

Safety Evaluation Report for the
Special Nuclear Material License SNM-362 Renewal Application
National Institute of Standards and Technology
Gaithersburg, Maryland

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I. INTRODUCTION

Special Nuclear material (SNM) License SNM-362 was first issued in 1960 by the Atomic Energy Commission to the National Bureau of Standards (renamed as the National Institute of Standards and Technology (NIST) in 1988). NIST is a federal agency within the Department of Commerce. NIST uses licensed materials for research, development, calibration, and testing activities. Under SNM-362, NIST develops, maintains, and disseminates national standards for ionizing radiation and radioactivity to support health care, industry, and homeland security at its Gaithersburg, MD, site.

License SNM-362 was renewed in 1979, 1985, 1991, and 1997. The current license, which also recognizes NIST as a Type A Broad Scope License, was scheduled to expire on July 31, 2007. On June 29, 2007, NIST submitted an application requesting renewal of license SNM-362 for a period of ten years, under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, to continue its authorization to possess and use SNM (Agencywide Documents Access and Management System [ADAMS] Accession No. ML071930318). SNM-362 has thus remained in effect, in accordance with 10 CFR 70.38(a), during the U.S. Nuclear Regulatory Commission (NRC) review of the renewal application. The NRC acknowledged receipt of the application on August 3, 2007 (ADAMS Accession No. ML072080154). Several Requests for Additional Information (RAIs), supplemental correspondence and revised License Renewal Applications (LRA) have been received since that time. These are cited in the text and listed in Section V., References.

In preparing the LRA, NIST followed the format described in Appendix C-1 of NUREG 1556, Volume 11 "Consolidated Guidance about Materials Licenses – Program Specific Guidance about License of Broad Scope" dated April 1999. Additionally, NIST used NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" to address requirements pertaining to SNM.

II. DISCUSSION

This Safety Evaluation Report (SER) documents NRC's review and findings with regard to NIST's LRA. The review of NIST's LRA included a review of the application dated June 29, 2007, as subsequently revised, the RAI responses, and the licensee's compliance history. The review included an evaluation of the applicant's overall organization, to include financial assurance, radiation protection, environmental protection, fire safety, and nuclear criticality safety programs. Details are included regarding the possession limits, authorized activities, place of use, technical qualifications, training, material control and security and compliance history.

1.0 General Information

1.1 Licensed Materials

The NRC staff reviewed the materials listed in NIST's LRA to determine whether the application included the information required in 10 CFR 70.22(a), including 70.22(a)(4). Item 5 of the LRA describes the type of material, the chemical and physical form, and the quantity of SNM to be possessed and used under the license. The quantity of SNM is greater than a critical mass (as defined in 10 CFR 70.4), and is SNM of low strategic significance (as defined in 10 CFR 73.2).

Table 1.1 lists the maximum quantities of SNM that may be possessed by NIST under SNM-362. SNM is identified by isotope, enrichment (where appropriate), chemical and physical form, and mass. Byproduct material that NIST is authorized to possess is identified by nuclide, chemical and physical form, and either mass or activity in curies.

Certain possession limits identified in this SER are modified from what was submitted in the original LRA. The requirements of 10 CFR 70.22(i) and 10 CFR 30.32(i) require a licensee submit an emergency plan for responding to a release of radioactive material, or demonstrate that the dose to a person offsite, due to a release of radioactive material does not exceed an effective dose equivalent of 1 Rem. NIST completed an analysis on October 25, 2012 and requested a reduction in its possession limits for specific byproduct radionuclides to ensure that any release of radioactive material would not exceed the dose limit requirement. The requested reduced possession limits, shown in Table 1.1 below, are incorporated into the renewed license.

Table 1.1 - Possession Limits

NUCLIDE	CHEM/PHYS FORM	POSSESSION LIMIT
A. Uranium enriched to less than 20 wt % in the U-235 isotope	Any form except UF ₆	
B. Uranium enriched to or greater than 20 wt % in the U-235 isotope	Any form except UF ₆	
C. Uranium-233	Any form except UF ₆	
D. Natural Uranium	D.1 Any soluble form except UF ₆ D.2. Any insoluble form except UF ₆	
E. Uranium Depleted in U-235 (Primarily U-238)	E.1. Any soluble form except UF ₆ E.2. Any insoluble form except UF ₆	
F. Any separated Uranium isotope other than U-233, U-235, or U-238	F.1 Any form except UF ₆	
U-232	F.2 Any form except UF ₆	
G. Uranium	As UF ₆	
H. Any isotope of Plutonium, except Pu-238	Any form	
H.1 Pu-236		

Table 1.1 - Possession Limits, cont.

H.2 Pu-239		
H.3 Pu-240		
H.4 Pu-241		
H.5 Pu-242		
H.6 Pu-244		
I. Plutonium	Sealed sources(e.g. PuBe)	
J. Plutonium enriched to more than 80% in the Pu-238 isotope	Any form	
K. Th-228	Any form	
L. Th-229	Any form	
M. Th-230	Any form	
N. Th-232 (Natural Thorium)	Any form	
O. Any Thorium other than Th-228, Th-229, Th-230, or Th-232	Any form	
P. Radium	Any form	
Q. Radium	Sealed sources (includes RaBe sources)	
R. Co-60	Sealed sources (e.g., irradiators)	
S. Cs-137	Sealed sources (e.g., irradiators)	
T. Po-210	Sealed sources	
U. Am-241	Sealed sources (e.g., AmBe)	
V. Cf-252	Sealed sources	
W. Sr-90	Sealed sources	
X. Pm-147	Sealed Sources	
Y. I-125	Sources sealed in titanium or stainless steel	

Table 1.1 - Possession Limits, cont.

<p>Z. Byproduct material</p> <p>Any nuclide of half-life less than 30 days</p> <p>Any nuclide of half-life more than 30 days except for the following nuclides:</p> <p>H-3</p> <p>Au-198</p> <p>Kr-85</p> <p>Cs-137, Mo-99, Tc-99m, and Xe-133</p> <p>C-14 and Co-60</p> <p>Rn-220, Rn-222</p> <p>I-120m</p> <p>Pa-230</p> <p>In-115</p> <p>I-124, I-126, I-129</p> <p>Pb-210</p> <p>Ac-227</p> <p>Am-241, 242m, and 243</p> <p>Bk-247, Es-254</p> <p>Cf-248, 249, 250, 251, 252, and 254</p> <p>Cm-242, 243, 244, 245, 246, 247, and 248</p> <p>Gd-149, Gd-152, Pa-231, and</p>	<p>Any form</p>	
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Table 1.1 - Possession Limits, cont.

Cm-250 Np-236 and Np-237 Sm-146 and Sm-147		
AA. Any byproduct material with Atomic Number 3 to 83 except for the following nuclides: I-129, Sm-146, Bi-210m	Any form- Neutron activated materials (e.g., research sample or sample container)	
BB. Irradiated Fuel U-235	Pellets	

1.2 Compliance History

Table 1.2 below summarizes NIST’s compliance history from 1997 to 2012. In this regard, the staff evaluated the history of NIST’s escalated enforcement actions (EAs). Such actions involve safety-significant violations that are categorized as Severity Level (SL) I, II, or III under the NRC’s Enforcement Policy. Over the last 15 years, the NRC has not issued an escalated EA to NIST. However, NIST has had a number of non-escalated EAs, which were either SL IV or non-cited violations during this time period. These are identified in Table 1.2 below.

Additionally, on June 9, 2008, a plutonium spill occurred at the NIST facility in Boulder, CO resulting in personal contamination to two laboratory workers. This is mentioned here, because the Boulder Facility reports to the Headquarters Facility in Gaithersburg, but operates under a separate license. NRC sent a special inspection team to independently assess the on-site radiological conditions and verify the adequacy of corrective actions. NRC issued the Boulder Facility Confirmatory Order, EA-09-142, identifying ten apparent violations of requirements. The Gaithersburg Facility was involved in the response and was assigned actions in the Confirmatory Order.

Table 1.2 – NIST Compliance History

Year	EA Number & Severity Level Violation	Event	Resolution
July 2001	SLV-IV EA-01-203	Inappropriate storage or lost source	Retraining provided
June 2008	EA-09-142 EN 10-010* Severity level N/A not identified as a result of arbitration	Plutonium contamination event at NIST’s Boulder facility – 10 apparent violations cited – one willful	ADR - further enforcement action not pursued - Confirmatory Order issued

July 2010	SLV-IV EGM 06-003	Failure to have a workable unauthorized intrusion system	System repaired and tested satisfactory
April 2010	Non-cited EN 10-042*	Inappropriate Pu disposal	Increased training and improved procedures
Sept. 2011	SLV-IV 2 violations	Unauthorized delivery and improper labeling of a shipment	Procedure changes and training provided

*Enforcement Notice (EN)

1.3 Security Orders

Table 1.3 below summarizes Security Orders sent to NIST during the period of their current license. Since the issuance of Amendment 3 to NIST's license on June 26, 2000, NRC issued two security orders requiring the implementation of interim security measures as a result of changes in the threat environment following the events of September 11, 2001. These security orders were issued to licensees that possess radioactive materials in quantities of concern. The first order, EA-05-090, required NIST to enhance protection of radioactive material, place greater controls on access to such material, and protect sensitive security-related information. The second order, EA-07-305, required NIST to perform fingerprinting and conduct a Federal Bureau of Investigation (FBI) identification and criminal history records check for any individual who is permitted unescorted access to licensed radioactive materials. This order was considered an enhancement to the trustworthiness and reliability requirements previously specified in the above "Increased Controls" Order.

