# TEXAS DEPARTMENT OF STATE HEALTH SERVICES

## Drugs and Medical Devices Group

**DSHS Web Site: http://www.dshs.state.tx.us/dmd**

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# Internal Quality Audits

**Guidance Document**

Notice to Industry

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The Drugs and Medical Devices Group of the Department of State Health Services (department) has developed this guidance document in the hope that it will assist regulated firms in their compliance efforts. This document provides general guidance information only. Its contents have not been incorporated as statutory requirements nor adopted as rules by the department. Therefore, this document has no official legal status and is not binding on the regulated industry or on the Department of State Health Services.

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# Internal Quality Audits

## 1.0 THE INTERNAL QUALITY SYSTEM AUDIT

### 1.1 AUDIT REQUIRMENTS

25 Texas Administrative Code, Sections 229.601 - 229.614 (Rules for Regulation of Device Salvage Establishments and Brokers) (rules) require that medical device salvage establishments reconditioning c**lass II and/or III** devices perform planned audits of their operation an at least an annual basis. The audit is performed to verify that the business is in compliance with the rules and that the processes used to recondition distressed medical devices are adequate.

The audits are to be performed in accordance with written procedures by appropriately trained individuals who do not have direct responsibility for the matters being audited. Audit results shall be documented in written audit reports, which should be reviewed by the management personnel with responsibility for the matters audited. Corrective actions shall be implemented to correct any deficiency noted during the audit. Follow-up, including re-audit of deficient matters, should be taken to confirm that corrective actions were effective in that they prevented recurrence of the noted deficiency.

### 1.2.0 WRITTEN AUDIT PROCEDURE

Each salvage establishment reconditioning a class II and/or III device is required to establish a written audit procedure for conducting their internal audits. Before you start writing your procedure, it may also be helpful to rearrange the key elements for the procedure into a basis outline. An example of a simple outline is shown below:

- Who? Internal Auditor
- What? Quality System audit
- When? At least annually
- How? Per audit worksheet
- Results? Audit report/ management review of audit findings
- Actions? Implement corrective actions for noted deficiencies

An outline helps define the key requirements that need to be addressed in the audit procedure. Hopefully, the use of an outline will reduce the length and increase the clarity of audit procedures.

### 1.2.1 ELEMENTS OF THE PROCEDURE

Although there are elements of an audit procedure that will apply to any organization, the procedure should be customized to your specific operation. Therefore, audit procedures will vary bases on the size, complexity, and the nature of the salvage operations. In spite of the company to company differences, all audit procedures should include:

- an objective,
- audit scope,
- the audit schedule,
- assignment of responsibilities,
- audit evaluation criteria,
- management review of results, and
- corrective action policies

### 1.2.2 OBJECTIVE

Formal procedures should start with an objective. A suitable objective for a salvage establishment's internal audit procedure might be:

*To establish a process for planned internal audits of the quality system and, through this process, to ensure that all salvage activities comply with DSHS requirements and result in the adequate reconditioning of distressed medical devices.*

### 1.2.3 SCOPE

The audit scope should include all functions that impact on whether the devices will meet specifications. These functions include personnel training, facilities, environment, device master and history records, equipment calibration, receiving activities, label control, process controls and validation, complaint files, corrective action system, and data feedback. Audits should cover all buildings and operations necessary to make certain that the desired and required quality system is properly implemented.

The audit required by the rules is a system audit and is not intended to be a product audit. However, the adequacy of processes and procedures used to determine product acceptability should be audited periodically. Product audits (a reinspection of a product that has passed final inspection) and review of the device master record are desirable as part of the over-all audit process; however, audits of the entire system are required for the auditor to fully evaluate the reconditioning process and not simply a single product's fitness for use and conformance to specification.

Full quality system audits help to ensure that:

- the established quality system is adequate for producing devices that consistently meet the device master record requirements.
- all system requirements are being met, and
- the system will continue to function even though different types of distressed products are introduced for reconditioning, changes are made to the reconditioning process, the workforce is understaffed, and the manager is absent from the operation

To assure that company quality goals will be routinely met and to comply with the rules, quality system audits should:

- measure the effectiveness of the quality system"
- provide objective evidence that adequate controls are in place; and
- assure that all products and processes conform with specifications.

