REQUEST FOR ADDITIONAL INFORMATION

Department of Commerce – National Institute of Standards and Technology

SNM-362 License Renewal Application

September 10, 2012

Each of the following requests for additional information (RAI's) is based on the revised license renewal application (LRA) submitted by NIST on March 23, 2011 and subsequent submittals. Please provide the following information.

1. NIST's LRA does not address the responsibility of the Ionizing Radiation Safety Committee (IRSC) to review, approve and record safety evaluations of proposed uses of byproduct material prior to its use. It also doesn't address the IRSC's responsibility to approve individuals who may use byproduct material.

   10 CFR 33.13 states the requirements for the issuance of a Type A specific license of broad scope. Included in these requirements is a description of the requirements for management review necessary to assure safe operations. Please describe how NIST's radiation safety program meets the requirements of 10 CFR 33.13. 10 CFR 33.17(b) requires that byproduct material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee. NIST will provide a description of how its radiation safety program meets these requirements.

2. NIST's LRA does not fully address the activities to fabricate sealed sources using licensed material for calibration standards and calibration sources and the service activities performed using such sources or other licensed materials to calibrate instruments. The LRA also does not address quality assurance and quality control procedures used during these activities to confirm that the material meets approved design requirements for sealed sources.

   10 CFR 32 provides the requirements for manufacturers of sealed sources. Accordingly, NIST will provide the following:

   a. A brief description of its activities to fabricate sealed sources using licensed material for calibration standards and calibration sources and the service activities performed using such sources, or other licensed materials to calibrate instruments.

   b. 10 CFR 32.210(c) provides the requirements for QA/QC procedures used during manufacturing of calibration standards and calibration sources in meeting the design requirements for sealed sources. NIST will provide a description of how its manufacturing program meets these requirements.

   c. 10 CFR 32.19(c) provides the requirements for the marking and labeling of sealed sources. NIST will provide a description of how their manufacturing program meets these requirements.

d. 10 CFR 32.19(d) provides the requirements for instructions to be provided to users of sealed sources. NIST will provide a description of the instructions that it to users of sealed sources that it uses to meet these requirements.

3. The licensee's LRA does not provide a description of the training provided to irradiator operators.

   10 CFR 36.13 provides the requirements for training irradiator operators. NIST will provide a description of its training program for irradiator operators in the meeting these requirements in each of the following areas:

   a. Classroom training,

   b. On-the-job or simulator training,

   c. Safety reviews,

   d. Means used to test each operator's understanding of the Commission's regulations and licensing requirements and the irradiator operating and emergency procedures; and

   e. Minimum training and experience of personnel who may provide training.

4. NIST's LRA does not provide a description of the procedures used to decontaminate off-site locations where unsealed materials are used or where leak testing of sources is performed.

   NIST will provide a description of its procedures used to decontaminate off-site locations where unsealed materials are used or where leaking testing of sealed sources is performed and a leaking source is discovered. NIST's description will include methods used to decontaminate as necessary and of radiation surveys of the site prior to unrestricted release.

5. NIST's LRA does not provide a description of the procedures used to perform leak tests of sealed sources stored for 10 years or more.

   NIST will provide a description of their procedures used for leak testing of sealed sources that are stored for 10 years or more.

6. NIST's LRA does not provide a description of the effluent sampling methods for all effluents released to the environment, including verification of the use of calibrated sampling and measuring equipment.

   10 CFR 20.1301, 1302, and 1501 provide the requirements for effluent sampling methods for effluents released to the environment. NIST will provide a description of its procedures used in effluent sampling methods for all effluents released to the environment, including verification of the use of calibrated sampling and measuring equipment.

7. According to NIST's LRA, decay-in-storage may be used prior to disposal of radioactive wastes in accordance with certain conditions listed. The description of disposal following decay-in-storage does not include a description of the recordkeeping maintained by the licensee.

   Provide a description of the recordkeeping maintained on decay-in-storage followed by radioactive waste disposal. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal. These records will be maintained for 3 years.

8. In support of not having a emergency management plan, NIST's LRA describes the requisite evaluation showing that the maximum dose to a person offsite due to a release would not exceed 1 rem effective dose equivalent, or 5 rem to the thyroid. This evaluation was completed and submitted in 1992. Being 20 years old, the evaluation no longer reflects the sources or quantities listed in the current possession limits of the LRA and the demographics may have changed in the area around the NIST facility.

   10 CFR 30.32(j) and 10 CFT 70.22(i) provide that an evaluation showing that the maximum dose to a person offsite due to a release would not exceed 1 rem effective dose equivalent, or 5 rem to the thyroid is a valid basis for not requiring an emergency management plan. Due to the changes in the under lying assumptions used in the evaluation referenced in the LRA, it is not possible to determine that the evaluation is sufficiently current to continue to be used as the basis for not requiring an emergency management plan. NIST will complete an assessment of the referenced evaluation to determine its continued validity. Failing this assessment, a new evaluation will be completed and submitted as the basis for not maintaining an emergency management plan.