U.S. NUCLEAR REGULATORY COMMISSION

December 2010
Revision 2

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 4.16

(Draft was issued as DG-4017, dated March 2010)

MONITORING AND REPORTING RADIOACTIVE MATERIALS IN LIQUID AND GASEOUS EFFLUENTS FROM NUCLEAR FUEL CYCLE FACILITIES

A. INTRODUCTION

This guide describes a method that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for the development and implementation of effluent monitoring programs described in license applications and for monitoring and reporting effluent data by licensees. The guidance is applicable to nuclear fuel cycle facilities, with the exception of uranium milling facilities and nuclear power reactors. The NRC has developed other regulatory guides applicable to those facilities.

Title 10, Section 70.59, "Effluent Monitoring Reporting Requirements," of the *Code of Federal Regulations* (10 CFR 70.59), requires licensees authorized to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, or in a uranium enrichment facility to submit semiannual reports to the NRC. These reports specify the quantity of each of the principal radionuclides released to unrestricted areas in liquid and gaseous effluents, and other information the NRC may require to estimate maximum potential annual radiation doses to the public resulting from effluent releases. As required by 10 CFR 40.65, "Effluent Monitoring Reporting Requirements," each licensee authorized to possess and use source material in the production of uranium hexafluoride, or a uranium enrichment facility must submit semiannual reports similar to those required by 10 CFR 70.59.

In addition, 10 CFR 20.1302, "Compliance with Dose Limits for Individual Members of the Public," requires surveys of radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public (i.e., 1 millisievert per year [mSv/yr] [100 millirems per year (mrem/yr)]). Furthermore, 10 CFR 20.2103(b)(4) requires that

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records of measurement results and calculations used to evaluate the release of radioactive effluents be maintained until the NRC terminates the license requiring the record.

As stated in 10 CFR 20.1101(b), the licensee shall use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve doses to members of the public that are as low as is reasonably achievable (ALARA). In addition, 10 CFR 20.1101(d) places an ALARA constraint of 0.1 mSv/yr (10 mrem/yr) on public exposure from emissions of airborne radioactive material, excluding radon-222 and its daughters. Furthermore, 10 CFR 20.1301(e) requires a licensee subject to the provisions of 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," to comply with those provisions. The regulations at 40 CFR 190.10, "Standards for Normal Operations," place limits of 0.25 mSv (25 mrem) to the whole body, 0.75 mSv (75 mrem) to the thyroid, and 0.25 mSv (25 mrem) to any other organ of any member of the public as the result of exposures to planned discharges of radioactive materials, excluding radon and its daughters, to the general environment from uranium fuel cycle operations and of exposures to radiation from these operations.

This regulatory guide contains information collection requirements covered by 10 CFR Part 40 and 10 CFR Part 70 that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0020 and 3150-0009, respectively. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number. The NRC has determined that this Regulatory Guide is not a major rule as designated by the Congressional Review Act and has verified this determination with the OMB.

B. DISCUSSION

Monitoring and reporting information on the identity, concentration, and quantity of radionuclides in liquid and gaseous effluents from nuclear fuel cycle facilities serves the following three purposes:

1. allows the NRC staff to evaluate the environmental impact of radioactive materials in effluents, including potential annual radiation doses to the public;

2. enables the NRC staff to ascertain whether licensees have met regulatory requirements and kept concentrations of radioactive material in liquid and gaseous effluents ALARA; and

3. permits the licensee and the NRC staff to assess the adequacy and performance of effluent controls.

A degree of uniformity in the programs for monitoring and reporting data on radioactive material in effluents is essential. This guide provides a basis for uniform reporting, for comparing data from different sources, and for permitting the preparation of consistent summaries for use by the NRC staff as the bases for assessing a licensee's effluent controls and the potential environmental impact of radioactive material in effluents.

C. REGULATORY POSITION

1. Methods of Sampling Analysis

The licensee should choose the sampling and analysis methods used in the effluent monitoring programs to provide information on the quantity and concentration of radionuclides in gaseous and liquid effluents. The bibliography in this guide provides useful references on sampling, analysis, statistical analysis, and preparation and maintenance of effluent monitoring programs.

2. Sampling Program

The sampling program should be sufficient to permit a determination of the quantities of radionuclides and the average concentration of radionuclides being discharged from the facility.

For most effluents, releases should either be batch controlled and released or continuous composite samplers should be employed. Licensees should only use periodic grab sampling at continuous release points to confirm the absence or negligible amount of radioactive materials in the effluent. When grab samples are collected in lieu of the use of continuous samplers, the licensee should ensure that the time, location, and frequency of such sampling is representative of the effluent. Licensees should take replicate grab samples periodically to determine the reproducibility of sampling. Interdispersed samples, spatially or temporally or both, should be collected periodically to verify their representativeness.

