UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-

November 16, 2012

Richard D. Thompson
Program Manager
NMSS/FCSS/FMB
U.S. Nuclear Regulatory Commission
One White Flint North
Rockville, MD 20852

Subject: Responses to NRC Requests for Additional Information

Dear Mr. Thompson:

I am hereby responding on behalf of the National Institute of Standards and Technology (NIST) to the following RAIs:

- RAI #1, dated September 10, 2012
- RAI #5, dated September 10, 2012 (revision to response provided by NIST on October 25, 2012)
- New RAI, dated November 8, 2012, issued by the NRC to clarify RAI #2, dated September 10, 2012.

The enclosure contains these responses.

NIST understands that each of the individual requests for additional information (RAIs) is based on the revised license renewal application (LRA) submitted by NIST on March 23, 2011 and subsequent submittals.

If you require any additional information, please contact the NIST Gaithersburg Radiation Safety Officer, Mr. Thomas J. O'Brien at 301-975-5801 or thomas.obrien@nist.gov.

Sincerely,

Richard F. Kayser
Chief Safety Officer

Enclosure

cc: Robert Johnson, NRC ✓
Thomas J. O'Brien, NIST

NIST

NIST Response to Nuclear Regulatory Commission
Requests for Additional Information (RAIs) Regarding SNM-362 License Renewal:

Response to RAI #1, Dated September 10, 2012

Revised Response to RAI #5, Dated September 10, 2012

New RAI, Dated November 8, 2012, Issued to Clarify RAI #2,
Dated September 10, 2012

November 16, 2012

RAI #1, Dated September 10, 2012

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.

Response:

Source User and Source Custodian Eligibility:

The IRSC procedure for approving Source Custodian and Source User eligibility requires the IRSC to review information on the Source Custodian or Source User to determine whether the criteria for approval (see below) have been met. When the IRSC has determined that the criteria have been met, the IRSC Chair (or Vice Chair) documents IRSC approval by signing and dating the appropriate form.

The criteria for IRSC approval of Source User and Source Custodian eligibility are as follows:

1. Education and Experience. Individuals who wish to be eligible to be Source Users or Source Custodians must meet the following criteria:
    a. Have a college degree at the associates level or higher, or equivalent training and experience in the physical, chemical, or biological sciences or in engineering; or
    b. Have a high school diploma and knowledge of the physical, chemical, or biological sciences or engineering sufficient to use licensed material.

2. Line Management Approval. Line management must confirm that the individual has met the requirements in Item 1 above and sign the appropriate form.

3. Training. Individuals who wish to be eligible to be Source Custodians or Source Users must successfully complete the radiation safety training provided by the Gaithersburg Radiation Safety Division (GRSD).

4. RSO Approval. Approval by the RSO (or their IRSC-approved designee) is indicated by signature on the appropriate form, indicating the successful completion of the required training. Refresher training is required biennially to maintain eligibility.

Proposed Uses:

The IRSC procedure for approving proposed uses of licensed material, to be effective upon NRC approval of NIST's license renewal application for license SNM-362, requires the IRSC (or a subcommittee of the IRSC) to review safety evaluations for the proposed use – including the hazard mitigation plan, the qualifications of the user(s), and the adequacy of the facility – to determine whether the criteria for approval (see below) have been met. When the IRSC has determined that the criteria have been met, the IRSC Chair (or Vice Chair if the Chair is absent) documents IRSC approval by signing and dating the appropriate form.

The criteria for IRSC approval of safety evaluations for proposed uses are as follows:

1. Source Custodian and Source User eligibility must have been approved by the IRSC.

2. Source Custodians and Source Users must be authorized as being qualified for the proposed use by their line management and OU Director (or Acting Director).

3. The radiation facility evaluation by GRSD must indicate that the facility is adequate for the specific source use under review.

4. The hazard mitigation plan provided by GRSD must be adequate and consistent with good radiation safety practices for achieving doses that are ALARA.

RAI #5, Dated September 10, 2012
Revision of Response Provided on October 25, 2012

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.

Response Provided on October 25, 2012:

NIST shall identify all sealed sources (that meet leak testing activity criteria) that have been in storage for 10 years or more and perform leak testing as described in the model leak test program published in Appendix T of NUREG-1556, Volume 11, Program-Specific Guidance About Licenses of Broad Scope. As this is a new requirement, NIST shall leak test these sources within six months of issuance of the renewal.

Revised Response:

All sealed sources that have been in storage for 10 years or more and that require leak testing shall be leak tested as described in the model leak test program published in Appendix T of NUREG-1556, Volume 11, Program-Specific Guidance About Licenses of Broad Scope.

