INSPECTION PROCEDURE 85403

MEASUREMENT CONTROL PROGRAM

PROGRAM APPLICABILITY: 2683

85403-01 INSPECTION OBJECTIVE

The objective of this inspection procedure is to verify that the licensee's[1] material control and accounting (MC&A) program, for a Category III fuel facility or uranium enrichment facility, includes a measurement control program that meets the appropriate regulatory requirements, including the stated general performance objectives, and specific MC&A measurement uncertainty criteria, for the applicable type of facility.

85403-02 INSPECTION REQUIREMENTS

The inspector should verify that licensees have implemented a measurement control program which assures that measurement bias and variability are measured and controlled. The inspector should review the following:

02.01 Organization and Management. Review the licensee's organization charts, the measurement control plan and procedures, measurement system qualification procedures and records, measurement procedures and equipment, and MC&A analyst training and qualification records.

02.02 Measurement Standards. Review the handling and control procedures for calibration standards.

02.03 Calibration. Review measurement system maintenance and calibration records.

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[1]Hereinafter, the term licensee subsumes the term "certificate holder," which applies in the case of the gaseous diffusion plants (GDPs). Likewise, all certificate-related requirements, including those in GDP compliance plans and corrective action commitments, are subsumed under the term "license."

02.04 Statistics. Review control charts for the implemented measurement systems, statistical program descriptions and statistical analysis reports, and procedures for resolving out-of-control measurement systems.

02.05 Contractor Program Audits and Reviews. Review audits and reviews performed to ensure that use of measurements by a contractor or off-site laboratory do not compromise the licensee's ability to meet any measurement or measurement control requirement in the applicable regulations or in its Fundamental Nuclear Material Control (FNMC) Plan.

85403-03 INSPECTION GUIDANCE

General Guidance

The inspector should verify that the uncertainties associated with the measured values that support the MC&A system are quantified, and that the licensee continually controls the quality of measurement systems employed for MC&A to a level sufficient to satisfy the capabilities required for loss detection, response, and accounting. The goal of the measurement control program, which is in the nature of a quality assurance program for special nuclear material (SNM) measurements, is to maintain the total MC&A measurement uncertainty for a given material balance within the limits specified in 10 CFR 74.31(c)(4) or 10 CFR 74.33(c)(3)(ii), as applicable.

To prepare for the inspection, the inspector should:

1. Review those portions of the FNMC Plan and the license conditions pertaining to the planned inspection activities.

2. Review the previous two MC&A inspection reports for the site.

3. Review any unresolved or follow-up items from the previous inspections to be addressed during the current inspection.

4. Review the content of any communications (including information notices and bulletins) to the licensee that were issued since the last inspection.

Specific Guidance

03.01 Organization and Management. The inspector should verify that: (1) the organization and management of the measurement control program are adequate to ensure that the program is independent of those individuals who are performing MC&A measurements; and (2) measurement bias and uncertainties are monitored and controlled. Training and qualification requirements for measurement personnel should be maintained.

Measurement control procedures should be maintained, and control limits should be calculated and maintained for each measurement used for MC&A purposes. Those measurement systems contributing the

largest quantity of uncertainties, and whose uncertainties accumulate to at least 90 percent of the total measurement contribution to standard error of the inventory difference (SEID), must be regarded as key measurement systems, and be included in the measurement control program. Additionally, any measurement system (regardless of its uncertainty contribution to SEID) used to measure a total SNM quantity, during an inventory period, in excess of 25 percent of the active inventory, should be classified as a key system and subject to the measurement control program.

The facility should document the procedures used to identify key measurement systems. Justification should be provided for excluding from the measurement control program, any systems used for MC&A measurements that were not identified as key measurement systems. The measurement control procedures should address measurement system calibration and qualification; use of calibration and control standards; the generation, collection, and assessment of control data; and the implementation of corrective actions. Control data should be statistically analyzed and monitored to detect out-of-control conditions, and the out-of-control conditions should be appropriately resolved.

