(5) Establish records that will demonstrate that the performance objectives of §74.41(a)(1) through (4), the system capabilities of paragraphs (b) and (c) of this section and §74.45(b) and (c) have been met, and maintain these records in an auditable form, available for inspection, for at least 3 years, unless a longer retention time is specified by §74.19(b), part 75 of this chapter, or by a specific license condition.

[67 FR 78146, Dec. 23, 2002]

## § 74.45 Measurements and measurement control.

- (a) General. Licensees subject to §74.41 of this part shall establish and maintain the measurement and measurement control capabilities required by paragraphs (b) and (c) of this section.
  - (b) Measurements. The licensee shall:
- (1) Establish, maintain, and use a program for the measurement of all SNM received, produced, transferred between internal control areas, on inventory, or shipped, discarded, or otherwise removed from inventory, except for:
- (i) Sealed sources that have been determined by other means to contain less than 10 grams of uranium-235, uranium-233, or plutonium each;
- (ii) Samples received, transferred between internal control areas, or on inventory that have been determined by other means to contain less than 10 grams of uranium-235, uranium-233, or plutonium each:
- (iii) Receipt of sealed sources, of any quantity, previously manufactured and shipped by the licensee and which are returned to the licensee, provided the unique identity and encapsulation integrity have not been compromised, and the booked receipt quantity equals the previously shipped quantity for the involved sealed sources; and
- (iv) Heterogeneous scrap that cannot be accurately measured in its as received form, provided this scrap is measured after dissolution within 18 months of receipt. The after dissolution measurement must include measurement of both the resulting solution and any undissolved residues, before any co-mingling with other scrap solutions or residues.

- (2) Maintain and follow a program for the development and use of written procedures that includes documented review and approval of these procedures, and any revisions thereof, before use, for:
- (i) Preparing or acquiring, maintaining, storing, and using reference standards:
- (ii) Calibrating measurement systems, performing bulk mass and volume measurements, conducting non-destructive assay measurements, obtaining samples, and performing laboratory analyses for element concentration and isotope abundance; and
- (iii) Recording, reviewing, and reporting measurements.
- (c) Measurement control. To maintain measurement quality and to estimate measurement uncertainty values, the licensee shall:
- (1) Assign responsibility for planning, developing, coordinating, and administering a measurement control program to an individual who has no direct responsibility for performing measurements or for SNM processing or handling, and who holds a position at an organizational level which permits independence of action and has adequate authority to obtain all the information required to monitor and evaluate measurement quality as required by this section.
- (2) Ensure that any contractor who performs MC&A measurements services conforms with applicable requirements in paragraphs (c)(5), (6), (7), (10) and (11) of this section. Conformance must include reporting by the contractor of sufficient measurement control data to allow the licensee to calculate bias corrections and measurement limits of error.
- (3) Ensure that potential sources of sampling error are identified and that samples are representative by performing process sampling tests using well characterized materials to establish or verify the applicability of utilized procedures for sampling SNM and for maintaining sample integrity during transport and storage. These sampling tests or sample integrity tests, as appropriate, shall be conducted whenever:

## § 74.45

- (i) A new sampling procedure or technique is used, or new sampling equipment is installed:
- (ii) A sampling procedure, technique, or sampling equipment is modified to the extent that a systematic sampling error could be introduced; and
- (iii) Sample containers, sample transport methods, or sample storage conditions are changed or modified to the extent that a systematic sampling error could be introduced.
- (4) Establish and maintain a measurement control program so that for each inventory period the SEID is less than 0.125 percent of the active inventory, and assure that any MC&A measurements performed under contract are controlled so that the licensee can satisfy this requirement.
- (5) Generate current data on the performance of each measurement system used during each material balance period for the establishment of measured values and estimated measurement uncertainties, including estimates of bias, variance components for calibration, sampling, and repeat measurements. The program data must reflect the current process and measurement conditions existing at the time the control measurements are made.
- (6) Use standards on an ongoing basis for the calibration and control of all measurement systems used for SNM accountability. Calibrations shall be repeated whenever any significant change occurs in a measurement system or when program data indicate a need for recalibration. Calibrations and control standard measurements shall be based on standards whose assigned values are traceable to certified reference standards or certified standard reference materials. Additionally, control standards shall be representative of the process material or items being measured by the measurement system in question.
- (7) Conduct control measurements to provide current data for the determination of random error behavior. On a predetermined schedule, the program shall include, as appropriate:
- (i) Replicate analyses of individual samples;
- (ii) Analysis of replicate process samples;

- (iii) Replicate volume measurements of bulk process batches;
- (iv) Replicate weight measurements of process items and bulk batches, or alternatively, the use of data generated from the replicate weighings of control standard weights as derived from the control standard program; and
- (v) Replicate NDA measurements of individual process containers (items), or alternatively, the use of data generated from the replicate measurements of NDA control standards as derived from the control standard program.
- (8) Use all measurements and measurement controls generated during the current material balance period for the estimation of the SEID.
- (9) Evaluate with appropriate statistical methods all measurement system data generated in paragraph (c)(5) of this section to determine significant contributors to the measurement uncertainties associated with inventory differences and shipper-receiver differences, so that if SEID exceeds the limits established in paragraph (c)(4) of this section, the cause of the excessive SEID can be identified for corrective action with respect to controlling the standard error within applicable limits.
- (10) Establish and maintain a statistical control system, including control charts and formal statistical procedures, designed to monitor the quality of each measurement device or system. Control chart limits must be established to be equivalent to levels of significance of 0.05 and 0.001.
- (11) Promptly investigate and take any appropriate corrective action whenever a control datum exceeds an 0.05 control limit, and whenever a control datum exceeds an 0.001 control limit, the measurement system that generated the datum shall immediately be placed out-of-service with respect to MC&A measurements until the deficiency has been corrected and the system brought into control within the 0.05 control limits.

 $[67 \; \mathrm{FR} \; 78146, \; \mathrm{Dec.} \; 23, \; 2002]$