



Maine Center for Disease
Control and Prevention
An Office of the
Department of Health and Human Services

John E. Baldacci, Governor

Brenda M. Harvey, Commissioner

Department of Health and Human Services
Maine Center for Disease Control and Prevention
286 Water Street
11 State House Station
Augusta, Maine 04333-0011
Tel: (207) 287-2070
Fax: (207) 287-4172; TTY: 1-800-606-0215

M E M O R A N D U M

TO: Maine Board of Environmental Protection, Maine DEP

FROM: Tera Pare and Matthew Sica, Division of Environmental Health, Maine CDC, Maine DHHS

RE: Joint Rulemaking (DHHS & DEP) for Lab Certification Rules

DATE: February 18, 2010

**Proposed Rule Amendments to the Maine
Comprehensive And Limited Environmental Laboratory Certification Rules, 10-144 CMR 263**

AUTHORITY:

22 M.R.S.A. § 567 authorizes both DHHS and DEP to establish rules that govern the lab certification process in Maine. The following summary explains the proposed changes from DHHS, Maine CDC's Lab Certification Officer Matthew Sica.

ORIGINAL RULE CHANGES:

Chapter 263 is changed to reduce regulatory barriers for laboratories that have obtained or seek to obtain certification with the State of Maine. These changes remove ambiguous direction due to conflicting policies among agencies and correct inadequate lists of analytes available for certification, in order to help the Maine Laboratory Certification Program expand their use of certified laboratories. These extensive changes, which results in an entire repeal and replacement of the original Chapter 263, will ensure that data of known quality is used to make sound decisions for the protection of human health and the environment.

- (1) **Updated and Increased Definitions.** The proposed amendments incorporate more definitions to ensure consistency in the use of terminology. Other terminology has been updated to reflect current usage within the environmental testing industry. For example, the term "performance evaluation" is obsolete and has been replaced by the term "proficiency testing";
- (2) **Incorporation of Current Policies and National Standards.** The proposed amendments define a consistent set of rules for the administration of the environmental laboratory review process. This update is intended to assist regulated parties to achieve compliance by incorporating several existing industry standards, along with current MELCP rules and policies. The rules also incorporate detail from existing guidance documents, which include the following:

- Incorporation of Quality System elements, the 2003 National Environmental Laboratory Accreditation Conference NELAC standard and the International Organization for Standardization / International Electrotechnical Commission, ISO/IEC 17025:1999;
- Allowance for performance-based methods and method flexibility, where applicable by program; and
- Updated use of new methods.

- (3) **Proficiency Testing Requirements.** With these proposed changes, DHHS also amended the proficiency testing requirements for laboratories and proficiency test providers. Laboratories will be required to perform one proficiency test per year instead of the current rule's requirement for two tests. The NELAC Institute's (TNI) PT Board reviewed statistical data, which showed only a small increase of laboratory effectiveness, if two PTs per year occurred, compared to one PT per year. This study analyzed the pass/fail data for PT sample data sets for laboratories performing two PT samples per year and other laboratories performing one PT sample per year. This change would realize a cost savings to the laboratories, without detriment to quality;
- (4) **On-site Inspections.** DHHS proposes to amend the manner in which on-site inspections are conducted. Currently, a laboratory located in Maine could receive NELAC accreditation from another state and be exempted from the biennial onsite inspection of the MELCP. This practice limited the effectiveness of the MELCP on regulating these particular laboratories, whereas this change would require laboratories located in Maine to be inspected by the MELCP. If adopted, this change would require the MELCP to perform out-of-state laboratory inspections when the resident state's inspections are performed at a frequency of greater than two years. The MELCP would perform inspections for all of its programs, including the MEDRO/GRO program for the DEP Leaking Underground Storage Tanks [LUST] Program. Current rule does not require inspections for this program; and
- (5) **Re-organization of the existing rules.** With this proposed rule change, DHHS amended the organization of the rules themselves, in order to reflect the general sequence of the certification process, which promotes clarity and helps achieve compliance.

PROCEDURAL HISTORY:

The original public hearing for Chapter 263's rule changes occurred at a BEP meeting on October 1, 2010. Due to the extent of public comment for additional substantive changes, both agencies agreed to reopen the comment period to allow for comment on these additional changes. This comment period re-opening was advertised on December 30, 2009. The final comment period deadline was January 29, 2010. During the second comment period, no additional comments were submitted.

SUBSTANTIVE CHANGES RESULTING FROM PUBLIC COMMENT IN OCTOBER 2009:

The major changes proposed as a result of the original comment period, and agreed upon by both agencies, include the following:

- (1) **Added definition of mobile laboratory.** Because "mobile laboratories" are referred to in the rules, the agencies agreed it was prudent to define them;
- (2) **Clarification of purpose and scope.** This clarification states that lab certification is not required for analytes not required for certification by EPA, nor does it address the management of waste streams or the use of hazardous or toxic substances;

- (3) **Clarification of lab certification process.** Language was added to require the DEH Lab Certification Officer to conduct a comprehensive on-site inspection of any laboratory seeking certification, as well as a requirement for on-site inspections every two years thereafter for existing certified laboratories;
- (4) **Changing “assessments” to “inspections”.** Instead of on-site assessments, it was commented on, and agreed, that a more accurate terminology to describe the on-site process is to use “inspections”;
- (5) **Procedural changes for labs during a suspension or revocation.** Clarification on what is required of labs to do, when their lab certification for any analytes is suspended or revoked, in particular, with notification of any clients and proof to the certification officer;
- (6) **Expansion to include RCRA.** This addition gives added confidence to MEDEP programs which require the use of solid and hazardous waste data;
- (7) **Additional proficiency test requirement.** A requirement that all study data released from the PT provider will be scored for compliance with Chapter 263;
- (8) **Addition of electronic reporting requirement.** This addition required that a lab must electronically report results required by Chapter 263 in a format acceptable to the Drinking Water Program;
- (9) **Removal of full-time requirement for laboratory directors.** After receiving comment that not all laboratories have full-time laboratory directors, as is the case in Brewer, the Departments agreed that removing this requirement was reasonable;
- (10) **Clarifying temperature-reading devices.** Adding “thermometer” to devices was a crucial piece to accurately describe what the lab certification officer will accept for devices.
- (11) **Added Section 20 Waste Management.** This section will guide laboratories in acceptable waste management practices; and
- (12) **Changed fee structure to charging per test method.** Changing the fee structure to apply per method, due to the variety of sample preparation techniques which could favor one over another. This change creates a more equitable charging for fees.