GUIDE FOR QUALITY SYSTEM MANUAL INTERNAL AUDIT

MAY 1, 2006

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INTRODUCTION:
The following is a brief guide for conducting an Internal Audit of a PCI-Certified plant's conformance with its QSM. Included is an explanation of the planning, performing, documenting, and change implementation phases of the audit. Further, we have provided checklists, sample forms, or sample procedure outlines to aid producers in formalizing their own internal audit process. Above all, it is important to understand and keep in mind that the purpose of the QSM and the QSM audit is to make a better product.

INTERNAL AUDIT OVERVIEW
Auditing your plant for compliance with your company's QSM can be a very time-consuming job. In order to keep the audit effective and timely it is recommended that the auditor not go into intense depth on every item. Rather, the auditor should do a quick overview of the operation being audited and look for procedures that do not comply with company policies that you can focus on. Another good idea is to review past audits and look for weaknesses in those audits so you can specifically review that item in your audit. Remember, an audit is a snapshot in time so no one can expect you to check and/or catch everything.

Illustration A is a sample form that can be modified to reflect your plant's information and be used to conduct and document an audit of each chapter of your QSM on an annual basis. This should be a general review of the processes covered in the chapter to see that they are still current and should provide the intended output or results.

FOCUSED AUDIT
To conduct a more in-depth audit of suspected problem areas, we suggest the following procedure outline, checklists, and sample forms. The targeted processes should be chosen from the general or "overview" audit or problems that have surfaced. For this, we provide an explanation of the planning, performing, documentation, and change implementation phases of the audit.

1. PLANNING

- **Decide who will manage the audit**. Often it will be the quality manager but someone needs to handle the administrative details. Uncovering potential problems is one reason why internal auditors need to be intelligent and creative thinkers.
- **Define the audit objectives**. One will likely be trying to comply with standards or special specifications, or in some cases, we may be looking for improvement opportunities.
- **Define the scope of the audit**. Determine what specific activities or processes will be audited and what departments will be involved.
- **Define the audit criteria to be considered**. This would typically include SOPs or policies defined by the QSM, such as compliance with MNL-116.
- **Obtain and understand the objectives**.
- **Gather and understand product and process data and information for the area to be audited.**
- **Prepare the work papers.**
- **Prepare and distribute the audit plan.**

2. PERFORMING THE AUDIT

There is no single right way to do an audit. Auditing is about understanding requirements, looking for opportunities for improvement, looking for best practices, asking questions, gathering information, analyzing what's seen and heard, forming opinions, and reaching conclusions. This effort requires that auditors be prepared, fair, objective, impartial, and, above all, exercise good judgment. Remember that audits are not only to find what procedures need improvement, but an auditor also should recognize outstanding efforts and practices by individuals and note them in their report.

The following is a list of activities that should be considered for each audit:

- Hold an opening meeting with the person in charge of the area to be audited. Things to be done at this meeting include introducing all parties and reviewing the audit objectives and scope, as well as putting the audited party at ease with the whole process. This meeting can be short and held anywhere.
- Carefully observe the process and final output. Here the auditor probes to assess the degree to which the processes are operating in conformance with the requirements of the company's QSM.
- Ask questions. It is important to ask open-ended questions since the answers are rich in information about process performance and personnel competence. An open-ended question is one that requires more than a yes or no answer.
- Gather objective evidence of the extent to which requirements are or are not being met. For example, a QC lab technician breaking cylinders is required to document these breaks. Ask to see this documentation to ensure that it is being done and done properly.
- Keep great notes. Good notes will minimize the struggles to remember what was observed at various auditing points.
- Analyze objective evidence looking for opportunities for improvement. Auditors should ask themselves questions such as, Is the process operating under controlled conditions? Is there an opportunity for improving the process? Are the requirements outlined in the company QSM being met or exceeded?
- Take all aspects of the audit into account prior to reaching a conclusion. Is a failure observed to be an isolated event or is it systemic? Are there any areas that should be noted for consideration of action to improve performance, such as lowering cost, reducing rework, or improving output? Are there any individuals or crews who displayed uncommon diligence, professionalism, or attitude that merits special recognition?
- Hold a closing meeting with the person in charge of the audited area. It would also be a good idea to have the plant manager at this meeting. At this closing meeting, auditors should share their overall opinion on what they have observed, outlining the negative and positive observations. Explain the process for corrective action on any significant adverse findings. To the best of their abilities, auditors at this time should also try to resolve any disagreements the person in charge may have with the auditor's conclusions.

3. DOCUMENTATION

Documentation can be the most difficult part of the audit. This is where auditors write down their findings in a clear, concise, and brief summary of facts. As it was stated before, it is important to document both the good and bad observations. Documenting positive findings can be an effective tool in reinforcing good performance.

