



DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-4017

(Proposed Revision 2 of Regulatory Guide 4.16, dated December 1985)

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 mining and milling facilities and nuclear power reactors. The NRC has developed other regulatory guides applicable to those facilities.

Title 10, of the *Code of Federal Regulations* (10 CFR), Section 70.59, "Effluent Monitoring Reporting Requirements," 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 specifying the quantity of each of the principal radionuclides released to unrestricted areas and such other information as 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 uranium milling, the production of uranium hexafluoride, or a uranium enrichment facility must submit semiannual reports similar to those required by 10 CFR 70.59.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position.

Public comments are being solicited on this draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; e-mailed to nrcprep.resource@nrc.gov; submitted through the NRC's interactive rulemaking Web page at <http://www.nrc.gov>; or faxed to (301) 492-3446. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by April 5, 2010.

Electronic copies of this draft regulatory guide are available through the NRC's interactive rulemaking Web page (see above); the NRC's public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/>; and the NRC's Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML091310475.

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(4) requires that 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 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 to radiation from the operations.

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required.

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.

B. DISCUSSION

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 plant.

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/Health Physics Society (ANSI/HPS) N13.1-1999, "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities" (Ref. 1). Licensees should use this guidance to establish sampling and monitoring methods for those gaseous effluent points that emit 90 percent or more of the total radioactivity released from the facility, as well as those points that generate 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 plant, 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, while only periodic sampling or periodic administrative reviews may be adequate 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 emit radionuclides 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 has the potential to emit 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., quarterly) 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 plant. 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 one month or less. Licensees should not combine samples from different locations.

3 Quality Assurance and Quality Control

3.1 Regulatory Guidance

Licensees should apply a range of quality control (QC) checks and tests to the sampling and analytical process. 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 (QA) 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 utilized prescriptive approach, which specified MDCs of less than 10 percent of the applicable value given in Appendix B to 10 CFR Part 20. American National Standards Institute/American Society for Quality (ANSI/ASQ) E4-2004, “Quality Systems for Environmental Data and Technology Programs—Requirements with Guidance for Use” (Ref. 3), includes additional guidance for QA of effluent monitoring.

3.2 Minimum Detectable Concentrations (MDC)

The MDC 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 [$\mu\text{Ci/mL}$]) for gaseous effluents and 1×10^{-6} kBq/mL (3×10^{-8} $\mu\text{Ci/mL}$) 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 MDC 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 much 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 plants 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.

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 radiation monitoring systems used to quantify radioactive effluents) using reference standards certified by NIST or standards that have been calibrated against NIST-certified standards. Calibration standards should have the necessary accuracy, stability, and range required for their intended use. Licensees should calibrate continuous radioactivity monitoring systems against appropriate NIST standards. The relationship between concentrations and monitor readings should be determined over the full range of the readout device.

Calibration standards should utilize 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 utilize 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 in-service correlations that relate monitor readings to either the concentrations of radioactive material in the monitored release path or the release rates of radioactive material in the monitored release path or both. 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 standards certified by NIST. 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. Because it may be difficult to assign error terms for each parameter affecting the final measurement, detailed statistical evaluations of error are not required. 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. The sampling uncertainty is likely the largest component and includes uncertainties such as the uncertainty in volumetric and flow rate measurements and the laboratory processing uncertainties.

The total or expanded measurement 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 (i.e., 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, total effective dose equivalent (TEDE), based on measured liquid and gaseous radioactive effluents may be determined 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).

Licensees may use conservative bounding dose assessments in lieu of site-specific dose assessments of the maximum dose to individual members of the public. 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, maximum 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 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) and is typically not a fictitious fencepost resident or 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. 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 uncertainty of gross alpha and gross beta activity for each principal radionuclide released;
- (5) the average concentrations and uncertainty of gross alpha and gross beta activity for each principal radionuclide released; and
- (6) estimates of exposure for the maximally exposed receptor.

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 receptor 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 receptor including maximum organ exposure; and
- (3) an estimate of the direct exposure resulting from licensed radioactive materials for the maximally exposed receptor.

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 microcurie per milliliter. Estimates of exposure should be reported in units of microsievert or millirem.

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 which 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 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 less 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 semi-annual (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 zero 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).

6.6 Format

Appendix B to this regulatory guide illustrates a sample format.

Licensees should not use the terms "not detected," "< MDC," or similar terms. Licensees should report each result as a value and 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.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC's plans for using this draft regulatory guide. The NRC does not intend or approve any imposition of a backfit in connection with its issuance.

The NRC has issued this draft guide to encourage public participation in its development. The NRC will consider all public comments received in development of the final guidance document. In some cases, applicants or licensees may propose an alternative or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for license applications, license amendment applications, and amendment requests.

REGULATORY ANALYSIS

Statement of the Problem

The NRC staff issued Revision 1 to Regulatory Guide 4.16, "Monitoring and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Processing and Fabrication Plants and Uranium Hexafluoride Production Plants," in December 1985. Revision of this regulatory guide is necessary to update references and practices and to communicate its applicability to the enrichment plants which have come under the regulatory authority of the NRC since the issuance of Revision 1 of the guide.

