

**Insert Your
Logo Here**

**QUALITY MANAGEMENT PROCEDURE
FOR
INTERNAL QUALITY AUDITS**

**Document: QMP-020
Issue: 1
Revision: 0
Date: November 23, 2001**

Insert Your
Logo Here

QUALITY MANAGEMENT PROCEDURE

ISS: 1

REV: 0

Page: 2 of 11

SUBJECT: INTERNAL QUALITY AUDITS

DOC: QMP-020

REVIEWED BY:

APPROVED BY:

November 23, 2001

1.0 PURPOSE

- 1.1 To describe the methods to be employed and the personnel responsible for conducting internal quality audits in order to determine the status, adequacy and effectiveness of [\(Insert Company Name\)](#) 's quality system.

2.0 SCOPE

- 2.1 This procedure applies to all internal quality audits conducted by [\(Insert Company Name\)](#).

3.0 DEFINITIONS

- 3.1 Quality Audits: A documented activity aimed at verifying, by examination and evaluation, that the applicable activities and processes of the quality system have been established, are adequately documented and are effectively implemented in accordance with specified requirements.
- 3.2 Internal Quality Audits: Quality audits conducted by [\(Insert Company Name\)](#) personnel against the requirements defined within established Quality Management Procedures.
- 3.3 Auditor: A competent person with sufficient experience or training in auditing techniques to plan and conduct audits in accordance with this procedure.
- 3.4 Audit Guide: A person representing the Auditee, having knowledge of the activity or process(es) to be audited.
- 3.5 Objective Evidence: Information that can be proved true, based on facts obtained through observation, measurement, test or other means.
- 3.6 CAR: Corrective Action Request

4.0 RESPONSIBILITIES

- 4.1 The Quality Manager is responsible for scheduling and coordinating all internal quality audits in accordance with this procedure and the guidelines established within ISO 10011-1:1990.
- 4.2 The individuals selected to perform internal quality audits are responsible for

Insert Your
Logo Here

QUALITY MANAGEMENT PROCEDURE

ISS: 1

REV: 0

Page: 3 of 11

SUBJECT: INTERNAL QUALITY AUDITS

DOC: QMP-020

REVIEWED BY:

APPROVED BY:

November 23, 2001

preparing and/or updating audit checklists, conducting and documenting these audits in accordance with this procedure and for verifying the effective implementation of any required corrective action as requested by the Quality Manager.

- 4.3 The Quality Manager is responsible to provide the members of the Management Team Review with an assessment of the status, adequacy and effectiveness of each of the quality system processes which make up [\(Insert Company Name\)](#) 's quality management system.
- 4.4 Department managers are responsible for providing knowledgeable individuals to participate and assist Auditors during the performance of internal audits, providing a written response to all CARs issued as a result of audits performed and for ensuring that prompt corrective action is taken when deviations from approved procedures are identified.
- 4.5 The Quality Manager is responsible to provide a written response to all CARs issued in accordance with activities that relate to the Quality department and to ensure prompt corrective action is taken when deviations from approved procedures are identified.

5.0 PROCEDURE

5.1 Pre-Audit Activities

- 5.1.1 The Quality Manager shall prepare an internal Annual Quality Audit Schedule (or more frequently if determined to be appropriate by the Quality Manager) using FRM-808. The schedule shall include all processes that make up [\(Insert Company Name\)](#) 's quality management system.
- 5.1.2 The purpose and intent of performing each audit is to determine:
- The effectiveness and continued suitability of [\(Insert Company Name\)](#) 's quality management system;
 - Whether the quality management system conforms to planned arrangements;
 - The extent to which the quality management system conforms to the requirements of the ISO 9001:2000 standard; and
 - The extent to which the quality management system conforms to requirements established by [\(Insert Company Name\)](#) management.
- 5.1.3 The determination as to the priority to be given to each process as well as the criteria

Insert Your
Logo Here

QUALITY MANAGEMENT PROCEDURE

ISS: 1

REV: 0

Page: 4 of 11

SUBJECT: INTERNAL QUALITY AUDITS

DOC: QMP-020

REVIEWED BY:

APPROVED BY:

November 23, 2001

to be used, the scope of assessment and the auditing frequency within the schedule shall be based on:

- The results of previous audits;
- results of trend analysis;
- The relative importance and complexity of the process within ([Insert Company Name](#));
- The dates and extent of revisions to applicable documentation;
- Major changes in a department's organizational structure;
- Ongoing documented nonconformances of activities involved; and
- Contract commitments.

5.1.4 Normally, the Quality Manager shall perform all internal quality audits with the following exceptions:

- The activity to be audited will require more than one auditor; or
- Time restraints because of other activities or duties are such that scheduled audits cannot be performed.

