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RAMCO AVIATION SOLUTION
VERSION 5.8

# USER GUIDE
# QUALITY AUDIT MANAGEMENT

# ABOUT THIS MANUAL

This manual briefly describes the basic processes and functions in Ramco Aviation Solution.

## WHO SHOULD READ THIS MANUAL

This manual is intended for users who are managing the Aviation industry processes and are new to Ramco AviationSolution. This manual assumes that the user is familiar with the Aviation Industry nomenclatures and systems based software.

## HOW TO USE THIS MANUAL

Ramco Aviation Solution provides extensive Online Help that contains detailed instructions on how to use the application. Users are suggested to use this manual for specific references, along with the Online Help. This manual contains enough information to help the users perform the basic tasks and points toward the Online Help for more detailed information.

## HOW THIS MANUAL IS ORGANIZED

The User Guide is divided into 5 chapters and index. Given below is a brief run-through of what each chapter consists of.

Chapter 1 provides an overview of the **Audit Management** business process. The sub processes are explained in the remaining chapters.

Chapter 2 guides you through the **Set Options, Maintain Quick Codes, Maintain Root Cause Codes** and **Maintain Check List** sub processes.

Chapter 3 guides you through the **Maintain Quality Audit Schedules** sub process.

Chapter 4 guides you through the **Initiate Quality Audit** sub process.

Chapter 5 guides you through the **Process Non-Conformities / Report** sub process.

The **Index** offers a quick reference to selected words used in the manual.

## DOCUMENT CONVENTIONS

- The data entry has been explained taking into account the “Create” business activity. Specific references (if any) to any other business activity such as “Modify” and “View” are given as “Note” at the appropriate places.
- **Boldface** is used to denote commands and user interface labels.

  Example: Enter **Company Code** and click the **Get Details** pushbutton.
- Italics used for references.

  Example: *See Figure 1.1.*
- The  icon is used for Notes, to convey additional information.

## REFERENCE DOCUMENTATION

This User Guide is part of the documentation set that comes with Ramco Aviation Solution. The documentation is generally provided in two forms:

- The Documentation CD in Adobe® Systems’ Portable Document Format (PDF).
- Context-sensitive Online Help information accessible from the application screens.

## WHOM TO CONTACT FOR QUERIES

Please locate the nearest office for your geographical area from www.ramco.com for assistance.

# contents

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# INTRODUCTION

Quality Audit Management business process facilitates the Quality Audit department to develop and maintain processes that promote continuous compliance with regulatory requirements. The quality audit involves the following tasks.

- Maintaining audit schedules
- Maintaining root causes information for non-conformities
- Tracking audits from initiation to closure
- Recording results of audit
- Recording corrective and preventive action
- Recording audit references
- Initiating follow-up audits for unresolved non-conformities
- Maintaining of resolution history of non-conformities

This manual familiarizes users with the following,

The **Set Options** sub-process: facilitates the setting of processing parameters for carrying out the Audit Management function.

The **Maintain Quick Codes** sub-process: enables the users to define Meta data under specific categories.

The **Maintain Root Cause Codes** sub-process: enables users to identify and define all the possible root causes for non-conformities, under specific categories.

The **Maintain Check List** sub-process enables you to maintain and perform quality audits

based on a predefined checklist master in which questionnaires are built.

The **Maintain Quality Audit Schedules** sub-process: enables users to create / update quality audit schedules / calendars for a specific period.

The **Initiate Quality Audit** sub-process: records key details of scheduled and unscheduled audits at the time of commencement. An audit report is created and the information generated by the audit is recorded at various junctures of the auditing processes till its final closure.

The **Process Non-Conformities / Report** sub-process: enables users to act on the NCs / recommendations of the auditor.

# SET PROCESS DATA

This chapter provides the step-by-step procedure that you require to define parameters as well as user-specific data for the quality audit business process. Also, this chapter gives details of maintaining and performing quality audits based on a predefined checklist master in which questionnaires are built.

# 2.1 SET OPTIONS

## 2.1.1 SETTING PARAMETERS

This sub process helps in defining the processing parameters for the audit process.

1. Select the **Set Options** link under the **Quality Audit** business component. The **Set Options** page appears. *See Figure 2.1*.

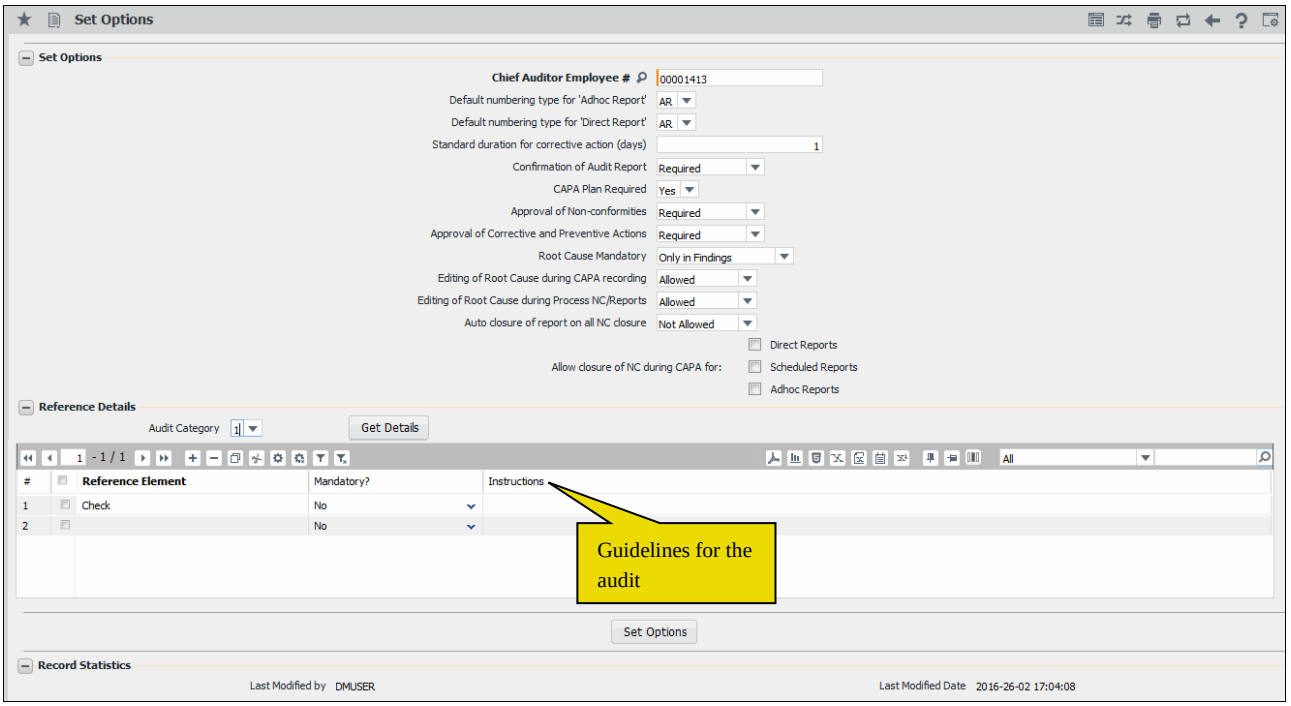


**Figure 2.1 Setting parameters**

Define the following in the **Set Options** group box.

2. The employee code of the chief auditor in the **Chief Audit or Employee #** field.
3. The default numbering type for Adhoc reports in the **Default Numbering Type for 'Adhoc Report'** field.
4. The default numbering type for Direct reports in the **Default Numbering Type for 'Direct Report'** field.
5. The normal / permitted duration for implementing corrective action, in days, in the **Standard Duration for Corrective Action (Days)** field.
6. The confirmation of an audit report is mandatory/not mandatory in the **Confirmation of Audit Report** field.
7. Whether the CAPA Plan as a step in auditing is mandatory in the **CAPA Plan Required** field.
8. The approval of an audit report is mandatory/not mandatory in the **Approval of Non-conformities** field.
9. The approval of Corrective and Preventive actions taken as part of audit is mandatory/not mandatory in the **Approval of Corrective and preventive Actions** field.
10. Whether the selection of root cause is mandatory in "Record Corrective and Preventive Action" screen (Option "Only CAPA") or "Record Quality Audit Findings" screen (Option "Only Findings") or both in the **Root Cause Mandatory** field.
11. The modification of the root cause information during the recording of CAPA is allowed /disallowed in the **Editing of Root Cause Info during CAPA Recording** field.
12. The modification of the root cause information during the recording of CAPA is allowed /disallowed in the **Editing of Root Cause during Process NC/Reports** field.
13. The audit report can be closed automatically when all the NCs of the report are closed, in the **Auto Closure of Report on all NC Closure** field.

To specify **Allow Closure of NC during CAPA** for:

14. Select the **Direct Reports** box to allow closure of NC during CAPA recording.
15. Select the **Scheduled Reports** box to allow closure of NC during CAPA recording.
16. Select the **Adhoc Reports** box to allow closure of NC during CAPA recording.

In the **Reference Details** group box,

17. Select the **Audit Category.**
18. Select the **Get Details** pushbutton.

Specify the following in the multiline.

19. The reference element for the audit, such as work order and part, in the **Reference Element** field.
20. Whether the reference element is mandatory for the audit in the **Mandatory?** field.
21. Any guidelines for the audit process in the **Instructions** field.
22. Select the **Set Options** pushbutton.

# 2.2 MAINTAIN QUICK CODES

## 2.2.1 MAINTAINING QUICK CODES

This sub process helps in defining the Meta data or user-specific data under specific categories for use in the sub processes.

1. Select the **Maintain Quick Codes** link under the **Quality Audit** business component. The **Maintain Quick Codes** page appears. *See Figure 2.2*.