**1.2.4 AUDIT SCHEDULE**

The rules require that an audit of the quality system be performed at least annually for salvage establishments reconditioning class II and/or III devices. Still, each firm should take responsibility for determining the audit frequency that is appropriate for their operation. The frequency should depend upon previous audit finding, any indications of problems, and known stability of the process. If an audit reveals no problems, the audit intervals could be lengthened, so long as the entire quality system is audited at least annually. If problems are identified, audits may need to be conducted more often.

Audits are usually conducted at 1, 3, 4, 6 or 12 month intervals, but shall occur at least once every 12 months. Some companies split their audit into parts, and perform one or more parts per month or quarter, or audit one or more operations per month or quarter. This approach is valuable because it tends to direct attention toward problems that can be resolved within reasonable time limits and existing budgets. However, such segmented audits may fail to identify company-wide problems. Thus, reviewers of segmented audit reports should look closely for any indications of company-wide problems.

**1.2.5 ASSIGNMENT OF RESPONSIBILITIES**

Responsibilities must be defined for management and the auditors(s). Management is responsible for ensuring that the auditor is qualified to perform the audit and that the audits are performed in accordance with requirements. Management should also ensure that the audits are performed as scheduled, that audit reports are reviewed in a timely manner and that effective corrective action are implemented for all deficiencies identified in the audit report. The auditor is responsible for planning audits in accordance with the audit schedule, performing the audit, and reporting audit finding to the appropriate member of management.

The requirement for an auditor independent of the process being audited should generally be met; however, for very small firms, particularly firms in which every employee is

directly involved in all of the reconditioning activities, having an auditor independent of the process could be unduly burdensome or impractical. Under such circumstances, the requirement for independence may be waived. However, if DSHS finds, as a result of inspection or by other means that this waiver has compromised the quality system, DSHS may require that future audits be performed by individuals independent of the process, increase the frequency of DSHS inspections, or take other appropriate regulatory action. Individual(s) responsible for conducting audits should be sufficiently trained and experienced to detect variations and problems in the quality system. As with any quality system related training, a record shall be maintained of the audit training given each employee. An auditor is expected to objectively compare existing employee training, reconditioning processes, facilities, environmental control, device master records, device history records, test/inspection activities, equipment calibration system, label control systems, feedback, etc., against what they should be. To do this, the individual(s) should have a working knowledge of:

- the reconditioning process,
- all process controls activities,
- knowledge of how changes are controlled, and
- the quality assurance principles that apply.

Because audit results require documentation, auditors should have sufficient writing skills to
effectively communicate their findings and recommendations to management. The effectiveness of the audit begins with the audit planning. Management should start by defining the purpose and scope of their audit, while keeping in mind their quality systems requirements. Auditors should be identified early in the planning process. The auditors should possess skill and knowledge of quality system principles. Preparing an audit checklist or worksheet will help to ensure that the auditor covers all of the quality system requirements. Review of previous audits and their resulting reports is an excellent way for the auditor(s) to correctly evaluate their quality system audit program. The background preparation should also include becoming familiar with company policies, operations, and the types of medical devices that are reconditioned. The auditor(s) should notify the parties they will audit and, if there are several auditors involved (an audit team), then the audit team should hold a pre-audit conference among the audit team members to clarify exactly what the audit will include and what the objective(s) of their audit will be. Thus, preparing for an audit should include elements such as:

- selecting a knowledgeable auditor or audit team,
- preparing an audit checklist or worksheet,
- developing a planned and systematic audit procedure,
- structuring the audit to determine both positive and negative trends, and
- structuring the audit and report to promote follow-up actions.

### 1.2.6 AUDIT EVALUATION CRITERIA

Each firm shall determine the criteria to be used for conducting the audit. In general, medium to large companies will need extensive documentation outlining the areas to be audited and the acceptable criteria for each of these areas. The rules are a baseline for the evaluation criteria; however, because these rules are broad, each company must tailor the criteria to their reconditioning operations. Small companies may need only minimal documentation, and this may consist of an audit checklist with appropriate ancillary instructions to assure that all aspects of their quality system are covered. An audit checklist will typically consist of a series of questions, phrases, trigger words, or any combination of these that will prompt auditors to cover the entire quality system. The checklists should cover all requirements of the rules applicable to a company's products, operations, and other areas company management has decided are included in their total quality system. If operations or devices change, evaluation criteria and checklists shall be appropriately updated.

