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RECOMMENDATIONS FOR THE USE OF CHECKLISTS DURING A NELAC ON-SITE ASSESSMENT

A Report Prepared by

The Environmental Laboratory Advisory Board,
An EPA-Sponsored Federal Advisory Committee

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FOREWORD

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EXECUTIVE SUMMARY

The Environmental Laboratory Advisory Board (ELAB) was established on July 31, 1995, in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2 Section 9 (c). As specified by federal charter, ELAB provides advice and counsel to the United States Environmental Protection Agency's (USEPA) Administrator, Deputy Administrator, and Environmental Monitoring Management Council, the National Environmental Laboratory Accreditation Conference (NELAC) Board of Directors, and other federal agencies concerning the systems and standards of accreditation for environmental laboratories.

This report presents the recommendations of the Environmental Laboratory Advisory Board (ELAB) on the use of checklists during laboratory on-site assessments by accrediting authorities recognized by the National Environmental Laboratory Accreditation Program (NELAP). ELAB recommends that:

> The NELAC On-Site Assessment Committee develop checklists to perform Quality Systems and Technical Systems reviews during laboratory assessments.
>
> Checklists strive for simplicity and brevity, and that their structure parallel the order of events of on-site assessments.
>
> Method-specific checklists be primarily reserved for assessing performance of method-defined parameters.
>
> That ensuring consistency of assessments be redirected to efforts to develop sound assessor training courses.

ELAB RECOMMENDATIONS

1. Checklists are tools to use during laboratory on-site assessments, but should be used in the context of other tools available to assessors. Checklists should help assessors determine logically the conformance of a laboratory with its quality system and the adequacy of such a system for its intended use.

Accordingly, NELAC assessors should determine laboratory competence by focusing on reviewing a laboratory's quality system. Checklists developed for this purpose should:

- Be sufficiently detailed to be useful reminders but should not attempt to be exhaustively comprehensive.
- Reflect assessor knowledge of the discipline under evaluation.
- Have a structure that corresponds to the flow and order of laboratory processes.
- Strive for simplicity.
- Be logical.
- Be prescriptive but not restrictive.
- Include space to document assessment findings.
- Help laboratories understand why a finding constitutes a deficiency.
- Make reference to pertinent sections of the NELAC standards.
- Be universally available.
- Strive for brevity.

2. Checklists are primarily needed to assess laboratory compliance with the NELAC standards, especially Chapter 5, Quality Systems.

3. Checklists should accommodate both essential technical requirements in mandated methods and performance-based measurement systems (PBMS).

4. Checklists for specific methods may be appropriate when methods do not include Quality Control (QC) information, or when methods define the assayed parameter (e.g., BOD, TCLP). Technical Systems review checklists, independent of the specific method used by a laboratory, can be used to evaluate correct execution of method and technology essentials in most assessments.

5. Although checklists can standardize some aspects of laboratory assessments, consistency of on-site assessments is best accomplished by uniform assessor training on the NELAC Quality Systems Standard, the NELAC accreditation process, technical competencies, and proper use and interpretation of checklists.

6. Technical Systems checklists should:

- Be organized by analytical technology or instrumentation.
- Segregate preparatory and determinative steps in an analysis.
- Document a review of a laboratory's data collection processes.
- Document a review of a laboratory's data reduction and verification processes such as calculation checks, raw data conversions, data transfers, and permanence and incorruptibility of electronic files.
- Verify the implementation of a laboratory's Quality System by analysts at the bench level.

7. NELAC should establish a defensible process for developing, publishing and updating on-site assessment checklists.

BACKGROUND

The 1992 report prepared by the Committee on National Accreditation of Environmental Laboratories stated that the key elements of a national program for laboratory accreditation would be "on-site audits, performance evaluation testing, and data audits."

On April 22, 1998, draft method checklists were posted on the NELAC website. Based on a review of these checklists, ELAB decided to form a workgroup to:

> Provide recommendations to ELAB regarding key elements of a laboratory assessment (audit) reflecting audit consistency, a reasonable level of detail and an eye towards PBMS. Ideally, the recommendation would include a detailed model checklist that could be used by laboratory assessors.

The Workgroup members worked on this activity from May through June of 1998 and presented their findings to ELAB on July 1, 1998. The Workgroup reviewed NELAC Chapters 3 and 5, the Assessor Training Manual and the draft method checklists posted on the NELAC Website. Workgroup members shared other audit checklists, related technical information and participated in several conference calls to develop the findings that were presented to ELAB.

On July 1, 1998, ELAB recommended this report be forwarded to the NELAC On-Site Assessment Committee for consideration.

A prototype for a Quality Systems checklist is included with this report (Attachment 1). This prototype is provided to show the level of detail and organization envisioned by ELAB. The checklist would need further refinement to allow for adequate space to record findings and to improve its utility.

ELAB has also considered future directions based on draft ISO Standard 17025. These comments are provided in Attachment 2.

