MassDEP Laboratory Advisory Committee
June 3, 2015

SUMMARY OF PROPOSED REVISIONS TO THE LABORATORY CERTIFICATION REGULATIONS (310 CMR 42.00)

Prevention and Detection of Fraudulent and Deceptive Laboratory Practices and Penalties for Fraudulent and Deceptive Laboratory Practices

- Expands opportunities for MassDEP review of data generated by MassDEP-certified labs by clarifying which labs are subject to 310 CMR 42.00
- Requires documentation of allowed manipulation of instrument data
- Requires labs to have a laboratory ethics training program and specifies the topics to be included in that training
- Rewritten and expanded section on denial, downgrading, and revocation of certification to clearly define grounds for Department action and to allow the possibility of indefinite revocation, if warranted.
- Requires inclusion of date of sample extraction as well as date of analysis
- Establishes timeline for notification to Department of unavailability of critical lab equipment
- Requires labs to keep records of sample preparation
- Applies Right of Entry to inspections
- New section on orders, violations, and penalties related to non-compliant activities including making false statements to the Department

Changes to Meet MassDEP Program Needs

- Requirements for timely notifications and for timely reporting of data to meet regulatory requirements. Requirement to explain conditions affecting data usability.
- Expansion of certification to include 1,4-dioxane in drinking water
- Delete fecal coliform in treated drinking water from potable water certification—no longer needed; delete fecal coliform and *Salmonella* in Sewage Sludge from non-potable water certification—not needed
- Addition of secondary contaminants to drinking water scope of certification (certification is already offered for some of the secondary contaminants)
- Changes to meet EPA requirements for certification for trihalomethanes, haloacetic acids, chlorite, and bromate in drinking water

Technical Fixes/Updates and Clarifications

- Clarifies that data audits and data reviews are inspections
- Clarifies the laboratory's responsibility to perform, document, and report corrective action following the Department's report of deficiencies following an inspection
- Clarifies that ventilation systems are to be checked to ensure proper operation
- Adds expiration date to information required on lab container labels
- Clarifies that instrument calibration must take place immediately prior to analysis
- Prescribes procedure for verifying calibration curves set by an instrument manufacturer
- Clarifies how microbiological media must be stored and when it should be discarded
- Clarification on addition of dechlorinating agent to sample bottles to account for manufacturer-prepared bottles
- Eliminates requirement to adjust total coliform counts to account for verification
- Removes paragraph regarding provisional certification as provision is specified elsewhere in the regulation
- Makes clear that certified labs must comply with all of 310 CMR 42.00
- Clarifies requirements regarding reporting of certification status
- Clarifies the administrative procedure for renewal of certification
- Clarifies reporting requirement for provisionally certified labs
- Updates ownership change notification timeline, specifies calendar days, and requires notice in writing
- Clarification to require lab records to be readable during time of retention
- Throughout the regulations, "days" are specified as "calendar days."