4740.2010 DEFINITIONS.

Subpart 1. **Scope.** The terms used in parts 4740.2050 to 4740.2120 have the meanings given them in this part and in the National Environmental Laboratory Accreditation Conference (NELAC) Standards, chapters 1 to 6, effective July 1, 2005, or a more current revision, provided the revision is in effect, upon the date it becomes effective. The standards are incorporated by reference, are not subject to frequent change, and are available on the Internet at http://www.epa.gov/nelac or by contacting the National Technical Information Service in the United States Department of Commerce.

Subp. 2. **Acceptable performance or acceptable results.** "Acceptable performance" or "acceptable results" means analytical test results generated by a laboratory using methods as specified in part 4740.2060 that fall within the acceptance range allowed by the approved provider.

Subp. 3. **Approved provider or approved PT provider.** "Approved provider" or "approved PT provider" means a provider of proficiency testing samples that the commissioner has determined meets the requirements of part 4740.2075.

Subp. 4. **Base certification.** "Base certification" means acknowledgment by the commissioner that a laboratory has the policies, procedures, equipment, and practices to produce reliable data in the analysis of environmental analytes.

Subp. 5. **Batch.** "Batch" means one to 20 environmental samples of the same matrix that are prepared together with the same process and personnel, using the same lot of reagents, with the maximum time between the start of processing of the first sample and the start of processing of the last sample being 24 hours, unless the method requirements are more stringent.

Subp. 6. **Bias.** "Bias" means the systematic or persistent distortion of a measurement system that causes errors in one direction, so that the expected sample measurement is different from the true value.

Subp. 7. **Calibration.** "Calibration" means testing an instrument's response by analyzing a series of analyte standards of differing concentrations, which are plotted on a graph that defines the instrument's linearity and dynamic range.

Subp. 8. **Calibration range.** "Calibration range" means the concentrations between and including the concentration of the lowest calibration standard at or above the detection limit and the highest concentration at which linearity has been established.

Subp. 9. **Certified test category or test category.** "Certified test category" or "test category" means a group of analytes available for certification. The analysis of the analytes is intended to test for compliance with specific environmental programs.

Subp. 10. **Certification.** "Certification" means the written acknowledgment of a laboratory's demonstrated capability to perform tests for a specific purpose.

Subp. 11. **Chain of custody.** "Chain of custody" means the procedures and records that document the possession and handling of samples from collection through disposal.

Subp. 12. **Chemical materials.** "Chemical materials" means a product or by-product of an industrial process or collection mechanism that results in a matrix not otherwise defined in subpart 30.

Subp. 13. **Commissioner.** "Commissioner" means the commissioner of health or the commissioner's designee.

Subp. 14. **Corrective action.** "Corrective action" means an action taken by the laboratory to eliminate or correct the causes of an existing nonconformance to prevent the recurrence of the nonconformance.

Subp. 15. **Corrective action plan.** "Corrective action plan" means a report, including specific items addressed and a specific date of completion, generated by a laboratory in response to deficiencies.

Subp. 16. **Deficiency or deviation.** "Deficiency" or "deviation" means a failure of the laboratory to meet any of the requirements in parts 4740.2010 to 4740.2120.

Subp. 17. **Denial.** "Denial" means the commissioner's refusal to certify a laboratory after submission of an application.

Subp. 18. **Document.** "Document" means any written or pictorial information describing, defining, specifying, reporting, or certifying any activities, requirements, procedures, or results.

Subp. 19. **Drinking water.** "Drinking water" means water used or intended for use as potable water.

Subp. 20. **Duplicate.** "Duplicate" means replicate.

Subp. 21. **EPA.** "EPA" means the United States Environmental Protection Agency.

Subp. 22. **Fees.** "Fees" means the fees described in Minnesota Statutes, section 144.98, subdivision 3.

Subp. 23. **Field of testing.** "Field of testing" means the combination of analyte, method, matrix, and test category for which a laboratory has applied or received certification by the commissioner.

Subp. 24. **Inspection.** "Inspection" means an on-site evaluation of laboratory facilities, records, personnel, equipment, methodology, and quality assurance practices by the commissioner for compliance with the applicable provisions of this chapter.

Subp. 25. **Internal standard.** "Internal standard" means a pure analyte or analytes added to a test sample, extract, or standard solution in known amounts and used to measure the relative responses of other method analytes and surrogates that are components of the sample or solution. The analyte or analytes used for the internal standard is not present in the test sample.

Subp. 26. **Laboratory.** "Laboratory" means the state, a person, corporation, or other entity, including a governmental entity, that examines, analyzes, or tests samples.

Subp. 27. **Laboratory control sample or LCS.** "Laboratory control sample" or "LCS" means a sample of a controlled matrix known to be free of the analyte of interest, to which the laboratory has added a known and verified concentration of analyte and that the laboratory has taken through all preparation and analytical steps in the method.

Subp. 28. **Laboratory director.** "Laboratory director" means an agent or affiliate of the laboratory responsible for ensuring compliance with parts 4740.2010 to 4740.2120.

Subp. 29. **Managing agent.** "Managing agent" means a person, as defined in Minnesota Statutes, section 326.71, subdivision 8, who is legally authorized to direct the activities of a laboratory and commit the appropriate resources to comply with parts 4740.2010 to 4740.2120.

Subp. 30. **Matrix or matrices.** "Matrix" or "Matrices" means the predominant material of which the sample to be analyzed is composed. Matrices include but are not limited to air, drinking water, nonpotable water, sewage sludge, and solid and chemical materials.

Subp. 31. **Matrix spike.** "Matrix spike" means a sample prepared by adding a known quantity of analyte and subjecting the sample to the entire analytical procedure to determine the ability to recover the known analyte or compound.

