

**SUBCHAPTER F: ANALYTICAL QUALITY ASSURANCE AND QUALITY CONTROL**  
**§§330.261, 330.263, 330.265, 330.267, 330.269, 330.271, 330.273, 330.275, 330.277,**  
**330.279, 330.281, 330.283, 330.285, 330.287, 330.289**  
**Effective March 27, 2006**

**§330.261. Applicability and Purpose.**

(a) This subchapter applies to municipal solid waste facilities submitting laboratory data and analyses for use in commission decisions regarding any matter under the commission's jurisdiction relating to permits or other authorizations, compliance matters, enforcement actions, or corrective actions. Owners and operators of municipal solid waste facilities shall apply to modify permits to comply with the comprehensive rule revisions in this chapter as adopted in 2006 (2006 Revisions) to this subchapter within 180 days of the 2006 Revisions becoming effective. The permittee or registrant is under an obligation to apply for a modification not subject to public notice in accordance with §305.70(l) of this title (relating to Municipal Solid Waste Permit and Registration Modifications) to remove any inconsistent provisions. To the extent that a requirement has been changed by the 2006 Revisions, the facility may continue to operate under requirements contained in previously issued authorizations until a final decision is made on the modification application. This subchapter expires on January 1, 2009.

(b) The goal of a quality assurance (QA) and quality control (QC) program is to establish appropriate field and laboratory sampling and analysis procedures for all tested analytes to ensure proper collection preparation, and analysis of representative samples of waste, soil, water, and other media, and evaluate completeness, correctness, and conformance or compliance of a specific data set against method, procedural, or contractual requirements. To achieve accuracy (correctness) and completeness, the owner or operator shall adopt acceptable data quality standards and ensure that all sample collection, preparation and analyses, and data management activities are conducted in accordance with the standards. These activities shall be reviewed regularly to ensure compliance with the standards. QC checks must be performed and corrective action taken when indicated.

(c) The owner or operator shall evaluate the QC results supplied to the executive director to ensure compliance with program and/or permit-specific data quality standards and discuss the analytical quality of each specific data set as stated in all approved work plans, permit or registration provisions, enforcement order provisions, and applicable federal and state guidance documents.

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**§330.263. Laboratory Analyses.**

(a) The owner or operator shall identify the laboratory analyses to be performed on the samples collected for analysis. The analytical methods must be noted within the data package that is to be submitted to the executive director.

(b) The owner or operator shall also describe the practical quantitation limits for the constituents of concern, which must be below the maximum contaminant level values or as low as practicably feasible.

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**§330.265. Reporting Requirements.**

(a) Sample analytical results must be reported to the executive director in a data package that contains, at a minimum, the analytical test reports documenting the analytical results and methods for each sample and analyte. The test reports must include the method-required quality control information needed to evaluate the analytical results of sampling and analysis with comparison to quality control standards and corrective action upon failure.

(b) The owner or operator shall ensure that the results of each test analysis carried out by the laboratory shall be reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific instruction in the test method, work plan, permit, or program.

(c) The results shall be reported in a test report and include all the information requested in this chapter and necessary for the interpretation of the test results and all information required by the method used, project quality objectives, or permit.

(d) Unless otherwise specified by project objectives, all analytical results reported for soil and sediment samples must be reported on a dry weight basis with the percent solids (or percent moisture) also reported on the test reports, to allow back calculation of the result to a wet weight basis.

(e) The owner or operator shall ensure that each test report include at least the following information, unless the laboratory has valid reasons for not doing so:

(1) a title (e.g., "Test Report");

(2) the name and address of the laboratory or facility and the location where the test and calibrations were carried out;

(3) unique identification of the test report, and on each page an identification in order to ensure that the page is recognized as a part of the test report;

(4) name and address of the owner or operator;

(5) identification of the analytical method used;

(6) dates of measurements, as well as the report date;

(7) reference to the sampling plan and procedures used by the laboratory where these are relevant to the validity or application of the results;

(8) the test results and units of measurement;

(9) the names, functions, and signatures or equivalent identification of persons authorizing the test report; and

(10) where necessary for the interpretation of the test results, a laboratory case narrative in accordance with §330.289 of this title (relating to Laboratory Case Narrative).

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### **§330.267. Records Control.**

The owner or operator must ensure that all quality assurance/quality control records be legible and stored and maintained in such a way that the records are readily retrievable and stored in an acceptable environment to prevent damage, deterioration, or loss. At a minimum, analytical records retention shall meet the commission requirement for a five-year record retention schedule.