Table 1.3 – Security Order History

Year	Security Order	Description	Resolution
2005	EA 05-090	Increased controls for certain radioactive materials	Complied
2007	EA 07-305	Finger printing for access to materials	Complied

EA-05-090 was issued January 14, 2005, calling for implementation by May 13, 2006. NIST responded to the Order as compliant on December 13, 2005. This was verified by inspection on June 13, 2007. EA-07-305 was issued on December 5, 2007, calling for implementation by June 2, 2008. NIST responded to the Order, stating compliance on January 29, 2008, designating a Trustworthiness & Reliability Official on May 22, 2008. Since the Orders were issued, inspections have been routinely conducted by NRC Region I, on at least an annual basis.

The staff has determined that NIST has met the requirements imposed by the orders discussed in this section. NIST has made numerous changes to its safety program and demonstrates a willingness to improve the safety and security of its operations following either a violation or receipt of a security order. Inspection results for the Gaithersburg facilities indicate that the performance of NIST is adequate in this area and supports renewal of the SNM-362 license.

1.4 Evaluation Findings

The staff has reviewed the materials list and compliance history for NIST. On the basis of the review, the NRC staff has determined that the applicant has adequately described the types, forms, and quantities, of licensed material to be authorized at NIST's facilities, in accordance with 10 CFR 70.22(a)(4). The staff finds the performance history of NIST to be compliant with the requirements of 10 CFR 70.22(a)(8) and the additional requirements imposed by the Increased Controls Orders as addressed in Section 1.3.

2.0 Organization and Administration

2.1 Regulatory Requirements

10 CFR 70.22(a)(6) through (8), 70.23(a)(2) through (4) and 10 CFR 33.13(c)(1) and (2) require an applicant to describe the technical qualifications of the staff, adequacy of proposed facilities and equipment, and procedures to provide adequate safety for workers, the public and the environment.

2.2 Authorized Activities and Place of Use

The NRC staff reviewed the site description, facilities and general purposes of the mission of NIST, provided in in Items 3, 6 and 9 in the LRA, to determine whether it addressed all the requirements of 10 CFR 70.22, "Contents of Applications," and 10 CFR 33.13, "Requirements for the issuance of a Type A specific license of broad scope." The staff conducted its review to determine whether the application included an adequate overview of the site facilities and a description of the activities for which the material would be used during the renewed license term.

NIST is authorized to use licensed material under SNM-362 at its facility located in Gaithersburg, Montgomery County, MD, about 25 miles north of Washington, DC. This NIST site is bordered to the east by Interstate 270 and Muddy Branch Road, to the north by Clopper Road, and to the west by Quince Orchard Road. The Gaithersburg site is fenced and encompasses 234 hectares (578 acres) on which there are 52 structures and facilities, including 23 laboratory buildings.

Item 3 identifies the specific locations on the NIST Campus where the activities conducted under this license will be conducted. Building 245 is the site of much of the primary activity of this license. The primary radioactive material laboratories and material storage areas are also located in building 245. The calibration facilities and irradiators are also located there. Buildings 215, 217, 227 and 235 also contain radiation facilities for use under this license.

Item 6 addresses the purpose for which the materials under this license are to be used. NIST develops, maintains, and disseminates national standards for ionizing radiation and radioactivity to support radioactivity assessment and radiation measurement and the study of radiation interactions and processes in materials. There are no authorizations for administration of radiopharmaceuticals, or exposures of human or animal subjects. This license authorizes the use of radiation sources for research and development, calibration and testing, and training activities.

Item 9 describes equipment and procedures. Hazard assessments are required of all proposals to use radioactive material. Assessments are developed by the investigator, who will submit

this for review by NIST's Gaithersburg Radiation Safety Division (GRSD). Assessments must consider things, such as dose and dose rate, potential for contamination, use of shielding, ventilation controls and posting requirements.

Special authorizations of limited scope and duration may be granted by NIST GRSD for the use of sealed or encapsulated sources at off-site locations for testing materials, instruments, and devices in field conditions. The SNM-362 license was amended in November 1999, to revise License Condition 9 to include the use of radioactive material at offsite locations under NRC jurisdiction and subject to the controls listed in Item 3 of the LRA, which requires the following:

- 1) GRSD review and approval of the proposed use;
- 2) NIST shall be responsible for the safe use of the radioactive material, which shall be controlled by an authorized and trained individual(s) who shall possess written operating instructions while engaged in the project;
- 3) Written operating instructions shall include a hazard assessment, hazard mitigation plan, source security and control instructions, and incident response plan;
- 4) Source or containment integrity shall be verified by appropriate testing for contamination prior to utilization;
- 5) Use of devices shall conform to the manufacturer's recommendations, operating procedures, and the associated device specific license requirements. Such devices may include but are not limited to lead-in-paint detectors, density gauges, moisture gauges, explosives detectors, or similar devices;
- 6) For sources not incorporated into a manufactured device, the total quantity of radioactive material for a single authorized use shall not exceed 100 times the activity listed in 10 CFR 20, Appendix C, or, for those radionuclides not listed in Appendix C, may not exceed 100 microcuries of activity;
- 7) During use of the radioactive material, the area shall be controlled by the authorized and trained individual(s) to ensure the dose to members of the public shall not exceed 2 millirem in one hour or 100 millirem in one year; and
- 8) Transportation of the radioactive material to and from the use location shall be conducted in accordance with all applicable U.S. Department of Transportation (DOT) requirements.

2.3 Organization

The NRC staff reviewed the organization of NIST to determine if NIST's management and staff are qualified by reason of training and experience to use the material for the purposes requested in accordance with 10 CFR 70.22(a)(6) and 10 CFR 70.23(a)(2). This review evaluated whether management policies provide reasonable assurance that the licensee plans, implements, and controls site activities in a manner that ensures the safety of workers, the public and the environment. These findings are discussed below.

Item 7 of the LRA describes the organizational responsibilities and authority for the radiation safety program.

2.3.1. NIST Director. As the chief executive at NIST, the NIST Director has the ultimate responsibility for radiation safety. The responsibilities assigned to the Director are:

- 1) Establishing and maintaining an effective ionizing radiation safety program;
- 2) Appointing members of the Ionizing Radiation Safety Committee (IRSC), subject to NRC license requirements;
- 3) Providing direction to the Chief Safety Officer (CSO) and IRSC, as necessary;
- 4) Providing executive leadership on issues involving the status of the Gaithersburg site with regard to worker safety, regulatory compliance, and environmental impacts; and
- 5) Reviewing IRSC recommendations and directing action on those recommendations as necessary to ensure radiation safety and regulatory compliance.

2.3.2 Chief Safety Officer. The NIST CSO reports directly to the NIST Director and is responsible for:

- 1) Overseeing the establishment, implementation, and maintenance of ionizing radiation safety program at NIST supporting the SNM-362 NRC license; and
- 2) Submitting applications for renewals of and amendments to NRC License Number SNM-362 pursuant to IRSC review and approval.

2.3.3. Ionizing Radiation Safety Committee. The IRSC provides oversight of the operations and activities of NIST's radiation safety programs but does not include the operations and activities related to the NRC Test Reactor License (TR-5). A minimum of five voting members shall serve on Committee, to include a designated Chair and Vice Chair. There are five *ex officio* positions to the Committee, to include the RSO. The RSO may not serve as Chair or Vice Chair. Additional members are appointed by the NIST Director. Members with full voting rights must be full-time Federal employees. Members of the IRSC shall have, at a minimum, a Bachelor of Science degree or equivalent professional training in their respective fields of expertise, and at least two years of relevant experience. The primary responsibilities of the IRSC are:

1. Approving requests for the acquisition and use, or changes in use, of radioactive material, Source Users, Source Custodian, and storage locations (i.e., Radiation Facilities).
2. Approving proposed program changes and revisions to procedures that are within the scope of the license approved by the NRC, without amendment of the license. Any such changes or revisions shall be documented and shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.
3. Reviewing reportable occurrences at NIST, and
4. Conducting an annual review of the radiation safety program content, implementation and program effectiveness through either an internal or external audit.

The IRSC also provides the RSO with independent advice and oversight for the ionizing radiation safety program at NIST Gaithersburg. This description meets the requirements of 10 CFR 33.13(c)(1).

2.3.4. Radiation Safety Officer. The NIST Gaithersburg RSO serves as the SNM-362 license manager and as the point of contact with the NRC. The RSO is responsible for managing the radiation safety program and all aspects of the utilization of ionizing radiation sources. The RSO has the authority, as delegated by the NIST Director, to meet his responsibilities and immediately stop operations that may (1) compromise the health or safety of NIST employees and non-NIST personnel, (2) have an adverse impact on the environment or public, or (3) result in non-compliance with NRC, State or local requirements.

The NIST Gaithersburg RSO must be certified in Health Physics by the American Board of Health Physics or must have at least a Bachelor's degree in a science or engineering field and have at least five years of professional-level experience in applied Health Physics. This description is consistent with the requirements of 10 CFR 33.13(c)(2).