Licensees should use appropriate sampling equipment, proper locations of sampling points, and proper procedures for collection and storage of samples to ensure that they obtain representative samples.

2.1 Gaseous Effluents

The NRC recognizes the guidance developed in American National Standards Institute (ANSI)/Health Physics Society (HPS) N13.1-1999, "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities," issued 1999 (Ref. 1). Licensees should use this guidance to establish sampling and monitoring methods for those gaseous effluent points that cumulatively emit 90 percent or more of the total radioactivity released from the facility, as well as those points that cumulatively contribute 90 percent or more of the total estimated offsite exposure from facility releases. Licensees may sample and monitor other gaseous effluent points in a manner consistent with the test methods outlined in Appendices A-1 through A-8 to 40 CFR Part 60, "Standards of Performance for New Stationary Sources," as applicable.

Licensees should consider gaseous effluents from all operations associated with the facility, including, but not limited to, such nonprocessing areas as laboratories, experimental areas, storage areas, and fuel element assembly areas, for inclusion in a sampling program. Licensees may use a graded approach to determine sampling and monitoring methods and frequencies. For example, a review of process information and the potential for offsite doses to members of the public could lead the licensee to implement continuous monitoring of emissions from particular points of release, continuous sampling of emissions for most other release points, and only periodic sampling or periodic administrative reviews for release points where material has little potential to be released.

Continuous monitoring is the appropriate method for determining released quantities of gaseous effluents from process systems that use materials that may be easily dispersed (in either gaseous or fine powder form) and that have a potential for exposures to the public above the limits found in Table 2 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) for Radionuclides

for Occupational Exposures, Effluent Concentrations, Concentrations for Release to Sewerage," to 10 CFR Part 20, "Standards for Protection against Radiation," or when rapid detection of accidental releases is necessary.

If a particular point of release could be expected to emit radionulides that have a potential for exposures to the public above 10 percent, but less than 100 percent, of the effluent concentrations listed in Table 2 of Appendix B to 10 CFR Part 20, the licensee should conduct continuous sampling and review the data to identify trends.

For an individual point of release that could be expected to emit radionuclides that have a potential for exposures to the public less than 10 percent of the effluent concentrations listed in Table 2 of Appendix B to 10 CFR Part 20, the licensee may use periodic sampling (e.g., weekly). However, the licensee should perform periodic sampling in such a manner that significant batch releases or other releases that contain significantly elevated concentrations of radionuclides (also called "irregular" releases) are sampled appropriately.

If no radiological source can contaminate an effluent, sampling of the effluent for radionuclide concentrations is not necessary (e.g., a nonradiological stack). However, licensees should evaluate each effluent point periodically (e.g., annually) to verify that its radiological status has not changed.

Licensees may combine gaseous samples for analysis if they are collected at the same location and if they represent a sampling period of 1 week or less. Licensees should not combine samples from different locations.

2.2 Liquid Effluents

Licensees should collect representative samples at each liquid release point to determine the quantities and average concentrations of radionuclides discharged in any liquid effluents that could reach an unrestricted area. For continuous releases, licensees should continuously collect representative samples at each release point. For batch releases, licensees should collect a representative sample of each batch.

For some liquid effluents, the licensee may establish, by periodic sampling or by other means, that radioactivity in the effluent from a particular release point poses minimal risk and does not require continuous sampling. In such cases, licensees should periodically sample the particular effluent stream at least quarterly. However, the licensee should perform periodic sampling in such a manner that significant batch releases or other releases that contain significantly elevated concentrations of radionuclides (i.e., off-normal releases) are sampled appropriately. The licensee should provide supplemental information documenting that these samples are representative of actual releases. For the purposes of this guide, a liquid effluent release is considered to pose minimal risk if the concentration averaged over a calendar quarter is no more than 10 percent of the appropriate concentration listed in Table 2 of Appendix B to 10 CFR Part 20.

The sampling program should be sufficient to determine the quantities and the average concentration of radionuclides being discharged from the facility. The sampling rate at each release point should ensure that a representative sample of the effluent is collected. Licensees should report the volume of liquid effluents and should calculate and report the quantities of radionuclides discharged and the potential exposure to a member of the public.

Licensees may combine liquid samples collected at the same location if they represent a sampling period of 1 month or less. Licensees should not combine samples from different locations.

