

On June 21, 2011, the HASQARD Focus Group approved the following revision to Section 10 in Volume 1 of the HASQARD replacing the original Section 10 found in Revision 3 of HASQARD in its entirety:

10.0 ASSESSMENTS

Assessments document how the organization determines the suitability and effectiveness of the implemented quality system and the performance of the programs to which the quality system applies.

Assessments may be performed by agencies or groups that are not under the control of laboratory management such as regulators (e.g., EPA, Washington State Department of Ecology, Washington State Department of Health), clients, and the DOE. Assessments may consist of inspections, interviews, and/or evaluations that focus on the organization's ability to meet client, program, and/or regulatory requirements. Management shall be responsible for initiating, tracking, following up, and documenting in a timely manner all corrective actions that are required as a result of the assessments.

Assessment programs consist of management assessments, independent assessments (e.g., internal independent assessments and external audits/assessments) and performance evaluation assessments to assess adequacy and effectiveness of the quality assurance program and technical systems. Surveillances, peer reviews and readiness reviews are acceptable assessment techniques that use observation and monitoring to provide confidence that on-going processes and activities are adequately and effectively performed.

At a minimum, the laboratory and/or field organization's assessment program shall address the following:

- Management assessments
- Independent assessments
 - Internal independent assessments
 - External audits
- Performance evaluation assessments

The QA program shall identify each assessment element and the frequency of each assessment; the position or individual responsible for each assessment; the qualifications, responsibilities, authority, and accountabilities of the assessor(s); the format of the assessment; action owner(s); expectation for timely corrective action; expectation for timely closure of the corrective action; follow-up actions required and associated dates; and required distribution for all related documentation.

Assessments shall be scheduled on the basis of the importance of the activity to be assessed. Independent assessments shall be carried out by personnel independent of those having direct responsibility for the activity being evaluated.

10.1 MANAGEMENT ASSESSMENTS

Management assessments ensure that managers regularly assess their management processes and identify and correct problems that hinder the organization from achieving its objectives. The

organization's QA program provides a solid basis for this assessment. The purpose of this assessment is to evaluate the following:

- Effectiveness of the management control systems that are established to achieve and assure quality
- Adequacy of resources and personnel available to achieve quality objectives to which the quality systems apply
- Effectiveness of training and assessment
- Applicability of data quality requirements
- Client complaints.

Management assessments identify noteworthy accomplishments, significant QA problems, and opportunities for improvement. Management assessments shall be conducted annually at a minimum.

10.2 INDEPENDENT ASSESSMENTS

Independent assessments shall be carried out by personnel independent of those having direct responsibility for the activity being evaluated that are technically qualified and knowledgeable about the area to be assessed. Independent assessments include internal independent assessments conducted by a laboratory or field organization's QA function and external audits conducted by a party external to the laboratory or field organization being assessed.

10.2.1 Internal Independent Assessments

Internal independent assessments are directed by the laboratory, field and/or program's QA function. This assessment measures the performance or effectiveness of the organization's technical and/or quality systems and their elements with respect to documented specifications and objectives. Internal independent assessments consist of a review of laboratory or field operations, specific procedures, and related documentation. For example, areas of interest might include:

- Measuring and testing equipment calibration or control procedures
- Document control procedures
- Technical procedure compliance
- Adherence to data quality requirements (i.e., data quality review)
- Identification, control, storage, and preservation of samples or standards
- Communication of client expectations
- Client complaints.

Internal independent assessments should be conducted periodically and should vary, such that over time, critical elements are evaluated.

10.2.2 External Audits

External audits are independent assessments conducted by parties external to the laboratory or field sampling organization. External audits are conducted at a frequency commensurate with the quality assurance requirements of the organization conducting these independent assessments. The frequency expectation for participation in external audits is consistent with the policies of the organizations for which data are produced using the HASQARD. Laboratories using the HASQARD as a basis for QA requirements should be audited by an external audit to assess the laboratory's compliance to HASQARD at least once every three years.

10.3 PERFORMANCE EVALUATION ASSESSMENTS

Performance evaluations are generally considered blind or double-blind tests introduced into a process to provide an independent evaluation tool of the quality of the process. Performance evaluations can be applied to laboratory and field operations but can also provide information regarding the effectiveness of management systems for organizations or programs, depending on when and by whom they are introduced. These assessments should be coordinated by the organization's QA function, whenever practical, to avoid any conflict of interest.

A strong performance evaluation program will typically consist of both internal and external performance measures. However, a program based on external blinds is considered the minimum acceptable.

Internal programs might include standard materials prepared in the field or laboratory or by a source independent of the activity being tested. Most of these performance programs are blind programs.

Each organization's assessment program shall identify all internal and external performance evaluation program(s) required. The QA program shall also identify the position or individual responsible for administering each program, how performance information will be disseminated, how identified corrective actions will be resolved, and the timeframe required for corrective action. This information shall be made available to regulators and clients upon request.