2.4 Evaluation Findings

The regulatory basis for the review of NIST's qualifications is contained in 10 CFR 70.22(a)(6) through (8), 70.23(a)(2) through (4) and 10 CFR 33.13(c)(1) and (2), which requires the applicant to be qualified by reason of training and experience to use the radioactive materials for the proposed uses. In Item 7 of the LRA, NIST described its organization and management policies for providing adequate management for the safe operation of the facility. The staff concludes that NIST has an acceptable organization and administrative policies and sufficient competent resources to provide for the safe operation of the facility. Staff further concludes that the NIST RSO and IRSC member minimum education and experience requirements are adequate prerequisites for their positions and responsibilities. The staff finds that NIST management and staff are qualified by reason of training and experience to use the material for the purpose requested in accordance with 10 CFR 70.22(a)(6) through (8), 70.23(a)(2 and (3), and 10 CFR 30.33(a)(2) and (3). The following license conditions will be retained in the SNM-362 license:

9. Authorized place of use: The licensee's existing facilities at Gaithersburg, Maryland, and offsite locations that are under NRC jurisdiction and that are subject to the provisions listed in NIST's license renewal application in Item 3, "Offsite Locations."
10. Authorized Use: For use in accordance with statements, representations, and conditions of the licensee's renewal application dated June 29, 2007; and revised on February 29, 2008; June 24, 2010; March 23, 2011; and June 5, 2013

While NIST has had an established IRSC, the licensee established additional administrative controls and committee requirements, in accordance with Appendix E-1 of NUREG-1556, Vol. 11, to obtain increased flexibility in decision making to make changes within the scope of their license, and thus eliminating the need for some license amendments. NIST formally requested this authority in the LRA. The staff finds this consistent with NRC guidance and the following license condition will be added to the renewed license:

19. The Ionizing Radiation Safety Committee (IRSC) shall meet the requirements of 10 CFR 33.13(c) including the review, approval, and recording of safety evaluations of all proposed new uses of byproduct material prior to use of the byproduct material.

3.0 Integrated Safety Analysis

The NRC staff reviewed the LRA to determine whether NIST was required to provide Integrated Safety Analysis (ISA) Summary information, pursuant to the provisions in 10 CFR Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material." Staff determined that Subpart H requirements are not applicable to NIST because its proposed activities for which the SNM would be used are not within the scope of 10 CFR 70.60.

4.0 Radiation Protection

4.1 Regulatory Requirements

The regulatory requirements for this review of radiation protection (RP) are contained in 10 CFR 70.23(a)(3)-(4) which requires that the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property; and that the applicant's proposed procedures to protect health and to minimize danger to life or property are adequate. Other requirements include 10 CFR 19.12, "Instruction to Workers;" 10 CFR 19.13, "Notifications and reports to individuals;" and 10 CFR 20, "Standards for Protection Against Radiation."

4.2 Radiation Protection Program Overview

The staff conducted this review to determine whether the RP program described in the NIST LRA is adequate to protect the radiological health and safety of workers and to comply with the associated regulatory requirements in 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, and 10 CFR Part 70. SNM-362 license is a Type A broad scope license as described in 10 CFR 33.11(a). Such licenses can be renewed if the licensee meets 10 CFR 33.13(c)(3), which includes specific requirements for radiation safety committees to oversee the use of byproduct material, and such committees must review and approve safety evaluations of proposed new uses of byproduct material. The LRA identified several changes to the program:

- 1) The RP program has been repositioned in the NIST organization, such that the RSO now reports to the Chief Safety Officer who reports directly to the NIST Director. Previously the RSO was further removed from the Director. .
- 2) The IRSC now requires participation of management on the committee and its responsibilities have been broadened to provide for greater oversight of research activities involving radiation safety.
- 3) Training for individuals using materials under this license has received increased emphasis, commensurate with the employee's role within the program, to include testing.
- 4) A formal Hazards Assessment is now required prior to new uses of radioactive material. Included in the assessment are consideration of dose rates to individuals as well as the public, potential contamination and effluent releases. Concepts of As Low As Reasonably Achievable (ALARA), such as use of shielding, ventilation controls, and contamination controls are evaluated.

- 5) Proposals to use radioactive material on and off the Gaithersburg site are reviewed and approved by the IRSC and GRSD. The NIST staff is required to submit and obtain approval for proposed uses of radioactive material. Only trained and authorized individuals may use the material in accordance with written operating instructions.

4.3 ALARA Program

NIST has a stated policy to conduct all radiation research activities using ALARA principles. The NIST Director has committed to maintaining an effective ionizing radiation safety program. The following are commitments identified in the LRA:

- 1) Acquisition of radioactive materials, or new uses of materials on the NIST license, are approved by the IRSC. Research is conducted with written, approved procedures, in accordance with 10 CFR 20.1101(b).
- 2) Proper engineering controls are implemented for all research involving radioactive materials. Hazard assessments are conducted and documented, to include dose and dose rates, contaminations controls, effluent releases and an evaluation of the need for ventilation controls.
- 3) The RSO is integral to all hazard assessments and mitigation planning conducted. He is centrally involved in making recommendations for proposed research and implementing corrective action where necessary.
- 4) Any individual who may potentially receive more than 100 millirem in association with the work carried out at NIST is trained, commensurate with their level of involvement with the program. A significant part of the training includes the principles and tools of ALARA, as well as the requirements of 10 CFR 19.12.
- 5) NIST commits to regular review of their radiation safety program. In addition to annual review conducted by the IRSC, a quarterly audit of the radiation safety program is conducted by the GRSD staff. This includes an evaluation of personnel radiation exposures, effluent releases, assessments of security and posting, audits of processes of Source Users and Custodians and development of metrics for review by the IRSC.
- 6) All NIST staff who, in the course of their work, could potentially receive greater than 100 millirem will be monitored for occupational radiation exposure.

NIST commits to ensuring that radiological activities are carried out in accordance with ALARA principles. All radiological activities at the facility undergo assessment by the GRSD staff to evaluate key ALARA concepts such as time, distance, and, shielding. Monitoring is conducted on any individual likely to receive above 100 millirem. A result above this limit requires an investigation and evaluation of corrective actions, if appropriate. The IRSC will monitor and report ALARA progress as part of the annual report to the NIST Deputy Director. The RSO will have primary responsibility to ensure ALARA practices are incorporated into all safety evaluations. The staff finds that these commitment to an effective ALARA program are acceptable because the procedures are based upon sound radiation protection principles to

achieve occupational doses and doses to members of the public that are ALARA, as required by 10 CFR 20.1101(b).

4.4 Commitment to Written Procedures

Item 7 of the LRA states that the IRSC is responsible for reviewing any new requests or changes in use of radioactive materials. The IRSC will approve proposed program changes and revisions to procedures that are within the scope of the license. These are items that would not require an amendment submitted to the Agency for approval. Hazard assessments are performed on requests for the acquisition and use of radioactive materials as described in Item 9 of the LRA. The assessment evaluates: a) the hazards associated with each radionuclide, and b) the planned RP measures. The radioactive material is not released to the Source Custodian until the protocol receives approval. Use of new material or new procedures is approved by the IRSC once the hazard assessment has been completed and reviewed by the RSO. The staff finds these commitments acceptable because the applicant's proposed procedures to protect health and to minimize danger to life or property are adequate and in accordance with 10 CFR 20.1101(b) and 10 CFR 70.23(a)(4).

4.5 Training

As described in Item 8 of the LRA, NIST requires that appropriate training is provided to individuals likely to receive more than 100 millirem of occupational exposure in a year. All such individuals receive training in accordance with 10 CFR Part 19.12. The extent of training is commensurate with the individual's workplace and specific duties. Access to portions of the facility by a single individual is controlled and requires prior GRSD training on facility specific and internal procedures. Trainees are evaluated on their understanding of the instructional material, and the results are kept on record. All individuals authorized to work independently with licensed radioactive material receive biennial refresher training, and irradiator workers receive facility specific annual refresher training. The staff finds that these training commitments in the LRA meet the requirements of 10 CFR 19.12, and are therefore adequate. Additionally, staff finds records are kept in accordance with 10 CFR 20.2110.

4.6 Ventilation Protection Program

Item 9 of the LRA states that hazard assessments are conducted for all work involving radioactive material at NIST. In addition to radiation considerations, such as dose rate and contamination, ventilation controls are evaluated as necessary, e.g. where work with unsealed material might be used. In these types of examples, consideration for room or local ventilation is evaluated, as well as filtration. NIST primarily uses engineering controls to limit airborne exposure and does not currently perform work requiring respiratory protection as a means of controlling exposure to airborne radioactive material. Item 9 of the LRA discusses the use of chemical fume hoods or other forms of local exhaust ventilation. The hoods may be configured with HEPA filters as required when source term analysis or measurement indicates the need for filtration to ensure effluent control. The hoods are monitored quarterly to ensure face velocities remain at a minimum of 80 linear feet/minute. Hoods which fail to meet the required face velocity are taken out of service and operations suspended until corrective action is taken. The staff finds the respiratory controls commitments are acceptable to control the concentration of radioactive material in the air, thereby meeting the requirements of 10 CFR 20.1701.

4.7 Radiation Survey and Monitoring Program

4.7.1. Instrumentation. Item 10.2 of the LRA describes NIST's instrument servicing and calibration program. This includes portable radiation survey and surface contamination equipment, as well as fixed personnel contamination stations. NIST will calibrate and maintain instruments in accordance with manufacturer's instruction and maintain calibration on an annual basis. Calibrations will be performed with NIST-traceable standards and evaluated at 20% and 80% of each scale or decade. Instruments that cannot be calibrated with +/- 20% of the expected value will be removed from service. The staff reviewed this program and finds it acceptable, meeting the requirements of 10 CFR 20.1501(a) and (b). Records of calibrations will be maintained for three years in accordance with 10 CFR 20.2103(a).