### 1.2.7 CORRECTIVE ACTION POLICIES

When a quality system audit program has been established in accordance with the rules, it will have been implemented in sufficient depth to detect undesirable variations and trends in operating procedures. Management is made aware of these undesirable variations through their review of the audit report, which should be reviewed by all key management personnel, especially those responsible for the matters audited. Where deficiencies have been cited in the audit report, the review of the audit findings must result in the implementation of effective corrective actions. These corrective actions must be documented and, through follow-up activities including re-audits, shown to be effective in preventing a recurrence of the cited deficiency. When properly implemented, the internal audit process will help to ensure that your firm is producing safe, reliable, and effective medical devices.

## 2.0 DSHS INSPECTIONS

DSHS performs routine, annual inspections of salvage firms (Salvage Establishments and Salvage Brokers). During these inspections, the DSHS Investigator will usually ask questions regarding the internal quality audit such as:

- when was the audit performed;
- is there an audit schedule;
- is there an audit procedure;
- who performed the audit;
- what are the auditor's qualifications;
- are records available to document that the auditor is qualified (resume, training records, or others);
- what does the quality audit include;
- do you use a checklist;
- using the checklist how should the audit be conducted;
- who prepared the report;

- when was the report written;
- who reviewed the information in the report;
- were corrective action and re-audit(s) taken based on the audit result; and
- are the corrective actions documented.

Investigators will also routinely review the written audit procedure, the most recent audit report, documentation of corrective actions, and documentation that the implemented corrective actions are effective.

**3.0 SAMPLE PROCEDURE FOR QUALITY SYSTEM AUDIT**

In response to requests from medical device salvage firms, the DSHS Drugs and Medical Devices Group has developed this procedure as an example of a generic procedure for quality system audits. Following the procedure are comments to aid firms in completing the procedure and developing a checklist that should be used with it.

**3.1 SAMPLE PROCEDURE A:**

Title: **POLICY/PROCEDURE FOR QUALITY SYSTEM AUDIT** No. _____ Rev. _____

Approved by_____Date_____

1. An audit of the entire quality system shall be performed by_____ every____ months (an audit team may be used).

2. The latest company approved audit checklist (number) _____shall be used. The audit checklist shall be updated as required and approved by _____to reflect our current quality system needs.

3. The completed checklist and audit results summary report shall be reviewed with the following managers, as appropriate, who are responsible for the matters audited: _____,_____and_____ ___ . These managers will assign a corrective action, with a scheduled date for completion, for any deficiencies identified during the audit.

4. Corrective actions shall be taken by all affected persons as discussed in the review meeting. _____ will coordinate the corrective actions, re-audits, and keep management informed. A summary report of the status of the corrective actions, as determined by a re-audit of the affected areas or other appropriate means, will be written by _____ and filed with the original audit report. The status report shall be updated at least bimonthly if there are any uncompleted corrective actions. In addition to the status report, an on-going log shall be kept of all corrective actions that have been assigned, which will include the date the corrective

action was assigned, the individual(s) responsible for implementing the corrective action, the scheduled date for completion of the corrective action, and the current status of the corrective action (completed or not completed).

* * * * * * * * * *

***Comments on the Policy/Procedure***

A. "Rev." is the revision level of the latest company approved procedure.
B. The above blanks should be completed with employee position titles and, if desired, employee names.
C. An audit checklist may be a detailed series of questions, phrases, trigger words or any combination of these to assure that the auditor covers the entire quality system. The checklist should cover the requirements of the DSHS rules applicable to each company's products and operations plus other areas that company management has decided are to be included in the quality audit. You should develop some checklist questions for each area of the quality system and the questions should be applicable to specific products and operations at your firm. If operations or devices change, the checklist should be updated!

**3.2 SAMPLE PROCEDURE B:**

## ABC Company's Internal Audit Procedure **No. _____ Rev. _____**

**Approved by_____Date_____**

**OBJECTIVE:** Periodic and planned audits of systems, training documentation processes, product flow and feedback shall be performed to assure compliance with regulatory and company requirements.

**SCOPE:** All facilities, device receiving, handling, and storage processes, complaint handling system, master production records, device history records, receiving and distribution records, measuring/test equipment calibration, and other aspects of medical device reconditioning operations.

**PROCEDURAL GUIDE:** Routine quality audits of selected reconditioning operations shall be conducted each month. The entire medical device reconditioning operation (receipt of device through to device distribution) shall be covered during a 12-month cycle. An area may be audited more than once. An "Action Audit" for any area or element may be initiated by the Manager of Quality Assurance at any time if a special problem arises or recurring deficiencies are identified.

