TEMPORARY CHANGE REQUEST

TCR NO. TCR-QA-002,R9-001
(e.g., TCR-ENG-021,R0-001)

The Temporary Change Request (TCR) Form is to be used to process urgent or minor changes for PPPL Policies, Organization/Mission Statements and Procedures. The TCR should be used when changes are:
1) urgent, and can not wait the 2-4 week period for Department Head review/comment, or
2) minor, and do not warrant Department Head review.

Person Requesting Change: Andy Morrison **Phone Ext: 2841**

Department Name: Best Practices

Document Number: QA-002 **Revision No.: 9**

Document Title: PPPL Audit Program

Reason for change:
Update procedure to reflect that audit exit meetings will be held before obtaining and negotiating corrective action commitments; avoiding delays in issuing the reports and concluding audit activities.
Update to reflect change in organization names and titles.

Change description: (Summarize and attach changed pages, with changes clearly indicated)
Moved the process steps for holding an audit closing/exit meeting before the steps for committing to corrective actions.
Updated organization names and titles in several places changing from Quality Assurance to Best Practices and Quality Assurance; changing from ESH&S to ES&H.

1. Does this TCR significantly alter the intent or scope of the document? **YES:** **NO:X**

2. Does this TCR significantly impact **ES&H**? **YES:** **NO:X**

If 1 or 2 is **YES**, Explain why the changes should not be routed for Department Head review:

Jim Graham signature on file — 8/26/16
Department/Division Head Approval **Date**

John DeLooper signature on file — 9/1/16
Head, Best Practices and Outreach/designee **Date**

Release/Effective date of this TCR: **9/1/16**

Incorporate this TCR into next revision of this document? **YES:X** **NO:**

Subject:	Effective Date:	Initiated by:
PPPL Audit Program	**May 13, 2015**	Head, Best Practices and Quality Assurance
	Supersedes: QA-002 Rev 8 Dated 03/28/14 and TCRs 1-4	**Approved:** Director

TCR-QA-002,R9-001

Management System (Primary): 12.00 Assurances and Improvement
Management System Owner: Head, Best Practices and Outreach Department
Management Process: 12.31 QA Audits of quality management systems
Process Owner: Head, Best Practices and Quality Assurance
Subject Matter Expert (SME): Head, Best Practices and Quality Assurance

TCR-QA-002,R9-001

Applicability

This procedure is applicable to the entire Laboratory and its activities and to outside organizations or suppliers performing work for PPPL.

Introduction

The Department of Energy requirements for quality assurance at PPPL is defined in DOE O 414.1D. This document specifies two types of assessments: management and independent assessments. Management assessments are performed by line personnel with the goal of continuous improvement. Guidance on performing these assessments is provided in QA-025, Management Assessments. Independent assessments known as audits, are the responsibility of Quality Assurance. Audits are typically comprehensive evaluations of systems or programs, such as the PPPL Environmental Monitoring Plan or the PPPL Configuration Control Program.

The requirement for independent assessments is from DOE O 414.1D. This criterion specifies the following:

> "(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.
>
> (2) Establish sufficient authority and freedom from line management for the group performing independent assessments.
>
> (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed."

The frequency of an audit of a particular area is sometimes specified by regulation, DOE Orders, or internal documents; an example is the audit of the occupational radiological protection program, which is required by 10 CFR 835 to be performed every three years. When not specified, it is determined by a variety of factors including area performance, changes occurring in the area, availability of staff to perform the audit, etc.

Audits and their associated findings are tracked by QA.

Note that the following reports will be assigned audit numbers and tracked as indicated in this procedure as if they were audits:

- Occurrence Reporting and Processing System (ORPS) reports – reference GEN-006
- Noncompliance Tracking System (NTS) reports – reference GEN-006
- Root Because Analyses (RCA) – reference QA-019
- Lessons Learned – reference P-083
- Corrective Action Requests – reference QA-012

Definitions

Audit Area	An organizational unit of the Laboratory or outside organization to be included in the audit. Audit areas may be Divisions, Departments, Projects, PPPL as-a-whole, specific shops, suppliers, etc.
Compliance-based Audit	Audits which primarily focus on verifying adherence to DOE requirements, regulatory requirements, policies, plans, procedures, milestones, or other predetermined requirements. These audits may identify performance issues but generally only if they result from compliance issues.
Corrective Action	Measures taken to rectify problems or conditions identified in an audit and, where necessary, to preclude repetition.
External Audit	An audit of a PPPL Department, Division, Project, or Functional Area by an outside organization, typically DOE, a DOE contractor, or a state of NJ oversight organization.
Finding	The documented result of an audit or surveillance which identifies a problem in sufficient detail to enable corrective action to be taken by the organization responsible for the area included in the audit or surveillance. The finding may document non-compliances to system requirements or performance issues that have or could have the potential for significant impact on the product, process, or system from either a quality or an environmental, safety, and health perspective.