4.7.2. Dosimetry. Item 10.4 of the LRA describes the personnel monitoring program for NIST. GRSD provides National Voluntary Laboratory Accreditation Program (NVLAP) accredited dosimeters to individuals likely to exceed 100 millirem Total Effective Dose Equivalent (TEDE) as discussed in Item 10.4 of the LRA. Extremity dosimetry is provided for tasks where there is a potential for Shallow Dose Equivalent (SDE) exposure. Unsealed radioactive material will be handled inside exhaust ventilation hoods to minimize internal occupational radiation exposures. Bioassay measurements will be conducted on individuals with a potential for internal exposure. Personnel monitoring equipment is checked annually and maintained consistent with American National Standards Institute (ANSI) standards and manufacturing specifications. This complies with the requirements of 10 CFR 20.1501(a) for the use of accredited dosimetry and 10 CFR 20.1502(a)(1) for personnel monitoring requirements.

4.7.3. Facility Surveys. Item 10.7 of the LRA provides the description of the NIST program for completion and documentation of facility surveys for radiation or contamination, as appropriate. Criteria have been developed and approved by NIST, which schedule survey frequency, dependent on the use of the facility and the potential dose rates. Contamination control or threshold tables have been constructed to dictate posting requirements, as necessary. All posted facilities are surveyed at least annually. In addition, NIST conducts and documents environmental monitoring on the NIST grounds as a means of demonstrating compliance with dose and dose rate limits for members of the public. The staff has reviewed all elements of the survey and monitoring program and find that it is an acceptable method to monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits in 10 CFR Part 20 as required by 10 CFR 20.1502, and sufficient to meet the records requirements in 20.2103.

4.8 Source Control and Accountability

Inventory and control of licensed SNM, Source Material, and Byproduct Material from outside suppliers is described in Item 10.3 of the LRA. Acquisition of materials shall be reviewed by the RSO or designee and approved by the IRSC. Proposals to acquire sources shall be reviewed and approved or rejected based upon evaluation of issues such as:

- License limits and conditions;
- Intended radioactive material utilization and protocols;
- Facility and equipment compatibility;
- Source Custodian training, and skills;
- Source User training, and skills;
- Hazard analysis and control safety requirements;
- Dosimetry and monitoring requirements; and
- Inventory control, transfer, waste disposal, and effluent or disposition considerations.

Item 10.3 requires GRSD will maintain inventory records for unsealed licensed sources with activity greater than or equal to 10 CFR 20, Appendix C quantities and all sealed sources requiring leak testing. Source Custodians will maintain inventory records of, and conduct an annual physical inventory for, all sealed and unsealed licensed sources under their responsibility. Source Custodians will also comply with applicable shipment, transfer, and waste disposal requirements for all sealed and unsealed licensed sources under their responsibility.

Item 7 of the LRA states the IRSC will review and for approve all proposed acquisition and new uses of radioactive materials, to include Source Users, Source Custodians, and storage locations. Source Users are those investigators who will be handling and using radioactive material in their work. Responsibilities include completing a hazard assessment for radioactive material under their purview as well as authorizing the use of such material by a Source User. The Source Custodian also is responsible for maintaining and reporting an semi-annual inventory of radioactive material to the RSO.

Sealed sources will be tested for leakage and contamination semiannually as stated in Item 10.7 of the LRA. Any sealed source in storage must be leak tested prior to usage or removal from storage. Leaking sources are withdrawn from use for decontamination and repair. In NIST's RAI response dated November 16, 2012, NIST stated that sealed sources stored for 10 years or more that require leak testing will be tested as described in the model leak test program published in Appendix T of NUREG-1556, Volume 11. For sealed sources stored for 10 years or more, leak testing will be done before such sources are used. The following license condition will be added to ensure that the NIST meets this standard as follows:

20. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

Item 10.3 of the LRA states the NIST SNM accountability office administers the inventory and reporting program for SNM. NIST will maintain an SNM inventory and reporting program consistent with the requirements in 10 CFR 74.13, and continue to conduct physical inventories of its SNM and maintain the required records in accordance with 10 CFR 74.19. NIST shall report the transfer and receipt of SNM, consistent with the requirements in 10 CFR 74.15.

The general performance objectives in 10 CFR 74.31(a)-(d) to submit a formal MC&A plan for NRC approval, do not apply to NIST, because the quantity of SNM of low strategic significance (LSS) that NIST is authorized to possess is below one effective kilogram. In accordance with 10 CFR 74.31(a), the one effective kilogram calculation does not include sealed sources of SNM, and thus the 450 grams of sealed plutonium sources which NIST is authorized to possess is not considered in the calculation.

The NRC staff reviewed the information and commitments provided by NIST in the LRA. Based on NIST's commitments, the staff concludes that NIST will maintain SNM inventory and reporting requirements in accordance with 10 CFR 74.11, 10 CFR 74.13, 74.15 and 74.19 and that the NIST procedures are therefore acceptable. The staff has reviewed the program for material control and accountability and finds that it establishes appropriate administrative procedures to assure the control of procurement and use of byproduct material, thereby meeting the it acceptable and meets the requirements of 10 CFR 33.13 (c)(3)(i).

4.9 Radiological Accidents and Emergency Response

The emergency management plan requirements are in 10 CFR 30.32(i) and 10 CFR 70.22(i) and state that licenses authorizing radioactive material exceeding certain thresholds must either (1) submit an emergency plan, or (2) submit 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. The LRA in Item 10.6 under “Radiological Emergencies” referenced a 1992 NIST evaluation showing that the maximum dose to a person offsite would not exceed these levels. The evaluation was reviewed and approved by NRC on December 10, 1993.

On September 10, 2012, staff requested that NIST re-evaluate the potential for offsite dose to ensure that no requirement for an Emergency Plan still exists. In its RAI response dated October 25, 2012, NIST submitted an updated evaluation using the possession limits above, consistent with the NUREG-1140 Methodology, and included demographic changes in the Gaithersburg area surrounding the NIST facility. The updated evaluation showed 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. Staff has verified that an emergency management plan is not required.

NIST has committed to Appendix R of NUREG-1556, Vol. 11, which presents the model procedure for response of a facility to spills, fires, explosions and major emergencies. Fire Protection is further addressed in Section 6.0 of this SER. Staff has reviewed the NIST program evaluation and finds it establishes that the maximum dose to a member of the public offsite due to a release of radioactive materials would not exceed the limits outlined in the regulations, and thus, NIST is not required to have an Emergency Plan, meeting the requirements of 10 CFR 30.32(i)(1)(i) and 70.22(i)(1)(i).

4.10 Waste Management

Item 11 of the LRA describes the NIST waste management program, that includes procedures for handling, characterization, minimization, storage and disposal of radioactive wastes. Potentially contaminated or radioactive materials are collected and sorted according to physical characteristics, such as liquid or dry and associated half-life. GRSD trains individuals in the appropriate collection and documentation of radioactive waste to protect the health and safety of the public and the environment.

Item 11 in the LRA states that NIST primarily uses a Decay-in-Storage method of waste management for materials with a half-life of less than 120 days, in accordance with the “Revised Decay-In-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material”, RIS 2004-017, revision 1. NIST provided a description of its procedures for record keeping of its decay-in-storage program in its RAI response dated October 25, 2012. Its program includes the date containers are sealed, the date of disposal, the survey instrument used, background radiation level, the radiation level measured at the surface of each waste container, and the individual who performed the disposal procedure. NIST keeps these records for 3 years. These procedures are consistent with the requirements of 10 CFR 20, Subpart K and the Model Guidance of Appendix V of NUREG-1556, Vol. 11. The staff finds that the methods of waste management described in the application will protect the health and safety of employees, the public and the environment, and meet the requirements of 10 CFR 20, Subpart K.

4.11 Records and Audits

Item 10.1 of the LRA describes the audit or self-review program for NIST. GRSD conducts routine reviews of the radiation protection program at NIST, to include surveillance monitoring of work, reviewing dosimetry results and trends and compiling program metrics for the use of the IRSC. GRSD shall conduct quarterly audits of those Radiation Facilities approved and posted for use or storage of licensed radiation sources that have significant potential for radiation exposures or effluent releases in excess of 10% of the applicable limits. Audits shall include an assessment of radiological conditions and a review of security, posting, and labeling. Where feasible, such audits include observation and discussion of work practices with Source Custodians and/or Source Users. Results of these audits shall be documented and any identified needs for corrective action found during the audits shall be transmitted to Source Custodians or other appropriate individuals. GRSD shall review and document program actions, surveillance monitoring, dosimetry trends, and other program metrics for each calendar year as the data required by the report become available. This report shall be submitted to the IRSC.

The Ionizing Radiation Safety Committee shall ensure that representatives, other than GRSD staff, audit the radiation safety program annually, reviewing performance, quality of operations, and targeted aspects of protocols and procedures. The audit results shall be reported to the IRSC. The IRSC shall report any findings to appropriate NIST management.

Item 10.1 requires that NIST will maintain records of the RP program (including program provisions, audits, and reviews of the program content and implementation), and radiation survey results (air sampling, bioassays, external-exposure data from monitoring of individuals, internal intakes of radioactive material). Requirements for records of various activities are found in the LRA Item 5 for financial assurance, Item 8 for training, Item 10.1 for audits, Item 10.2 for monitor calibration, Item 10.7 for results of source leak tests, and Item 11 for annual effluent records.

