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Revision Log

1.0 PURPOSE

To provide guidance in establishing responsibilities and procedures for conducting planned assessments to verify that all activities are in conformance with the requirements of the NSLS and NSLS II Quality Assurance Programs.

2.0 SCOPE

This procedure is applicable to all NSLS and NSLS II activities.

3.0 POLICY

3.1 Assessments shall be conducted to verify compliance with the procedures of the Light Sources Directorate Quality Assurance and Light Sources Directorate ESH Policies & Requirements Manual. Assessments shall be performed by the NSLS or NSLS II Quality Representative (QR), or by a technically qualified designee who does not have direct responsibilities for the activities being audited.

3.2 Assessments shall be conducted in accordance with a predetermined schedule and on an as needed basis. The NSLS or NSLS II Self Assessment Plan/ESH&Q Improvement Plan will be the primary basis for the schedule.

3.3 Assessments shall be performed with the use of prepared assessment aids, checklists or instructions. Comparisons shall be made between actual operations or documentation and established requirements. Assessments are not limited to the study of documents, but should evaluate work performance that can be reflected solely by documents.

3.4 Assessment reports incorporating a description of all findings and corrective action measures shall be distributed to the individual responsible for correcting the nonconformance, the Quality Rep., the NSLS ESH/Q Associate Chair, and the NSLS II Quality Assurance Manager.

3.5 The NSLS or NSLS II Family Assessment Tracking System (F-ATS) will be used to track all findings until they have been closed-out.

4.0 REFERENCES

4.1 "Integrated Assessment", subject area

5.0 DEFINITIONS

5.1 **Assessment** A planned and documented activity to determine the implementation and

effectiveness of a Department/Division/Project program using observation, investigation, examination, or evaluation of objective evidence.

5.2 **Cognizant Engineer or Scientist (CE/CS)** Specific individual assigned technical design or scientific responsibility for an item, research activity, or function.

5.3 **Corrective Action** Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

5.4 **Finding** An assessment conclusion which identifies a significant violation of a procedural requirement and usually leads to a condition having a significant adverse effect on quality.

5.5 **Nonconformance**: Objective evidence exists that a requirement has not been addressed (intent), a practice differs from the defined system (implementation) or the system is not effective (effectiveness).

- **Major nonconformance**: A system element is missing, or there is evidence that a system element is not implemented or not effective. Multiple minor nonconformances may be grouped together as a major if they are all examples of the same type of nonconformance.
- **Minor nonconformance:** A single observed discrepancy in the system, with evidence that the overall system is defined, implemented, and effective.

5.6 **Noteworthy Practice**: Performance that exceeds expectations in terms of efficiency and/or effectiveness and provides a model for others to follow. A noteworthy practice is a positive condition or strength.

5.7 **Observation:** Not a nonconformance, but something that could lead to a nonconformance if allowed to continue uncorrected or an existing condition without adequate supporting evidence to verify that it constitutes a nonconformance. Observations can be written if a direct nonconformance to a procedure was noted, but was an isolated incident or minor problem. Also, an observation can be based on an unsatisfactory condition not covered by a specific requirement.

5.8 **Opportunity for Improvement/Recommendation**: An Opportunity for Improvement/Recommendation is not a nonconformance or observation. It is a suggested means of accomplishing an activity, fulfilling the intent of a procedural requirement, or improving the efficiency or effectiveness of the Light Sources Directorate Environmental Management System.

5.9 Quality Representative (QR) The technical representative assigned to coordinate, assist, and monitor the implementation of quality assurance activities within a Department/Division.

5.10 **Surveillance** Monitoring or observing an activity in order to determine whether the activity is performed in accordance with applicable procedures and/or requirements.

6.0 PROCEDURE

6.1 The NSLS or NSLS II QR shall follow the scheduled assessments in the NSLS or NSLS II Self Assessment Plan/ESH&Q Improvement Plan and/or, develop an additional or detailed schedule of planned assessments to assure that activities affecting ES&H and/or QA are carried out in accordance with the applicable documented programs, procedures, and instructions.

6.2 Consider the following factors when preparing the assessment schedule:

6.2.1 The criticality of the activity or item to be assessed.

6.2.2 The findings and responses concerning corrective actions required from previous assessment reports.

6.2.3 Problems encountered with the project, activity, or item.

6.2.4 The scheduling of specific activities.

6.2.5 The availability of interview candidates and qualified assessors.

6.2.6 Personnel who perform assessments should not have any direct responsibility for the activities that they assess. However, if this is not feasible then it may be permitted following discussion with the NSLS Associate Chair for ESH&Q or the NSLS II Quality Assurance Manager.

6.3 The QR shall review and insure that nonconformances reported in previous assessments are included in the assessment aid, checklists, or instructions of scheduled assessments until it has been determined that the nonconformances have been corrected.

6.4 The QR shall prepare an assessment checklist, instructions, or utilize an assessment aid prior to each assessment. Each checklist, aid, or instruction should include:

6.4.1 A sufficient number of characteristics to adequately cover the project, activity, or item reviewed. Characteristics may be derived from a review of:

- Findings and responses from previous assessments.
- Requirements appearing in contractual documents, design descriptions, procedures, instructions, and other applicable documents that are necessary for the satisfaction of requirements or the achievement of programmatic objectives.

Note: Characteristics shall be verified by examination of objective evidence demonstrating that activities, procedures, instructions and

records are being properly executed and documented.