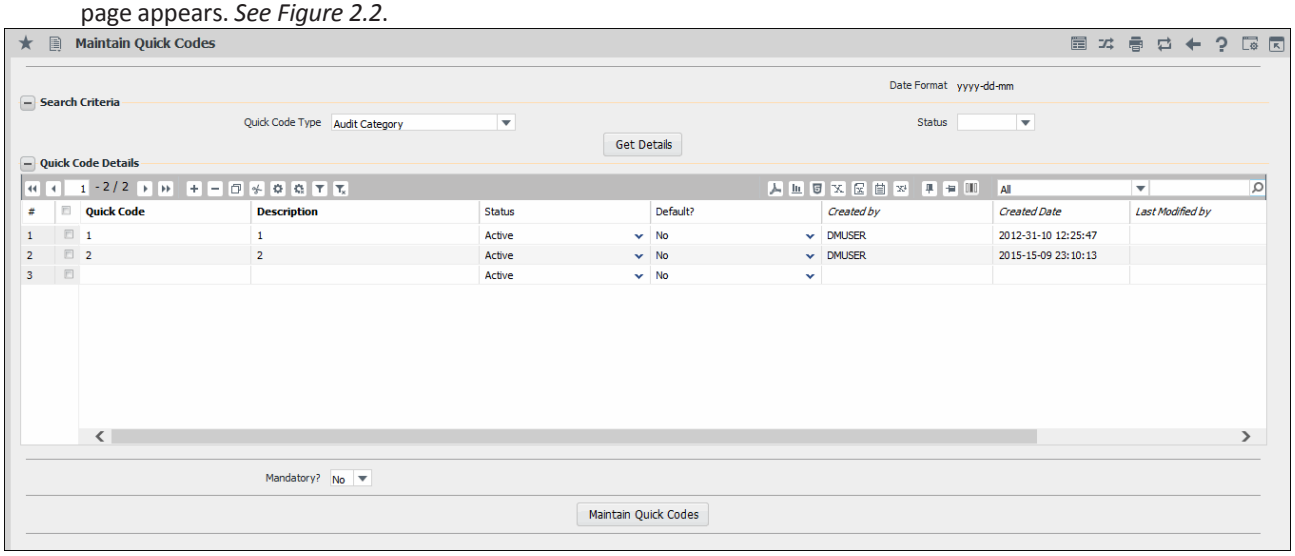


**Figure 2.2 Maintaining quick codes**

Enter the following in the **Search Criteria** group box.

2. The **Quick Code Type** under which you want to create the quick code
3. The **Status** of the quick code.
4. Select the **Get Details** pushbutton

The Quick Code Details multiline displays the following details of existing quick codes under the selected quick code type: **Quick Code**, **Description**, **Status**, **Default**, **Created by**, **Created Date**, **Last Modified by** and, **Last Modified Date**.

5. You can add the following fields to create a new quick code: **Quick Code**, **Description**, **Status**, and **Default**.
6. Select the **Maintain Quick Codes** pushbutton to save the modified details.

# 2.3 MAINTAIN ROOT CAUSE CODES

## 2.3.1 MAINTAINING ROOT CAUSE CODES

This sub process helps in creating an entire set of root causes / contributing factors that can be attributed to NCs ascertained by the auditor during the audit process.

1. Select the Maintain Root Cause Codes link under the Quality Audit business component. The Maintain Root Cause **Codes** page appears. *See Figure 2.3.*

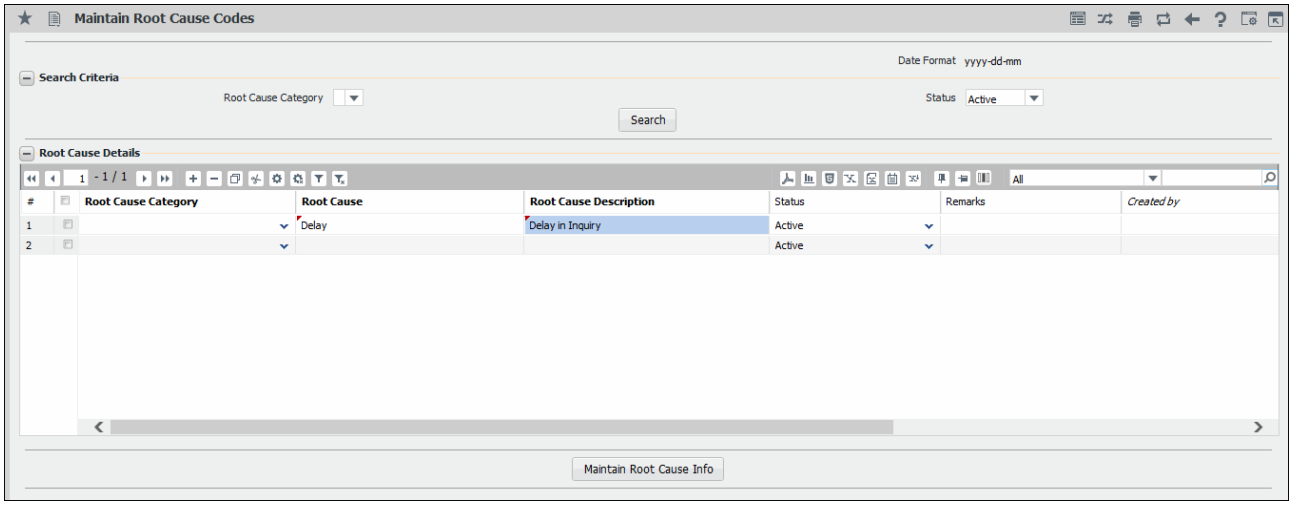


**Figure 2.3 Maintaining root cause codes**

2. Enter the following in the Root Cause Details multiline: Root Cause Category, Root Cause ID, Root Cause Description, **Status** and **Remarks**.
3. Select the **Maintain Root Cause Info** pushbutton to save the specified details.
4. To modify a root cause, use the **Search Criteria** to find the root cause you want to change and follow the same procedure that is illustrated for creation

# 2.4 MAINTAIN CHECK LIST

## 2.4.1 MAINTAINING CHECK LIST

This sub process enables you to maintain and perform quality audits based on a predefined checklist master in which questionnaires are built. These questionnaires can be used as templates for conducting the audit.

1. Select the **Maintain Check List** link under the **Quality Audit** business component. The **Maintain Check List** page appears. *See Figure 2.4*.

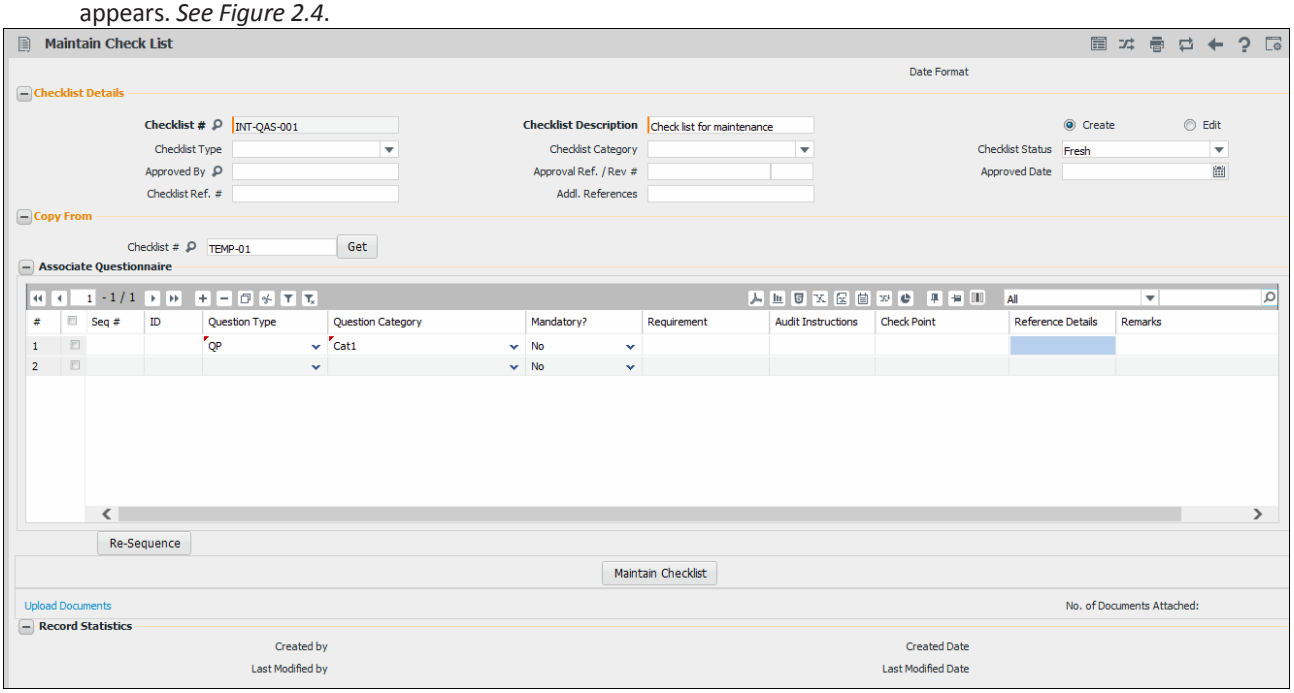


**Figure 2.4 Maintaining check lists**

In the Checklists Details group box:

2. Enter the unique code identifying the checklist used for auditing in the **Checklist #** field.
3. Provide a textual description of the checklist in the **Checklist Description** field.
4. Select the **Create** radio button if you wish to create a new checklist.
5. Select the **Edit** radio button if you wish to modify details of a checklist.
6. Enter the **Checklist #** from which you wish to copy details in the **Copy Details** group box.
7. Select the **Get** pushbutton to retrieve the checklist details in the multiline.
8. In the **Associate Questionnaire** multiline:
9. Enter the **Question Type**, **Question Category** and if the given question is mandatory to be responded while auditing in the **Mandatory?** drop-down list box.
10. Enter the requirement text in the **Requirement** field.
11. Provide the step-by-step instructions on how the audit must be conducted in the **Audit Instructions** field.
12. Enter the broad classification based on which question is asked. E.g. Safety in the **Check Point**.
13. Provide **Reference Details** and **Remarks** regarding the questions.
14. Select the **Re-Sequence** pushbutton to repopulate the sequence column
15. Select the **Maintain Checklist** pushbutton.

## To proceed, carryout the following:

- Select the **Upload Documents** link at the bottom of the page to upload files in the system against the checklist #.

# MAINTAIN QUALITY AUDIT SCHEDULES

This chapter provides the step-by-step procedure that you require to create quality audit schedule

# 3.1 MAINTAIN QUALITY AUDIT SCHEDULES

This activity enables a QA manager to prepare audit calendar for a specified period. You can define a fixed number of audits of a specific type to be carried out at fixed time intervals in an audit calendar / schedule.