These documented facts must be truthful, objective, apply to the scope of the audit, and must be written in a way that all parties involved can understand them. The findings must simply show that they comply with the requirements of the QSM or they do not.

The audit report is the official record of the audit and should contain:

- Scope and criteria of audit
- Listed objectives of audit
- Auditor's name and area being audited (remember not to use names except that of the auditor)
- Date and location of audit
- Findings and positive practices
- An overall closing statement, which could include action items for area reviewed.

Illustration B is a sample Internal Audit Form that can be modified to reflect your plants information and needs, and **Illustration C** is a sample of this form filled out.

4. CHANGE IMPLEMENTATION

During the course of performing an internal audit for compliance with the Quality System Manual, non-conformances should be documented as would occur during the PCI audit. The purpose of the internal audit being both preparation for the PCI audit and self regulation for conforming to the published QSM, documented non-conformances should be handled in the same manner and with the same degree of seriousness as any found during the PCI audit. A log of non-conformances and intended corrective action should be established.

The Quality Committee should be convened to hear the internal auditor's report with each non-conforming item or area being thoroughly identified and explained. It would be a function of this committee to ascertain whether or not the noted item is, in fact, not in conformance with the QSM. Beyond that, the committee might want to consider whether the QSM accurately reflects good, standard practice with respect to the item in question and, if not, consider taking the appropriate steps to update the manual.

Upon agreement that the item is non-conforming and needs correction, it would be the responsibility of the committee to assign responsibility for making the necessary changes to a specific individual or group of individuals with a target date for completion. A clear outcome of the intended correction should be available.

The Quality Committee and/or the QC manager should monitor the items with respect to agreed upon completion date. Once the responsible party has so informed the committee and/or the QC manager, it will be the responsibility of the QC manager to verify that the item is now within conformance or the committee should request that the individual performing the initial audit review the item and verify conformance. The non-conformance log for the audit should be so noted that the item has been satisfactorily addressed as of that date. The report and the non-conformance log should be kept on file for future reference.

SAMPLE FORM

Company Name
Address
Phone & Fax Numbers

MNL-116 & 117 Quality System Manual – Internal Audit Overview

Date: _____
Location: _____
Auditor: _____
Products Produced: _____
_____

Distribution: _____
_____

Section of Manual			Audit Information
Title Page			_____
Table of Contents			_____
Introduction			_____
1	Management Responsibility		_____
	A.1	Quality Policy Statement	_____
	A.2	Quality System Awareness	_____
			_____
			_____
13	Quality Records		_____
			_____
14	Internal Quality Reviews		_____
			_____
15	Training		_____
			_____

Appendix A

INTERNAL AUDIT FORM

Area for Audit

Personnel for Audit = Date for Audit

Plan of Action for Audit (use reverse side if necessary)

Audit Notes (use reverse side if necessary)

Review of Audit Results with QSM Committee (use reverse side if necessary)

Action Items for Area Reviewed (use reverse side if necessary)

Implementation Dates	*Signed By*	*Title*	*Date*

SAMPLE INTERNAL AUDIT FORM

Area for Audit

Stud Weld Shop

Personnel for Audit = Date for Audit

Carl Smith, Plant Drafting	*October 1, 2005*

Plan of Action for Audit (use reverse side if necessary)

1. Be at weld shop for start of 10/1/05 shift.
2. Review WPS (Welding Procedure Specification) with Welder to confirm he has correct one and understands settings.
3. Observe welding of initial studs and testing of same.
4. Did studs pass test?
5. Did welder check length of stud and change from pre-weld?
6. Did welder correct test welds?
7. Is testing record completed for previous months?

Audit Notes (use reverse side if necessary)

10/1/05 – Arrived at weld shop site. Welder sick and out for the day. Rescheduled for 10/8/05.
10/8/05 – Arrived at weld shop site and found the following: WPS for studs not on hand; first two studs tested with hammer since no pipe available for testing; second stud failed; two more welded and welds passed; weld record only recorded in September; no record in June, July, or August; stud length before and after weld not checked

Review of Audit Results with QSM Committee (use reverse side if necessary)
Committee Meeting 10/15/05 with Plant Manager, Chief Engineer, and QC Manager

1. WPS for stud weld needs to be developed.
2. Pipe for bend testing needs to be obtained.
3. Training session to be set up for welder.
4. Records should be checked for confirmation by QC weekly and signed off on a record sheet.

Action Items for Area Reviewed (use reverse side if necessary)

• *Weld Shop Foreman – set up WPS, obtained pipe for testing, and set training time for welder.*

• *QC Manager – Attend training session and monitor weld test records.*

Implementation Dates ***Sig***
Date

	Carl Smith	*Plant Draftsman*	
		Welder	
		Weld Shop Foreman	
		QC Manager	