3 Quality Assurance and Quality Control

3.1 Regulatory Guidance

Licensees should develop a Quality Assurance (QA) program applicable to monitoring effluents. Regulatory Guide 4.15, Revision 2, "Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination)—Effluent Streams and the Environment," issued July 2007 (Ref. 2), describes the quality assurance program activities for ensuring that radioactive effluent monitoring systems and operational programs meet their intended purpose. Regulatory Guide 4.15 contains guidance for determining the appropriate sensitivity levels for analytical instrumentation based on data quality objectives (DQOs). The NRC staff believes that the use of DQOs provides a better technical basis for determining sensitivity levels (minimum detectable concentration [MDC]) than the previously used prescriptive approach, which specified MDCs of less than 10 percent of the applicable value given in Appendix B to 10 CFR Part 20. ANSI/American Society for Quality (ASQ) E4-2004, "Quality Systems for Environmental Data and Technology Programs—Requirements with Guidance for Use," issued 2004 (Ref. 3), includes additional guidance pertinent to quality assurance of effluent monitoring.

3.2 Minimum Detectable Concentrations

The MDCs for any sampling and analysis method should be consistent with developed DQOs for the sampling and analysis program. In the prior revision to this guidance, the NRC staff considered MDCs to be acceptable if they were less than 10 percent of the concentration limits listed in Table 2 of Appendix B to 10 CFR Part 20. For example, the NRC staff considered the MDC for soluble uranium-238 to be acceptable if less than 1×10^{-11} kilobecquerel per milliliter (kBq/mL) (3×10^{-13} microcurie per milliliter [μCi/mL]) for gaseous effluents and 1×10^{-6} kBq/mL (3×10^{-8} μCi/mL) for liquid effluents. If the actual concentrations of the sampled radionuclides are known to be elevated in comparison to the MDC requirements, DQOs should establish that the sampling and analysis procedures need only be adequate to measure the actual concentrations. However, in such cases, the MDCs should be low enough to accommodate fluctuations in the concentrations of the effluent.

Appendix A to this regulatory guide describes an acceptable method for calculating the MDC.

3.3 Quality Control Checks

Licensees should conduct QC checks of laboratory instrumentation either daily or before use and monitor background variations at regular intervals to demonstrate that a given instrument is in working condition and functioning properly. QC records should include results of routine tests and checks, background data, calibrations, and all routine maintenance and service. Tests should be applied to analytical processes, including duplicate analysis of selected effluent samples and periodic cross-check analysis with independent laboratories.

Because many of the data to be reported may be based on gross radioactivity measurements, the program should include periodic tests to ensure that such measurements represent actual quantities of individual radionuclides in samples. For example, in facilities handling uranium, the licensee should perform a chemical or isotopic analysis for uranium at least quarterly on selected samples for comparison with the gross radioactivity analyses. The use of supplemental analysis for comparison to gross activity analyses has several QC applications: to independently verify the gross activity analytical method; to identify biases developing in the analytical methodologies; and to verify the mixture of materials present (e.g., if gross analytical results change significantly relative to isotopic results, additional investigation is warranted as the mixture of materials may have changed).

3.4 Functional Checks

Licensees may perform routine qualitative tests and checks (e.g., channel operational tests, channel checks, or source checks to demonstrate that a given instrument is in working condition and functioning properly) using radioactive sources that are not traceable by the National Institute of Standards and Technology (NIST). The schedule for source checks, channel checks, channel calibrations, and channel operational tests should be consistent with developed DQOs.

3.5 Procedures

Licensees should use individual written procedures to establish specific methods of calibrating installed radiological monitoring systems and grab sampling equipment. Written procedures should document calibration practices used for ancillary equipment and systems (e.g., meteorological equipment, airflow measuring equipment, in-stack monitoring pitot tubes). Calibration procedures may be compilations of published standard practices or manufacturers' instructions that accompany purchased equipment, or they may be specially written in-house to include special methods or items of equipment not covered elsewhere.

Calibration procedures should identify the specific equipment or group of instruments to which they apply. Licensees should use written procedures to maintain counting room instrument accuracy, including maintenance, storage, and use of radioactive reference standards; instrumentation calibration methods; and QC activities, such as collection, reduction, evaluation, and reporting of QC data.

Licensees should also establish procedures to ensure that the samples are not affected by improper handling or storage before analysis. For example, liquid samples may require chemical treatment to prevent losses to the walls of storage containers, and samples containing solids should either be made homogeneous or the liquid and solid portions should be analyzed and reported separately.