Staff has reviewed the reporting and record commitments of the LRA are adequate to meet the reporting and record requirements of Subparts L and M of 10 CFR 20. Staff finds that the audit program is sufficient to ensure compliance with the requirements of Subparts L and M of 10 CFR 20. The audit program meets the requirements of 10 CFR 20.1101(c) and 10 CFR 33.13(c).

4.12 Evaluation Findings

The regulatory requirements for this review of RP are contained in 10 CFR 70.23(a)(3)-(4) which requires that the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property; and that the applicant's proposed procedures to protect health and to minimize danger to life or property are adequate. Other requirements include 10 CFR 19.12, "Instruction to Workers;" 10 CFR 19.13, "Notifications and reports to individuals;" 10 CFR 20, "Standards for Protection Against Radiation," 10 CFR 33.13(c) "Requirements for the Issuance of a Type A specific license of broad scope," and 10 CFR 74 Subpart B "General Reporting and Recordkeeping Requirements." The applicant has committed to maintaining its RP program that will continue to include the following elements:

- 1) documentation of an acceptable RP program,
- 2) RP training for all personnel who have access to restricted areas;
- 3) an effective documented program to ensure that occupational radiological exposures are ALARA;

- 4) approved written RP procedures for RP activities;
- 5) an organization with adequate qualification requirements for the RP personnel;
- 6) a radiation survey and monitoring program that includes requirements for controlling radiological contamination within the facility and monitoring of external and internal radiation exposures; and
- 7) a program to control airborne concentrations of radioactive material with engineering controls as specified in the hazard mitigation plan;
- 8) programs to maintain records.

The staff finds that the radiological risk posed by the byproduct material, source material and SNM will be adequately addressed by the NIST RP Program described in the LRA. The RP safety program procedures are sufficient to provide reasonable assurance of compliance during the term of the renewed license. The NRC staff concludes there is reasonable assurance that during the renewed license term the applicant's radiation protection program will meet the applicable requirements of 10 CFR Parts 19, 20, 33, 70 and 74 as discussed in Section 4.1.

5.0 Nuclear Criticality Safety

5.1 Regulatory Requirements

The regulatory basis for the review of nuclear criticality safety (NCS) is contained in 10 CFR 70.22, "Contents of Applications;" 10 CFR 70.23, "Requirements for the Approval of Applications;" 10 CFR 70.24, "Criticality Accident Requirements;" and 10 CFR 70.52, "Reports of Accidental Criticality."

5.2 Staff Review and Analysis

NIST has submitted a LRA to possess SNM of various forms, including enriched uranium and plutonium. These materials were identified in item 5 of the LRA for evaluation of NCS. Item 10.7 in the LRA contains a description of criticality controls used to meet the requirements of 10 CFR 70.22(a)(8), which mandates procedures to avoid and mitigate accidental criticality events so as to protect health and minimize danger to life or property. NIST states that those discrete sources that exceed the Nuclear Material Management and Safeguards Systems (NMMSS) reporting mass will be segregated into three reporting areas in three separate buildings. The source acquisition approval process will include checks to verify and limit source inventories and use locations. This will ensure no single location can aggregate a critical mass of SNM. NIST committed to adequate practices to ensure that, by applying the sum of the fractions rule, no combination of fissile uranium and plutonium exceeding 80 percent of a critical mass, as specified in 10 CFR 70.4, shall be used or stored at any single location. These practices provide adequate assurance that the requirements of 10 CFR 70.22(a)(8) are met.

In Item 7 of the LRA, NIST states the NIST Director has the ultimate responsibility for providing executive leadership on issues involving compliance with regulatory requirements and the conditions of the license. The IRSC provides oversight of the operations and activities of NIST's radiation safety programs and the RSO's responsibilities include establishing and updating guidance, procedures, instructions, and other requirements to promote regulatory compliance.

NIST is authorized to possess a limited amount of SNM as enriched U235 and plutonium. NIST has committed to using and storing its SNM in separate locations as described above. Thus, the NRC staff concludes that there is a low probability of a criticality accident at NIST's Gaithersburg facility. The NRC staff concludes that the handling, storage, and use of the SNM do not pose a credible risk that a nuclear criticality event will occur. Based on this information as well as observations during the site visit, NIST has met the requirements for 10 CFR 70.22(a)(6) and 70.23(a)(2) with respect to criticality safety.

5.3 Evaluation Findings

As discussed above, the staff finds that the NCS program at NIST as described in the LRA Items 7 and 10.7 provide assurance that the licensee will have in place a staff that is qualified to develop, implement and maintain the NCS program in accordance with the NCS program objectives for safety. Based on the low mass of the individual SNM sources, the laboratory segregation, inventory control, and storage requirements, the NIST procedures will be sufficient to assure compliance with the NCS protection requirements of 10 CFR 70. The staff's review finds that the applicant's program provides reasonable assurance for the protection of public health and safety and the environment, and meets the requirements of 10 CFR 70.22(a)(8).

6.0 Fire Protection

6.1 Regulatory Requirements

The regulatory basis for the fire safety review can be found in 10 CFR 70.23(a)(3) and 10 CFR 70.23(a)(4). In the LRA, NIST submitted an exemption request from 10 CFR 36.27(a) and (b). Title 10 CFR 36.27(a) requires that a panoramic irradiator have heat and smoke detectors, which activate an audible alarm and return the sources to their fully shielded position. This had originally been approved for exemption on November 23, 1999. The request for exemption from 10 CFR 36.27(a) was withdrawn on August 19, 2013, with NIST submitting a statement of full compliance and no need of the exemption. Title 10 CFR 36.27(b) requires that the radiation room must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. This exemption is addressed in detail in section 11.3.

6.2 Staff Review and Analysis

NIST's LRA provides a description of its fire protection program in Item 10.6. The licensee's facility complied with the applicable building code regulations for Federal buildings at the time of construction. Installed fire protection systems include smoke detection, heat detection, manual fire alarm pull-boxes, standpipes, and sprinkler systems in a few areas of moderate fire load.

Portable fire extinguishers are deployed in all buildings in accordance with industry standards. An underground fire main supplied by the municipal water system provides fire protection water to the facility. Fire hydrants are located throughout the facility in accordance with industry standards. Adequate separation is provided between laboratories through continuous (slab to slab) block walls. Building renovations and building operations are reviewed by the NIST Safety Office for code compliance

The facilities authorized for use herein are monitored by a fire detection system that alarms in Physical Security and at the on-site Fire Station. Additional manual pull fire alarm boxes are placed throughout NIST's facilities authorized for use herein in accordance NIST Fire Protection Group (FPG) recommendations. NIST's facilities are equipped with centrally monitored fire

detection systems. NIST has an established FPG at the Gaithersburg Facility and provides fire emergency training as a part their ongoing training program discussed in Item 8 of the LRA.

The applicant has established facility fire protection satisfying the appropriate acceptance criteria in Chapter 7 of NUREG 1520, "Standard Review Plan for the Review of a license renewal application for a Fuel Cycle Facility". Fire prevention, inspection, testing, and maintenance of fire protection systems, and the qualification, drills, and training of facility personnel are in accordance with applicable National Fire Protection Agency (NFPA) codes and standards.

6.3 Evaluation Findings

The staff concludes that the applicant's fire protection capabilities meet the appropriate criteria in Chapter 7 of NUREG 1520. The staff concludes that the applicant's proposed equipment, facilities, and procedures provide a reasonable level of assurance that adequate fire protection will be provided to meet the safety performance requirements of 10 CFR 70.23(a)(3) and 10 CFR 70.23(a)(4).

7.0 Decommissioning Financial Assurance

The NRC staff conducted this review to determine with reasonable assurance that the licensee will be able to decommission the facility safely and in accordance with NRC regulations. Nuclear facilities licensed under 10 CFR Part 70 are required to comply with financial assurance and recordkeeping requirements in 10 CFR 70.25, "Financial Assurance and Recordkeeping for Decommissioning." In addition, licensees must submit decommissioning plans for NRC approval in accordance with 10 CFR 70.38(g).

Financial assurance and decommissioning funding requirements are found in 10 CFR 70.22(a)(9) and 70.25, which require licensed nuclear facilities to establish adequate financial assurance to cover the estimated costs for site decommissioning, decontamination and reclamation. NIST is required by 10 CFR 70.25 to provide an acceptable financial assurance mechanism consistent with Section A.16 of Appendix A to NUREG 1757, Volume 3. In accordance with the requirements of 10 CFR 70.25 (e), NIST must also provide a certification of financial assurance consistent with Section A.2.4 of Appendix A to NUREG 1757, Volume 3. LRA Item 5 discusses the NIST commitment to meet the financial assurance and recordkeeping requirements.

As explained in responses to NRC's RAIs, NISTs' decommissioning cost estimate is based on costs of a third party contractor, does not take credit for any salvage value and includes a 25% contingency factor. NIST estimates that the cost to decommission the facility is \$6,592,276. From its previous DCE, the licensee has increased the period of long-term maintenance and surveillance for portions of the accelerator areas to 26 years. The costs associated with this increased long-term maintenance and surveillance have increased the DCE by \$3,468,195, which includes costs for surface shielding that will be installed during the long-term surveillance period. Relying on the DCE and responses to RAIs, the staff finds that the submitted DCE is based on reasonable and documented assumptions, and adequately estimates the cost, at this time, to carry out required decommissioning activities prior to license termination. As a government entity, NIST commits to seek funding from the appropriate budgetary authorities to cover the expenses at the time of initiating the license termination process. On the basis of the staff's review, NIST has demonstrated that the DCE in the amount of \$6,592,276 is consistent with NUREG-1757, Volume 3, and is acceptable.