Attachment 1. Example of a Quality Systems Checklist

Pre-Assessment	5.4 ORGANIZATION AND MANAGEMENT 5.4.1 Legal Definition of Laboratory 5.4.2 Organization Job Descriptions for All Positions. Clear Description of Lines of Responsibility. *Technical Director* (Resp. For Tech. Operation) *QAO* (Resp. For QS Implementation & Independent from Lab Operations Oversee QS) • Perform Internal Audits Yearly & Doc. Corrective Actions • Maintains *Quality Manual*		
	5.6.1 General requirements for laboratory staff Combination of Exp. & Ed. To Do the Job All Must Comply with Quality Manual Define Exp. & Ed Requirements (Proof: PT; IDC; Splits) Have Training & Training Doc. Have Read/Understand Quality Documents Adhere to Sample Acceptance Policy Comply with Sample Tracking System Document Quality of All Reported Data		
	5.6.2a Laboratory Management Responsibilities (defining personnel minimal qualification and experience)		
	5.5.2 Quality Manual		
Pre - Analytical Assessment	5.5.2i (Project Management) Manual specifies mechanisms for ensuring laboratory reviews all potential new work to ensure it has the appropriate facilities and resources before commencing such work • Table of Contents • Quality Policy statement • Organizational Structure & Job Descriptions • Record System/Procedures • Approved Signatories • Procedures for Traceability of Results • Listing of Test Methods • Sample handling Procedures • Feedback and Corrective Action • Confidentiality Procedures • Procedures for Audits & Data Review • Procedures to Assure Needed Training/Experience • Reporting Procedures (Analytical Results) • Listing of References/Glossaries/Appendices		
	5.15 (Procurement) OUTSIDE SUPPORT SERVICES AND SUPPLIES (Bottles, sample containers, preservatives) Also other procurement practices of supplies * Of Adequate Quality to: Sustain Confidence in the Lab Tests. * Records Maintained of All Such Suppliers/Vendors.		
	5.11 SAMPLE HANDLING, SAMPLE ACCEPTANCE POLICY AND SAMPLE RECEIPT 5.11.1 Sample Tracking * Unique Number for Each Container * Linked to Field Id * Durable Labels 5.11.2 Sample Acceptance Policy Containers/ Holding Time/		

	Preservation./Volume/ Records * If Unacceptable All Data Flagged 5.11.3 Sample Receipt Protocols * General condition of Samples Noted * Procedures to Check Preservatives (e.g., pH, Temp.) * Permanent Chronological Record * Link Sampling/Field Information & Measurements * Chain-of-Custody Records Retained (If Needed; see 5.12.4) 5.11.4 Storage Conditions * Established Protocols Consistent with Regulations * Acceptance Criteria established: e.g., above freezing to 6C * Security as Appropriate To Maintain Integrity Sample Disposal * SOP for Sample Disposal		
	5.12.4 Legal or Evidentiary Custody (Complete when required.) 5.12.4.1 Basic Requirements 5.12.4.2 Required Information in Custody Records 5.12.4.3 Controlled Access to Samples 5.12.4.4 Transfer of Samples to Another Party 5.12.4.5 Sample Disposal		
Analytical Section Assessment	5.7 PHYSICAL FACILITIES - ACCOMMODATION AND ENVIRONMENT 5.7.1 Environment 5.7.2 Work Areas <u>Do Not Invalidate or Adversely Affect Results</u>: <u>Monitoring of Conditions</u>: As Per Test Method Requirement (Example: 9222D MF))		
	5.9.4.2.1 Analytical Support Equipment (Balances, refrigerators, ovens, pipetors) - Calibration - Control limits - Corrective Action - Record Keeping Acceptance Criteria for Support Equipment: All Calibrated Yearly vs. NIST Traceable Reference (When Available) Each Working Day: Balances, Ovens, Ref. Freezers, Incubators, Water baths checked with NIST Traceable References Each Week: Liquid Dispensing Devices Checked for Accuracy (Except Class A) * Example = Media Dispensers Per Use: Autoclaves Temp.& Pressure Doc. Effective * Sterility Tests-- NOT Heat Tape Alone!		
	5.8 EQUIPMENT 5.8a Equipment Maintenance 5.8c Out-of-service equipment 5.8d Records Records of: * Maintenance Procedures (Clean & Maintained) * Manufacturer &. Operator Instructions. * Location; A Use Status (labeled when Defective/Out-Of-Service) * History of Malfunctions/Repairs/Modifications		
	5.10.5 Documentation and Labeling of Standards and Reagents Manufacturer's Certificates of Purity, etc. Details of Preparation (SOPs) Labeled w/ Unique Identifier & Expiration Dates		
	5.9.3 Reference Standards		