Internal Audit	An audit performed by PPPL personnel of programs that are under the direct control of the Laboratory and within its organizational structure.
Observation	Either an anomaly that does not warrant a finding or a practice that could cause future problems. Observations do not require formally specified corrective actions or tracking by Quality Assurance.
Observer	Individuals who are not part of the audit team but are allowed to observe the performance of the audit. The rules under which the observer position is implemented are defined in Attachment 4.
Performance-based Audits	Audits that primarily focus on the product, process, and system to determine how well they meet the customer's and PPPL's needs (specified and unspecified). These audits may identify compliance issues as a secondary concern, especially if these issues impact performance.
Recommendation	A suggestion for improvement made by the audit team usually based on good industry practices. The audited organization is not required to respond to recommendations.
Scope of Audit	The scope of an audit specifies the focus, extent, and boundary of a particular audit. It can include the primary organizations that will be included in the audit, the processes and activities that will be audited, and the time period that will be covered.
Supplier Audit	An audit performed by PPPL of a contracted Supplier.
Tracker	The individual assigned to track an audit to closure and to verify corrective action. For internal audits, this is usually the individual who led the audit.

Reference Documents

10 CFR 835, Radiological Protection
10 CFR 851, Worker Safety and Health Program
DOE Order 414.1D, Quality Assurance
EQP-004, PPPL Institutional QA Plan
P-044, External Audits and Appraisals and PPPL Submissions to the ORPS and NTS
QA-017, PPPL Issues Tracking System
QA-019, Root Cause Analysis/Extent of Condition Analysis
QAT-001, Training for the PPPL Audit Program

Procedure

A. Scheduling Audits

Responsibility	Action
Audit Program Manager	1. Requests input for the schedule for internal and supplier audits at the Assessments and Action Items meetings and from Department and Division Heads approximately two months prior to the start a fiscal year.
	2. Proposes fiscal year audit schedule based on the following: – The received input, – The list of required and recommended audits found at http://www-local.pppl.gov/qa/QAReqd_RecAudits/Req-RecAud-Current.pdf – Potential problem areas as identified in other systems such as performance indicators or occurrence reports, – Areas that are determined to have the greatest impact or risk on short-term and long-term Laboratory goals, – And other areas for which an audit would be beneficial, employing a graded approach.
	3. Meets with manager(s) of potential areas to be audited to discuss benefits of the proposed audit. If determined to be value added, discusses the type (performance-based, compliance-based, or combination), scope, general criteria for the audit, and timing. Solicits suggestions for the audit team composition, ideally consisting of representative(s) from the area(s) to be audited as well as customers served by the audited area (a). The responsibilities of the representative are to: – Serve as an escort for the audit team within his or her home organization, – Serve as an independent auditor for audit activities that do not involve his or her home organization, – Observe the problems identified by the audit team, work to correct any misconceptions, and work within the home organization to correct the identified problems, – Maintain open communications with his or her management so that they are aware of the progress of the audit, – Perform a level of organizational self-assessment. Note, in order to assure the independence required by DOE O 414.1D, QA reserves the right to make the final decisions regarding the audits to be performed, their objectives, and the audit team members.

Audit Program Manager	4. Assigns Lead Auditors for each audit. Usually lead auditors are from within Best Practices and Quality Assurance. However, the Head of Best Practices and Quality Assurance can select other PPPL employees with line management approval as long as the employees have the appropriate qualifications and experience to lead the audit. Audits of areas covered by 10 CFR 835, Occupational Radiation Program, and 10 CFR 851, Worker Safety and Health Program, must be performed by qualified PPPL Lead Auditors.
Head, Best Practices and Quality Assurance	5. Transmits proposed fiscal year schedule to the Head, Best Practices and Outreach.
Head, Best Practices and Outreach	6. Approves and issues fiscal year audit schedule (initial and revisions) to Supervisors and participating team members and DOE/PSO.

B. Conducting Internal Audits

In the performance of audits, auditors should never go into non-office areas, e.g., research areas, without escorts knowledgeable about the area. Before entering the area, auditors must read and sign any associated Job Hazard Analyses.