The staff finds that the licensee's plans and financial assurance for decommissioning are in accordance with 10 CFR 70.25(e), 70.25(g), and 70.38(g) and is consistent with NUREG-1757, Volume 3. The NRC staff has evaluated the licensee's plans and financial assurance for decommissioning provide reasonable assurance of protection for workers, the public, and the environment during the renewed license term.

8.0 Environmental Protection

This review was conducted to determine whether the environmental protection measures proposed by NIST are adequate to protect public health and safety and the environment, as required by 10 CFR Parts 20 and 70. This chapter does not address whether NIST complied with the requirements of 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." The environmental review required by 10 CFR Part 51 is discussed in Chapter 12 of this SER.

NIST described its organization and management policies for providing adequate management for the safe operation of the facility in Item 7 of the LRA. The application describes an existing program which has been reviewed and inspected for many years. The application proposes no significant changes to the environmental protection program. Organizational and administrative elements describe responsibilities and associated resources for the safe operation of the facility. Proposals to use radioactive material on and off the Gaithersburg site are reviewed and approved by the IRSC and GRSD, as stated in Item 3 of the LRA. NIST commits to ensuring that radiological activities are carried out in accordance with "as low as reasonably achievable" (ALARA) principles.

Item 10.7 explains that NIST conducts and documents monitoring at appropriate locations within the NIST grounds and facilities as part of the documentation for demonstrating compliance with dose and dose rate limitations for members of the public. In correspondence dated October 25, 2012, NIST described its procedures for liquid and airborne radioeffluent monitoring. In Item 9 of the LRA, Unsealed Source Radiation Facilities, of its application, NIST states that gaseous and liquid effluents, if any, will be within 10 CFR Part 20 limits and will be subject to appropriate effluent monitoring and controls. For example, any laboratory operations determined to have significant potential for exceeding 10% of the 10 CFR 20, Appendix B, Table 2, release limitations shall be monitored on an as needed basis, and liquid effluents collected in holding tanks will be sampled to assure compliance with 10 CFR Part 20, Appendix B, limits prior to any release to the sanitary sewer. Item 11 of the LRA states that releases of liquid and gaseous radioeffluents shall be verified to be in compliance with the public dose limits specified in 10 CFR 20.1301 and in accordance with the requirements of 10 CFR 20.1302.

The applicant has developed a program to implement adequate environmental protection measures during operation, which measures include: (1) environmental and effluent monitoring, and (2) effluent controls to maintain public doses ALARA as part of the radiation protection program. The NRC staff concludes that the NIST program, as described in the license renewal application, is adequate to protect the environment and the health and safety of the public during the license renewal term, and complies with the applicable regulatory requirements in 10 CFR 20.1101, 20.1301, 20.2003, and those in 10 CFR Part 70, Subpart H.

9.0 Physical Protection and Physical Security

9.1 Regulatory Requirement. A review was conducted to determine that the LRA, as submitted on March 23, 2011, under the provisions of 10 CFR 70.22 and subsequent RAI responses dated June 5, 2013, as supplemented by the clarification of RAI responses received from the NIST

staff on July 16, 2013, were acceptable and provided reasonable assurance that the requirements for the fixed and in-transit physical protection of special nuclear material of low strategic significance (SNM-LSS) would be met. The regulatory basis for this review was to determine whether NIST's physical protection program and security programs meet the requirements of 10 CFR 70.22, 73.67, "Licensee fixed site and in transit requirements for the physical protection of special nuclear material of moderate and low strategic significance," which include the general performance objectives of 10 CFR 73.67(a)(1) and (2), and 10 CFR 73.67(f).

NIST is not subject to the 10 CFR 73.67(c) requirements to submit a physical security plan, because NIST does not possess SNM of low strategic significance in quantities of 10 kilograms or more. NIST does not possess SNM of moderate strategic significance, and is thus not subject to the 10 CFR 73.67(d) and (e) requirements. Based on its RAI response dated December 21, 2012, NIST does not transport SNM of low strategic significance and, therefore, is not subject to the requirements of 10 CFR 73.67(g).

The general performance objectives in 10 CFR 73.67(a) specify that facilities with SNM of low strategic significance must minimize the possibilities for unauthorized removal of SNM and facilitate the location and recovery of missing SNM. To achieve these objectives, NIST's physical protection and security management program provides for: (1) early detection and assessment of unauthorized access or activities by an external adversary within the controlled access area containing SNM, (2) early detection of removal of SNM by an external adversary from a controlled access area, (3) assure proper placement and transfer of custody of SNM, and (4) respond to indications of an unauthorized removal of SNM and then notify the appropriate response forces of its removal in order to facilitate its recovery. These specific areas are addressed below:

9.2. Unauthorized Access. NIST stated in its LRA in Item 10.6 that its physical security management program provides for ongoing security for early detection of missing material and assessment of unauthorized access through management controls of the storage and usage areas and security guards monitoring the facilities authorized herein. Early detection and assessment of the unauthorized removal of SNM by an external adversary is accomplished by intrusion systems that will alarm within the Controlled Access Area (CAA), a Category III Storage Area. Response procedures are in place and implemented to respond to alarms from the storage area. Police Services Group (PSG) responds to intrusion alarms within a short timeframe and performs an assessment based on the circumstances that exist. NIST also stated that its program provides for training on access and control of materials under their material control and accounting procedures and that it provides for proper handling and transfer through management controlled access.

9.3. Unauthorized Removal. Unauthorized removal of radioactive material including SNM-LSS is minimized through NIST's layered security methodology, described in a response to an RAI on June 5, 2013. Specifically, access is limited such that only personnel with the unescorted access and Trustworthiness and Reliability qualification will be allowed to enter a CAA. The CAA has suitable physical barriers as well as intrusion systems. NIST maintains a coordinated infrastructure involving GRSD, NIST Center for Neutron Research (NCNR), PSG and NIST Administrative personnel that fully supports the physical protection of material inventories requested in our license amendment application. The response to the RAI explains that NIST developed and implemented administrative controls, hardware and procedures to minimize the possibility for unauthorized removal of SNM.

9.4. Proper Placement. Item 10.6 of the LRA explains that proper placement and transfer of custody of SNM is achieved by NIST procedures that outline receipt from shipment; establishment of ownership; identification of authorized users and rooms; and ultimately transfer of custody outside of NIST after it has been determined that the SNM is no longer needed. While at NIST, radioactive material, including SNM-LSS, is inventoried on a semi-annual basis as specified in GRSD procedure to ensure the material is within the appropriate safety and security envelope.

9.5 Response Forces. According to Item 10.6 of the LRA, the PSG respond to indications of an unauthorized removal of SNM. PSG procedures detail response methods and, when applicable, notification of response forces and other support via a call down list. In the event of theft of SNM, GRSD staff is included in the call-down list for notification. The NIST physical protection system has elements of an on-site police force with offsite response capabilities and these forces have procedures in place to facilitate a response to all unauthorized penetrations or activities associated with the CAA.

Notification to NRC is outlined in the GRSD Security Plan and support procedures. Described therein is the type of communication, content and methodology for submission. The GRSD representative (in this case it would most likely be the RSO) would notify the NRC of an event involving physical security. NIST states in their response to an RAI on June 5, 2013, that copies of response procedures shall be retained as a record for three years after the close of period for which the licensee possesses the SNM under each license for which the procedures were established.

On May 6, 2013, NRC staff issued a RAI package that contained 25 separate RAIs regarding the LRA's description of the PSG. By letter dated June 5, 2013, NIST provided a response to the May 6, 2013, RAIs and clarified certain aspects of their LRA. The NRC staff noted that some additional clarification was needed and a follow-up meeting was held on July 16, 2013.

Based on this information, the staff concludes that the NIST physical security controls meet the general performance objectives of 10 CFR 73.67(a) and (f) because the controls will allow NIST to detect unauthorized access and activities within a controlled area, detect, respond to, and report the removal of SNM from a controlled area and assure proper placement and transfer of custody of SNM. The NIST notification process procedures adequately described the NRC notification protocols to be followed and the process for the establishment and maintenance of response procedures for dealing with threats of thefts or thefts of this material is outlined in GRSD's Security Plan. The staff finds that the security plans referenced in the LRA are clear and specific and in the proper format. As discussed above, the staff reviewed the NIST plans against the requirements of 10 CFR Part 73 and applicable security orders. The staff finds that these plans for the physical protection of Category III material at the NIST site provide reasonable assurance that NIST will continue to provide adequate protection during the license renewal term.

10.0 Transportation of Special Nuclear Material

The NRC staff conducted this review to ensure that the NIST LRA complies with the requirements in 10 CFR 73.67 (a) and (g) regarding physical protection of SNM in transit. The general performance objectives of 10 CFR 73.67(a) requires that each licensee possessing, uses or transports SNM of moderate or low strategic significance shall establish and maintain a physical protection system that will achieve the following objectives: (i) Minimize

the possibilities for unauthorized removal of SNM consistent with the potential consequences of such actions; and (ii) Facilitate the location and recovery of missing SNM.

In Item 10.8 of the LRA, NIST has an established security plan that would support the security of radioactive material in transit for SNM of Low Strategic Significance (LSS). NIST has not shipped SNM during this renewal cycle, but regularly transports byproduct material. The information in the GRSD Security Plan provides guidelines that would provide the basis for constructing detailed procedures necessary for the security and transportation of SNM of LSS, if so required.