The processes / departments that require audit are identified in addition to the number of audits to be carried out in the schedule and the time interval between two audits.

The details of the audit schedule can be also be modified, if required before any scheduled audit is initiated. You can record vital information about an audit schedule including the name, scope, type, entity, auditing agency, scheduled date, estimated duration of audit, reference, time interval between audits, number of audits and, the auditor.

> *Note: The quality audit schedule # acts as the identification number and hence cannot be modified anytime after creation.*

## 3.1.1 MAINTAINING AUDIT SCHEDULES

1. Select the **Maintain Quality Audit Schedules** link under the Quality Audit business component. The **Maintain Quality Audit Schedules** page appears. *See Figure 3.1*

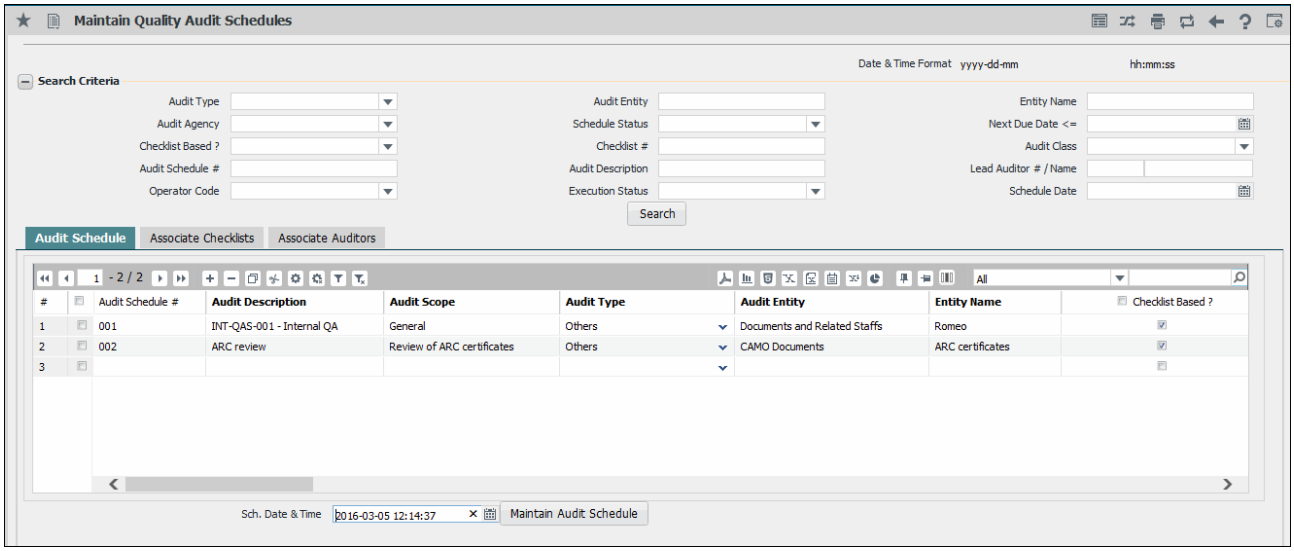


**Figure 3.1 Setting quality audit schedules**

In the **Search Criteria** group box,

2. Enter the **Audit Type**, **Audit Entity**, **Entity Name** and other details in the group box to retrieve details of the audit schedule in the multiline.
3. Click the **Search** pushbutton, the system displays information on the audit schedules that matches the search criteria entered.
4. Select the **Audit Schedule** tab to create an audit schedule.
5. Select the **Associate Checklists** tab to associate a checklist to the audit schedule.
6. Select the **Associate Auditors** tab to associate an auditor to the audit schedule

### Maintaining Audit Schedule

This tab appears by default on launch of the **Maintain Quality Audit Schedules** activity. *See Figure 3.2*

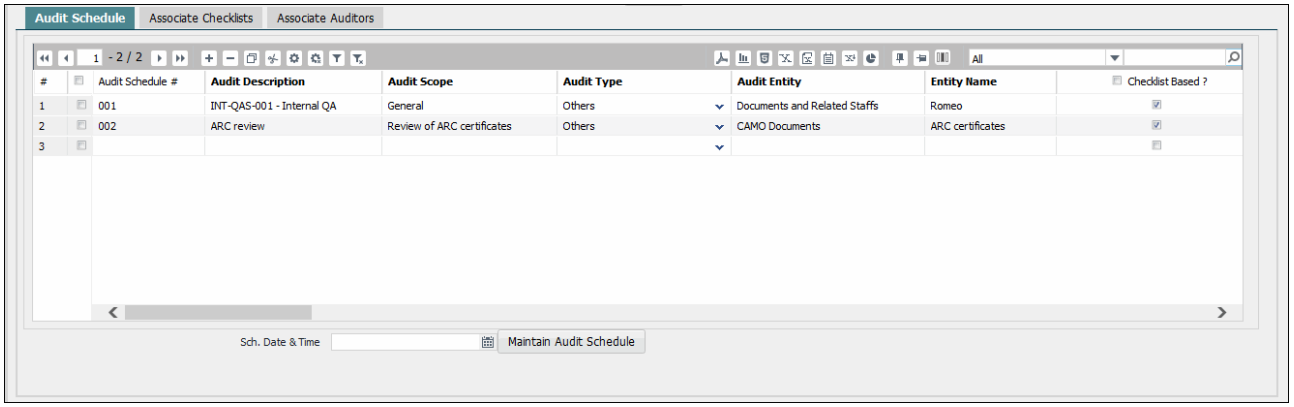


**Figure 3.2 Audit Schedule tab**

1. Enter the **Audit Description, Audit Scope, Audit Type, Audit Entity, Entity Name** and other details in the multiline.

   *Note: Ensure that at least one record is entered in the multiline.*

   *Note: The system does not allow deletion of an already existing record.*

2. Enter the date and time when the audit schedule is expected to begin in the **Sch. Date & Time** field.

3. Click the **Maintain Audit Schedules** pushbutton.

### To proceed, carryout the following:

4. Select the **Associate Checklists** tab to associate a checklist to the audit schedule.

5. Select the **Associate Auditors** tab to associate an auditor to the audit schedule

## Associating checklists to audit schedule

1. Select the **Associate Checklist** tab in the **Maintain Quality Audit Schedules** page. The **Associate Checklists** tab page appears. *See Figure 3.3.*

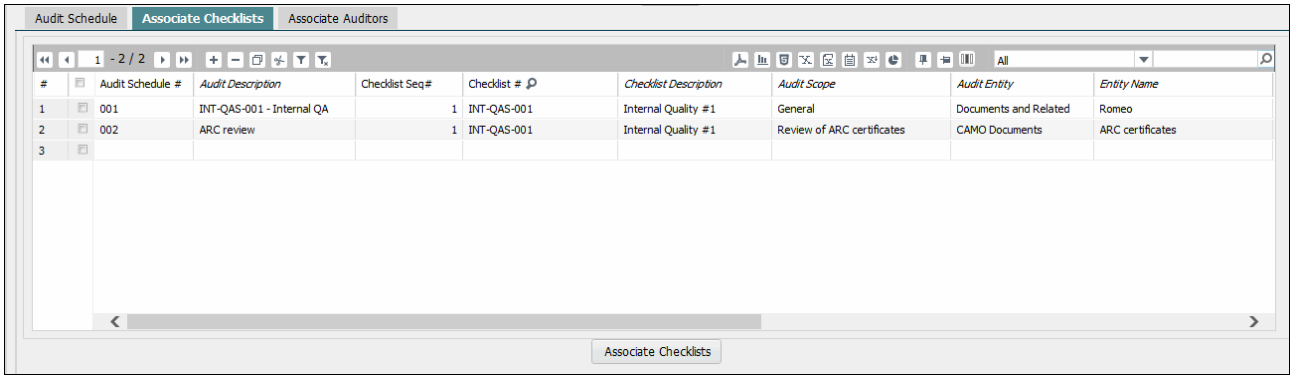


**Figure 3.3 Associate Check Lists**

2. Enter the **Audit Schedule #**, **Checklist Seq. #**, **Checklist #** and other details in the multiline.

3. Click the **Associate Checklists** pushbutton to associate checklist to the audit schedule

### To proceed, carryout the following:

4. Select the **Audit Schedule** tab to create an audit schedule.

5. Select the **Associate Auditors** tab to associate an auditor to the audit schedule

## Associating Auditors to audit schedule

1. Select the **Associate Auditors** tab in the **Maintain Quality Audit Schedules** page. The **Associate Auditors** tab page appears: *See Figure 3.4*.

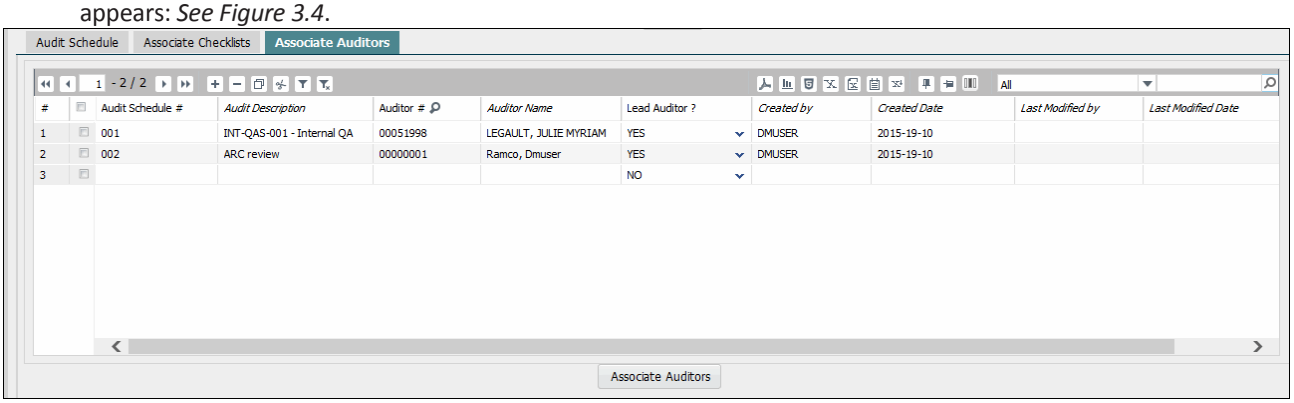


**Figure 3.4 Associate Auditors**

2. Enter the **Audit Schedule #**, **Auditor #** and other details in the multiline.
3. Click the **Associate Auditors** pushbutton to associate auditors to the audit schedule.