3.6 Calibration of Laboratory Equipment and Radiation Monitors

Licensees should perform calibrations (e.g., of laboratory equipment and continuous radioactivity monitoring systems used to quantify radioactive effluents) using reference standards certified by NIST or secondary standards traceable to NIST. Calibration standards should have the necessary accuracy, stability, and range required for their intended use. The relationship between concentrations and monitor readings should be determined over the full range of the readout device.

Calibration standards should use radionuclides of appropriate radiation and energy. Calibration standards for natural or depleted uranium are typically fashioned from natural uranium. For enriched uranium, alpha calibration standards are commonly fashioned from thorium-230, whereas beta standards are commonly fashioned from technetium-99. Calibration standards may use other radionuclides, but their impact should be understood and appropriate for the radionuclides of interest in the analysis.

Licensees may apply NIST-traceable sources, combined with mathematical efficiency calibrations, to instrumentation used for radiochemical analysis (e.g., gamma spectroscopy systems), if employing a method provided by the instrument manufacturer.

The adequacy of the system should be judged on the basis of reproducibility, time stability, and sensitivity. Licensees should perform periodic inservice correlations that relate monitor readings to the concentrations or release rates (or both) of radioactive material in the monitored release path. This will validate the adequacy of the system. These correlations should be based on the results of analyses for specific radionuclides in grab samples from the release path.

3.7 Calibration of Measuring and Test Equipment

Licensees should calibrate measuring and testing equipment using reference standards certified by NIST or standards that have been calibrated against NIST-certified standards. The calibration standards should be representative of the sample types analyzed and have the necessary accuracy, stability, and range required for their intended use.

3.8 Calibration Frequency

Calibrations should generally be performed at regular intervals, in accordance with developed DQOs. A change in calibration frequency (either an increase or a decrease) should be based on the reproducibility and time stability characteristics of the system. For example, an instrument system that gives a relatively wide range of readings when calibrated against a given standard should be recalibrated at more frequent intervals than one that gives measurements within a more narrow range. Any monitoring system or individual measuring equipment should be recalibrated or replaced whenever it is suspected of being out of adjustment, excessively worn, or otherwise damaged and not operating properly.

3.9 Measurement Uncertainty

Licensees should estimate the measurement uncertainty (formerly called measurement error) associated with the measurement of radioactive materials in effluents. Counting statistics can provide an estimate of the statistical counting uncertainty involved in radioactivity analyses. Normally, the statistical counting uncertainty decreases as the amount (concentration) of radioactivity increases. Thus, for the radioactive effluent release report, the statistical counting uncertainty is typically a small component of the total uncertainty.

Because it may be difficult to assign error terms for each parameter affecting the final measurement, detailed statistical evaluations of error are not required. The sampling uncertainty is likely the largest component and includes uncertainties such as that in volumetric and flow rate measurements and the laboratory processing uncertainties. The total or expanded measurement uncertainty (also referred to as the systematic uncertainty) associated with the effluent measurement should include the cumulative uncertainties resulting from the total operation of sampling and measurement. Expanded uncertainty should be reported with measurement results. The objective should be to evaluate only the important contributors and to obtain a reasonable measure of the uncertainty associated with reported results. Detailed statistical and experimental evaluations are not required. The overarching objective should be to obtain an overall estimate of measurement uncertainty. The formula for calculating the total or expanded uncertainty classically includes the square root of the sum of the squares of each important contributor to the measurement uncertainty.

Licensees should round the uncertainty estimate to either one or two significant figures and the measured value to the same number of decimal places as its uncertainty.

4. Analysis of Gaseous and Liquid Samples

As required by 10 CFR 70.59 and 10 CFR 40.65, fuel cycle licensees must report, within 60 days after January 1 and July 1 of each year, the quantity of principal radionuclides released to unrestricted areas in liquid and gaseous effluents during the previous 6 months of operation.

Licensees should perform radionuclide analyses on selected samples unless: (1) the gross alpha and gross beta activities are so low that individual radionuclides could not be present in concentrations

greater than 10 percent of the quantities specified in Table 2 of Appendix B to 10 CFR Part 20 or (2) the radionuclide composition of the sample is known through such operational data as the composition of the feed material.

Examples of cases in which operational data may not be adequate to determine radionuclide composition include the following:

(1) uranium processing facilities in which extraction, ammonium diuranate precipitation, ion exchange, or other separation processes could result in concentration of thorium isotopes (principally thorium-234);

(2) facilities in which uranium of varying enrichments is processed during the period of consideration;

(3) facilities processing plutonium in which significant variation in the plutonium-238 and plutonium-239 ratio among batches of plutonium and the continuous ingrowth of americium-241 would preclude the use of feed material data in determining the radionuclide composition of effluents; and

(4) uranium hexafluoride production facilities in which evaluations based on feed materials show significant changes in the radionuclide ratios (e.g., uranium, radium, and thorium radionuclides, which may result in an estimated exposure variability of at least 10 percent).