The GRSD Security Plan describes the process to be followed for in-transit physical protection of the material, including any arrangements, agreed in writing, with a licensed shipper. The methodology for providing advanced notification to the receiver of any planned shipment of SNM-LSS, including mode of transport, estimated time of arrival, location of the nuclear material transfer point, name of carrier and transport identification is outlined in GRSD's Security Plan. Further, the plan describes how arrangements are made with regard to immediate notification of shipment arrival at its destination, or shipment that is either lost or unaccounted for after the estimated time of arrival at its destination. Information in the GRSD Security Plan is meant to provide guidelines to develop further detailed procedures for transport in a tamper-indicating sealed container, to verify the integrity of containers and seals prior to shipment, and for in-transit physical protection of material in accordance with 10 CFR 73.67(g)(3).

NIST maintains a coordinated infrastructure involving GRSD, NIST Center for Neutron Research (NCNR), PSG and NIST Administrative personnel that fully supports the physical protection of material inventories requested in the LRA. The staff has reviewed the commitments made and information provided by NIST in support of a transportation program for LSS SNM and find the program adequate and consistent with the requirements of 10 CFR 73.67 (g).

Based upon the review of NIST's LRA and subsequent changes, as submitted by letter dated June 5, 2013, as supplemented by the clarification of RAI responses, the NRC staff finds that NIST could meet the applicable requirements specified in 10 CFR 73.67, "Licensee fixed site and in-transit requirements for the physical protection of SNM of moderate and low strategic significance." Therefore, NRC staff finds that the NIST LRA is acceptable and provides reasonable assurance that the requirements for in-transit physical protection of SNM-LSS will be met.

11.0 Exemptions

11.1 General.

License SNM-362, Amendment 3, contained 8 exemptions, which were originally requested on May 20, 1998, and issued on November 23, 1999. The LRA submitted for license renewal on June 29, 2007 requested continuance of 2 of these original exemptions and a request for a new exemption. Subsequent correspondence dated March 5, 2013 requested continuation of three more of the original exemptions. The final list of exemptions requested is:

- The requirement in 36.23(b) for a backup access control alarm that must also alert another individual who is onsite of the entry to an irradiator.
- The requirement in 36.23(c) for activation of the alarm in the case of attempted personnel entry while the radiation monitor measures high radiation levels.

- The requirement in 36.27(b) that a room for a panoramic irradiator be equipped with a fire extinguishing system capable of putting out a fire with no one entering the room.
- The requirement in 36.31(a) that the key that activates the mechanism for exposing an irradiator source be attached to portable survey meter and the door to the radiation room require the same key
- The requirement in 70.24(a) to maintain a CAAS in each location where SNM is used or stored. This is the new exemption request.

11.2 Part 36 Irradiator Access Controls, 10 CFR 36.23(b) and 36.23(c).

11.2.1. Exemption Requests. These two exemption requests, which are continuations of exemptions, originally granted November 23, 1999, were requested in a March 5, 2013 correspondence from NIST. A review of the March request, along with a review of the purpose of the request, demonstrates no change is required or requested in licensee operations.

The requirement of 10 CFR 36.23(b) is for a panoramic irradiator to have an independent backup access control to detect personnel entry, and that upon detection of entry, cause the sources to return to their fully shielded position. In addition, the regulation requires that one other individual onsite be alerted of entry via this system. The 1999 TER, which analyzed the original exemption request, described the review of the systems of controls identified by NIST that were relevant to the requirements of 36.23(b) and concluded that NIST compensated with comparable safety measures and recommended authorizing the exemption if NIST armed the independent backup access control system when an operator was not present. The condition was imposed on the licensee as part of license condition 12 issued in 1999. The staff examined the request for continuation of the exemption which described the multiple interlocks and alarms for the irradiator facility. The alarm is in the local area of the irradiator facility, and not to another site on the NIST grounds (e.g. Fire Department).

The staff concurs with NIST's assessment that the cost of modifying the alarm system to install an additional alarm at a separate location would not enhance safety. The staff agrees that the system of interlocks and alarms identified in Attachment 1 to its March 5, 2013, request for continuation of the exemption and the requirement in the license condition to arm the independent backup access control system when an operator is not present provides a level of safety comparable to that called for by 10 CFR 36.23(b). Therefore, the staff agrees with the continuation of the exemption with the continuation of the associated requirement in the license condition to arm the independent backup access control system when an operator is not present.

The requirement of 10 CFR 36.23(c) is that a radiation monitor be integrated with personnel access door locks, such that attempted personnel entry while high radiation levels are present would activate an alarm. The 1999 TER, which originally analyzed this exemption request, also described the review of the systems of controls identified by NIST that were relevant to the requirements of 36.23(c). The TER concluded that NIST compensated with comparable safety measures and recommended authorizing the exemption if NIST continued to use an electrical interlock system pursuant to 35.615(b). The requirement to comply with 35.615(b) was imposed on the licensee as part of license condition 13 issued in 1999. The staff examined the request to continue the exemption which discussed the multiple interlocks and local alarms identified in Attachment 1 to its March 5, 2013 request. The staff concurs with NIST's assessment that the cost of modifying the alarm system to install an additional alarm at a separate location would not enhance safety. The staff agrees that the system of interlocks described in Attachment 1 to its

March 5, 2013 request for exemption along with continuation of the requirement to comply with 10 CFR 35.615(b) provides a level of safety comparable to that called for by 10 CFR 36.23(c).

11.2.2. Environmental Review. As discussed in Chapter 12 of this SER, pursuant to 10 CFR 51.22(c)(14)(v), renewal of materials licenses issued under 10 CFR Part 70 for research and development and for educational purposes is a category of actions which the NRC has determined does not individually or cumulatively have a significant effect on the human environment, and as such, this category of actions does not require environmental review or the preparation of an Environmental Assessment (EA). However, NIST has also requested these exemptions from specific NRC regulations and exemption requests require environmental review unless the exemptions themselves are also subject to categorical exclusion. Granting continued exemption request is an action categorically excluded from the need to conduct a further environmental review under 10 CFR 51.22(c)(25) provided that (i) there are no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; (v) there is no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve one of the nine types of requirements set forth under 10 CFR 51.22(c)(25)(vi), which include "(C) inspection or surveillance requirements."

An access control to detect personnel entry or a radiation monitor to detect high radiation levels, with both providing alarms in the case of detection, are systems that perform surveillance functions. The 10 CFR 36.23(b) requirement to have a personnel detection system and the 10 CFR 36.23(c) requirement to have a radiation detector are both surveillance requirements. Based on the compensatory measures NIST has committed to and the NRC's evaluation of these controls as discussed above, the staff finds that granting exemption from the 10 CFR 36.23(b) and (c) requirements would neither significantly change or increase the types or amounts of effluents released offsite; result in a significant increase in individual or cumulative public or occupational radiation exposure; result in a significant construction impact; nor result in a significant increase in the potential for or consequences from radiological accidents. Also, granting the exemption would not introduce a significant hazards consideration because there will be no criticality or criticality-related gamma or neutron radiation to detect resulting from the NIST research activities during the license renewal term, and such research activities will not individually or cumulatively have a significant effect on the human environment.

Because the NIST exemption requests fall within the categorical exclusion of 10 CFR 51.22(c)(25)(vi)(C), and neither an EA nor an EIS is required in connection with granting the requested exemption from 10 CFR 36.23(b) or 10 CFR 36.23(c). The staff has determined that granting continued exemption to 10 CFR 36.23(b) and (c) meets the criteria for categorical exclusion, neither of these actions having, individually or cumulatively, significant effect on the human environment.

11.2.3. Conclusion. Under 10 CFR 36.17(a), the NRC may grant exemptions from part 36 requirements as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest. For the reasons stated above, the staff concludes that the exemption requests discussed above meet the requirements of 10 CFR 36.17(a), and the request for a continuation of the exemption from 10 CFR 36.23(b) and 10 CFR 36.23(c), is granted. LCs 12 and 13 are being retained in the renewed license as follows:

12. Notwithstanding the requirements of 10 CFR 36.23(b), the licensee is exempt from the requirements that: (1) detection of entry, by an independent backup access control, while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard, and (2) the alarm must alert at least one other individual who is onsite of the entry. When an operator is not present the licensee shall arm the independent backup access control system identified in the licensee's letter dated March 24, 1999.
13. Notwithstanding the requirements of 10 CFR 36.23(c), the licensee is exempt from the requirements that attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in 10 CFR 36.23(b). The licensee shall comply with 10 CFR 35.615(b).

11.3 Part 36 Exemption Request and Environmental Assessment, 10 CFR 36.27(b) and 10 CFR 36.31(a)

11.3.1. Exemption Request. As a part of NIST's license renewal request, NIST requested continuation of the exemptions from 10 CFR 36.27(b) and 10 CFR 36.31(a). The requirement in 10 CFR 36.27(b) from which NIST seeks continued exemption, is that the irradiator be equipped with a fire extinguishing system capable of extinguishing a fire without personnel entering the room. NIST also requested a continuation of the exemption from 10 CFR 36.31(a), which requires that the key that operates the irradiator be attached to a portable radiation survey meter by a chain or cable and must be the same key that opens the door. Both of these exemptions were originally granted in 1999 after review, and were requested to be continued in the LRA submitted in July 2007.

