

Massachusetts Department of Environmental Protection  
Division of Environmental Laboratory Sciences  
Senator William X. Wall Experiment Station

*Laboratory Certification Program*  
*Guidance for Compliance with the Ethics Training Requirement*  
*of 310 CMR 42.00 for MA-Certified Laboratories*

Effective Date: 01-06-2017

**Background.** Regulations for the Certification and Operation of Environmental Analysis Laboratories at 310 CMR 42.00 have been revised and were effective November 4<sup>th</sup>, 2016. The revised regulations at 310 CMR 42.08(6) require that all laboratory personnel participate in a laboratory ethics program on an annual basis. During the public comment period for the revised regulations, commenters requested guidance for compliance with this requirement.

**Ethics Training Requirement.** 310 CMR 42.08(6) specifies:

On an annual basis, certified laboratories and laboratories seeking certification shall require all personnel to participate in a laboratory ethics training program. Training shall include the following topics: ***proper procedures to ensure data integrity, recognition and prevention of improper laboratory practices, the promotion of objectivity and impartiality in the generation and reporting of analytical data, and procedures for confidential reporting of data integrity concerns to a laboratory supervisor, director, or owner as appropriate.*** The laboratory must document the content of the training and the date of participation in the training for each staff member and shall make this documentation and the materials used in the training available for review during an inspection.

**Acceptable Format and Types of Training.** The regulations permit laboratories to participate in ethics programs in any format convenient to their specific situation, and programs may be developed in-house or obtained from outside sources. No specific format or method of presentation is specified in the regulations. The ethics training program may consist of, or include, any or all of the following elements:

- Manuals or standard operating procedures
- PowerPoint presentations
- Video presentations
- Webinars
- Attendance at training seminars

A search of the internet for “Ethics Training for the Environmental Lab” provides a number of resources that may be adapted for use at an individual laboratory. For example, the following training materials with a variety of content were found with a recent internet search:

<http://www.health.state.mn.us/divs/phl/accreditation/docs/ethics.pdf>

<https://www.epa.gov/sites/production/files/2015-07/documents/2014aphllabethicstraining.pdf>

[http://www.wadsworth.org/sites/default/files/WebDoc/1690848527/DIandEthicstraining\\_Rev111014.pdf](http://www.wadsworth.org/sites/default/files/WebDoc/1690848527/DIandEthicstraining_Rev111014.pdf)

<http://public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Documents/ethics2014.pdf>

**Required Content.** Training sessions or materials must include the following, as required by the regulations:

1. The practices to be followed at the laboratory to ensure data integrity is maintained (e.g., data traceability and data validation);
2. Improper practices (e.g., time travel or back dating, “dry labbing”, manipulation of data or calibrations to imply that quality control criteria were met when in fact they were not, incorrect manual integrations, use of unapproved changes to a methodology);
3. The necessity to maintain laboratory neutrality and objectivity when performing or reporting analyses; and
4. The means for laboratory staff to report suspected data integrity issues confidentially and without fear of repercussions (e.g., providing an anonymous mailbox located within the laboratory and monitored by senior staff).

Laboratories may also consider providing optional descriptions of recent laboratory fraud cases. Case descriptions may be easily found by searching the internet for “Environmental Laboratory Fraud Cases”.

**Level of Detail Required.** The full content and duration of the training will, by necessity, vary among laboratories. For example, it is not necessary for a laboratory that is certified only for wet chemistry analyses such as pH and conductivity to include training relating to proper integration of chromatograms.

**Maintaining Records of Training Provided.** The regulations require that each laboratory document the content of the training and the date of participation in the training for each staff member and make this documentation and the materials used in the training available for review during an inspection. Laboratories may maintain records of training in hardcopy or electronic format. Documentation of participation in the ethics training may be maintained using methods such as signed attendance forms for presentations or signed acknowledgments that employees have read and understood written policies and procedures.

*Contact the MassDEP Laboratory Certification Program, Division of Environmental Laboratory Sciences (DELS), Senator William X. Wall Experiment Station (WES) at 978-242-1201 or at [labcert@state.ma.us](mailto:labcert@state.ma.us). if you have questions about the ethics training requirement.*