Licensees should conduct radionuclide isotopic identification and quantification analyses as follows:

(1) at the beginning of a monitoring program until a predictable radionuclide composition of effluents is established,

(2) whenever there is a significant (e.g., at least 10 percent) unexplained increase in gross radioactivity, or

(3) whenever a process change or other circumstance might cause a significant variation in the radionuclide ratios or composition in effluents such that public exposure may vary at least 10 percent.

Licensees should use the results of the analyses of the samples for each release point to determine the following:

(1) the total gross alpha and gross beta activity (as applicable) discharged,

(2) the average concentration of gross alpha and gross beta activity (as applicable) discharged, and

(3) the total activity and average concentrations of each of the radionuclides discharged.

Reports in which the estimated quantities of individual radionuclides are based on methods other than direct measurement should explain and justify the way in which the result was obtained.

5. Exposure Estimates

Estimates of exposure, in terms of total effective dose equivalent, should be based on measured liquid and gaseous radioactive effluents. Such estimates should be calculated consistent with applicable guidance in Regulatory Guide 1.109, Revision 1, "Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR Part 50, Appendix I," issued October 1977 (Ref. 4). Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors" (Ref. 5), discusses additional acceptable methods for determining exposure resulting from gaseous effluents. Estimates of public exposure should include any direct or external exposure component that may be present. Licensees should also determine and report exposures for the maximally exposed organ to demonstrate compliance with 40 CFR Part 190 (0.25 mSv/yr [25 mrem/yr] whole body, 0.25 mSv/yr [25 mrem/yr] for the maximally exposed organ, 0.75 mSv/yr [75 mrem/yr] for the thyroid).

In assessing the maximum dose to individual members of the public, licensees may use conservative bounding dose assessments in lieu of actual or realistic dose assessments. A conservative bounding dose assessment may be performed for a hypothetical individual located at the site boundary. If bounding assumptions are made, the effluent release report should annotate such assumptions.

If bounding assessments are not used, licensees should perform evaluations to determine the dose to a real, maximally exposed member of the public, regardless of whether the individual is in an unrestricted area or a controlled area. If no member of the public is allowed in the controlled area, the evaluation need consider only members of the public in the unrestricted area. A member of the public is typically a real individual (as opposed to a fictitious fencepost resident) in a designated location where there is a real exposure pathway (e.g., a real garden, real cow, real goat, or actual drinking water supply), rather than an exposure pathway that includes a virtual goat or cow. Licensees are encouraged (but not required) to use real individual members of the public when performing dose assessments for radioactive discharges. Table 1 in Regulatory Guide 1.109 enables licensees to perform a dose evaluation at a location where an exposure pathway and dose receptor actually existed at the time of licensing.

6. Reporting Results

6.1 Sampling and Analysis Results

Licensees should summarize all data on a semiannual basis. Licensees should not use the terms "not detected," "< MDC," or similar terms. Licensees should report each value with its associated uncertainty; however, if the analytical value is negative, a value of zero and the estimated uncertainty of the original value should be reported (see Section 6.5). For each release point, the following should be reported, as appropriate (see Appendix B to this guide for a sample format):

(1) type of sample (gaseous or liquid),

(2) sampling location,

(3) dates during which samples were collected,

(4) the quantities and analytical uncertainty of gross alpha and gross beta activity for each principal radionuclide released,

(5) the average concentrations and analytical uncertainty of gross alpha and gross beta activity for each principal radionuclide released,

(6) estimates of exposure for the maximally exposed individual, and

(7) estimates of the total or expanded system uncertainty (expressed as a percentage).

Each report should include the following in the summary:

(1) for all gaseous releases, the total quantities of gross alpha activity, gross beta activity (if appropriate), each principal radionuclide, and estimates of exposure for the maximally exposed individual, including maximum organ exposure;

(2) for all liquid releases, the total quantities of gross alpha activity, gross beta activity (if appropriate), each principal radionuclide, and estimates of exposure for the maximally exposed individual, including maximum organ exposure; and

(3) an estimate of the direct exposure resulting from licensed radioactive materials for the maximally exposed individual.