In cases such as these, the Quality Manager may select competent personnel within ([Insert Company Name](#)) to perform these audits.

5.1.5 Individuals selected must be independent of those having direct responsibility for the activity or process that is being evaluated and must have a good understanding of basic auditing techniques as a result of previous experience or formal training.

5.1.6 Prior to performing a specific audit, the relevant internal Quality Audit Checklist (QACL-001 through 027) must be reviewed by the Auditor(s) involved to ensure that all items contained within the checklist accurately reflect the applicable requirements of the process being audited and are based on the latest approved procedure.

5.1.7 In the event that no quality audit checklist has been created, a new checklist must be developed using the Audit Checklist Template, FRM-308.

5.1.8 Based on the timetable established within the Annual Quality Audit Schedule, the responsible manager for the process(es) to be evaluated must be notified by the Quality Manager at least five (5) working days prior to the audit via an internal memo or e-mail.

5.1.9 The audit notification must contain the following information:

Insert Your
Logo Here

QUALITY MANAGEMENT PROCEDURE

ISS: 1

REV: 0

Page: 5 of 11

SUBJECT: INTERNAL QUALITY AUDITS

DOC: QMP-020

REVIEWED BY:

APPROVED BY:

November 23, 2001

- The process or activity to be audited;
- The date and time of audit commencement;
- The expected duration of the audit; and
- The name(s) of the auditor(s).

5.2 Audit Activities

5.2.1 On the date and time previously defined within the audit notification, the audit will be initiated by holding a brief pre-audit meeting between the auditor(s) and the manager(s) or supervisor(s) responsible for the process or activity being audited during which the following will be discussed and clarified as required:

- The audit scope;
- The methods that will be used to conduct the audit; and
- The personnel who will be acting as audit guides.

5.2.2 The audit function must include, but must not be limited to, the assessment of production and administrative methods and the adequacy of the verification techniques employed, as well as the completeness, accuracy and current validity of the associated documentation.

5.2.3 During the audit, the auditors will utilize the previously prepared audit checklist(s) to verify that the system process is fully documented, controlled and implemented as identified in the applicable documents by selecting at random an item or items from the relevant production or administration cycle being evaluated.

5.2.4 The items will be re-inspected, retested and/or evaluated to ensure the adequacy of the process involved as well as the effectiveness and efficiency of the quality management system in place.

5.2.5 The audit checklist shall be used by the auditor to indicate the status of the results obtained. The status codes used are:

AC Acceptable
IR Improvement Required
UN Unacceptable
N/A Not Applicable

5.2.6 To the right of the status column, auditors will record all items which were selected and reviewed during the audit as well as all observations of compliance and non-

Insert Your
Logo Here

QUALITY MANAGEMENT PROCEDURE

ISS: 1

REV: 0

Page: 6 of 11

SUBJECT: INTERNAL QUALITY AUDITS

DOC: QMP-020

REVIEWED BY:

APPROVED BY:

November 23, 2001

compliance.

5.2.7 All non-compliances will be evaluated as to whether they are systemic in nature or considered isolated cases.

5.2.8 When an audit reveals that procedures have not been fully implemented, or defined quality practices are not being followed, the auditor shall prepare a Corrective Action Request (CAR) using FRM-836.

5.2.9 All CARs are to be entered into the Corrective Action Request Log, FRM-837.

5.2.10 On the basis of the completed audit checklist, a Quality Audit Summary Report, FRM-811, is to be prepared and must include:

- The assigned audit report number;
- The date of the audit.;
- The name of the auditor(s);
- The system process being audited;
- The name of the person responsible for the process(es) being audited;
- Any audit findings;
- Reference to any CARs raised as well as their reference numbers; and
- The Auditor's signature and date.

5.2.11 At the conclusion of the audit, a post-audit meeting is to be held with the responsible manager(s) or supervisor(s) to discuss the overall results of the audit and to ensure the timely corrective action to resolve any deficiencies found, including their causes.

5.3 Post-Audit Activities

5.3.1 Copies of the completed Quality Audit Summary Report as well as any CARs raised are to be issued to the responsible Manager or Supervisor.

5.3.2 The responsible Manager or Supervisor shall review the deficiency, complete the appropriate parts of the CAR stating what action has or will be taken to correct the deficiency, include a target date for completion and return the CAR to the Quality Manager within fifteen (15) working days from time of receipt.

5.3.3 If the corrective action proposed is acceptable, the Quality Manager is to indicate acceptance on the CAR and a date for follow-up verification of the completed corrective action is to be assigned.