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### **§330.269. Matrix Spikes and Matrix Spike Duplicates.**

(a) The owner or operator shall ensure that matrix spikes and matrix spike duplicate sample recovery percentages and relative percent differences for each matrix and analyte are included in the data package. If analytes are not specified for a project or if only a subset of the project analytes are evaluated with matrix spikes and matrix spike duplicates, the owner or operator shall ensure that the subset include analytes representative of the chemical properties of the project analytes of concern.

(b) The owner or operator shall ensure that each matrix spike and matrix spike duplicate test report include the spike concentration added to the sample for each matrix spike, the measured concentration of the analyte in the unspiked sample, the measured concentration of the analyte in both the matrix spike and matrix spike duplicate, the calculated percentage matrix spike/matrix spike duplicate recoveries and relative percent difference, and the laboratory and/or method quality control limits (acceptance criteria) for both matrix spike/matrix spike duplicate recovery and relative percent difference. The data set must also include the laboratory batch number and the laboratory identification number of the sample spiked.

(c) The owner or operator shall ensure that the laboratory perform matrix spikes at a minimum frequency of one out of every 20 samples per matrix type, except for analytes for which spiking solutions are not available (e.g., total dissolved solids, total volatile solids, total solids, pH, color, temperature, or dissolved oxygen).

(d) When results of the matrix spikes and matrix spike duplicate are outside of the acceptable limits, the owner or operator shall arrange for the laboratory to check other quality control results (e.g., laboratory control sample), and if appropriate, have the laboratory qualify the results or use another analytical method. The results of the matrix spikes and matrix spike duplicate are sample and matrix-specific and may not normally be used to determine the validity of the entire batch of samples.

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**§330.271. Method Blanks.**

The owner or operator shall ensure that the laboratory reprocess any sample associated with the contaminated blank that exceeds a concentration greater than one-tenth of the measured concentration of any sample in the associated batch or exceeds the concentration present in the samples and is greater than one-tenth of a specified regulatory limit for analysis or the results reported with appropriate data-qualifying codes and submitted in the data package. These are minimum criteria to be used in cases where blank acceptance criteria are not defined in the referenced methodology used for analysis.

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**§330.273. Laboratory Control Samples and Laboratory Control Sample Duplicates.**

(a) The laboratory control sample and laboratory control sample duplicate are composed of a sample matrix that is free from analytes of interest and spiked with known amounts of analytes or material containing known and verified amounts of analyses. The laboratory control sample and laboratory control sample duplicate are used to establish intra-laboratory or analyst-specific precision and accuracy of certain parts of the analytical methodology.

(b) The owner or operator shall ensure that the laboratory analyze laboratory control samples at a minimum of one of each per batch of 20 samples or less, per matrix type, except for analytes for which spiking solutions are not available as referenced in §330.269(c) of this title (relating to Matrix Spikes and Matrix Spike Duplicates). A laboratory control sample duplicate will be processed with the batch where needed to demonstrate precision.

(c) The owner or operator shall ensure that the laboratory calculate the results of the laboratory control sample to assess precision based on the recovery percentages of the analytes of interest within the analytical methodology.

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**§330.275. Surrogates.**

The owner or operator shall have the laboratory review the surrogate recoveries used to measure method efficiency. The laboratory can, with qualifications, estimate the overall method efficiency.

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**§330.277. Data Reduction, Evaluation, and Review.**

(a) The owner or operator shall ensure that a data reviewer consider the project data quality objectives to determine if the sample test results meet the project needs with regard to completeness, representativeness, and accuracy (bias and precision).

(b) The owner or operator shall review all data prior to submittal for commission review. The data review must include examination of the quality control results and other supporting data, including any data review by the laboratory, and must identify any potential impacts such as bias on the quality of the data using qualifiers in the test reports tied to explanations in footnotes and in the laboratory case narrative.

(c) The criteria used to evaluate each quality control parameter must be defined in the owner or operator's groundwater sampling and analysis plan, project quality objectives, and/or other reference(s) of documented analytical laboratory or method criteria.

(d) The owner or operator shall ensure that the recordkeeping system allow historical reconstruction of all laboratory activities used in the data reduction, validation, and review of the analytical data, as the history of each sample must be readily understood throughout documentation, including intra-laboratory and inter-laboratory transfers of samples and sample extracts.

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**§330.279. Matrix Interferences and Sample Dilutions.**

(a) The owner or operator shall ensure that the laboratory document and report problems and anomalies observed during analysis that might have an impact on the quality of the data. The laboratory must document any evidence of matrix interference or any situation where the analysis is out of control (quality control results outside of laboratory or method limits), as well as the measures taken to eliminate or reduce the interference or corrective action to bring the analysis back into control.