### To proceed, carryout the following:

4. Select the **Audit Schedule** tab to create an audit schedule.
5. Select the **Associate Checklists** tab to associate a checklist to the audit schedule.

# INITIATE QUALITY AUDIT

This chapter provides the step-by-step procedure to do the following tasks.

- Initiating schedule based and adhoc audit reports.
- Recording audit details for schedule based, adhoc and direct reports.
- Recording CAPA for schedule based, adhoc and direct reports.
- Recording reference details for schedule based, adhoc and direct reports.

# 4.1 INITIATING QUALITY AUDIT

This sub process enables QA managers to the record vital information at the outset of the audit for schedule-based audits.

QA personnel can also specify scope, objective, type, auditor, auditee, location, estimated duration, scheduled date and time of the audit besides follow-up and carryover items from the previous audit.

In addition, the sub process enables to,

- Record reference documents
- Record audit findings
- Record corrective and preventive action (CAPA) as recommended by the auditor

1. Select the **Initiate Quality Audit** link under the Quality Audit business component. The **Initiate Quality Audit** page appears. *See Figure 4.1.*

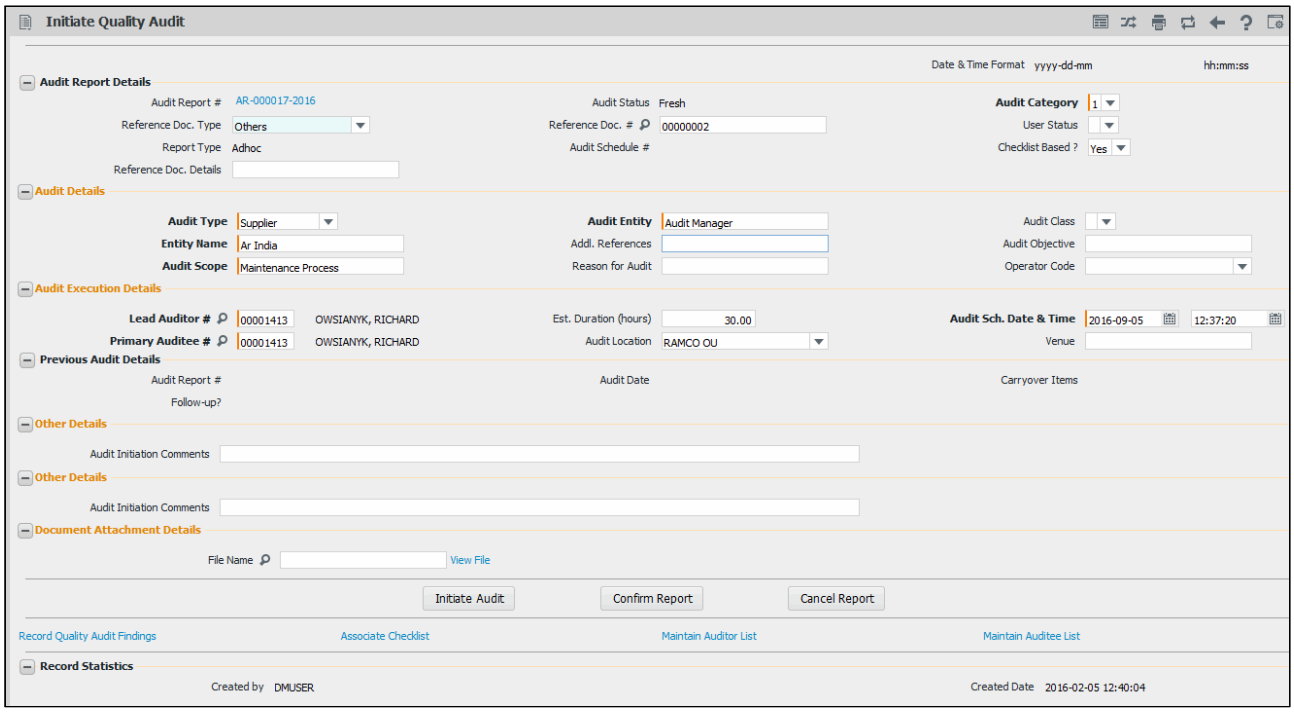


**Figure 4.1 Initiating quality audit**

Enter the following in the **Audit Report Details** group box.

2. The category of the audit, in the **Audit Category** field.
3. The reference document type for the audit, in the **Reference Doc. Type** field.
4. The identification number of the reference document for the audit, in the **Reference Doc. #** field.
5. The user status of the audit, in the **User Status** field.
6. Any details of the reference document, in the **Reference Doc. Details** field.

*Note: The system displays the audit report # as per the parameters set in the Set Options sub process. The report type is displayed as "Adhoc". The audit status is set after you save the details.*

*Note: If this page is accessed through the **Initiate Schedule based Audit** link, the report type is displayed as "Scheduled" and, the audit schedule # as selected in the **Select Quality Schedule** page is displayed.*

Enter the following in the **Audit Details** group box.

7. The type of audit, in the **Audit Type** field.
8. The process/department/entity that is audited, in the **Audit Entity** field.

    *Note that for the audit type selected, if a valid audit entity is specified in this field, the system retrieves the Entity Name.*

9. The class of audit, in the **Audit Class** field.
10. The name/description of the audit entity, in the **Entity Name** field.

    *Note that for the audit type selected, if a valid entity name is specified in this field, the system retrieves the Audit Entity.*

11. Any details of additional references for the audit, in the **Addl. References** field
12. The purpose of the audit, in the **Audit Objective** field.
13. The activities that are covered in the audit, in the **Audit Scope** field.
14. The causes that necessitated the audit, in the **Reason for Audit** field.

Enter the following in the **Audit Execution Details** group box.

15. Enter the employee code of the auditor who heads the audit team in the **Lead Auditor #** field.
16. The planned duration of the audit, in hours, in the **Est. Duration (Hours)** field.
17. The planned date and time of the audit, in the **Audit Sch. Date & Time** field.
18. The employee code of the auditee in the **Primary Auditee** # field.
19. The organization unit in which the audit is carried out, in the **Audit Location** field.
20. Any details on the location of the audit, in the **Venue** field.

In the **Other Details** group box,

21. Specify remarks / additional information on the initiation of audit, in the **Audit Initiation Comments** field. In the **Document Attachment Details** group box,
22. The document file associated with the audit, in the **File Name** field.
23. Select the **Initiate Audit** pushbutton to commence the audit.

    *On initiation, the audit status becomes "Fresh".*

24. Select the **Confirm Report** pushbutton to validate the audit.

    *On confirmation, the audit status of the audit report is set to "Initiated", by the system. If the audit report is based on an audit schedule, the schedule status of the audit schedule becomes "Active" and the execution status "Initiated".*

25. Select the **Cancel Report** pushbutton to stop the audit.

    *On cancellation, the system sets the audit status to "Cancelled".*

## To proceed, carryout the following:

- Select the **Report Quality Audit Findings** link at the bottom of the page to record the non-conformities (NCs) and the recommendations / observations of the audit.
- Select the **Associate Checklist** link at the bottom to associate a checklist to the audit.
- Select the **Maintain Auditor List** link at the bottom of the page to modify the list of auditors mapped to the audit report.
- Select the **Maintain Auditee List** link at the bottom of the page to modify the list of auditees mapped to the audit reports.

### 4.1.1 RECORDING QUALITY AUDIT FINDINGS

This sub process helps auditors to record the non-conformities (NCs) and the recommendations / observations of schedule based / adhoc audits.

For direct audits, employees can also use this sub process to record the NCs or recommendations to improve a process / department as ascertained by their own analysis.

*Note: This task is required for all the audit report types.*

## For direct audit report types

1. Select the Record Audit Findings link in the Initiate Quality Audit / Edit Quality Audit page. *See Figure 4.1*.

## For schedule based audit report types

1. Select the **Record Audit Findings** link in the **Select Quality Audit Schedule** page. Prior to this, you must initially select the **Initiate Schedule based Quality Audit** link to open the **Select Quality Audit Schedule** page. *See Figure 4.2.*