	5.9.4.3 Instrument Calibrations		
	5.9.4.4 Calibration Verification 5.9.4.4.1 Initial Calibration Verification 5.9.4.4.2 Continuing Calibration Verification		
	5.9.2 Traceability of Calibration		
	5.5.4 Essential Quality Control Procedures (use specific checklists developed for appendix D types of testing) +/- Controls (Blanks, Reference Materials) Variability/ Repeatability(Replicates) Accuracy (Calibration, PTs.) Method Capability (MDLs, Quant. Limits) Appropriate Formulae (Calculations) Reagent/Std. Quality (Reagent Grade) Established *QC Acceptance Criteria* (Control Limits) Sample *Acceptance Policy* (Criteria to Reject Samples) All QC listed in Methods Manual (Yearly Audit) Essential QC for Specific Fields of Testing (Appendix D)		
	5.12.3.2 (Records) Laboratory Support Activities		
	5.12.3.3 Analytical Records		
	5.10 TEST METHODS AND STANDARD OPERATING PROCEDURES 5.10.1.1 Standard Operating Procedures (SOPs) Up-To-Date, Organized & Readily Available to Staff. * May Cite Published Methods (By Reference ok!) * Must Doc. Any Changes to Published Methods * Organized with Effective Date & Rev. # Fully Documented and Validated		
	5.12.3.3 Analytical Records		
	5.10.4 Data Verification		
	5.5.3.5 Corrective Actions		
Reporting Section Assessment	5.13 LABORATORY REPORT FORMAT AND CONTENTS 17 Must Items, Including: Out of Control QC; < 3.18 * MDL Values Exceptions: Facility Lab Providing Compliance Data Solely for the Facility Information 1-17 Available for Review By Accrediting Authority		
	5.13c LABORATORY REPORT subcontract laboratory data * Clients Must Be Advised in Writing * Subcontractor Must Be NELAC Accredited For Tests Performed.		
	5.10.6 Computers and Electronic Data Related Requirements Computers: Performing, Manipulation and Reporting of Test Data Follow: A 2185 Good Automated Laboratory Practices-- Section 8.1- 8.11"		
Management Assessment	5.12.2 Records Management and Storage 5.12.1 Record Keeping System and Design Two Levels: Sample Tracking Legal/Evidentiary Generally Redundant with Previous Sections....Additions Include: * Indelible Ink * No Obliterations- Single Line		

	* Record Management System (Access Log, Protected from Fire, Theft, Flood, Pests More Emphasis on Security than TrackingScenario		
	5.12.3.4 Administrative Records		
	5.10.2.1 Method Validation/Initial Demonstration of Method Performance		
	5.6.2b-c (TRAINING and documentation) Laboratory Management Responsibilities		
	5.5.3 Audits 5.5.3.1 Internal Audits + Corrective Action 5.5.3.2 Managerial Review + Corrective Action 5.5.3.3 Audit Review + Corrective Action 5.5.3.4 Performance Audits + Corrective Action 5.5.3.5 Corrective Actions (process) *Audits:* Self-Assessment Review *Internal Audits*: (Yearly QAO - Compliance with QS) *Management Review* : (Yearly Review by Management of QS to Assure Continued Suitability & Effectiveness) *Performance Audits*: (Ongoing Checks to Monitor Quality of Analytical Activities) * QC Procedures & Control Limits * Qtly QCs 2nd Source vs. Calibration Stds. * Logic Checks, e.g., P04 < TP Corrective Actions: * For Each of the Audit Type * For Out-of-Control QC (Qualify Data) EXTERNAL AUDITS: ON-SITE ASSESSMENT @ 2 YRS		
	5.16 COMPLAINTS + Corrective Action * Doc. Policy & Procedures for Resolution of Complaints * Serious Complaints: [Concern Quality of the Calibration or Tests] = Lab Shall Perform an Internal Audit		

Attachment 2. Comments for Future Consideration

ISO Guide 25 is the basis of the lab accreditation system of NELAC, but the Guide is being changed to an ISO standard, proposed as 17025. The changes (additions) of categories could be used to restructure the Quality Systems audit checklist and process into 2 parts: Management requirements, and technical requirements. These are subdivided into the following areas:

Management Requirements

- Organization and management
- Quality system
- Document control
- Request, tender and contract review
- Sub-contracting of tests and calibrations
- Purchasing services and supplies
- Service to the client
- Complaints
- Control of nonconforming testing and/or calibration work
- Corrective action
- Preventive action
- Records
- Internal audits
- Manage reviews

Technical Requirements

- General
- Personnel
- Accommodation and environmental conditions
- Test and calibration methods including sampling
- Equipment
- Measurement traceability
- Sampling
- Handling and transportation of test and calibration items
- Assuring the quality of test and calibration results
- Reporting the results

The addition of sampling will require a written description of sub-sampling and also fits with the "Measurement System" part of PBMS. The "request, tender and contract review" makes sure the lab understands and can commit to do the work requested as is called out in 5.5.2i, Quality Manual, in the Quality Systems Checklist. These requirements also cover continuous improvement (preventive action) and management reviews, in line with the EPA's Executive Order 5360.1. Measurement traceability is also key, considering lack of available PT samples and certified reference standards in some areas (5.9.3, Reference Standards). The Guidance and Requirements documents from EPA (G-7 and R-7) covering assessments could also be considered in the content of the Quality System Checklist.