The inspector should verify the following:

a. The measurement control program is documented and implemented.

b. Procedures for identifying key measurement procedures are documented.

c. Key measurement procedures are identified and included in the measurement control program.

d. The measurement control program uses procedures for monitoring key measurement systems used for MC&A purposes.

e. Implementation procedures ensure that the measurement control procedures will be performed as specified.

f. A measurement control program manager (or coordinator) is designated, and either reports to the MC&A manager, or is at the same management level as the MC&A manager, if in a different organizational unit.

g. The measurement control program manager has the authority to enforce the measurement control program requirements.

h. Only qualified and calibrated measurement methods are used for MC&A measurements.

i. Measurement methods are validated and requalified whenever changes are made.

j. The measurement control function ensures that MC&A measurements are not performed until the measurement system demonstrates satisfactory performance.

k. A qualification program is documented and implemented, which ensures that measurement personnel demonstrate acceptable levels of proficiency before performing MC&A measurements.

l. Measurement personnel training, including qualification and requalification requirements, is documented.

m. Training, qualification, and requalification requirements for each measurement method are specified in the training plan.

n. The training plan is reviewed and updated to reflect changes in measurement technology.

o. The training plan specifies criteria for the frequency of requalification of measurement personnel.

p. Records of the training, qualification, and requalification of measurement personnel are maintained.

q. Control limits are calculated and monitored for all measurement methods used for MC&A purposes.

r. The measurement control program monitors measurement performance throughout the facility, and assesses the acceptability of MC&A measurements, based on requirements of the measurement control program.

s. The measurement control function reports to management the measurement performance for the previous reporting period.

t. Statistical analyses are properly summarized and reported to the measurement and measurement control organizations.

03.02 Measurement Standards. The inspector should verify that measurement standards used for the calibration or control of measurement systems are properly selected and qualified (i.e., certified) for their intended use and are protected against events that could change their assigned value. Measurement standards should be stored under controlled conditions that ensure the continued validity of the assigned values. The assigned values of these standards should be traceable through an unbroken chain of comparisons to the national system of measurement standards. If the standard's true value could change (e.g., because of moisture pickup, evaporation, or oxidation), the value of the standard should be validated periodically. When nonconsumable standards (e.g., certified weights) are used, the standards must be periodically recertified (e.g., biannually). Recertification of the assigned values of standards should be done in accordance with commitments contained in the FNMC Plan.

Calibration standards need not be representative of the process material or items to be measured by the calibrated device or system. It is the primary measurement device, not the whole system, that generally is calibrated. However, when practical, the calibration standard should be subject to all the process steps

involved in the measurement process to which the sample unknowns are subject.

Control standards should be representative of materials being measured. When practical, each control standard should have a matrix and uranium concentration resembling that of the material being processed. Although they need not be identical to the sample material, any factor in the sample matrix that could produce a bias effect on the measurement should also be present in the control standard. For scales used to measure very large items (e.g., UF_6 cylinders), artifact items should be used to avoid buoyancy and point loading bias effects. However, when the use of fully representative control standards is not practical, the use of partially representative standards is recommended.

The inspector should verify the following:

a. Measurement systems are calibrated against certified reference standards or materials that establish traceability of measurements to the national measurement base.

b. All reference standards and working standards used in the measurement control program are traceable to the national measurement base.

c. Procedures for the proper use and storage of reference standards are documented and implemented.

d. Reference standards are periodically revalidated or recertified.

e. Reference material value uncertainties are smaller than the uncertainties of the measurement method for which they are used, where practical.

f. Control standards used in a measurement control program are representative of the type and composition of the material being measured, when the material matrix may affect the measured values.

03.03 Calibration. The inspector should verify that the licensee has calibration procedures for all MC&A measurement systems, and that the measurement systems have been calibrated in accordance with commitments contained in the FNMC Plan. These procedures should clearly state the criteria to be used for performing the initial and subsequent calibrations of a system and for determining the need for recalibration. The criteria should include the calibration frequency, the types of reference materials to be used, and the range of calibration. The calibrated range must span the anticipated range of process material values. Any results outside of the range of calibration should not be used for MC&A purposes. This range may not extend beyond the lowest and highest standards used for calibration by the amount of the uncertainty values associated with the standard. The inspector should verify that calibration procedures conform to approved practices.

The inspector should verify the following:

a. Calibration procedures for all measurement systems are documented and implemented.

b. The results of all calibrations are documented.

c. Scales and balances are maintained in good working condition and recalibrated according to an established schedule.

d. The calibration range or ranges cover the range expected for the parameter being measured.

e. The calibration standards are traceable to the national measurement system.

f. The precision and accuracy of the calibration are statistically evaluated.

g. Parameters (i.e., temperature, density) that affect the calibration are identified and controlled.

h. Calibration standards are used to perform relative calibrations for confirmatory measurements.

i. Process instruments are calibrated by using appropriate standards, when available, or, at a minimum, by comparing measurement values with more accurate measurement systems on a prescribed basis, with the frequency being defined by demonstrated instrument performance.

j. All waste monitors are calibrated using SNM materials representative of those found in the material balance area (MBA).

