§ 70.56 Tests.

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part, including tests of (a) special nuclear material, (b) facilities wherein special nuclear material is utilized, produced or stored, (c) radiation detection and monitoring instruments, and (d) other equipment and devices used in connection with the production, utilization or storage of special nuclear material.

[21 FR 764, Feb. 3, 1956. Redesignated at 25 FR 1607, Feb. 25, 1960, and 25 FR 12730, Dec. 13, 1960]

§ 70.57 Measurement control program for special nuclear materials control and accounting.

(a) As used in this section:

(1) *Measurement* includes sampling and means the determination of mass, volume, quantity, composition or other property of a material where such determinations are used for special nuclear material control and accounting purposes.

(2) *Measurement system* means all of the apparatus, equipment, instruments and procedures used in performing a measurement.

(3) *Reference standard* means a material, device, or instrument whose assigned value is known relative to national standards or nationally accepted measurement systems.

(4) *Traceability* means the ability to relate individual measurement results to national standards or nationally accepted measurement systems through an unbroken chain of comparisons.

(5) *Random error* refers to the variation encountered in all measurement work, characterized by the random occurrence of both positive and negative deviations from a mean value.

(6) A *systematic error* is a constant unidirectional component of error that affects all members of a data set; its value can, in some instances, be estimated by the deviation of the mean of a measurement process from a reference value. A systematic error whose value has been determined in this manner is called a bias, whose effect can be corrected for.

(7) *Uncertainty* is the extent to which a measurement result is in doubt because of the effects of random error variances and the limits of systematic errors associated with a measurement process, after the measurements result has been corrected for bias.

(8) *Calibration* means the process of determining the numerical relationship between the observed output of a measurement system and the value, based upon reference standards, of the characteristics being measured.

(b) In accordance with § 70.58(f), each licensee who is authorized to possess at any one time and location strategic special nuclear material, or special nuclear material of moderate strategic significance, in a quantity exceeding one effective kilogram and to use such special nuclear material for activities other than those involved in the operation of a nuclear reactor licensed pursuant to part 50 of this chapter, those involved in a waste disposal operation, or as sealed sources, shall establish and maintain a measurement control program for special nuclear materials control and accounting measurements. Each program function must be identified and assigned in the licensee organization in accordance with § 70.58(b)(2), and functional organizational relationships must be set forth in writing in accordance with § 70.58(b)(3). The program must be described in a manual which contains the procedures, instructions, and forms prepared to meet the requirements of this paragraph, including procedures for the preparation, review, approval, and prompt dissemination of any program modifications or changes. The licensee shall retain the current program as a record until the Commission terminates the license authorizing possession of the nuclear materials. The licensee's program shall include the following:

(1) The licensee shall assign responsibility for planning, developing, coordinating, and administering the program to an individual in his organization who has no direct responsibilities for the operation of the analytical laboratory or for the processing of material, holds a position at an organizational level which will permit independence of action and objectivity of decision and

has authority to obtain all the information required to monitor and evaluate measurement quality as required by this section.

(2) Provisions must be made for management reviews to determine the adequacy of the program and to assess the applicability of current procedures and for planned audits to verify conformance with all aspects of the program. These reviews and audits must be performed at intervals not to exceed 12 months. Audits and reviews must be performed by trained individuals independent of direct responsibility for the receipt, custody, utilization, measurement, measurement quality, and shipment of special nuclear material. The results of reviews and audits must be recorded and reported to licensee management. The licensee shall retain each record of a review or an audit for three years after the record is made.

(3) The licensee shall ensure that any person who contracts to perform materials control and accounting measurement services conforms with applicable requirements of paragraphs (b) (4) through (8) and (10) through (12) of this section. Conformance must include reporting by the contractor of sufficient error data to allow the licensee to calculate bias corrections and measurement limits of error. All statistical studies must be reported or references in the measurement report submitted to the licensee, who shall have access to the contractor's supporting control data. The licensee shall perform reviews to determine the adequacy of the contractor's program and audits to verify conformance with all aspects of the program. Reviews and audits must be performed at intervals not to exceed 12 months. The results of reviews and audits must be documented and reported to licensee management. The licensee shall retain the record of the results of the licensee review and audit of the contractor's program for three years after the record is made.

(4) In order to ensure that potential sources of sampling error are identified and that samples are representative, process and engineering tests must be performed using well characterized materials to establish or to verify the applicability of existing procedures for sampling special nuclear materials and for maintaining sample integrity during transport and storage. The licensee shall record the results of the above process and engineering tests and shall maintain those results as a record for as long as that sampling systems is in use and for three years following the last such use. The program must ensure that such procedures are maintained and followed, and that sampling is included in the procedures for estimating biases, limits for systematic errors, and random error variances.

(5) The program shall include provisions for the review and approval, before use, of written procedures for:

(i) Preparing or acquiring, maintaining, storing and using reference standards,

(ii) Calibrating measurement systems, performing bulk measurements, obtaining samples, and performing compositional analyses,

(iii) Recording, analyzing and reporting the program data and information, and

(iv) Controlling measurement performance.

(6) To ensure the adequacy of each measurement system with respect to process flows, sampling and measurement points, and nominal material compositions, engineering analyses and evaluations must be made of the design, installation, preoperational tests, calibration, and the operation of each system. These analyses and evaluations must be repeated whenever a significant change is made in any component of a system. The licensee shall record the results of these analyses and evaluations and retain these records for three years after the life of the process or equipment.

(7) Procedures and performance criteria must be established for the training, qualifying, and periodic requalifying of all personnel who perform sampling and measurements for materials control and accounting purposes. The licensee shall retain as a record the results of personnel qualification or requalification for three years after the record is made.

