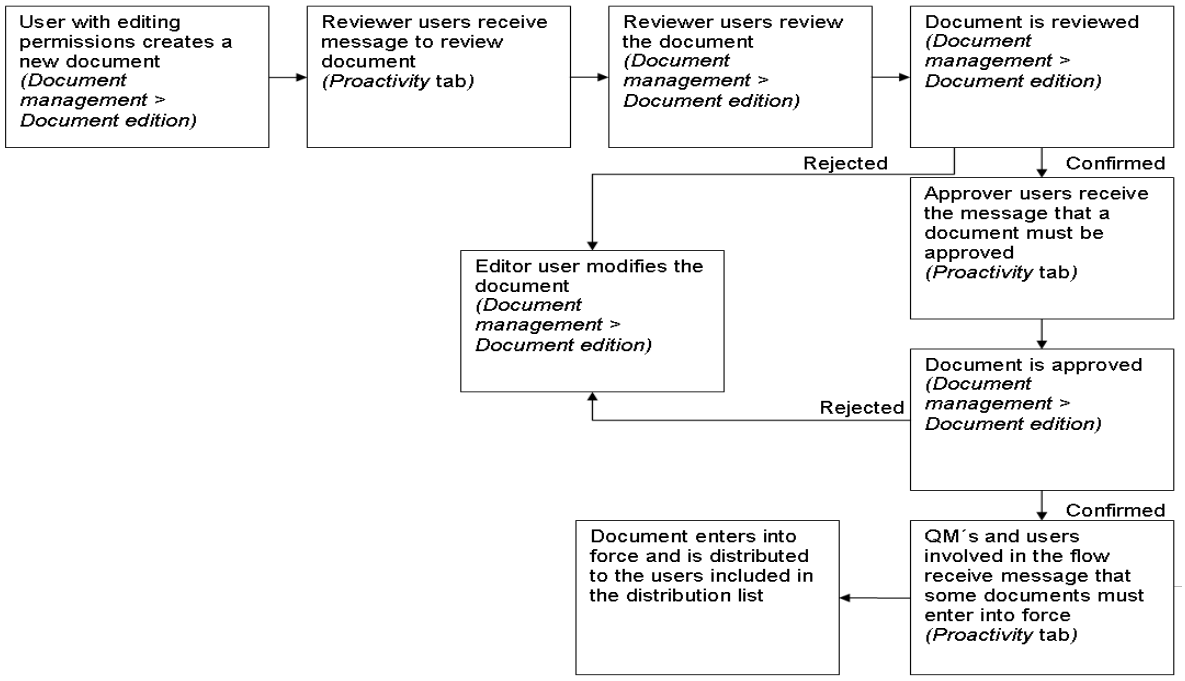


Figure 5 Document management flow

Managing issues generated when supervising equipment

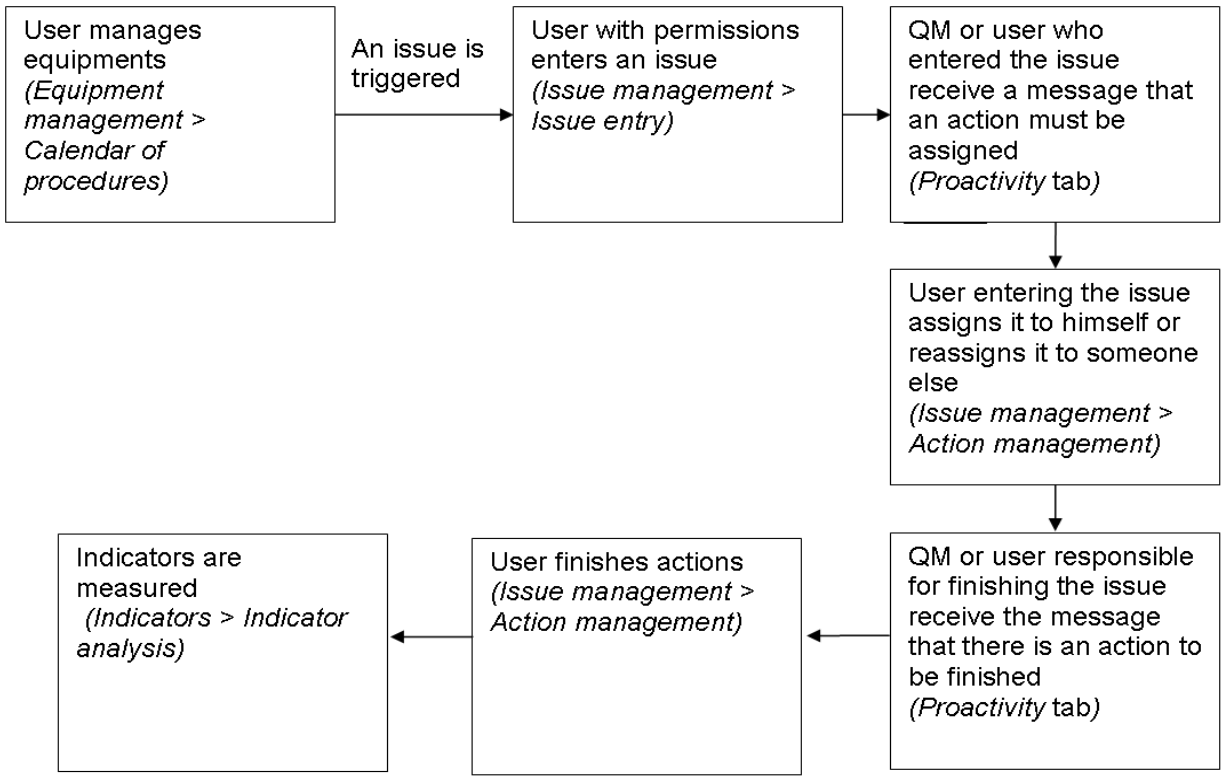