03.04 Statistics. The inspector should verify that measurements employed for MC&A purposes are obtained from measurement systems that are in a state of statistical control. The measurement control program must monitor the measurement of control standards and replicates analyzed for MC&A purposes, unless specifically exempted within the FNMC Plan. Control limits should be established at the 0.05 (i.e., warning) and 0.001 (i.e., out-of-control) levels of significance, or at levels defined in the FNMC Plan. A system generating a control measurement, that falls beyond the out-of-control limits, should be immediately removed from generating accounting data until it has been shown to be back in control (i.e., within the warning limits). An out-of-control condition must be promptly reported to the measurement control program manager, and corrective actions implemented. Sample unknowns affected by the out-of-control condition should be remeasured.

a. Measurement Control Procedures and Equipement. Measurement control data should be reviewed and statistically evaluated at least monthly. Control limits should be recalculated at a predetermined frequency (e.g., every 3 to 4 months), and modified, if necessary. The review of program data should assess the frequency of control data exceeding the warning limits and the occurrence of trends. In general, a minimum

of two control standards should be measured each week for each measurement system when in use. During a material balance period, a minimum of eight control standards should be measured (in accordance with the FNMC Plan) for those systems used during that period (16 measurements recommended).

The inspector should determine that control charts, or their equivalent, are used in conjunction with more comprehensive statistical analyses of control data during and at the end of each material balance period. Such analyses should include but not be limited to trend analysis, analysis of out-of-control data, analysis of the appropriateness of control limits, and tests for randomness and normality. The results of these analyses should be reported to all individuals who have direct or indirect responsibility for performing the associated measurements.

The inspector should verify the following:

1. Statistically based acceptance and rejection criteria are documented and used for confirmatory measurements on inventory items when such measurements are used to confirm prior measurements.

2. MC&A measurements are not performed when the measurement system does not demonstrate satisfactory performance in the measurement of control standards.

3. A response plan is documented for resolving control measurements that fail the acceptance criteria.

4. All control measurements failing the acceptance criteria are evaluated and resolved.

5. Procedures to correct out-of-control conditions are documented.

6. Scales and balances are checked daily for accuracy and linearity before they are used for MC&A purposes.

7. Control limits are calculated and monitored for each measurement system or method used for MC&A purposes.

8. Limits for control, including uncertainties for each analyst and procedure combination are established for measurement methods relying substantially on operator technique.

b. Replicates. The inspector should verify that replicate measurements of single samples, and/or measurements of replicate samples, are performed to estimate the combined analytical and sampling errors. The number of replicate measurements and/or replicate samples and their frequency should be performed in accordance with the FNMC Plan. As a general rule, the licensee should analyze replicate samples from 10 percent of the MC&A batches, but as a minimum should analyze at least 15 replicate samples (unless fewer than

15 accounting batches are present). The licensee need not measure more than 50 samples during each material balance period for each material type.

Random error variances for scales, balances, destructive analysis, and nondestructive assay (NDA) can be determined from replicate measurements of control standards or process items. Bulk-volume measurements do not require replicates; error variances should be determined from reproducibility results obtained during calibration.

The inspector should verify the following:

1. Replicate measurements and replicate samples are measured in accordance with the FNMC Plan.

2. Sufficient replicate measurements are performed to permit calculation of the combined analytical errors plus sampling errors, for each measurement system that uses sampling.

3. Replicate samples are independent of their corresponding original sample.

c. Calculation of the SEID. The inspector should verify that current data generated during the inventory period are used by the licensee for establishing bias correction values, uncertainties on calibration factors, and random error variances. The inspector should determine whether sufficient control standard measurements and replicate analyses of process materials were performed to permit a determination of the standard deviation associated with each error component for each measured quantity. The amount of effort expended to determine the magnitude of random and systematic errors should be related to the role that such errors play in the calculation of the SEID.

The inspector should verify the following:

1. A program is documented, for the statistical evaluation of measurement data, to determine control limits, calibration limits, and precision and accuracy levels for each MC&A measurement system.