## For direct audit report types

1. Select the **Report Non-Conformities (Direct)** link under the **Quality Audit** component. *See Figure 4.2.*

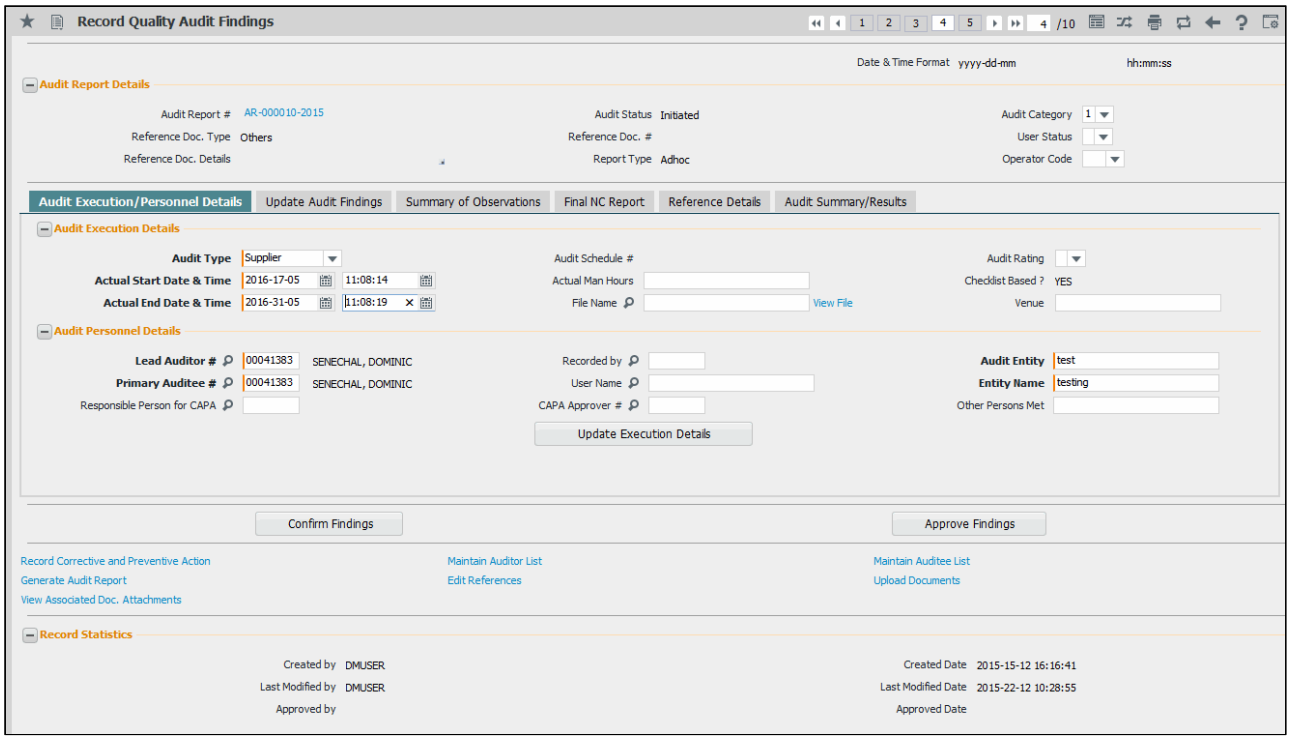


**Figure 4.2 Recording audit execution personnel details**

2. Record the following details in the **Audit Report Details** group box: **Audit Category** and **User Status**.
3. Select the **Audit Execution/Personnel Details** tab to record details of audit process and employees involved in the audit.
4. Select the **Update Audit Findings** tab to update details of the audit findings.
5. Select the **Summary of Observations** tab to record observations of the auditor.
6. Select the **Final NC Report** tab to record details of the non-conformance report.
7. Select the **Reference Details** tab to record details of references.
8. Select the **Audit Summary / Results** tab to record summary and closing details of the audit
9. Select the **Confirm Findings** pushbutton to validate the details.

*Note: The system sets the status to "Findings Confirmed".*

10. Select the **Approve Findings** pushbutton to approve the details.

### To proceed, carry out the following:

- Select the **Record Corrective and Preventive Action** link to record CAPA details.
- Select the **Maintain Auditor List** link at the bottom of the page to modify the list of auditors mapped to the audit report.
- Select the **Maintain Auditee List** link at the bottom of the page to modify the list of auditees mapped to the audit reports.
- Select the **Generate Audit Report** link at the bottom of the page to
- Select the **Edit References** link to update reference details.
- Select the **Upload Documents** link to upload documents associated with the audit report to the central repository.

## Recording audit execution/personnel details for NCs

The Audit Execution/Personnel Details tab page appears by default on launch of the Report Non-Conformities (Direct) page. *See Figure 4.3*

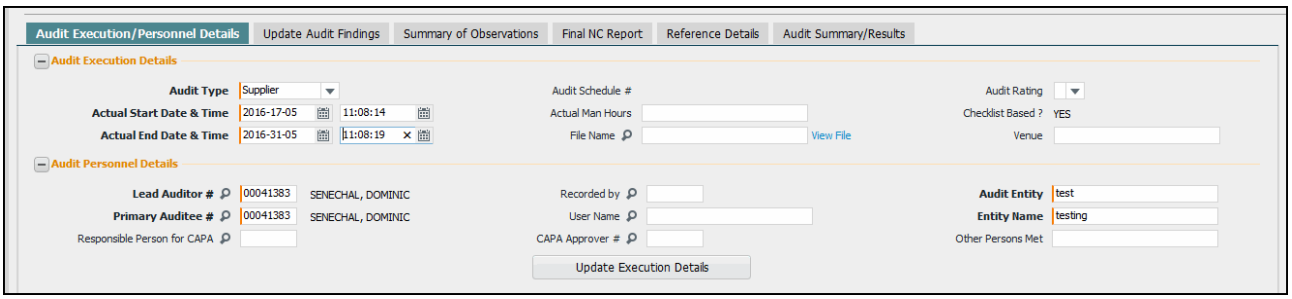


**Figure 4.3 Audit Execution / Personnel Details tab**

1. In the **Audit Execution Details** group box, specify **Audit Type, Actual Start Date & Time, Actual End Date & Time**, **Actual Man Hours**, **Audit Rating**, **File Name** and **Venue**.

In the **Audit Personnel Details** group box, enter the following.

2. Enter the employee code of the person who conducted the audit in the **Lead Auditor #** field.
3. The process/department/entity that is audited, in the **Audit Entity** field.
4. The employee code of the person who is audited for his work, in the **Primary Auditee #** field.
5. The name / description of the audited entity, in the **Entity Name** field.
6. The employee code of the person who is in charge of CAPA associated with the audit, in the **Responsible Person for CAPA** field.
7. The employee code of the login user, in the **User Name** field.
8. The details of the employees / persons that the auditor interacted with during audit, in the **Other Persons Met** field.
9. Click the **Update Execution Details** pushbutton to update the audit findings in the audit report.

## Update Audit Findings

1. Select the Update Audit Findings tab in the Report Non-Conformities (Direct) page. *See Figure 4.4.*

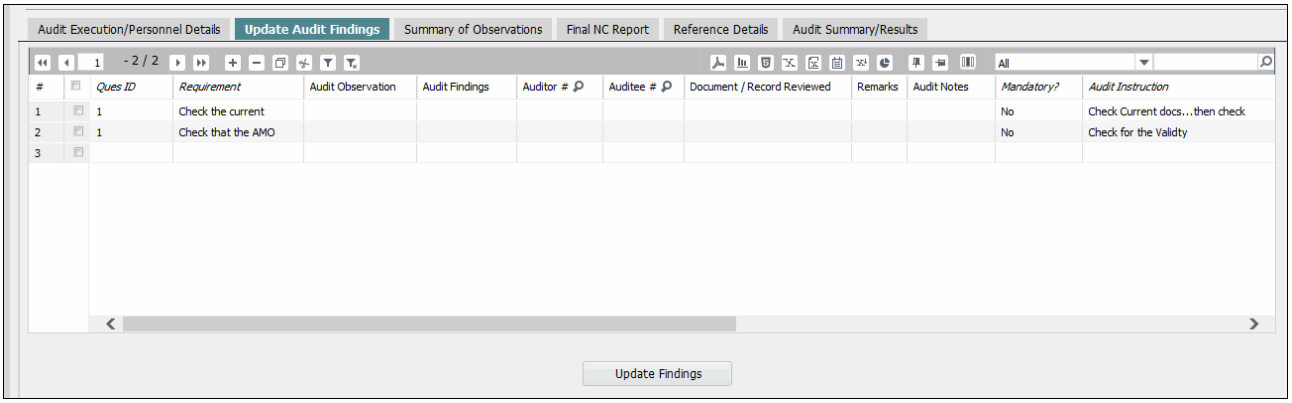


**Figure 4.4 Update Audit Findings tab**

2. Enter the **Audit Observation**, **Audit Findings**, **Auditor #**, **Auditee #** in the multiline.
3. Provide the reference of any document or record in a document supporting the observations and findings of the audit in the **Document / Record Reviewed** field.
4. Enter any **Remarks** regarding the questions and provide any information pertaining to the audit in the **Audit Notes** field.
5. Click the **Update Findings** pushbutton.

## Summary of Observations

1. Select the Summary of Observations tab in the Report Non-Conformities (Direct) page. The Summary of **Observations** tab page appears. *See Figure 4.5.*

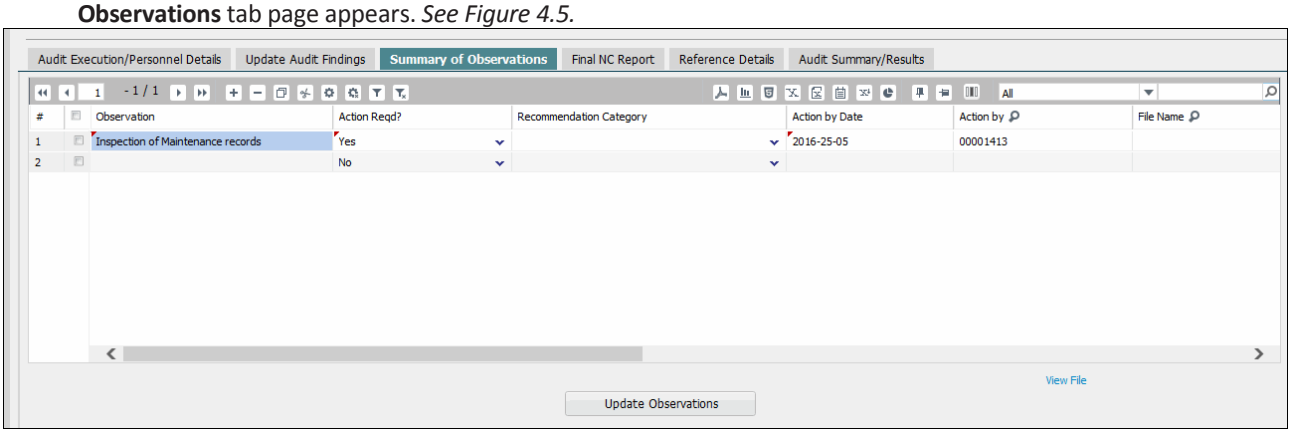


**Figure 4.5 Update Summary of Observations tab**

Enter the following in the multiline:

2. The description of the recommendation / observation of the auditor, in the **Recommendations** field.
3. Whether any action is required to implement the recommendation / observation, in the **Action Reqd.?** field.
4. The classification of the recommendation, in the **Recommendation Category** field.
5. The date on or before which any action, if required is to be carried out, in the **Action By Date** field
6. The employee code of the person responsible for any action, if required, in the **Action By** field.
7. The document associated with the recommendation / observation, in the **File Name** field.
8. Click the **Update Observations** pushbutton.