6.2 Supplemental Information

The first effluent monitoring report should include the following information (subsequent reports should include only changes to this information):

(1) description of sampling equipment;

(2) description of sampling procedures, including sampling times, frequencies, rates, and volumes;

(3) description of analytical procedures;

(4) description of calculational methods (e.g., calculation of radionuclide quantities using gross radioactivity measurements);

(5) discussion of random and systematic uncertainty estimates, including methods of calculation and sources of systematic uncertainty;

(6) description of the calculation of the MDC;

(7) discussion of the program for ensuring the quality of results;

(8) description of calibration procedures;

(9) discussion of any irregular releases, including the circumstances of the release and any data available on the quantities of radionuclides released; and

(10) the basis for any determination that a stack or liquid release point need not be continuously sampled.

6.3 Units

Licensees should report radionuclide quantities in becquerels (or multiples of becquerels) or curies (or multiples of curies). Radionuclide concentrations should be reported in becquerels per milliliter or microcuries per milliliter. Estimates of exposure should be reported in microsieverts or millirems.

Licensees should report the uncertainty estimate and the MDC in the same units as the result. Estimates of systematic uncertainty should be reported as a percentage of the result.

6.4 Significant Figures

Licensees should not report results with excessive significant figures, which imply a greater level of precision than actually exists. Reported results should contain the same number of decimal places as the reported uncertainty, and the reported estimate of uncertainty should only contain one significant figure.

In representing measured or calculated numbers, licensees should follow the convention of including all digits that are known with certainty and one digit that is uncertain. For example, 25.2±0.3 contains three significant figures, two digits known exactly (25) and one that is uncertain (0.2). The error, or uncertainty, pertains to the one digit that is uncertain.

Estimates of exposure should be limited to no more than two significant figures.

6.5 Consideration of Analytical Results Less Than the Minimum Detectable Concentration

Monitoring for radioactive materials in effluents may generate analytical results that fluctuate around zero and that are less than the MDC. When recording results for internal use, analytical results should include any values for radioactivity that are less than the MDC or that are negative, as well as the uncertainty associated with the result. This will avoid practices that may otherwise censure the data in subsequent summary reports. Sample results that are less than zero (i.e., are negative) have intrinsic value because tracking and trending of the data can identify biases occurring in the analytical methods. The licensee should investigate significantly negative numbers more than three standard deviations below zero, as it is unlikely that these values represent random uncertainties for a result near zero.

While there is value in obtaining analytical results that are less than zero for internal use, this practice may introduce confusion when summarizing data during preparation of semiannual (or annual) reports for external use (e.g., reports for regulators or the public). When preparing summary reports for external use, effluent estimates may be based on statistically few samples or may be applied to estimating exposures of relatively short duration. Use of negative analytical data in summarizing effluents could result in an estimate for releases and exposure that is less than zero. This can be misleading and should be avoided. Summary information reported to the NRC should substitute "0" for any negative analytical values obtained from analysis of samples and should be accompanied by a footnote indicating that a value of "0" was substituted for negative analytical results (or other appropriate verbiage).

The MDC concept is applicable to analyses of samples involving nuclear counting instrumentation; however, some licensees may use other analytical methods to obtain data. Many common laboratory instruments report analyte levels only in positive numbers, and a common practice for chemical analysis reporting is to simply note that the analyte was undetected if it is below the lower limit of quantification (LLOQ). The LLOQ is analogous to the MDC for radioanalytical analyses. However, unlike radioanalytical reporting of data, laboratories typically will not report chemical data below the

LLOQ. Licensees should use the value of the LLOQ for reporting data when no analyte is detected during chemical analyses or should justify the use of other estimate methods. This issue should be addressed through the DQO process when applicable.

6.6 Format

Appendix B to this regulatory guide illustrates a sample format.

D. IMPLEMENTATION

In connection with the issuance and use of this regulatory guide, the NRC does not intend or approve any imposition of a backfit.

Applicants or licensees may propose for use a previously established acceptable alternative method for complying with the NRC's regulations referenced in this regulatory guide. Otherwise, in reviewing applicant or licensee requests for licensing action (e.g., license applications, requests for license amendments), the methods described in this guide will be used in evaluating compliance with applicable requirements.

GLOSSARY

background level—A term that refers to the presence of radioactivity or radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout from nuclear weapons testing or past nuclear accidents involving radioactive material that was not under control of the licensee. From an analytical perspective, the presence of background radioactivity in samples and in sample media needs to be considered when clarifying the radioanalytical aspects of the decision or study question. Many radionuclides are present in measurable quantities in the environment.

batch release—The release of liquid (radioactive) wastes of a discrete volume or the release of a tank or purge of radioactive gasses into the site environs.

bias (of a measurement process)—A persistent deviation of the mean measured result from the true or accepted reference value of the quantity being measured, which does not vary if a measurement is repeated.

calibration—The set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known value of a parameter of interest.