(b) The owner or operator shall ensure that if a laboratory dilutes a sample medium to minimize matrix interferences or to bring an analysis back into control, that the dilution factor used by the laboratory be the smallest needed to overcome the problem of matrix interference.

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**§330.281. Chain of Custody.**

(a) Chain of custody forms are used to document custody of the samples during collection, transport, and initial receipt of samples at the analytical laboratory. A laboratory may also use chain of custody forms to document the movement and analysis of samples within the laboratory. The owner or operator shall ensure that the laboratory submit all data packages with completed field chain of custody forms and other documentation, including the following:

- (1) field sample identification;
- (2) date and time of sample collection;

- (3) preservation type;
- (4) analytical methods requested and/or analytes requested;
- (5) signatures of all personnel with custody prior to receipt by the laboratory;
- (6) signature of laboratory personnel taking custody samples; and
- (7) date and time of custody transfers.

(b) The owner or operator shall ensure that the laboratory document if samples are received outside of the recommended holding times for a particular analyte or method.

(c) The owner or operator shall ensure that upon receipt, the condition of the sample, including any abnormalities or departures from standard conditions as prescribed in the relevant test method be recorded.

(d) All samples that require thermal preservation shall be considered acceptable if the arrival temperature is either within 2 degrees Celsius of the required temperature or the method specified range. For samples requiring thermal preservation to 4 degrees Celsius, a temperature ranging from just above the freezing temperature of water to 6 degrees Celsius shall be acceptable.

(e) The owner or operator shall ensure that the laboratory have procedures for checking the chemical preservation using readily available techniques prior to or during sample preparation or analysis.

(f) The owner or operator shall ensure that the laboratory store samples according to the conditions specified by preservation protocols.

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**§330.283. Sample Collection and Preparation.**

(a) When possible, the owner or operator shall collect adequate sample volumes for all analytical needs for subsequent testing or analyses.

(b) The owner or operator shall base sampling plans, whenever reasonable, on appropriate statistical methods. Sampling procedures should describe the selection, sampling plan, collection, and preparation of a sample or samples from a waste or medium.

(c) The owner or operator shall collect representative samples of the waste or medium. The concentration of the analyses of interest, the types of analyses, and the sample media will determine the sample volume requirements.

(d) The owner or operator shall ensure that the method and federal regulatory program requirements for these sample management aspects be followed for all methods of testing and, if violated, have the data flagged and qualified.

(e) The owner or operator shall ensure that field personnel have procedures for recording relevant characteristics and other data relating to the sampling operations that form part of the testing or measurement that is undertaken. Chain of custody records and field notes shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant), diagrams or other equivalent means to identify the sampling location, and all associated sample identification numbers.

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**§330.285. Analytical Method Detection Limits and Method Performance.**

(a) The owner or operator shall ensure that the laboratory determine detection limits by the protocol in the mandated test method or applicable federal or state regulation. The owner or operator shall ensure that the laboratory utilize a test method that provides a detection limit that is appropriate and relevant for the intended use of the data and establish procedures to relate method detection limits with the practical quantitation limits.

(b) The owner or operator shall ensure that all samples are analyzed according to methods specified in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" (United States Environmental Protection Agency Publication Number SW-846) (September 1986) 3rd Edition, as revised and updated, or by other methods accepted by the executive director. If the protocol for determining detection limits is not specified in the test method, the selection of a procedure must reflect instrument limitations and the intended application of the test method. Whenever possible, analytical methods must have method detection levels that are one-fifth to one-third of the regulatory action level.

(c) The owner or operator shall take particular care to review all quality control data within the data package for compliance with the municipal solid waste program. All laboratory data and analyses submitted for use in commission decisions regarding any matter under the executive director's jurisdiction must include information regarding precision, bias, and accuracy. The executive director shall evaluate compliance with the quality assurance objectives on a case-by-case basis.

(d) Maximum quality control acceptance limits for organic analyses are limits that represent the level of quality control data necessary to support decision making by the owner or operator with regard to sample results. Data with quality control results outside of the quality control limits should be flagged in the data package with explanation of problems encountered by the laboratory and the corrective action(s) attempted to resolve the analytical problems.

(e) Failure to meet the quality control goals in accordance with the data quality standards of the study does not necessarily mean the data are unusable. The owner or operator shall ensure that the laboratory document all corrective action associated with the analysis and maintain all records.