Objective

The objective of this regulatory guidance is to communicate an acceptable method and practice for collecting and documenting information on the identity, concentration, and quantity of radionuclides in liquid and gaseous effluents from uranium enrichment plants, nuclear fuel processing and fabrication plants, and uranium hexafluoride production plants.

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 basis for assessing a licensee's effluent controls and the potential environmental impact of radioactive material in effluents.

Alternative Approaches

The NRC staff considered the following alternative approaches:

- Do not revise Regulatory Guide 4.16.
- Revise Regulatory Guide 4.16.

Alternative 1: Do Not Revise Regulatory Guide 4.16

Under this alternative, the NRC would not revise the guidance, and the current guidance would be retained. If the NRC does not take action, there would not be any changes in costs or benefit to the public, licensees, or the NRC. However, the "no-action" alternative would not address the concerns identified with the current version of the regulatory guide. The NRC would continue to review each application on a case-by-case basis. This alternative provides a baseline condition from which any other alternatives will be assessed.

Alternative 2: Revise Regulatory Guide 4.16

Under this alternative, the NRC would revise Regulatory Guide 4.16, taking into consideration that this guidance is now meant to encompass uranium enrichment facilities and that industry standards and other regulatory guidance with applicability to this subject have been developed since the last revision of the guide was issued.

One benefit of this action is that it would enhance uniformity among licensees and make NRC guidance consistent with current industry standards and guidance applicable to this subject area.

The impact to the NRC would be the costs associated with preparing and issuing the revised regulatory guide. The impact to the public would be the voluntary costs associated with reviewing and providing comments to the NRC during the public comment period. The value to NRC staff and its applicants would be the benefits associated with enhanced efficiency and effectiveness in using a common guidance document as the technical basis for license applications and other interactions between the NRC and its regulated entities.

Conclusion

Based on this regulatory analysis, the NRC staff recommends revision of Regulatory Guide 4.16. The staff concludes that the proposed action will enhance the collection and documentation of information on the identity, concentration, and quantity of radionuclides in liquid and gaseous effluents from uranium enrichment plants, nuclear fuel processing and fabrication plants, and uranium hexafluoride production plants. It could also lead to cost savings for the industry, especially with regard to the efficiency of the NRC staff's review of effluent impact, which includes: (1) reviewing the licensee's estimates of the potential annual radiation doses to the public; (2) determining whether the licensee met the requirements of applicable regulations and kept concentrations of radioactive material in liquid and gaseous effluents ALARA; and (3) assessing the adequacy and performance of the licensee's effluent controls.

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.

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.

minimum detectable concentration—The smallest concentration of radioactive material sampled that has a 95-percent probability of being detected (i.e., it yields an instrument response that leads the analyst to conclude that activity above the system background is present).

principal radionuclides—In the context of this guidance, principal radionuclides are those which 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.

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

¹ Publicly available NRC published documents such as Regulations, Regulatory Guides, NUREGs, and Generic Letters listed herein are available electronically through the Electronic Reading room on the NRC's public Web site at: <http://www.nrc.gov/reading-rm/doc-collections/>. Copies are also available for inspection or copying for a fee from 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 the non-NRC documents included in these references may be obtained directly from the publishing organization.

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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.

$$MDC = \frac{3 + 4.65S_b}{1 \times 10^3 E V Y e^{-\lambda \Delta t}}$$

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 DATA¹

B-1. Continuously Sampled Stacks

For each release point, report the following information:

- a. reporting period,
- b. stack location (process or area), and
- c. stack flow rate (cubic meters per second (m³/s)) or total stack flow (m³, if stack is not in continuous use)

<u>Radionuclide</u> ²	<u>Concentration</u> (kBq/mL)	<u>Uncertainty Estimate</u> ³ (± kBq/mL)	<u>MDC</u> ⁴ (kBq/mL)	<u>Quantity Released</u> (TBq)	<u>Estimated Exposure</u> (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 draft regulatory guide.)

² This list of radioactivity and radionuclides is typical for uranium fuel fabrication plants. 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 MDC calculation.

⁵ Comparison may also be made to the applicable guideline in Title 10, of the *Code of Federal Regulations*, Part 20, “Standards for Protection against Radiation,” 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,” Table 2. 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 Stacks⁶

For each release point, report the following information:

- date(s) sampled,
- stack location (process or area), and
- stack total flow (m³).

<u>Radionuclide²</u>	<u>Concentration (kBq/mL)</u>	<u>Uncertainty Estimate (± kBq/mL)</u>	<u>MDC (kBq/mL)</u>	<u>Quantity Released (TBq)</u>	<u>Estimated Exposure (µSv)</u>
Gross alpha					NA
Gross beta					NA
U-234					
U-235					
U-238					

B-3. Liquid Discharge

For each release point, report the following information:

- reporting period or date(s) sampled,
- location of sample collection,
- total liquid flow,
- batch or continuous sample, and
- dilution flow (if not included in total flow).

<u>Radionuclide²</u>	<u>Concentration (kBq/mL)</u>	<u>Uncertainty Estimate (± kBq/mL)</u>	<u>MDC (kBq/mL)</u>	<u>Quantity Released (TBq)</u>	<u>Estimated Exposure (µSv)</u>
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 draft 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.)