Subp. 32. **Matrix spike duplicate.** "Matrix spike duplicate" means a replicate matrix spike that is prepared and analyzed to determine the precision of the approved test method.

Subp. 33. **Measurement system.** "Measurement system" means any instruments, gauges, tools, devices, equipment, procedures, methods, or aggregates thereof, used to acquire or control sample data generated according to parts 4740.2010 to 4740.2120.

Subp. 34. **Method.** "Method" means the published scientific technique recognized by the commissioner for performing a specific measurement. Methods include instructions for sample preparation and sample analysis.

Subp. 35. **Method blank or blank.** "Method blank" or "blank" means a sample free of the analyte of interest and processed according to the laboratory's standard operating procedures manual according to part 4740.2065.

Subp. 36. **Method detection limit or MDL.** "Method detection limit" or "MDL" means the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero and is determined from the analysis of a sample in a given matrix type containing the analyte. Unless specified in the approved test method, the method detection limit is determined using the procedures specified in the applicable permit, program, or rule.

Subp. 37. **NELAC.** "NELAC" means the National Environmental Laboratory Accreditation Conference, which is a voluntary association of state and federal agencies whose purpose is to establish and promote mutually acceptable performance standards for the operation of environmental laboratories.

Subp. 38. **Nonconformance or noncompliance.** "Nonconformance" or "noncompliance" means deficiency of a laboratory to meet any requirement in parts 4740.2010 to 4740.2120.

Subp. 39. [Repealed, 44 SR 371]

Subp. 40. **Owner.** "Owner" means a person who:

A. is a sole proprietor of a laboratory;

B. holds a partnership interest in a laboratory; or

C. owns five percent or more of the shares in a corporation that owns a laboratory.

Subp. 41. **Parameter.** "Parameter" means an analyte.

Subp. 42. **Precision.** "Precision" means the measure of mutual agreement among individual measurements of a sample, usually under prescribed similar conditions, usually expressed as the standards deviation, variance, or range, in either absolute or relative terms.

Subp. 43. **Proficiency testing sample or PT sample.** "Proficiency testing sample" or "PT sample" means a sample obtained from an approved provider to evaluate the ability of a laboratory to produce an analytical test result meeting the definition of acceptable performance. The concentration of the analyte in the sample is unknown to the laboratory at the time of analysis.

Subp. 44. **Quality control.** "Quality control" means the overall system of technical activities, the purpose of which is to measure and control the quality of a product or service so that it meets the needs of users.

Subp. 45. **Quality control data.** "Quality control data" means data generated to assess the accuracy and precision of test data. Quality control data includes data on calibration standards, proficiency testing samples, known standards, duplicate samples, blanks, spiked samples, and limits for quality control spiked samples, reference standards, duplicates, and detection levels.

Subp. 46. **Quality system or quality assurance.** "Quality system" or "quality assurance" means the actions planned and taken that involve activities including control, assessment, reporting, and improvement in a laboratory's processes to ensure that a product or service meets the requirements of parts 4740.2010 to 4740.2120.

Subp. 47. **Quantitate.** "Quantitate" means the arithmetic process of determining the amount of analyte in a sample.

Subp. 48. **Replicate.** "Replicate" means two or more substantially equal aliquots analyzed independently for the same parameter.

Subp. 49. **Reporting limit.** "Reporting limit" means the lowest level of an analyte that can be accurately recovered from the matrix of interest, for example, the level of quantitation.

Subp. 50. **Revocation.** "Revocation" means a determination by the commissioner to invalidate in part or in total a laboratory's certification.

Subp. 51. **Sample or environmental sample.** "Sample" or "environmental sample" means a substance derived from a nonhuman source and collected for the purpose of analysis.

Subp. 52. **Scope of certification.** "Scope of certification" means the sum of all fields of testing for which a laboratory has been granted certification by the commissioner.

Subp. 53. **Second source.** "Second source" means a different vendor or manufacturer, or different lots from the same vendor or manufacturer, usually in reference to standards.

Subp. 54. **Solid.** "Solid" means:

A. soils as defined in Minnesota Statutes, section 103F.401, subdivision 10;

B. sediments as defined in Minnesota Statutes, section 103F.401, subdivision 9;

C. solid waste as defined in Minnesota Statutes, section 115A.03, subdivision 31; and

D. biosolids as defined in Minnesota Statutes, section 115A.03, subdivision 29.

Subp. 55. **Standard.** "Standard" means:

A. the certified reference materials produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method; or

B. the dilutions made from these certified reference materials for the purposes of calibration or determining accuracy of a test method.

Subp. 56. **Successor in interest.** "Successor in interest" means a laboratory that is owned or controlled by a majority of persons owning or controlling a laboratory certified under a previously issued certificate.

Subp. 57. **Surrogate.** "Surrogate" means a compound that is similar to the analytes of interest in chemical composition and behavior in the analytical process, but that is not normally found in environmental samples.

Subp. 58. **Suspension.** "Suspension" means the temporary invalidation in part or in total of a laboratory's certification for a defined period of time according to part 4740.2050, subpart 9, to allow a laboratory time to correct deficiencies or areas of noncompliance to comply with parts 4740.2010 to 4740.2120.

Subp. 59. **Target or target analyte.** "Target" or "target analyte" means an analyte or list of analytes within a test method that may be analyzed and for which the laboratory has obtained certification from the commissioner to test as part of a field of testing.

Subp. 60. **Verification.** "Verification" means confirmation by examination of and provision of objective evidence that specified requirements have been fulfilled. Verification is the process of examining a result of a given activity to determine conformance with parts 4740.2010 to 4740.2120.

Statutory Authority: *MS s 144.97; 144.98*

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