## Final NC Report

1. Select the **Final NC Report** tab. *See Figure 4.6.*

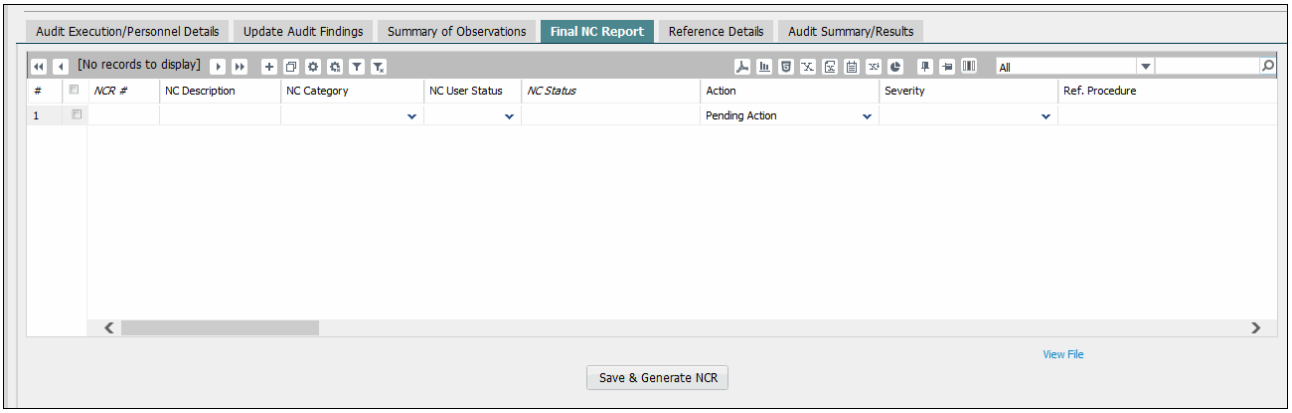


**Figure 4.6 Recording Final NC report details**

Enter the following in the multiline.

2. The name / description of the NC, in the **NC Description** field.
3. The category of the NC, in the **NC Category** field.
4. The NC user status of the NC, in the **NC User Status** field.
5. The action required for correcting or preventing the NC, in the **Action** field.
6. The severity of the NC, in the **Severity** field.
7. The procedures followed or used as reference for recording NCs, in the **Ref. Procedure** field.
8. A numeric value to Numeric value to quantify the risk caused by the NC. in the **Risk Index** field.
9. A qualitative or quantitative information, records or statements which can be verified as evidence for recording the NC, in the **Objective Evidence** field.
10. The corrective action proposed by the auditor against the NC, in the **Proposed Action** field.
11. The date by which corrective action must be complete, in the **Action By Date** field.
12. The employee code of the person in charge of corrective and preventive action to resolve the NC, in the **Responsible Person for CAPA** field.
13. The observation type of the NC, in the **Observation Type** field.
14. The root cause of the NC, in the **Root Cause** field.
15. The contributing factor of the NC, in the **Contributing Factor** field.
16. An analysis of the root cause of the NC in the **Root Cause Analysis** field.
17. The human factor responsible for the NC, in the **Human Factor** field.
18. The causal category of the NC, in the **Causal Category** field.
19. The document associated with the NC, in the **File Name** field
20. Any comments / additional information from the auditor, in the **Auditor Remarks** field.
21. Click the **Save & Generate NCR** pushbutton.

## Reference Details

1. Select the **Reference Details** tab. *See Figure 4.7.*

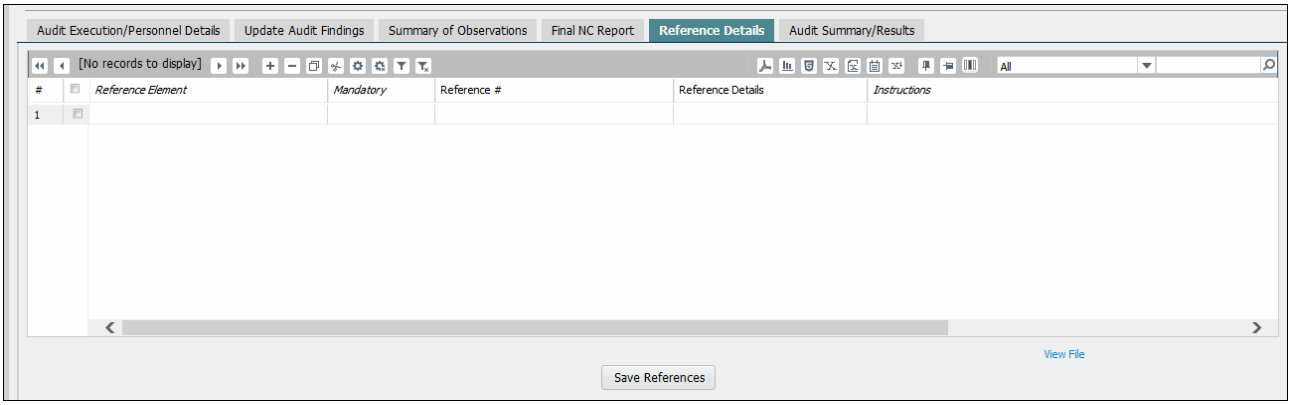


**Figure 4.7 Recording references**

Enter the following in the multiline.

2. The identification number of the reference, in the **Reference #** field.
3. Any details of the reference, in the **Reference Details** field.
4. The document associated with the reference, in the **File Name** field.

## Audit Summary/Results

1. Select the Audit Summary/Results tab. *See Figure 4.8.*

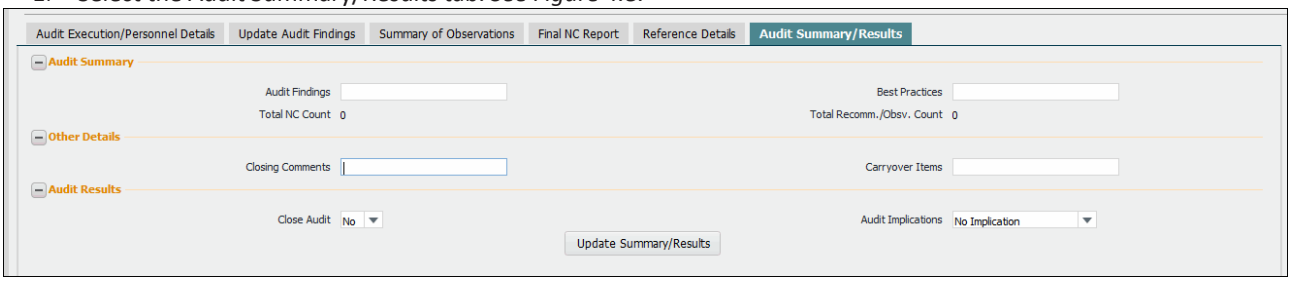


**Figure 4.8 Recording audit results**

2. Enter the following in the **Audit Summary** group box.
3. Information on the findings of the audit, in the **Audit Findings** field.
4. Model procedures for the audit / audit entity, in the **Best Practices** field.

Enter the following in the **Non-Conformance Report Other Details** group box.

5. Any NCs / recommendations to be resolved in the follow-up audit, in the **Carryover Items** field.
6. Any remarks or additional information from the auditor at the time of audit closure, in the **Closing Comments** field.

Specify the following in the **Audit Results** group box.

7. The result of the audit, in the **Audit Implications** field.
8. Whether to close the audit, in the **Close Audit** field.
9. Click the **Update Summary/Findings** pushbutton

## 4.1.2 RECORDING CORRECTIVE AND PREVENTIVE ACTION

This function enables an employee / auditee to record and forward CAPA details to the department head / concerned authority for approval. Additionally, the CAPA approver can also use this activity to approve the CAPA record.

On approval of CAPA, the audit report is processed to its logical end / closure.

The details of CAPA that you can record include the action and the date by which the action must be complete with

regard to NCs and recommendations.

*Note: This task is required for all the audit report types.*

1. Select the **Record Corrective and Preventive Action** link in the **Record Quality Audit Findings** page. *See Figure 4.9* in the next page.

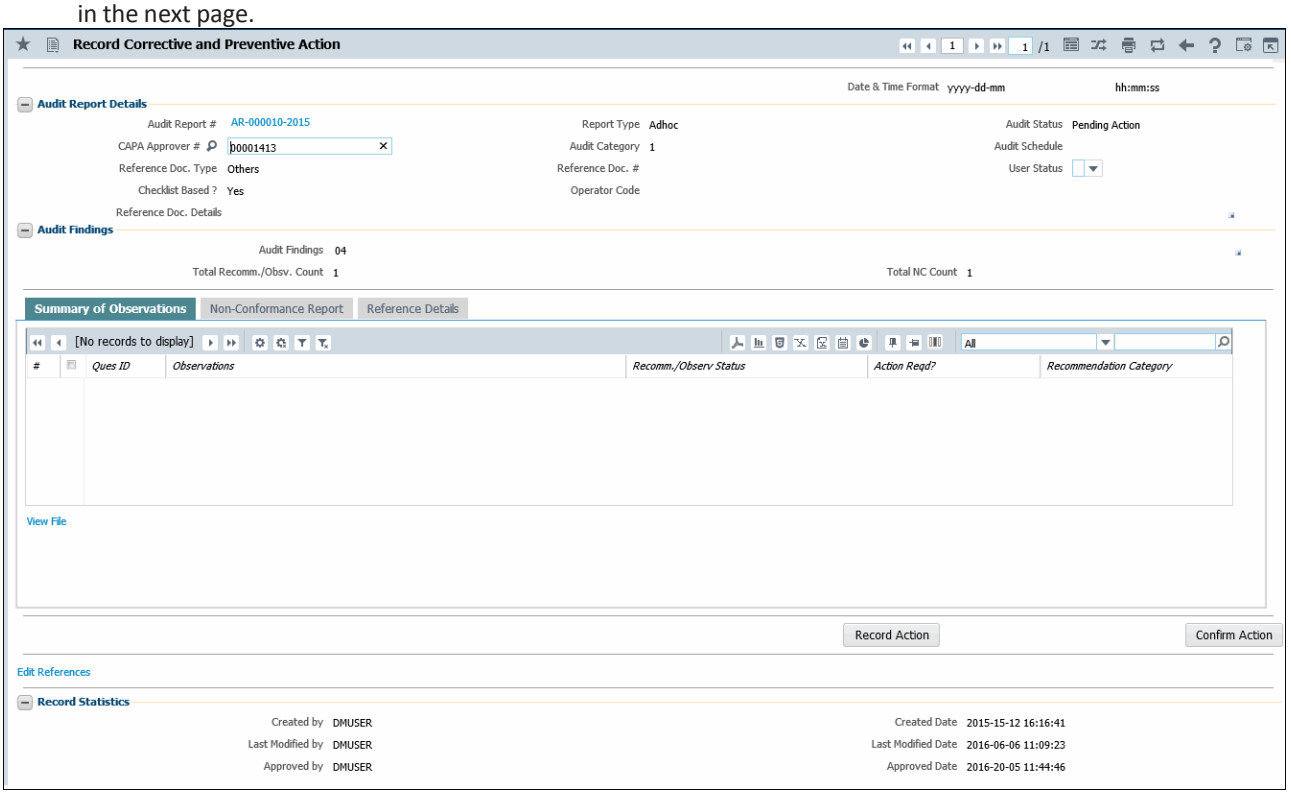


**Figure 4.9 Recording recommendations and observations**

In the **Audit Report Details** group box:

2. Specify the employee code of the CAPA approver, in the **CAPA Approver #** field.
3. Specify the user status of the audit report, in the **User Status** field.
4. Select the **Summary of Observations** tab to record response details and actions on observations.
5. Select the **Non-Conformance Report** tab to record response details and actions on NCs.
6. Select the **Reference Details** tab page to view reference details.
7. Select the **Record Action** pushbutton to save the CAPA details.
8. Select the **Confirm Action** pushbutton to authorize the CAPA details.

*Note: You must click the "Record Action" pushbutton before proceeding to "Confirm Action"*

## Recording summary of observations while recording corrective and preventive

The **Summary of Observations** tab page appears by default on launch of the "Record Corrective and Preventive Action" page. *See Figure 4.10*

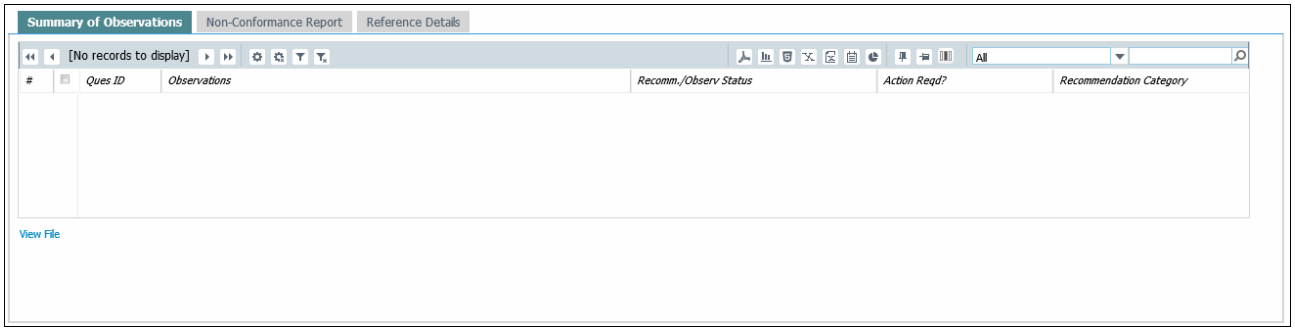


**Figure 4.10 Recording recommendations and observations**

Enter the following in the multiline.

1. The date on or before which the action required for the recommendation / observation must be complete, in the **Action By Date** field.
2. The action required for the recommendation, in the **Action** field.
3. Any comments of the auditee on the recommendation / observation and related action, in the **Auditee Remarks** field.
4. The employee code of the person who recorded the action-related details, in the **Updated By** field.
5. The date on which the action-related details were recorded, in the **Updated Date** field.
6. The identification number of the CAPA approver, in the **CAPA Approver #** field.
7. The document associated with CAPA, in the **File Name** field.
8. 16. Select the **View File** hyperlink to view the selected file.

## To proceed, carryout the following:

- Select the **Non-Conformance Report** tab to record response details and actions on NCs.
- Select the **Reference Details** tab page to view reference details.

# Recording Non-Conformance report of corrective and preventive action

1. Select the **Non-Conformance Report** tab. The **Non-Conformance Report** tab page appears. *See Figure 4.11*.


**Figure 4.11 Recording non-conformities**

2. Enter the following in the multiline: **NC Category, NC User Status, Action, Action by Date, Corrective Action, Preventive Action, Root Cause, Contributing factor, Root Cause Analysis, Human Factor, Causal Category, Impact Analysis, Impact Analysis Ref., CAPA Approver #, File Name** and **Auditee Remarks**.
3. Select the **View File** hyperlink to view the selected file.

## To proceed, carryout the following:

- Select the **Non-Conformance Report** tab to record response details and actions on NCs.
- Select the **Reference Details** tab page to view reference details.

## Recording Reference details of corrective and preventive action

1. Select the **Reference Details** tab in the **Record Corrective and Preventive Action** page. The **Reference Details** tab page appears. *See Figure 4.12*.

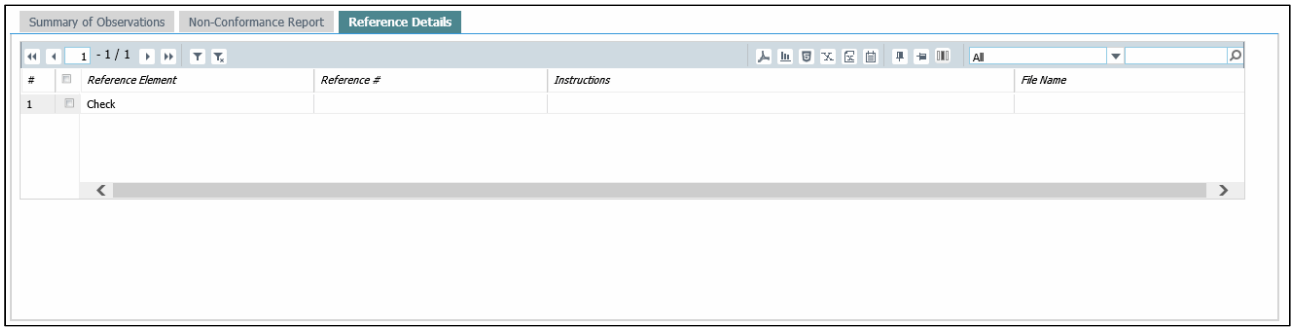


**Figure 4.12 Recording references**

The system displays the reference factor in the **Reference Element** field along with the **Reference #,** any procedural steps pertaining to the reference in **Instructions** and the **File Name** associated with the audit.

### 4.1.3 MODIFYING REFERENCES

*Note: This task is required for all the audit report types.*

1. Select the **Edit References** link in the **Record Quality Audit Findings** or **Record Corrective and Preventive Action** page. *See Figure 4.13*.

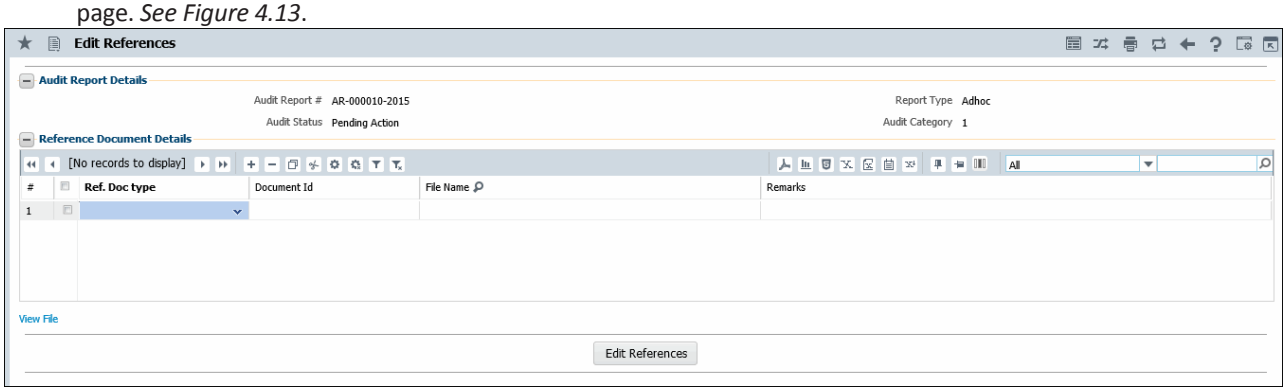


**Figure 4.13 Editing references**

Enter the following in the **Reference Document Details** multiline.

2. The type of the reference document, in the **Ref. Doc. Type** field.
3. The identification number of the reference document, in the **Document Id** field.
4. The reference document associated with the audit, in the **File Name** field.
5. Any comments on the reference, in the **Remarks** field.
6. Select the **Edit References** pushbutton to save the reference record.