Although the steps below indicate that the formal exit meeting is conducted after the audited organization proposes any corrective action, if the optional meeting discussed in step 20 is held to discuss the report and if the proposed corrective actions received after this meeting are acceptable to the audit team, a formal exit meeting is not required.

Responsibility	Action
Head, Best Practices and Quality Assurance	1. Assures all audit team members are trained prior to the start of the audit. See section G.
Audit Team Leader/ Audit Team	2. Compiles a history of area to be audited by reviewing previous audit, occurrence, accident, inspection, and nonconformance reports.
	3. Determines requirements for area to be audited. Typical sources include: • Safety Analysis Reports (SARs) • Safety Assessment Documents (SADs) • DOE Orders and Regulations • PPPL Procedures and Policies • Federal and state laws and regulations
	4. Reviews appraisal history gathered in step 2 and identifies areas of concern.

Audit Team Leader/ Audit Team	5. Identifies proposed and specific performance objectives and criteria (POCs). If a performance-based audit, these POCs should reflect the indicators of a successful system or program. If a compliance-based audit, these POCs should reflect the requirements for the program. The audit schedule identifies the type of audit, performance-based, compliance-based, or both.
	6. Meets with manager(s) responsible for programs or systems being audited to clarify the purpose of the audit. Determines the documents that specify the requirements for the program or system. If the audit is performance-based, obtains agreement on the performance objectives and criteria to be used for the audit.
	7. Develops audit plan and checklists, when required. Guidance on sampling is available in internal QA Division procedures found on the QA web page.
Lead Auditor	8. Transmits preliminary audit checklists, when required, to the manager(s) responsible for the programs or systems being audited. Checklists may be modified during the audit as additional information is obtained.
	9. Issues Audit Notification Form (attachment 1). Include DOE/PSO on distribution. Conducts the entrance meeting. The entrance meeting is the last opportunity to review the purpose and scope of the audit**.**
Audit Team	10. Performs audit. Distributes the Interviewee Survey Form to each individual interviewed during the audit. This form is available on the QA website.
Lead Auditor	11. During the performance of the audit, keeps managers of the audited areas informed of the status of the audit and any potential findings. Periodic debriefings are held to assure open communications throughout the audit. Debriefings may be either in person or via email as desired by the managers of the audited areas.
	12. When necessary, informs the appropriate PPPL line manager of any ongoing activities that should be corrected before completion of the observed action, e.g. before the subcontractor leaves the site or before the discrepant conditions result in more serious or multiple discrepancies. These are not necessarily the same managers as the ones identified in step 6.
Lead Auditor	13. Discusses potential occurrence reporting or Price Anderson concerns with the Head, Best Practices and Quality Assurance. It is important that this be performed in a timely manner since such items must be reported within a specified time frame.

Head, Best Practices and Quality Assurance	14. Brings potential occurrence reporting or Price Anderson concerns to the attention of appropriate PPPL management.
Audit Team	15. Generates draft of the audit report. When multiple problems are identified that could potentially result from the same root cause, it is preferable that they be documented on the same finding form. For each finding, assigns proposed priority using Attachment 2, Audit Finding Prioritization Form, and classifies it by type per Attachment 3.
Lead Auditor	16. Provides draft copies of the audit report and associated findings to the Audit Manager and to the Head, Best Practices and Quality Assurance.
Audit Program Manager and Head, Best Practices and Quality Assurance	17. Reviews draft report for completeness, clarity, and adherence to audit program requirements. Provides comments to audit team.
Audit Team	18. Updates audit report based on feedback and provides draft copies of the report and associated findings to the manager(s) responsible for the programs or systems being audited; the Deputy Director for Operations; the Head, Best Practices and Outreach; the Audit Program Manager; and the Head, Best Practices and Quality Assurance. Offers to meet and discuss the report prior to the determination of the corrective actions.
Program/System Manager(s)	19. Reviews draft report and associated findings for accuracy. Provides feedback to the Lead Auditor.
Audit Team	20. Reviews any feedback and responses. Responds to originator of the feedback. Updates audit report, as necessary.
Lead Auditor	21. Schedules formal exit meeting after comments or concerns are resolved and incorporated in the final report. Invites Program/System Manager(s), audit team, Deputy Director for Operations, Head of Best Practices and Outreach, and Head, Best Practices and Quality Assurance. If adequate dialog on the content of the report has occurred as a result of step 20 and no further concerns or issues are identified, step 20 can serve as the exit meeting. This decision must be documented in the final audit report.
	22. Conducts exit meeting, if necessary. Summarizes results and follow-up actions. Obtains signatures on audit report.