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**§330.287. Instrument and Equipment Calibration and Frequency.**

(a) The owner or operator shall ensure that the laboratory maintain equipment in proper working order and calibrate equipment and devices that may not be the actual test instrument, but are necessary to support laboratory operations and measurements as often as recommended by the manufacturer, using National Institute of Standards and Technology (NIST) traceable references when available, over the entire range of their use. These include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, and temperature measuring devices. Calibration results shall be within the specifications required for each application or measurement for which this equipment is used.

(b) The owner or operator shall ensure that the laboratory maintain records of corrective actions implemented to correct all measurements.

(c) Standards used for the calibration of field instruments shall be, when available, traceable to certified standards or reference material. The owner or operator shall ensure that laboratory equipment be calibrated or standardized against NIST traceable reference materials and standards. Documentation of the certificate of analysis and traceability of the standards and reagents must be maintained by field or laboratory personnel.

(d) The owner or operator shall ensure that calibration of field instruments and equipment be performed at approved intervals as specified by the manufacturer or more frequently as conditions dictate. Calibrations may also be performed at the start and completion of each test run. Records of calibration, repair, or replacement must be filed and maintained by the designated field staff. Calibration and standardization of laboratory equipment must be based on procedures described in each contract laboratory quality assurance plan or standard operating procedure. It is the responsibility of the person validating the data to ensure that the proper calibration protocols were used. Records of calibration, repair, or replacement must be filed and maintained by the designated laboratory personnel performing quality control activities in accordance with manufacturer requirements. Calibration records must be filed and maintained at the laboratory location where the work is performed and must be subject to commission review during a quality assurance audit.

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**§330.289. Laboratory Case Narrative.**

(a) The owner or operator shall ensure that reporting quality control (QC) results (precision and accuracy) within the laboratory case narrative (LCN) explain each failed precision and accuracy measurement determined to be outside of the laboratory and/or method control limits, and the effect of the failure on the results (positive or negative bias).

(b) The owner or operator shall ensure that the LCN state the exact number of samples, identification numbers, testing parameters, and sample matrix, as well as the name(s) of the laboratory(ies) involved in the analysis. A statement of the test objective regarding the samples must be

included. The LCN must also identify the applicable quality assurance (QA) and QC samples that require special attention by the reviewer, including:

- (1) field, trip, and laboratory blank(s);
- (2) duplicate(s);
- (3) field spike(s);
- (4) QA audit sample(s); and
- (5) laboratory control samples.

(c) The owner or operator shall ensure that an acknowledgment and reference to current standards regarding sample holding, extraction, and analytical times be included within the LCN along with a statement explaining whether the standards were met. If samples are not analyzed within the prescribed holding times, the owner or operator shall ensure that the laboratory describe the extent of the delay and if possible, provide an estimate of the bias within the data.

(d) The owner or operator shall ensure that the laboratory conducting the analyses for environmental decision making have a QA program run by a QA officer.

- (1) This program may include, but is not limited to, the following:

- (A) system audits of field and/or laboratory operations using field surrogate samples;
- (B) instrument calibration check samples used to determine the accuracy of the instrumentation;
- (C) blind spikes of blanks, where the concentration of the blind spike is known only to the QA officer;
- (D) verification of calibration accuracy via calibration check standard;
- (E) internal surrogate spikes for determination of analytical extraction recovery; and
- (F) overall assessment of the data quality based upon the reported QC data.

(2) The owner or operator shall ensure that all QC results included in each data set submitted to the executive director that affect the quality of the data be included within the LCN. The owner or operator shall ensure that the laboratory describe the bias within each data set as either positive or negative, when QC results are outside the method established and/or data quality objectives of the facility groundwater sampling and analysis plan.

(e) The owner or operator shall ensure that the precision and accuracy determinations are clearly presented with all results calculated. The LCN must explain each failed precision and accuracy measurement determined to be outside of the method control limits, and the effect of the failure on the results.

(f) The owner or operator shall ensure that the LCN review includes comments that identify the problems associated with the sample results and explains the limitations on data usability.

(g) The owner or operator shall ensure that when appropriate and/or requested, the LCN includes a statement on the estimated uncertainty of analytical results of the samples involved and/or within the QC of the analytical method of the permit, project, and/or program required analytical recoveries information.

(h) The owner or operator shall ensure that the LCN includes all deviations from, additions to, or exclusions from the test method, and information on specific test conditions.

(i) The owner or operator shall ensure that where relevant, the LCN includes a statement of compliance/noncompliance with requirements and/or specifications (e.g. holding times, dilutions, matrix interferences).

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