continuous release—An essentially uninterrupted release of gaseous or liquid effluent for extended periods during normal operation of the facility where the volume of radioactive wast is non-discrete and there is input flow during the release.

discharge point—A location at which radioactive material enters the unrestricted area. This would be the point beyond the veritical plane of the unrestricted area (surface or subsurface).

effluent—Liquid or gaseous waste containing facility-related, licensed, radioactive material emitted at the boundary of the facility (e.g., buildings, end-of-pipe, stack, or container).

licensed material—Means source material, special nuclear material, or byproduct material received, possessed, used, transferred, or disposed of under a general or specific license issued by the Commissison.

lower limit of quantification—The lowest quantity of a substance that can be distinguished from the absence of that substance (a blank value) within a stated confidence limit (generally 1 percent). The detection limit is estimated from the mean of the blank, the standard deviation of the blank, and some confidence factor. Another consideration that affects the detection limit is the accuracy of the model used to predict concentration from the raw analytical signal.

minimum detectable concentration—The smallest activity concentration that is practically achievable with a given instrument and type of measurement procedure. It depends on factors involved in the survey measurement process (surface type, geometry, backscatter, and self-absorption) and is typically calculated following an actual sample analysis (a posteriori). (See NUREG-1507, "Minimal Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions," issued June 1998).

principal radionuclides—In the context of this guidance, those radionuclides that should be considered when determining total releases and exposures. This includes any radionuclide that constitutes at

least 1 percent of the total activity released or contributes at least 1 percent of the exposure estimated for a member of the public from a specific effluent stream.

release point—A location from which radioactive materials are released from a system, structure, or component (including evaporative releases and leaching from ponds and lakes in the controlled or restricted area before release under 10 CFR 20.2001). For release points monitored by facilty process radiation monitoring systems, the release point is associated with the piping immediately downstream of the radiation monitor. Several release sources may contribute to a common release point.

REFERENCES[1]

1. ANSI/HPS N13.1-1999, "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities," American National Standards Institute/Health Physics Society, McLean, VA, 1999.[2]

2. Regulatory Guide 4.15, Revision 2, "Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination)—Effluent Streams and the Environment," U.S. Nuclear Regulatory Commission, Washington, DC, July 2007.

3. ANSI/ASQ E4-2004, "Quality Systems for Environmental Data and Technology Programs—Requirements with Guidance for Use," American National Standards Institute/American Society for Quality, Milwaukee, WI, 2004.

4. Regulatory Guide 1.109, Revision 1, "Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR Part 50, Appendix I," U.S. Nuclear Regulatory Commission, Washington, DC, October 1977.

5. Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," U.S. Nuclear Regulatory Commission, Washington, DC.

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[1] Publicly available NRC published documents are available electronically through the Electronic Reading room on the NRC's public Web site at: http://www.nrc.gov/reading-rm/doc-collections/. The documents can also be viewed on-line or printed for a fee in the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail PDR.Resource@nrc.gov.

[2] Copies of American National Standards Institute (ANSI) standards may be purchased from ANSI, 1819 L Street, NW., 6th floor, Washington, DC 20036; telephone (202) 293-8020. Purchase information is available through the ANSI Web site at http://webstore.ansi.org/ansidocstore/.

BIBLIOGRAPHY

U.S. Nuclear Regulatory Commission Documents

NUREG-Series Reports

NUREG/CR-4007, "Lower Limit of Detection: Definition and Elaboration of a Proposed Position for Radiological Effluent and Environmental Measurements," 1984.

Miscellaneous NRC Documents

NUREG-1576 and EPA-402-B-04-001, "Multi-Agency Radiological Laboratory Analytical Protocols Manual," 3 volumes, July 2004.

Draft Regulatory Guide DG-4008, "Monitoring and Reporting Radioactivity in Effluents from Nuclear Fuel Cycle Facilities," March 2000.

Regulatory Guide 1.21, "Measuring, Evaluating, and Reporting Radioactive Material in Liquid and Gaseous Effluents and Solid Waste," June 2009

American National Standards Institute/Institute of Electrical and Electronics Engineers

ANSI/IEEE N42.18, "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents," 1974, reaffirmed 1980, 1985, 1991, and 2004.

American Society for Testing and Materials

ASTM D 3685/D 3685M, "Standard Test Methods for Sampling and Determination of Particulate Matter in Stack Gases," 1998, reaffirmed 2005.

National Council on Radiation Protection and Measurements

NCRP Report 58, "A Handbook of Radioactivity Measurements Procedures," February 1985.

U.S. Department of Homeland Security

HASL-300, "EML Procedures Manual," 28th Edition, February 1997.