TCR-QA-002,R9-001

Lead Auditor	23. Issues the report. If there are no findings, the audit is closed when the report is issued. Note: Copies of all audit reports are transmitted to the Head, Best Practices and Outreach, for informational purposes; to the Head, Site Protection Division, for review of ORPS and NTS report ability; and to the appropriate Deputy Director. If there are ES&H related findings, a copy of the report is issued to the Head, ES&H and the Chairperson, ES&H Executive Board.
Program/System Manager(s)	24. Provides feedback to Quality Assurance by providing words for the management response section of the audit report.
Quality Assurance	25. Tracks open findings in the PPPL Issues Tracking System (QA-017). TCR-QA-002,R9-001
Program System Manager(s)	26. Proposes corrective action for each finding within 10 working days. Passive language should be avoided in all corrective actions. The proposed corrective action must include both the corrective action to resolve the finding and the preventive action to preclude the finding from recurring, the name of the individual responsible for implementing the corrective actions, and the date that the corrective action is scheduled to be completed. *Note: When extensive corrective actions are necessary or the corrective action impacts multiple processes and/or departments, the responsible manager should consider conducting a peer review of the corrective action plan that includes responsible line managers as well as representation from appropriate safety committees (e.g., Safety Champions, etc.)* TCR-QA-002,R9-001
Responsible Department/ Division Head	27. Determines, for high priority findings, if a formal root cause analysis is required per QA-019. Note that if a formal root cause analysis is required, then the performance of this analysis along with the name of the individual(s) assigned to do the analysis and the due date becomes part of the corrective actions for the audit. Any actions resulting from the root cause analysis are added to the QA tracking system as part of the audit itself.
Deputy Director for Operations	28. Approves determination for formal root cause analysis.

Audit Team	29. Evaluates to what extent the proposed corrective action addresses the issues that lead to the finding. Discusses potential weaknesses, if any, with the Program/System Manager(s) who has ultimate responsibility for the action.
Lead Auditor	30. Escalates unresolved corrective action(s) up the management chain, if necessary.
	31. Evaluates the effectiveness of the audit using the survey forms as input. Documents the evaluation and distributes to the Program/System Manager(s) and the Head of Best Practices and Quality Assurance.
Audit Program Manager	32. Closes Audit when all Corrective Actions are closed.

C. Conducting Audits of Suppliers

Note that in the steps below the term "supplier" refers to any outside organization being audited.

Responsibility	Action
Audit Team	1. Develops audit plan, notification, and checklist. Typical planning documents include: • Statements of Work and Specifications and referenced documents • Previous audits of the same supplier performed by PPPL or other DOE Laboratories, if available. Planning for the audit should involve the Procurement Quality Assurance (PQA) individual assigned to the procurement, the Princeton Technical Representative, and the Subcontract Administrator/Buyer.
Lead Auditor	2. Determines with Subcontract Administrator or Buyer how the audit notification, checklist, and eventual audit report should be issued to the supplier. Options are either Lead Auditor issues it directly to the supplier with a copy to Procurement or Procurement issues it directly to the supplier.
	3. Issues the audit notification per the decision of C.2, including the PQA representation, the PQA Program Manager, and to the PPPL Princeton Technical Representative (PTR). Copies of the preliminary checklist to be used for the audit should be attached to the notification.

Audit Team

4. Performs audit. During the performance of the audit, keeps the supplier informed of the status of the audit and any potential findings.

5. Conducts exit meeting with the supplier at the conclusion of the audit to present the audit results and verify any draft findings.

6. Reviews draft report with the PTR, Subcontract Administrator or Buyer, the PQA Representative associated with the subcontract, and the PQA Program Manager.

7. Issues the report per step 2 within 15 working days to the Supplier. If findings, informs the Supplier that a response of the proposed corrective actions is required within 30 working days of the date of issue. Copies of the report are also sent to the PTR, Procurement, the PQA Program Manager, and, if the audit addresses environmental, safety, or health issues, the Chairperson of the ES&H Executive Board.

Lead Auditor

8. Interfaces with suppliers and evaluates proposed corrective action with the PPPL Princeton Technical Representative. Informs the supplier of acceptance or rejection of proposed corrective action within 10 working days. Updates audit files.