2. A valid statistical technique is used to determine the total random and systematic error generated for each measurement system, to determine control limits, to develop sampling plans for measurement of nuclear material inventories, and to determine rejection limits and outlier criteria.

3. The uncertainty associated with each sampling method, measurement method, or combination is determined and maintained on a current basis.

4. Data from routine measurements are statistically analyzed to determine and ensure accuracy and precision of the measurements.

5. All major assumptions made in each data evaluation process are documented in accordance with the statistical program.

6. Measurement control data are analyzed, summarized, and reported to the responsible personnel at specified times.

d. Assessment of Measurement Proficiency. The inspector should review the SEID to compare the significant contributors to the ID variances with the descriptions in the FNMC Plan. If the licensee has difficulties with a measurement system, the inspector should determine whether a specific material type is the cause and whether this has been described in the FNMC Plan. The results of the evaluation should be discussed with the licensee.

The inspector should: (1) determine whether all measurement systems are monitored; (2) review several key measurement systems; and (3) observe procedural compliance. Materials measured by key measurement systems should be independently sampled and submitted for analysis by the inspector to determine the acceptability of the licensee's systems (UF_6 would normally be an exception). The number of samples needed should be determined using a 10 percent false alarm rate coupled with the degree of variation (i.e., the magnitude of allowable deviation) deemed appropriate by the inspector. Using this approach, the inspector should select a sample size that is large enough to support a meaningful comparative statistical analysis without placing an undue burden on the licensee.

The statistical methods used to evaluate the resultant data should include, as appropriate, tests of individual and cumulative differences, tests of means, and tests of variance. The results of all such analyses should be discussed with the licensee during a subsequent inspection and thoroughly documented in an inspection report. If the results obtained are inconclusive, the evaluation could be continued by either performing some additional sampling and analysis (e.g., split samples), or by having the licensee analyze independently certified standards brought in by the inspector.

03.05 Contractor Program Audits and Reviews. If the licensee uses an outside contractor or off-site analytical laboratory to perform MC&A measurements, the inspector should verify that the licensee has implemented a review program to ensure that the contractor or outside laboratory has an acceptable control program, and that use of the contractor's or laboratory's data will not compromise the licensee's ability to meet its measurement control commitments.

The inspector should verify that the contractor's measurement program complies with applicable NRC requirements, by analyzing the results of the licensee's annual reviews and audits of its contractor laboratory. If issues are identified for follow-up, then the inspector should discuss the concerns with the licensee's management and, as appropriate, schedule follow-up activities for the contractor. An occasional visit by inspectors to contractor

laboratories (perhaps every 2–3 years) might also be employed as an independent check on the effectiveness and compliance of these laboratories.

The inspector should verify the following:

a. The licensee's review program for outside contractor or off-site laboratory measurement control programs is documented and implemented.

b. An initial review of the contractor's measurement control program is performed before measurement data from the contractor are accepted for accounting use.

c. Findings of the licensee’s review program are evaluated by the managers of the MC&A and measurement control programs, and recommendations of corrective actions to be implemented are documented.

d. Persons reviewing the contractor laboratory are independent of and not associated with that laboratory.

85403-04 REFERENCES

Regulations

10 CFR 74.31, and 74.31(c)(3) and (4); 10 CFR 74.33(a) and 74.33(c)(3).

Regulatory Guides and Reports

NUREG-1065, Rev. 2, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control Plan Required for Low-Enriched Uranium Facilities," November 1995.

NUREG/CR-5734, "Recommendations to the U.S. Nuclear Regulatory Commission on Acceptable Standard Format and Content for the Fundamental Nuclear
Material Control (FNMC) Plan Required for Low-Enriched Uranium Enrichment
Facilities," Chapter 3, November 1991.

TID-26298, “Statistical Methods in Nuclear Material Control,” 1973.

NUREG/CR-4604, "Statistical Methods for Nuclear Material Management," December 1988.

NUREG/CR-1284, "Methods of Determining and Controlling Bias in Nuclear Material Accounting Measurements," June 1980.

NUREG/CR-0830, "Monitoring the Random Errors of Nuclear Material Measurements," June 1980.

NUREG/CR-0772, "Auditing Measurement Control Programs," October 1979.

LA-10811-MS, "Fundamental Data Analyses for Measurement Control," February 1987.

END