APPENDIX A

MINIMUM DETECTABLE CONCENTRATION

This appendix provides information on calculating the minimum detectable concentration (MDC) for radioactive materials in environmental media based on detection of the radiation emitted from the materials.

$$MDC = \frac{3 + 4.65S_b}{1\,x\,10^3\ EVY\ e^{-\lambda\Delta t}}$$

where:

MDC	is the minimum detectable concentration (kilobecquerel per milliliter)
S_b	is the standard deviation of the instrument background counting rate (counts per second)
1×10^3	is the number of disintegrations per second per kilobecquerel
E	is the counting efficiency (counts per disintegration)
V	is the sample volume (milliliters)
Y	is the fractional radiochemical yield (when applicable)
λ	is the radioactive decay constant for the particular radionuclide
Δt	is the elapsed time between the midpoint of sample collection and the time of counting

The licensee should base the value of S_b used in the calculation of the MDC for a particular measurement system on the actual observed variance of the instrument background counting rate rather than on an unverified, theoretically predicted variance.

Since the MDC is a function of sample, volume, counting efficiency, radiochemical yield, and the like, it may vary for different sampling and analysis procedures. Whenever there is a significant change in the parameters of the measurement system, the licensee should recalculate the MDC.

APPENDIX B

SAMPLE FORMAT FOR REPORTING EFFLUENT DATA[1]

B-1. Continuously Sampled Stacks

For each release point, report the following information:

a. reporting period,
b. stack location (process or area),
c. stack flow rate (cubic meters per second (m^3/s)) or total stack flow (m^3, if stack is not in continuous use), and
d. total estimated uncertainty.

Radionuclide[2]	Concentration (Bq/mL)	Uncertainty Estimate[3] (± Bq/mL)	MDC[4] (Bq/mL)	Quantity Released (TBq)	Estimated Exposure (µSv)[5]
Gross alpha					NA
Gross beta					NA
U-234					
U-235					
U-238					

1 This table is for illustration only and is not a complete listing of data to be reported. Licensees should also submit supplemental and explanatory information. (See Section 5.3 of the regulatory guide.)

2 This list of radioactivity and radionuclides is typical for uranium fuel fabrication facilities. It is not complete for all licensees, and not all licensees will need to report the radioactivity or the radionuclides shown. (For example, some licensees may need to report natural uranium or isotopes of plutonium, while others may not need to report gross beta activity.) The gross alpha and beta emissions, as well as isotopic emissions, are shown assuming that independent analyses are performed. If one is derived directly from the other, there is no need to show both, and the supplemental information should provide the derivation method.

3 Estimates of uncertainty should be calculated at the 95-percent confidence interval. The supplemental information should report significant systematic uncertainty, if appropriate.

4 The supplemental information should detail the minimum detectable concentration (MDC) calculation.

5 Comparison may also be made to the applicable guideline in Table 2 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) for Radionuclides for Occupational Exposures, Effluent Concentrations, Concentrations for Release to Sewerage," to Title 10, of the *Code of Federal Regulations,* Part 20, "Standards for Protection against Radiation.". Any comparison should be based on the applicable radionuclides, solubility classifications, and the like, as well as the derivation discussed in the supplemental information provided.

B-2. Other Sampled Stacks[6]

For each release point, report the following information:

a. date(s) sampled,
b. stack location (process or area),
c. stack total flow (m^3), and
d. total estimated uncertainty.

Radionuclide[2]	Concentration (Bq/mL)	Uncertainty Estimate (± Bq/mL)	MDC (Bq/mL)	Quantity Released (TBq)	Estimated Exposure (µSv)
Gross alpha					NA
Gross beta					NA
U-234					
U-235					
U-238					

B-3. Liquid Discharge

For each release point, report the following information:

a. reporting period or date(s) sampled,
b. location of sample collection,
c. total liquid flow,
d. batch or continuous sample,
e. dilution flow (if not included in total flow), and
f. total estimated uncertainty.

Radionuclide[2]	Concentration (Bq/mL)	Uncertainty Estimate (± Bq/mL)	MDC (Bq/mL)	Quantity Released (TBq)	Estimated Exposure (µSv)
Gross alpha					NA
Gross beta					NA
U-234 (dissolved)					
U-235 (dissolved)					
U-238 (dissolved)					
U-234 (suspended)					
U-235 (suspended)					
U-238 (suspended)					

[6] This section covers stacks or vents not routinely sampled (see Section 2.1 of the regulatory guide). (For example, some stacks or vents may need only to be sampled periodically to verify that radioactive effluents are insignificant or that the systems are used only intermittently.)