6.4.2 Reference to the requirement, program, procedure, or instruction to which each characteristic is applicable.

6.4.3 Provisions to add or delete characteristics.

6.5 Prior to performing an assessment, the QR shall:

6.5.1 Review assessment checklists, aids, or instructions to make certain that they have been updated to include the latest revisions of the applicable requirements.

6.5.2 Review the findings of previous assessments, and determine whether there are known problems with the project, activity, or item, that should be added to the checklist.

6.5.3 Confer with those responsible for the activity to determine the exact date(s) for the assessment, and the names and locations of the personnel who should be contacted.

6.5.4 Request information, procedures, data, etc. that will facilitate the conduct of the assessment.

6.6 **Assessment Performance**

6.6.1 The assessor shall verify the characteristics listed in the checklist through interviews, written or oral examinations, observing operations or tests, reviewing ES&H and/or QA documentation, reviewing operating & maintenance records by checking logs and records, and investigation, examination, or evaluation of other appropriate documentation evidence that demonstrates adherence to requirements.

6.6.2 In performing the assessment, the assessor should have a "show me" rather than a "tell me" attitude during interviews and should be complimentary when noteworthy practices are encountered.

6.7 The assessor shall record the results of the verification of each characteristic.

6.8 **Nonconformances** found by the assessor shall be brought to the attention of the individuals responsible for their respective area for possible resolution or correction prior to the completion of the assessment. No request for formal corrective action will be made for any deficiency satisfactorily resolved prior to the completion of the assessment. However, a record of the nonconformance will be included in the assessment report, and acknowledged as having been resolved.

6.9 When a critical nonconformance is revealed that could represent an imminent threat to safety or reliability, the assessor shall immediately notify the appropriate responsible individual and obtain a quick resolution of the problem.

6.10 At the completion of the assessment, the assessor should meet with or send a summary report to the individuals responsible for the assessed activities to provide individuals with a preliminary summary of the assessment findings and a list of nonconformances and/or recommendations.

6.11 The lead assessor shall prepare an **assessment report** which should include the following:

- Department, Project, name;
- Name or description of activity assessed;
- Date of the assessment;
- **Purpose**: this section should describe why the assessment was performed;
- **Scope**: describes what areas of the ES&H and/or QA program were reviewed during the assessment and lists the methods that were used to determine the results;
- Definition of terms section;
- The name(s) of the assessor(s);
- Person(s) contacted/interviewed;
- A list of documents, log and records reviewed;
- **Summary**: informs management of the effectiveness of the program being assessed. It should be brief, clear, and to the point. It should highlight cases of noteworthy practices and any significant findings. It should also provide an indication of the status and effectiveness of corrective actions to findings from previous assessment for the area reviewed;
- **Nonconformances, Observations**, and **Recommendations**: the number of nonconformances, observations, and recommendations should be identified in this section. **Nonconformances** should be listed first. Each nonconformance should identify the requirement and then describe the details of the conditions observed. Each **observation** should be similarly described. **Recommendations** should be worded as a suggestion or as a description of the area that could be improved. Each item should be concise and specific and reported in sufficient detail to enable the responsible individuals to provide appropriate corrective action;
- **Assessment Closeout** (if applicable): this section of the report documents the individuals who attended the assessment closeout meeting. It also reports the corrective action(s), if any, that were agreed on to resolve any discrepancies;

- **Attachments**: the assessment plan, a completed or unannotated assessment checklist, aid, or instruction, or any other pertinent information should be attached to the report;
- The signature of the assessor(s) and the date;
- The QR is responsible for final editing, distribution, filing, and maintenance of the assessment report as an ES&H and/or QA record.

6.12 The assessor shall, as a minimum, send copies of the assessment report to the person responsible for the activity that was assessed, that person's immediate supervisor/NSLS section head or NSLS II Division Director, and the NSLS ESH/Q Associate Chair or the NSLS II Quality Assurance Manager.

6.13 Upon receipt of the assessment report, the person responsible for the activity that was assessed, shall:

6.13.1 Assist in determining the root cause of the nonconformance(s).

6.13.2 Assist in correcting all nonconformances.

6.13.3 Immediately correct nonconformances that adversely affect safety or reliability.

6.13.4 Initiate interim actions (if needed) to provide needed controls while investigations and implementation of permanent corrective actions are accomplished.

6.13.5 Submit a written response addressing the findings in the assessment report, indicate the corrective action measures taken to correct each nonconformance, and the status of the action taken to correct each nonconformance. This will normally be handled through the Family Assessment Tracking System (F-ATS).

6.14 Assessments that have not revealed nonconformances, or the need for recommendations, shall be considered closed when the assessment report is issued.

6.15 Assessments that have uncovered nonconformances and/or resulted in recommendations shall be considered closed when corrective and preventive action responses are reviewed and the implementation verified by the Condition or Assessment owner identified in F-ATS. Documentation review, inspection, or re-assessment may accomplish this verification if corrective action is extensive or complex. If the verification effort produced negative findings, the cycle is repeated until the verification is positive.

6.16 As all the findings for an assessment are being satisfactorily completed, the QR will update the assessment documents on file or utilize the F-ATS as the means of recording

the final results. The assessment is considered closed when corrective action(s) on all nonconformances and observations (if applicable) have been properly verified.

6.17 The QR shall retain the assessment checklist and the reports generated in accordance to the Records Management subject area.

Document Review Frequency	
3	Years

Review signatures on file with master copy of controlled document

LIGHT SOURCES DIRECTORATE REVISION LOG	
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A	Initial Document for Light Source Directorate – see LS-QAP-1101	5/5/2008