- The teamwork approach shall be used to identify and correct deficiencies.

- The audit team shall consist of the Senior Quality Auditor (team leader) plus one or more individuals from other disciplines who have no direct responsibility for the area being audited.
- The Operation's Manager will select the team member.

**A. AUDIT PREPARATION -** The Quality Auditor (team leader) reviews all written procedures, device histories, complaint history, device labels and inserts, previous audits (audit reports, corrective actions, and follow-up audits), plus any other document relative to the audit.

**B. AUDIT INITIATION -** The Quality Auditor prepares/updates an audit checklist for systematic examination of the area to be audited. Prior to starting the audit, the Operation's Manager is informed that an audit is to be conducted. The employees of the area to be audited are notified at the start of the audit. Audit observations will be reviewed with the most responsible employee in the area being audited.

**C. AUDIT ANALYSIS -** The Quality Auditor reviews the data gathered, verifies important details, and writes an audit report using the audit report form.

**D. ISSUANCE OF AUDIT REPORT -** The Quality Auditor issues the completed audit report form to the President and Operation's Manager within three working days following completion of the audit. If deficiencies are identified that may allow nonconforming product to be distributed (critical condition), then the President and Operation's Manager must be informed within 12 hours following audit completion.

**E. CORRECTIVE ACTION -** The Operation's Manager shall be responsible for developing a schedule for correcting deficiencies cited in the audit report and submitting same within five working days to the President. Included in the correction schedule shall be the responsible individual, and the date when corrective action will be completed. The Operation's Manager will also complete the initial portion of the corrective action request form (CAR), by documenting the scheduled date for correction, the name of the individual that is responsible for initiating the correction, and by signing and dating the CAR. The original form will be forwarded to the responsible individual for implementation of the corrective action and a copy of the form will be forwarded to the Quality Auditor.

**F. AUDIT FOLLOW-UP -** Using his copy of the corrective action request form (CAR), the Quality Auditor will maintains a corrective action log listing deficiencies, responsible individual, target date for corrective action, and actual date of correction. If the deficiency has not been corrected by the scheduled date, a memo will be sent to the Operation's Manager advising him that the scheduled date for correction has been exceeded. The individual that is responsible for the correction will also receive a copy of the memo. If the same deficiency occurs on a second follow-up audit, the President shall be notified in writing that the same deficiency has been identified in multiple audits.

**G. LOG OF AUDITS AND FOLLOW-UP AUDITS -** The master log shall be maintained by the Quality Auditor. The audit log file shall include a copy of current audits, list of areas to be audited during the 12-month period, and of these, a list of areas audited to date. Audit records (logs, audit reports, and associated documents) shall be maintained for a minimum of five years.

**H. REPORT NUMBERS -** Audit numbers shall be composed from the last two digits of the current year, which is then followed by the sequential number of the audit being reported (e.g., 98-4 for the 4th audit performed in 1998).

**3.3 SAMPLE AUDIT CHECKLIST**

**Title: Quality Audit Checklist** **Document No. _____ Rev. _____**

**Checklist Approved by_____Date_____**

**Lead Auditor _____ Date of Audit _____**

**Audit Team Members:**

**_____ _____**
**_____**

**Reference and Audit Standards:_____**
**_____**
**_____**
**_____**

| Audit Area and Questions | Yes | No | Comments |
|---|---|---|---|
| **License Requirements** | | | |
| 1. Has a medical device salvage establishment license been obtained from the DSHS?<br>2. If the is also wholesaling non-distressed devices has a Distributor wholesale license been obtained from the DSHS?<br>3. Are all required DSHS licenses current?<br>4. Are all required DSHS licenses posted in an open public area?<br>5. Is a copy of a valid license maintained in each vehicle used by the salvage operation?<br>6. Does the license show the correct business name and address? | | | |

| Audit Area and Questions | Yes | No | Comments |
|---|---|---|---|
| **Physical Facilities** | | | |
| 1. Are salvage/reconditioning operations organized so that all necessary medical device reconditioning operations can be performed?<br><br>2. Are storage areas and reconditioning operations designed to prevent mix-ups and assure orderly handling of both the distressed and reconditioned devices?<br><br>3. Are all areas associated with the storage and reconditioning of medical devices clean, free of rubbish, adequately ventilated and in good repair?<br><br>4. Is lighting adequate?<br><br>5. Are birds and animals kept out of any area that is used to store or recondition medical devices?<br><br>6. Are adequate controls in place to ensure that medical devices (salvageable or salvaged) are protected from contamination and do these controls include the vehicles used to transport the medical devices?<br><br>7. Are adequate and conveniently located toilet facilities available for use by the employees?<br><br>8. Is refuse and garbage adequately stored and disposed of with sufficient frequency to prevent contamination?<br><br>9. Are cleaning operations conducted to prevent contamination of salvageable and reconditioned devices?<br><br>10. Have effective measures been established to control insect and rodents?<br><br>11. Are handwashing facilities, the water supply, and the sewage system adequate? | | | |