D. Training

1. Training for participating as an auditor:

   Training Method: Read-only, QAT-001, Training for the PPPL Audit Program, available on the QA website followed by a multiple choice test available from Training.

   Frequency: Once

2. Qualification for Lead Auditors:

   Target audience: Individuals assigned to lead QA Audits. Required for those leading audits of areas covered by 10 CFR 835, Occupational Radiation Program, and 10 CFR 851, Worker Safety and Health Program.

   Qualification Method: Specified in Q-005, Quality Assurance Staff Qualifications and Training, available on the QA website.

   Instructor: Audit Program Manager

E. Records Requirements

For this procedure, the QA Technical Specialist must assure that the record requirements are implemented.

Record Title	Record Custodian	Location	Retention Time[1]
Audit Reports and associated Closure Notice, if required	Lead Auditor/QA Technical Specialist	QA Server	75 years for audits of environmental, health, and safety topics [A22 (4)] Otherwise, until subsequent audit of area is completed.
Audit Supporting Documentation	Lead Auditor/QA Technical Specialist	QA Server	Until subsequent audit of area is completed.
Finding Closure Supporting Documentation	Lead Auditor/QA Technical Specialist	QA Server	75 years for audits of environmental, health, and safety topics [A22 (4)] Otherwise, until subsequent audit of area is completed.

Attachment 1 – Sample Audit Notification Form

Attachment 2 – Sample Audit Finding Prioritization Form

Attachment 3 – Classification of Audit Findings

Attachment 4 – Observers in the PPPL QA Audit Program

(All forms mentioned in the procedure are available on the QA Server)

[1] Based on GEN-023, Rev. 2. Reference to source of requirement (from GEN-023) specified in brackets.

AUDIT NOTIFICATION FORM

TO: key manager DATE: date

FROM: lead auditor

AUDIT NO.: # NAME: name

Per the audit schedule, the following audit has been scheduled for an area under your supervision. An entrance meeting has been scheduled as indicated below. After the completion of the audit, an exit meeting will be scheduled with yourself and other personnel prior to the release of the audit results to discuss these results and possible corrective action.

Findings identified during audits and the proposed corrective actions are reviewed at monthly assessments and actions items status meetings held by the Deputy Director for Operations. This practice allows for a broader discussion of findings and their possible relevance to the Laboratory, i.e., is a finding isolated to the organization being audited or could it be representative of a broader Laboratory issue, and also to review whether the proposed corrective actions would prevent recurrence of a finding.

Entrance Meeting The entrance meeting will be {date, time, and place}

Audit Scope

Requirements and Related Documents

1.

Other documents may be identified during the performance of this audit.

Performance Objectives and Criteria

Approach

Checklist

The checklist to be used for this audit is attached. The audit team reserves the right to make changes in the checklist during the performance of this audit.

Audit Schedule Dates

FROM _____ TO: _____

Feedback {for internal audit reports only} It is important that the final audit report be accurate and complete. Therefore, the audit process includes many opportunities for the audited organization to provide feedback on the performance and results of the audit. Such opportunities include:

1. Identifying potential concerns when the audit notification is first issued or during the entrance meeting
2. Providing feedback on the periodic debriefings provided by the audit team during the field investigation stage of the audit
3. Reviewing the draft audit report for accuracy and completeness and providing feedback that will be considered for inclusion in the final report.
4. Providing words for the "Management Reaction" section of the final report.

Lead Auditor - lead auditor

Team Members
1. Auditor 1
2. Auditor 2
3. Auditor 3

Followed by signatures of audit team members and Audit Program Manager/Head, Best Practices and Quality Assurance.

cc: Terry Brog, Deputy Director for Operations
John DeLooper, Head, Best Practices and Outreach Department
{Add other names}

Sample Audit Finding Prioritization Form[1]

Audit # _____ Finding # _____

Consideration	Yes (3 pts. each)	Yes (2 pt. each)	Yes (1 pt. each)
1. Reportable under the Federal Noncompliance Tracking System	☐		
2. Noncompliance to a federal or state regulatory or legal requirement	☐		
3. Has credible potential for injury to workers or the public.	☐		
4. Consistent with current global problem areas identified in DOE or other government reports.[2]		☐	
5. Noncompliance to a contractual requirement, e.g., DOE Order or Notice		☐	
6. Programmatic concern with the potential to impact the Laboratory S&H program (worker and/or public)		☐	
7. Repeat of findings or significant observations from prior audits, assessments, lessons learned, accident reports, etc.		☐	
8. Potential to significantly impact the schedule, cost, operation, or functionality of a project or collaboration		☐	
9. Potential to impact the Laboratory security program			☐
10. Potential to impact the schedule, cost, operation, or functionality of a project or collaboration			☐
11. Potential to impact the Laboratory environmental program			☐
12. Impacts multiple groups, e.g., Departments, Projects, Division			☐
13. Violation to PPPL plans, policies, or procedures			☐