# 4.2 INITIATING SCHEDULE BASED QUALITY AUDIT

## 4.2.1 SELECTING QUALITY AUDIT SCHEDULE

1. Select the **Initiate Schedule based Quality Audit** link under the Quality Audit business component. The **Select Quality Audit Schedule** page appears. *See Figure 4.14.*

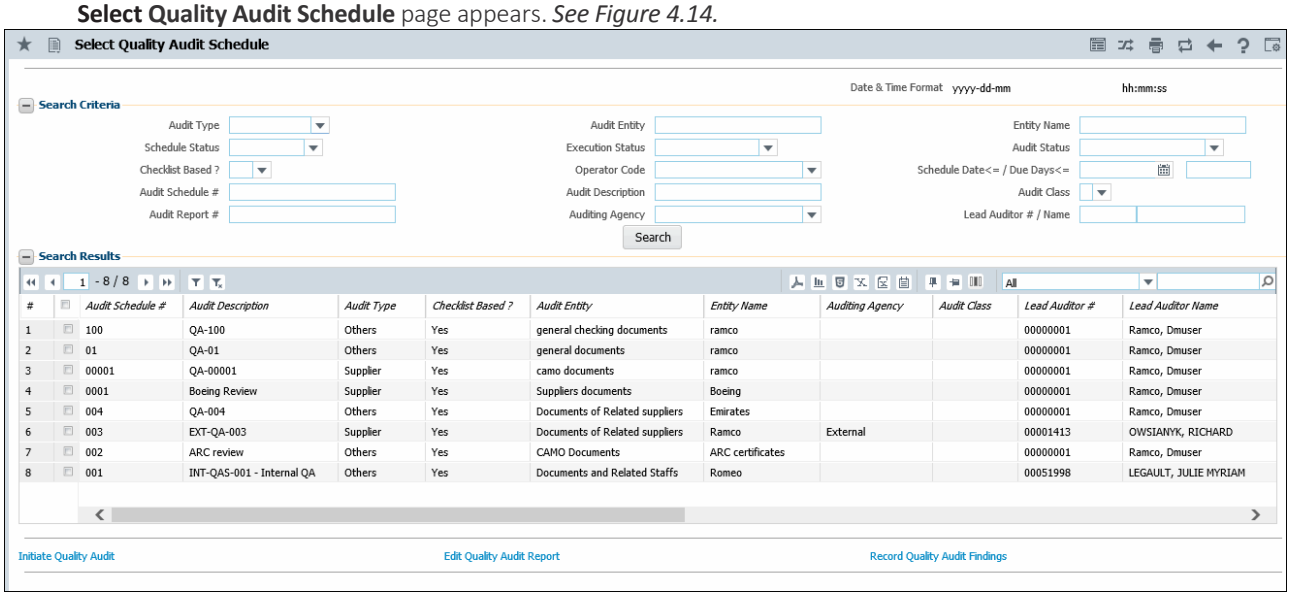


**Figure 4.14 Selecting quality audit schedule**

2. Enter the any or all the fields in the **Search Criteria** group box to find the audit report you want.
3. Select the **Search** pushbutton. The **Search Results** multiline displays the following for the records that match the specified search criteria.
4. Check the box preceding the audit schedule you want to work with.
5. Select the **Initiate Quality Audit** link to commence the Quality Audit process for the selected schedule.
6. Select the **Edit Quality Audit Report** link to modify details of the quality audit.
7. Select the **Record Quality Audit Findings** link to record the audit findings for the selected schedule.

## 4.2.2 INITIATING SCHEDULE BASED QUALITY AUDIT

Refer to the instructions in the Initiating Quality Audit section for further details

# PROCESS NON-CONFORMITIES / REPORT

This chapter provides the step-by-step procedure that you would require to process audit reports

# 5.1 PROCESSING NON-CONFORMITIES / REPORT

This function enables an auditor to take action on the non-conformities (NCs) determined by the audit process.

On approval of CAPA, the auditor reviews the action taken against the recommendation for every NC and carries out the following actions,

- Close audit report if no NCs is found.
- Close NCs against which satisfactory action has been taken.
- Accept or reject more time for resolving NCs. (If time extension for a NC is rejected, the NC must be resolved immediately. The NCs for which more time is provided, they must be resolved within the extended time.)
- Specify follow-up audits for carryover issues.

For follow-up audits, a new audit schedule can be created. The system maintains a history of NCs.

## 5.1.1 SELECTING QUALITY AUDIT SCHEDULE

1. Select the **Process Non-Conformities / Report** link under the **Quality Audit** business component. The **Select Quality Audit Report** page appears. *See Figure 5.1*.

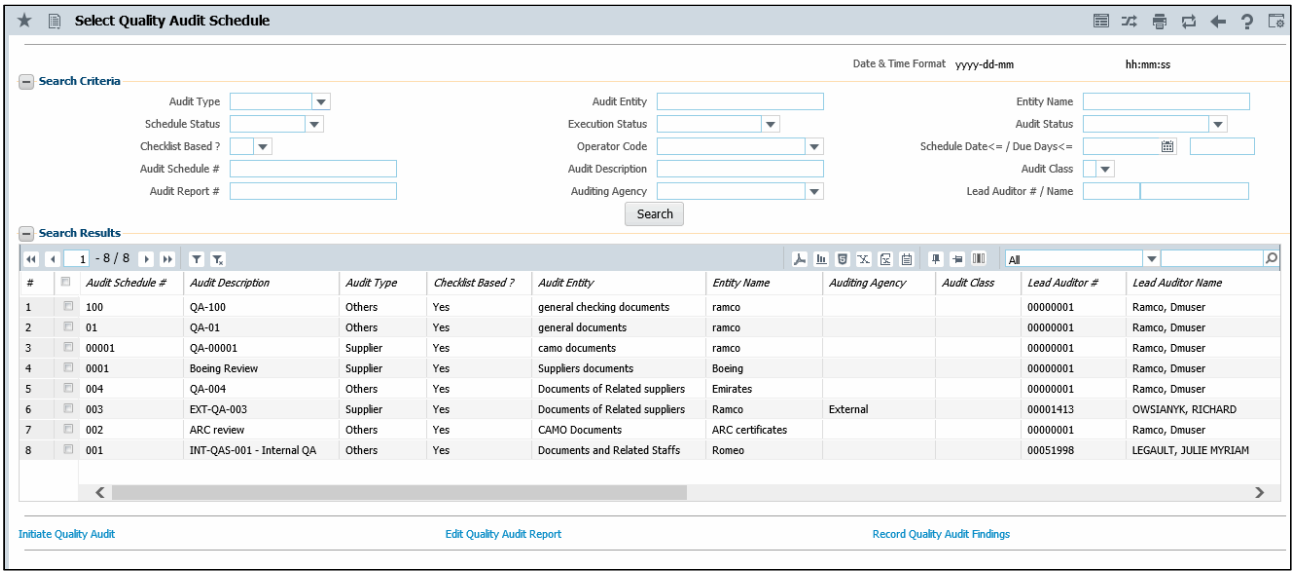


**Figure 5.1 Selecting quality audit report for recording non-conformities**

2. Specify any or all the fields in the **Search Criteria** group box.
3. Select the **Search** pushbutton. The **Search Results** multiline displays the following for the quality audit report matching the specified search criteria.
4. Select the check box for the audit report records that you want to close.
5. Select the **Close Audit Report** pushbutton to conclude the audit represented by the selected audit reports.

> *Note: The status of the NCR is updated to "Closed". The system automatically closes the audit report by updating the status of the audit report to "Actioned" on closure of all NCs, if you have selected "Allowed" in the "Auto Closure of Report on all NC Closure" drop-down list box of the "Set Options" activity.*

## 5.1.2 PROCESSING NON-CONFORMITIES / AUDIT REPORT

1. Select the hyperlink in the **Audit Report #** column for the audit that you want to process or carry out action, in the **Search Results** multiline of the **Select Quality Audit Report** page. The **Process Non-Conformities / Reports page** appears. *See Figure 5.2*.

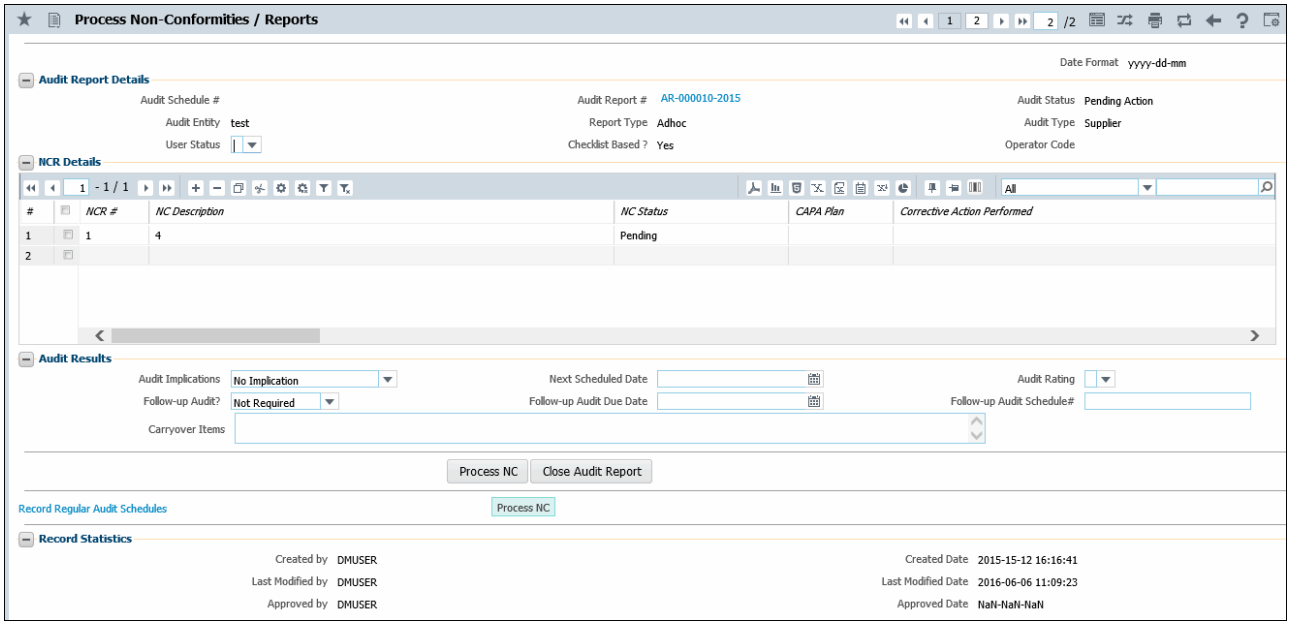


**Figure 5.2 Processing non-conformities**

2. You can modify the **User Status** field in the **Audit Report Details** group box.
3. Enter the following in the **NCR Details** multiline: **NCR User Status, Ext. By (Days), Root Cause, Contributing Factor, Corrective Action by QA, Closing Comments, Action, Follow-up Action?, Follow-Up Action Date, and Follow-Up Verification Comments.**
4. Enter the following in the **Audit Results** group box: **Audit Implications, Next Schedule Date, Audit Rating, Follow-up Audit?, Follow-up Audit Due Date, Follow-up Audit Schedule #, Carryover Items.,** .
5. Select **Process NC** pushbutton.
6. Select **Close Audit Report** pushbutton to end / stop the audit.

## To proceed, carryout the following:

- Select the **Record Regular Audit Schedules** link to open the **Maintain Quality Audit Schedules** page to record details of audit schedules.

# Index

## R



## S



## U

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