| Audit Area and Questions | Yes | No | Comments |
|---|---|---|---|
| **Receiving** | | | |
| 1. Are written records maintained for the receipt of distressed, salvageable, and non-salvageable medical devices?<br><br>2. Are salvageable devices segregated from nonsalvageable devices upon receipt?<br><br>3. Are nonsalvageable medical devices appropriately disposed of?<br><br>4. Are raw materials and components used in the reconditioning of distressed medical devices inspected, tested, or in some way verified to ensure that the item received is the item that was ordered and that it will conform to specified requirements? | | | |
| **Handling and Storage** | | | |
| 1. Are salvageable and salvaged medical devices stored in a manner to prevent damage and/or contamination?<br><br>2. Is the storage environment (temperature, humidity, etc.) appropriate for the storage of all of the medical devices?<br><br>3. Are reconditioned devices segregated from non-reconditioned devices and/or clearly identified by test status so that reconditioned devices and non-reconditioned devices will not be misidentified or mixed? | | | |

| Audit Area and Questions | Yes | No | Comments |
|---|---|---|---|
| **Labeling** | | | |
| 1. Does labeling conform to all regulatory requirements?<br><br>2. Is an inspection performed to ensure that the correct labeling is being used, that the labeling is accurately printed, and that it contains all required information, prior to release of the labeling for use on a medical device?<br><br>3. Are reconditioned devices labeled with a statement "Reconditioned by _____.," with the name and business address of the salvage establishment inserted in the blank?<br><br>4. Do acceptance documents confirm that reconditioned devices contain identity labels, manufacturer label, reconditioner label, user instructions/operator's manuals and all other required labeling prior to release for distribution? | | | |
| **Personnel** | | | |
| 1. Is the organizational structure established and each position's responsibility defined?<br><br>2. Are there sufficient personnel having the necessary education, background, training, and experience to assure that all reconditioning operations are correctly performed?<br><br>3. Are training programs documented?<br><br>4. Have personnel cleanliness and health requirements been established to prevent contamination of devices? | | | |

| Audit Area and Questions | Yes | No | Comments |
|---|---|---|---|
| **Process Control** | | | |
| 1. Has a written procedure been established to identify devices during all stages of receipt, reconditioning, distribution and installation so that mix-ups are prevented? | | | |
| 2. Are all employees made aware of device defects which may occur from the improper performance of their specific jobs? | | | |
| 3. For each medical device to be reconditioned, are device specifications, such as appropriate engineering drawings, component specifications and software specifications, maintained? | | | |
| 3. For each medical device to be reconditioned, are all necessary reconditioning process specifications and procedures established? | | | |
| 4. For each medical device to be reconditioned, are final acceptance procedures and specifications established? | | | |
| 5. Do the acceptance procedures and specifications include the criteria for acceptance/rejection, define the process to be used, and specify the measuring and test equipment that is to be used? | | | |
| 4. Are the device specifications, the reconditioning process specifications and procedures, and the final acceptance procedures and specifications available for use by the employees performing the reconditioning activity? | | | |

| Audit Area and Questions | Yes | No | Comments |
|---|---|---|---|
| **Complaints** | | | |
| 1.Are complaint files maintained? | | | |
| 2. Are all employees including salespersons made aware that they must report all complaints received from any source for inclusion in the complaint handling system? | | | |
| 3. Are all complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications reviewed, evaluated, and investigated? | | | |
| 4. Do all records of complaint investigation include:<br>a. the name of the device,<br>b. the date the complaint was received,<br>c. any device identification(s) and control numbers(s),<br>d. the name, address, and phone number of the complainant,<br>e. whether the complaint involved an illness or injury,<br>f. the nature and details of the complaint,<br>g. the dates and the results of the investigation,<br>h. any corrective action that is taken,<br>i. any reply to the complainant, and<br>j. the name and signature of the person who was responsible for investigating the complaint. | | | |