New RAI, Dated November 8, 2012

During the conference call held on November 8, 2012, between NIST staff (Richard Kayser and Tom O'Brien) and NRC staff (Robert Johnson, Betsy Ullrich and Richard Thompson) to clarify NIST's response to NRC's request for additional information dated September 10, 2012, NIST was asked to clarify their RAI response provided on October 25, 2012 under RAI #2 related to manufacturing of sources under 10 CFR Parts 30 and 32. NIST stated that they manufacture exempt quantities for distribution to persons who are exempt from licensing pursuant to 10 CFR 30.18, and distributes these items under License No. 19-23454-01E. This license authorizes exempt quantities in the form of calibration solutions and sealed sources. NRC staff further understands that NIST occasionally manufactures custom sources for distribution to persons who will possess them under a specific license. NIST's license renewal application (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 Parts 30.33 and 32.18/19/20 provide the requirements for manufacturing of exempt quantities for distribution to persons who are exempt from licensing. 10 CFR Part 30 and Subpart D of 10 CFR Part 32 provide the requirements for manufacturers of specifically-licensed 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. NIST should address both the exempt quantity items as well as sources distributed to persons who hold specific licenses.

Response:

NIST fabricates liquid (in solution) radioactive sources in glass ampoules, in metal containers (welded or electroplated), and added to matrix materials (soils, organic matter, etc.) for distribution to users. NIST performs calibrations, conducts assessments of instrument and device performance, compares source activities and emissions, assays activities and sample materials, and evaluates material properties.

Calibration Standards and Sources Manufacturing Activities Involving Byproduct Material

NIST's authorized uses involve possession, use, and processing incident to the manufacture of calibration standards and calibration sources. Authorized uses also involve packaging, storage prior to distribution, and distribution of calibration standards and calibration sources to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the NRC or any Agreement State. NIST also distributes a limited number of calibration standards under NRC License No. 19-23454-01E for Distribution of Exempt Quantities; this license is supplementary to NIST License No. SNM-362.

NIST conformance to the requirements of 10 CFR 32.19 (c) and (d) are currently under review by the NRC Office of Federal & State Materials and Environmental Management Programs, Division of Materials Safety and State Agreements following timely submittal of the application for renewal of License No. 19-23454-01E on September 28, 2012.

NIST Service Activities Involving Byproduct Material

NIST develops, maintains, and disseminates the national standards for ionizing radiations and radioactivity. The Radiation and Biomolecular Physics Division (RBPD) within NIST is responsible for the activities at NIST pertinent to this RAI. RBPD develops and operates well-characterized radioactive sources and beams of electrons, photons, and neutrons for primary radiation standards. RBPD also performs calibrations, conducts research on radiation interactions, and develops measurement methods. These efforts support the measurement and standards needs of the health care, biotechnology, security and defense, energy, and other industries in the areas of dosimetry, neutron physics, and radioactivity. RBPD disseminates the results of its work in scientific publications, highly accurate standard reference data for ionizing radiation and radioactive materials, Standard Reference Materials (SRMs), calibrations, and measurement quality assurance programs, providing measurement traceability to users such as hospitals, industry, states, and other Federal agencies.

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

Response:

NIST conformance to the requirements of 10 CFR 32.19(c) are currently under review by the NRC Office of Federal & State Materials and Environmental Management Programs, Division of Materials Safety and State Agreements following timely submittal of the application for renewal of License No. 19-23454-01E on September 28, 2012.

c. 10 CFR 32.19(d) provides the requirements for instructions to be provided to users of exempt quantity items. NIST will provide a description of the instructions provided to users of sealed sources in meeting these requirements.

Response:

NIST conformance to the requirements of 10 CFR 32.19(d) are currently under review by the NRC Office of Federal & State Materials and Environmental Management Programs, Division of Materials Safety and State Agreements following timely submittal of the application for renewal of License No. 19-23454-01E on September 28, 2012.

d. 10 CFR 32.210(c) provides the information needed for NRC review of sealed sources or devices for transfer to persons who are specifically-licensed. NIST will provide a description of how its manufacturing program meets these requirements.

Response:

The NIST Quality System for Calibration Standards, Calibration Sources, and Calibration Services

The RBPD Quality System describes the organizational structure, responsibilities, procedures, processes, and resources for the quality management of RBPD calibration services and standard reference material production.

The top level document, NIST-QM-I (all NIST relevant quality system documents can be found at http://www.nist.gov/pml/div682/qualitysystem.cfm), contains NIST-wide policies and procedures stemming (primarily) from the executive leadership of NIST, i.e., the NIST Director, Associate Director of Laboratory Programs, and individual Laboratory

Directors. Many of these policies and procedures govern all activities at NIST and thereby are controlling insofar as these activities are part of providing measurement services.

The second level document, IRD-QM-II (http://www.nist.gov/pml/div682/upload/RBPDQMIIv621.pdf), contains policies, guides, and procedures established and maintained by RBPD to meet its technical needs. The IRD-QM-II explicitly references NIST-QM-I and contains the quality-specific policies, guides, and procedures for RBPD service-related activities.

RBPD Guides are protocols for the operational aspects of the quality system. Guide examples include protocols for the management of complaints, nonconformances, and audits.

RBPD Procedures are the standard operating procedures for RBPD's measurement services, including standard reference materials.