Insert Your
Logo Here

QUALITY MANAGEMENT PROCEDURE

ISS: 1

REV: 0

Page: 7 of 11

SUBJECT: INTERNAL QUALITY AUDITS

DOC: QMP-020

REVIEWED BY:

APPROVED BY:

November 23, 2001

5.3.4 If no response to the CAR is received within twenty (20) working days from its date of issuance, or if the response is unacceptable, the Quality Manager is to contact the manager responsible and resolve the problem. Failing this, a copy of the CAR is to be distributed to the members of the Management Review Team and scheduled for discussion and resolution at the next available Quality Management Review meeting.

5.3.5 When follow-up verification indicates that corrective action has been fully implemented and is effective, the Quality Manager is to close the audit by signing and dating the CAR(s) issued and the Quality Audit Summary Report.

5.3.6 If follow-up verification indicates that corrective action has not been fully implemented or is considered ineffective, the Quality Manager is to contact the responsible Manager or Supervisor and ensure that adequate and effective corrective action is taken as quickly as possible.


5.3.7 Upon completion of all required corrective actions, a summary of audit findings is to be presented to the Management Review Team to determine if possible quality system improvements are required.

5.4 Records

5.4.1 The completed audit checklist used, the Quality Audit Summary Report and all associated CARs are to be filed in the Quality department for the purpose of objective evidence and future follow-up and performance comparison by the Quality Manager for a period of not less than five (5) years as defined within [\(Insert Company Name\)](#) 's Quality System Filing Index, QSFI.

6.0 REFERENCES

- | | | |
|-----|------------------|-----------------------------------------------------------|
| 6.1 | QSFI | Quality System Filing Index |
| 6.2 | FRM-308 | Audit Checklist Template |
| 6.3 | FRM-808 | Annual Internal Quality Audit Schedule |
| 6.4 | FRM-811 | Quality Audit Summary Report |
| 6.5 | FRM-836 | Corrective Action Request |
| 6.6 | FRM-837 | Corrective Action Request Log |
| 6.7 | ISO 10011-1:1990 | Guidelines for Auditing Quality Systems- Part 1: Auditing |
| 6.8 | QACL-001 to 027 | Internal Quality Audit Checklists |

	QUALITY MANAGEMENT PROCEDURE	ISS: 1	REV: 0	Page: 8 of 11
	SUBJECT: INTERNAL QUALITY AUDITS			
DOC: QMP-020	REVIEWED BY:		APPROVED BY:	November 23, 2001

7.0 ATTACHMENTS

- 7.1 Sample Internal Audit Notification Memo (page 9)
- 7.2 Flowchart #020a for Pre-Audit Activities (page 10)
- 7.3 Flowchart #020b for Internal Audit Activities (page 10)
- 7.4 Flowchart #020c for Internal Post-Audit Activities (page 11)

**Insert Your
Logo Here**

QUALITY MANAGEMENT PROCEDURE

ISS: 1

REV: 0

Page: 9 of 11

SUBJECT: INTERNAL QUALITY AUDITS

DOC: QMP-020

REVIEWED BY:

APPROVED BY:

November 23, 2001

INTERNAL AUDIT NOTIFICATION

TO:

FROM: QUALITY

DATE:

SUBJECT: INTERNAL QUALITY AUDIT

The Quality department will be conducting an internal audit on the management system process CONTROL OF DOCUMENTS on _____.

The scope of this audit shall encompass all aspects and requirements as defined within Quality Management Procedure QMP-003, Issue No. 1, Revision Level O. The audit shall be conducted in accordance with QMP-020.

The auditor(s) will be _____.

This audit will commence at _____ during which a brief pre-audit discussion regarding the scope and direction of the audit will take place. It is requested that representatives from the department(s) involved attend this pre-audit meeting. The duration of this audit is scheduled to be _____. The post-audit meeting will take place at _____.

Please ensure that individuals responsible for the implementation of the management system processes covered by the above procedure are available, and that a person familiar with the processes is appointed as an audit guide.

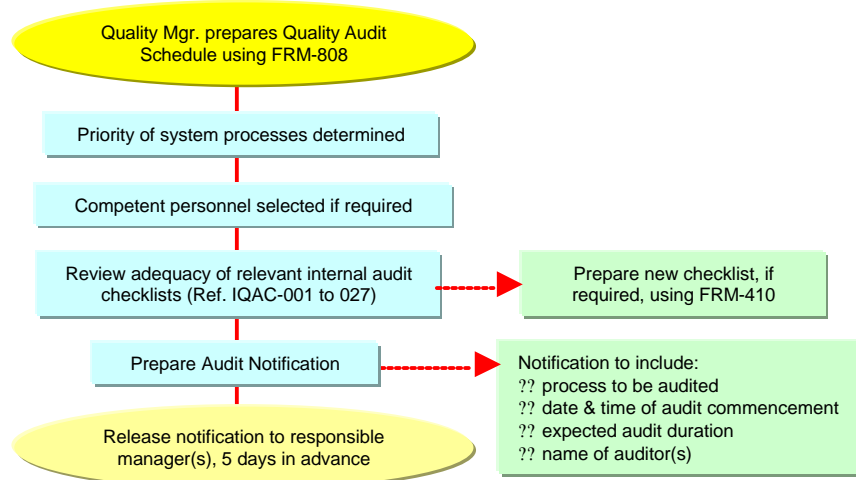
Should you have any questions regarding the above, please contact the undersigned.