| Audit Area and Questions | Yes | No | Comments |
|---|---|---|---|
| **Measuring and Test Equipment (Equipment Calibration)** | | | |
| 1. Is all measuring and test equipment, including mechanical, automated and/or electronic equipment, that is used in the reconditioning of distressed medical devices:<br>a. capable of measuring to the required accuracy and/or precision limits for the specification that the equipment is measuring or testing?<br>b. currently calibrated or placed "out of service"?<br>c. controlled to ensure that the equipment is appropriately maintained and producing valid results?<br><br>2. Are measuring and test equipment that have been placed "out of service" suitably identified and excluded from use in any medical device reconditioning operation?<br><br>3. Are calibration records maintained for all measuring and test equipment that are used in the reconditioning of class II and or III distressed medical devices?<br><br>4. Do calibration records include:<br>a. the equipment identification?<br>b. dates of calibration?<br>c. the identification of the individual performing the calibration?<br>d. date of when the next scheduled calibration is due?<br><br>6. When measuring/test equipment is found to be out of calibration:<br>a. is this nonconformance evaluated to determine if it adversely impacted upon any reconditioned device?<br>b. if it could adversely impact upon a device, are appropriate corrective actions implemented to ensure that the product meets all specifications prior to distribution? | | | |

| Audit Area and Questions | Yes | No | Comments |
|---|---|---|---|
| **Device History Records and Device Master Records** | | | |
| 1. Do device master records **(DMR)** exist for each type of device to be reconditioned? **(required for each type of class II or III device reconditioned)**<br><br>2. Does the DMR contain, or refer to the location of, all device specifications, reconditioning process specifications, final acceptance procedures and specifications, labeling specifications, and other documents that are necessary to properly reconditioning the device?<br><br>3. Are device history records **(DHR)** maintained for each batch, lot, or unit of device(s) that have been reconditioned? **(required for class I, II and III devices)**<br><br>4. Do the device history records include:<br>a. The dates of reconditioning,<br>b. The quantity reconditioned,<br>c. The quantity released for distribution,<br>d. Acceptance records to document that all devices released for distribution were reconditioned in accordance with the DMR?<br>e. Copies of any reconditioner applied/distributed labeling,<br>f. a record of any device identification or control number? | | | |

| Audit Area and Questions | Yes | No | Comments |
|---|---|---|---|
| **Distribution** | | | |
| 1. Is the distribution of distressed devices restricted to DSHS licensed Salvage Establishments and Brokers? | | | |
| **Records** | | | |
| 1. Do distribution records include the name of the individual/business that purchased the device, and the date of distribution?<br><br>2. Do inventory records include:<br>a. the general description of the distressed device upon receipt,<br>b. the source of the distressed device,<br>c. the date received, and<br>d. the type of damage.<br><br>3. Are all records associated with the reconditioning of a medical device maintained for a minimum of two years after the sale or disposal of the last device within a lot of merchandise? | | | |

**3.4 SAMPLE AUDIT REPORT:**

## QUALITY SYSTEM AUDIT REPORT

Area Audited _____ Audit No._____ Date: _____

Audit Team Members_____ _____ _____

Sr. Auditor's Signature: _____ (Team Leader)

**REPORT OUTLINE**

**1. PURPOSE AND AREA DESCRIPTION -** Describe initiating factors for the audit, limitations of audit, and area being audited.

_____
_____
_____
_____

**2. MAJOR FACTS -** Summarize for management review the most undesirable conditions and practices in order of their relative importance. Attach additional sheets if necessary.

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_____
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_____
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_____

**QUALITY SYSTEM AUDIT REPORT CONT.**

**3. OBSERVATIONS AND FACTUAL DETAILS -** Give a detailed account of the current practices and the deficiencies listed in four (4) below. Attach additional sheets if necessary.

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

**4. DEFICIENCIES -** List deficiencies in procedures, standards, documentation, safety, etc., along with identity of relevant regulation, rules, company procedure, etc.

_____
_____
_____
_____
_____
_____
_____

**5.CORRECTIVE ACTION -** State corrective action(s) taken to address deficiencies and plan(s) for follow-up review. Identify individual(s) responsible for implementing the corrective action. Provide completion due date(s) for corrective action(s).

_____
_____
_____
_____
_____
_____
_____

Reviewed by: Dated reviewed:

_____ on _____

_____on _____

Revised: 10/2008