(8) The program must generate current data on the performance of measuring processes, including, as appropriate, values for bias corrections and their uncertainties, random error

variances, limits for systematic errors, and other parameters needed to establish the uncertainty of measurements pertaining to materials control and accounting. The program data must reflect the current process and measurement condition existing at the time the control measurements are made. The licensee shall record this data and retain this record for three years after the record is made. Measurements which are not controlled by the program may not be used for materials control or for accounting purposes. The program must include:

(i) The ongoing use of standards for calibration and control of all applicable measurement systems. Calibrations shall be repeated whenever any significant change occurs in a measurement system or when program data, generated by tests performed at a predetermined frequency, indicate a need for recalibration. Calibrations and tests shall be based upon reference standards.

(ii) A system of control measurements to provide current data for the determination of random error behavior. On a predetermined schedule, the system shall include the replicate analysis of process samples, the replicate weight or volume measurement of bulk quantities of material, and the analysis of replicate process samples.

(9) The program data generated during the current material balance period shall be used for the determination of the limit of error of the plant material balance. Measurement error data collected and used during immediately preceding material balance periods may be combined with current data provided that the measurements are in statistical control, i.e., when repeated samples from the portion of the measurement system under test behave as random samples from a stable probability distribution. Under such conditions, data sets may be combined provided that the parameter estimates based on the current set of data and the previous set of data are not significantly different on the basis of appropriate statistical tests performed at a level of significance of 0.05.

(10) The licensee shall evaluate with appropriate statistical methods all program data and information, and relevant process data used to establish bias corrections and their associated uncertainties, random error variances, limits for systematic error, and other parameters pertaining to special nuclear materials control and accounting measurements, and to control measurement performance pursuant to § 70.58(f). Bias corrections shall be made by an appropriate statistical procedure.

(11)(i) The licensee shall establish and maintain a statistical control system, including control charts and formal statistical procedures, designed to monitor the quality of each type of program measurement. The licensee shall retain a copy of the current statistical control system as a record until the Commission terminates each license that authorizes possession of the material that the system affects and shall retain copies of such system documents for previous inventory periods as a record for three years after they are replaced.

(ii) Control chart limits must be established to be equivalent to levels of significance of 0.05 and 0.001. Whenever control data exceed the 0.05 control limits, the licensee shall investigate the condition and take corrective action in a timely manner. The licensee shall record the results of these investigations and actions and retain each record for three years after the record is made. Whenever the control data exceed the 0.001 control limits, the measurement system that generated the data must not be used for material control and accounting purposes until the deficiency has been corrected and the system has been brought into control at the 0.05 control level.

(12) The licensee shall provide a records system in which all data, information, reports, and documents generated by the measurement control program must be retained for three years. Records must include a summary of the error data utilized in the limit of error calculations performed for each material balance period. The records system must be organized for efficient retrieval of program information. Each reported result must be

readily relatable to the original measurement data and to all relevant measurement control information, including pertinent calibration data. Records must be available for NRC inspection.

(c) Applicants and licensees subject to the provisions of paragraph (b) of this section shall submit to the Commission for approval a detailed plan describing the program that will be used to comply with said provisions. The plan submitted shall include the identification of those measurements to be contracted and shall describe the steps the licensee shall take to assure the adequacy of such procedures. Licensee's plans shall be submitted on or before November 11, 1975.

(d) Licensees subject to the provisions of paragraph (b) of this section shall follow the plans submitted pursuant to paragraph (c) of this section after May 11, 1976, or thirty days after the submitted plan is approved by the NRC whichever is later. After May 11, 1976, an applicant subject to the provisions of paragraph (b) of this section shall immediately implement his plan, submitted pursuant to paragraph (c) of this section, following incorporation of said plan as a condition of license.

[40 FR 33652, Aug. 11, 1975, as amended at 40 FR 50704, Oct. 31, 1975; 42 FR 25721, May 19, 1977; 53 FR 19254, May 27, 1988]

§ 70.58 Fundamental nuclear material controls.

(a) Each licensee who is authorized to possess at any one time and location strategic special nuclear material in irradiated fuel reprocessing operations or special nuclear material of moderate strategic significance in a quantity exceeding one effective kilogram, and to use such special nuclear material except for sealed sources and those uses involved in the operation of a nuclear reactor licensed pursuant to part 50 of this chapter and those involved in a waste disposal operation, shall establish, maintain, and follow written material control and accounting procedures in compliance with the fundamental nuclear material control requirements specified in paragraphs (b) through (k) of this section and such other controls as the Commission determines to be essential for the control of and accounting for special nuclear material.

(b)(1) The overall planning, coordination, and administration of the material control and accounting functions for special nuclear materials shall be vested in a single individual at an organizational level sufficient to assure independence of action and objectiveness of decisions. In manufacturing organizations, such individual shall be independent of individuals or units that are solely responsible for production functions.

(2) Material control and accounting functions shall be identified and assigned in the licensee organization to provide a separation of functions so that the activities of one individual or organizational unit serve as controls over and checks of the activities of other individuals or organizational units.

(3) Material control and accounting functional and organizational relationships must be set forth in writing in job descriptions, organizational directives, instructions, procedure manuals, etc. This documentation must include position qualification requirements and definitions of authorities, responsibilities, and duties. Delegations of material control and accounting responsibilities and authority must be in writing. The licensee shall retain this documentation as a record until the Commission terminates each license that authorizes the activity that is subject to retention of the documentation, and if any portion of the documentation is superseded, retain the superseded material for three years after each change.

(c) A management system shall be established, maintained, and followed to provide for the development, revision, implementation, and enforcement of nuclear material control and accounting procedures. The system shall include:

(1) Provisions for written approval of such procedures and any revisions thereto by the individual with overall responsibility for the material control and accounting function and by licensee plant management.