Yours truly,

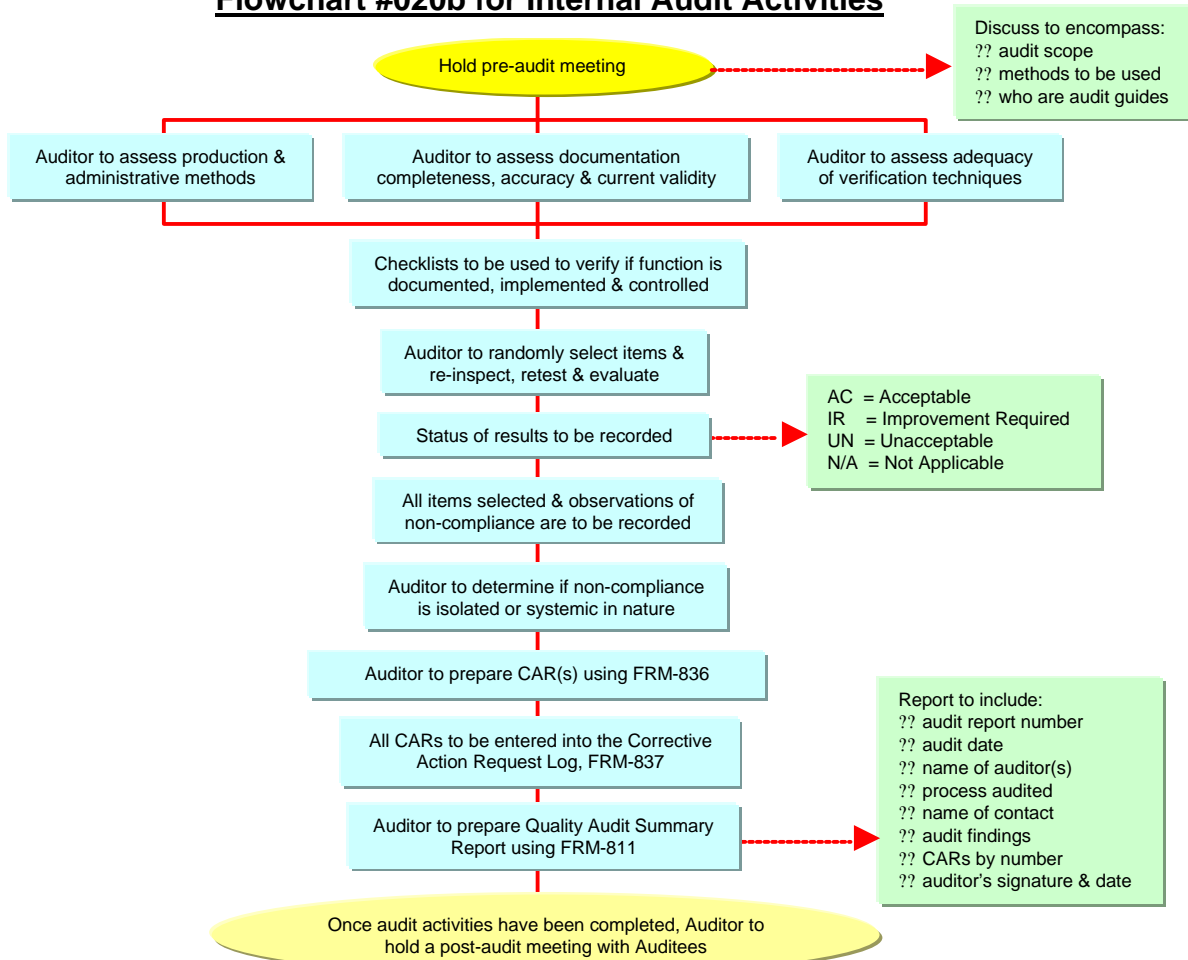
(Insert Name and Title of Quality Mgmt. Rep.)

Insert Your
Logo Here

Flowchart #020a for Pre-Audit Activities



Flowchart #020b for Internal Audit Activities



Insert Your
Logo Here

Flowchart #020c for Internal Post-Audit Activities