SCORE: _____(<= 4 – Low, <=8 – Medium, >8 – High)

NOTES:

1 From the U. S. Department of Energy, Office of Inspector General, Office of Audit Services, Special Report, Management Challenges at the Department of Energy, DOE/IG-0832, December 2009. The list of management challenges identified by the OIG includes environmental cleanup, safeguards and security, stockpile stewardship, contract administration, Recovery Act implementation, cyber security, energy supply, and human capital management. Additionally, not classified as management challenges, but warranting continued attention by Department management are infrastructure modernization and worker and community safety. The list of significant issues identified by DOE include environmental cleanup, nuclear waste disposal, security, stockpile stewardship, contract and project administration, acquisition process management, cyber security, and human capital management. (Note that Safety and Health is excluded from this list since it is already covered by #6 above.)

TCR-QA-002,R9-001

Classification Codes used for Audit Findings

Note that an audit finding may have more than one trend code associated with it.

Implementation: Inadequacies with implementing what is already defined in a plan, policy, or procedure.

Management: Inadequacies with management of the program or some subset of the program being audited. These might involve planning, organizing resources, leading, or feedback and improvement.

Plan: Inadequacies in the establishment of institutional level goals, objectives, and controls, e.g., Radiological (ALARA) Plan, Institutional Quality Assurance Plan. (Ref. ISM Document)

Policy: Inadequacy in a document that provides PPPL principles, position, or broad guidelines but do not specify "How" something is done. (Ref. P-032)

Procedure: Inadequacy in a document that provides a step-by-step method of accomplishing Laboratory operations, with established departmental responsibilities and actions. (Ref. P-032)

Process: Inadequacies in a process defined as any set of activities that has a defined purpose, an initiating event, established inputs, identifiable stakeholders, and expected outputs. The process may be contained within a single or several organizational units. (Ref. QA-023)

Program: Inadequacies in a program defined as a set of policies and/or processes that comprise a comprehensive program, e.g., at PPPL the Preventive Maintenance Program or the Health Physics Program.

Records: Inadequacy in defining, maintaining, and retaining records associated with the area or program audited.

Safety: Inadequacies in a program, policy, procedure, process, training, or implementation with the potential to impact PPPL's Environment, Safety, or Health program

Training: Inadequacy in training, either in definition or implementation

Purpose: For any audit, the role of the observer is to assess the effectiveness of the audit team and the audit process. Did the audit team demonstrate sound knowledge of the system and procedures, conduct thorough interviews; challenge and question responses, when appropriate; effectively employ the checklists? Were the members of the audit team qualified to do the audit and adequately independent? Were the conclusions of the audit consistent with the information obtained during the audit?

Rules of Observer Behavior:

1. The Audit Observer shall:
   a. Remember at all times that the role is purely observational.
   b. Maintain confidentiality throughout the audit process from the entrance notice to the final report.
   c. Maintain confidentiality of the names of the individuals interviewed and the content of the interviews, even after the audit report is issued.

2. The Audit Observer may:
   a. Take notes during an interview.
   b. Express concerns about the audit process to the Lead Auditor only and in private. At his or her discretion, the Lead Auditor may invite the audit team into these discussions. A form is attached for documenting any concerns.

3. The Audit Observer shall not:
   a. Talk during any interview or walkthrough.
   b. Take any active part in the audit program. This includes asking questions of interviewees, participating in audit team discussions unless invited to do so by the Lead Auditor, etc.
   c. Separately, on their own, further review or assess any aspect of the program or area being audited prior to the issuance of the final audit report.

Responsibilities of Lead Auditor With Respect to the Observer:

1. Include the Audit Observer in the distribution of the audit notification.

2. Provide the Audit Observer with a copy of the audit checklist prior to the start of the audit.

3. Invite Audit Observer to the entrance meeting, audit interviews or walk-throughs, team meetings, and the exit meeting (if held). The Audit Observer should recognize that team discussions may, unintentionally but necessarily, be impromptu.

4. Include the Audit Observer in the distribution of draft and final audit reports.