Figure 6 Issue management flow

Managing audits and non-conformities

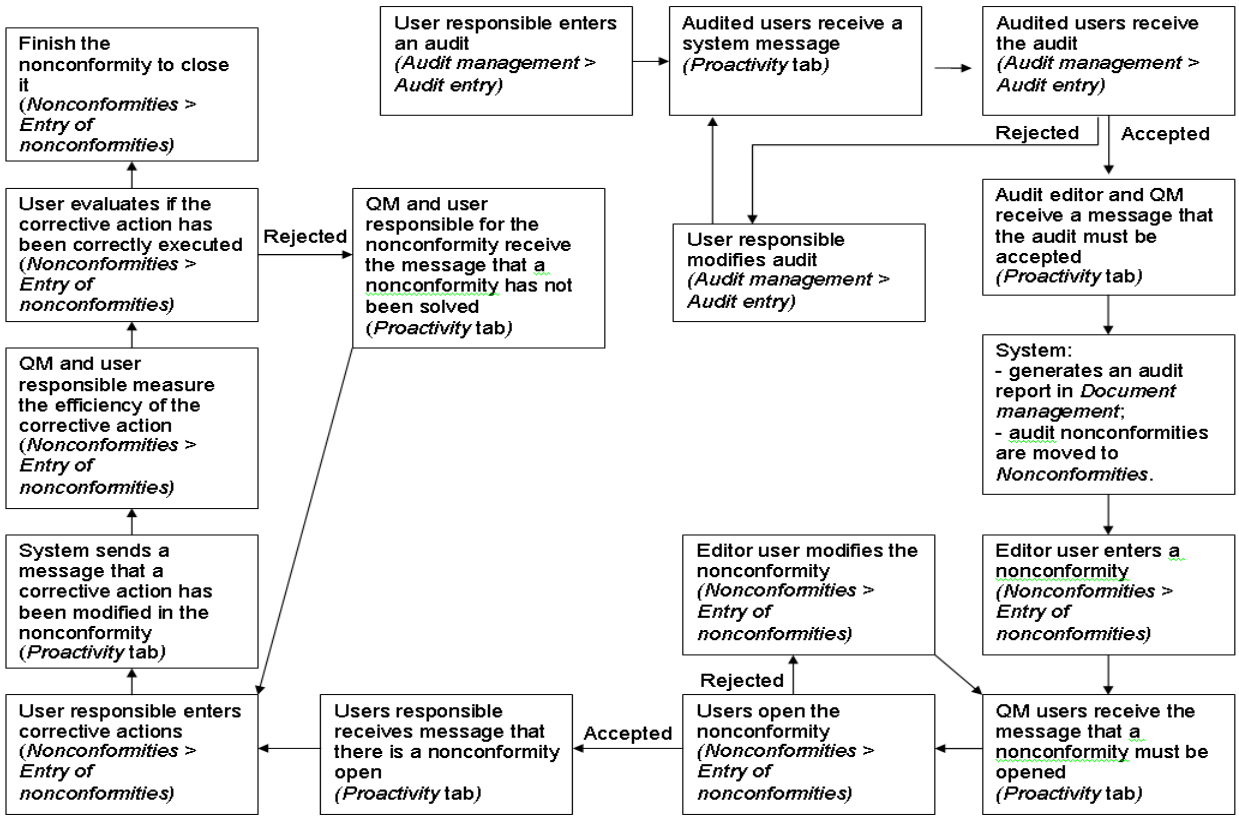


Figure 7 Non-conformities and audit management flow