In its 1998 request for exemption, NIST indicated that equipment limitations and facility age would prevent NIST from complying with the 10 CFR 36.27(b). To compensate for not complying with this regulation, NIST indicated that the signal from the heat or smoke detectors will alert the NIST FPG. The irradiators are designed to retract the source upon detection of heat or smoke. Fire extinguishers at the site are available for operators to fight small fires. The NRC granted NIST exemption from the 10 CFR 36.27(b) requirement in correspondence issued November 23, 1999, NRC staff determined that NIST had demonstrated that the alternative fire protection provisions identified by NIST provide an adequate level of safety for workers and the public.

In the 1998 request for exemption from 10 CFR 36.31(a), NIST stated that the age of the facility (then nearly 40 years old) and the interconnectivity of the safety features would make it prohibitively expensive to modify the facility to meet the same-key requirement of 10 CFR 36.31(a) and would offer no enhancement of safety. The requirement for the door to the radiation room and irradiator to be the same is to assure that no one inadvertently enters a high radiation area. NIST further stated that measurement of radiation levels and indications by other than with a hand-held survey meter should be acceptable. The operational radiation monitor in place causes the activation of an audible signal and a visible signal within the radiation room when triggered by a beam ON condition. NIST's position is that this provides backup assurance of radiation safety and an adequate level of safety for workers and the public. As part of this LRA review, the staff reviewed the request for continued exemption from the requirements of 36.27(b) and 36.31(a). The staff noted NIST's commitment to administrative limits on the storage of flammable material and the assessment by the NIST Fire Protection Group that the most credible fire would not endanger or engulf the sources. NIST continues to

take compensatory measures that are commensurate with the fire hazard at its Gaithersburg facility, including having portable fire extinguishers in the control room and radiation room and instructions to protect the source. NIST has radiation monitors inside the irradiation rooms in lieu of attaching the room key to a radiation survey meter. Attaching the room key to a survey meter is impractical because the NIST entry key is captured by the lock when the door is opened. NIST has committed to locking the entrance doors leading to the two cells, and limiting the number of keys.

Given the limited size of the facility and the NIST compensating measures, the staff concludes that the lack of a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room as required by 36.27(b) does not present a significant risk to life or property or the common defense and security. Moreover, the staff has determined that in regard to continuing the exemption from 10 CFR 36.27(b), the applicant has met the guidance provided in NFPA 801, "Standard for Fire Protection for Facilities Handling Radioactive Material" and NFPA 45, "Standard of Fire Protection for Laboratories Using Chemicals." Given the low risk to public health and safety, no in-depth fire hazards analysis or integrated safety analysis was required. In addition, the staff concludes that the NIST system for protecting against entry into a room with an exposed source is more effective than the key attached to a survey meter system described in 10 CFR 36.31(a). The staff agrees with continuation of the exemptions to 10 CFR 36.27(b) and 36.31(a).

11.3.2. Environmental Review. As discussed in Chapter 12 of this SER, pursuant to 10 CFR 51.22(c)(14)(v), renewal of materials licenses issued under 10 CFR Part 70 for research and development and for educational purposes is a category of actions which the NRC has determined does not individually or cumulatively have a significant effect on the human environment, and as such, this category of actions does not require environmental review or the preparation of an Environmental Assessment (EA). However, NIST has also requested these exemptions from specific NRC regulations and exemption requests require environmental review unless the exemptions themselves are also subject to categorical exclusion. Exemption requests related to 10 CFR 36.27(a) and (b), and 10 CFR 36.31(a) do not fall within the categorical exclusions outlined in 10 CFR 51.22(c)(14)(v). Therefore, the NRC prepared an EA in association with these exemption requests to assess the environmental impacts of continuing to exempt NIST from requirements in 10 CFR 36.27(b) and 10 CFR 36.31(a). On April 13, 2012, the NRC published notice of its EA and Finding of No Significant Impact in the *Federal Register* (72 FR 22362, 22364) and its' finding of no significant impact regarding the proposed continuation in the renewed license of the 10 CFR 36 exemptions. Based on the environmental review, the NRC has concluded that an environmental impact statement (EIS) need not be prepared.

The NRC prepared an EA in association with these exemption requests to assess the environmental impacts of continuing to exempt NIST from requirements in 10 CFR 36.27(b) and 10 CFR 36.31(a). On April 13, 2012, the NRC published notice of its EA in the *Federal Register* (77 FR 22362, 22364) and its' finding of no significant impact regarding the proposed continuation in the renewed license of the 10 CFR 36 exemptions. Based on the environmental review, the NRC has concluded that an environmental impact statement (EIS) need not be prepared.

Under 10 CFR 36.17(a), the NRC may grant such exemptions from part 36 requirements as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest. For the reasons stated above, the staff concludes that the licensee's exemption requests meet the requirements of 10 CFR 36.17(a),

and the request for a continuation of the exemptions is accordingly granted. The following license conditions are being retained in the renewed license and will continue to state:

16. Notwithstanding the requirements of 10 CFR 36.27(b) the licensee is exempt from the requirement that the radiation room must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room.
17. Notwithstanding the requirements of 10 CFR 36.31(a), the licensee is exempt from the requirements that (1) the console key must be attached to a portable radiation survey meter by a chain or cable, and (2) the door to the radiation room must require the same key used for source movement (i.e., control console key).

11.4 Criticality Accident Alarm System, 10 CFR 70.24(a)

11.4.1. Exemption Request. NIST has requested an exemption from the monitoring requirements of 10 CFR 70.24(a) in the renewed license and this is a new exemption request.

NIST is requesting this exemption on the basis of the low mass of SNM NIST is authorized to possess, the number of individual sources of SNM listed in the possession limits, the laboratory segregation, and the inventory controls utilized. Item 10.7, in the LRA, contains a description of criticality controls used to meet the requirements of 10 CFR 70.22(a)(8) and 70.23(a)(4), which mandate procedures adequate to avoid and mitigate accidental criticality events so as to protect health and minimize danger to life or property. The staff finds that the information submitted by the applicant and reviewed by the staff, demonstrates that the applicant's equipment, facilities, and procedures are adequate to assure subcriticality of the SNM, in accordance with 10 CFR 70.22(a)(8) and 70.23(a)(4), thus adequately protecting health and minimizing danger to life or property during the renewal period. The staff further concludes that there are no credible scenarios that lead to a criticality accident at NIST's Gaithersburg facility. Thus, a criticality monitoring system is not needed.

The staff finds that the installation of a criticality accident alarm system (CAAS) at the Gaithersburg facility would not significantly reduce the risk to the workers or the public because there is no credible criticality accident associated with the SNM. Therefore, the lack of a criticality alarm system will not endanger life or property or the common defense and security. Because installation of a CAAS is not necessary for safety and security, the staff has determined that the proposed License Condition authorizing the exemption will be in the public interest since it reduces unnecessary regulatory burden associated with implementation of the requirement.

11.4.2. Environmental Review. As discussed in Chapter 12 of this SER, pursuant to 10 CFR 51.22(c)(14)(v), renewal of materials licenses issued under 10 CFR Part 70 for research and development and for educational purposes is a category of actions which the NRC has determined does not individually or cumulatively have a significant effect on the human environment, and as such, this category of actions does not require environmental review or the preparation of an Environmental Assessment (EA). However, NIST has also requested these exemptions from specific NRC regulations and exemption requests require environmental review unless the exemptions themselves are also subject to categorical exclusion. Granting continued exemption requests is an action categorically excluded from the need to conduct a further environmental review under 10 CFR 51.22(c)(25) provided that (i) there are no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant

increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; (v) there is no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve one of the nine types of requirements set forth under 10 CFR 51.22(c)(25)(vi), which include “(C) inspection or surveillance requirements.”

Based on the Criticality Controls provided in the LRA in Item 10.7 and the NRC’s evaluation of these controls as discussed in Section 5.3 above, the staff finds that granting an exemption from the 10 CFR 70.24(a) requirement to install a CAAS as part of renewing the NIST license would neither significantly change or increase the types or amounts of effluents released offsite; result in a significant increase in individual or cumulative public or occupational radiation exposure; result in a significant construction impact; nor result in a significant increase in the potential for or consequences from radiological accidents. Also, granting the exemption would not introduce a significant hazards consideration because there will be no criticality or criticality-related gamma or neutron radiation to detect resulting from the NIST research activities during the license renewal term, and such research activities will not individually or cumulatively have a significant effect on the human environment.

Because a CAAS provides continuous monitoring and surveillance for criticality events, and provides an alarm in case of a criticality event, the system performs a surveillance function, and the 10 CFR 70.24(a) requirement to have a CAAS is a surveillance requirement. Accordingly, the NIST exemption request falls within the categorical exclusion of 10 CFR 51.22(c)(25)(vi)(C), and neither an EA nor an EIS is required in connection with granting the requested exemption from 10 CFR 70.24(a).

11.4.3 Conclusion. Under 10 CFR 70.17(a), the NRC may grant such exemptions from part 70 requirements as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. For the reasons stated above, the staff concludes that the licensee’s exemption request meets the requirements of 10 CFR 70.17(a) and the request for the exemption from the monitoring requirements in 10 CFR 70.24(a) is granted. The following license condition will be added to the renewed license:

21. The applicant is granted an exemption to the requirements of 10 CFR 70.24 to maintain a CAAS.

12.0 National Environmental Policy Act Review for the National Institute of Standards and Technology License Renewal

As stated in Section 1 above, NIST uses its license for research and development purposes. Pursuant to 10 CFR 51.22(c)(14)(v), renewal of materials licenses issued under 10 CFR parts 30 or 70 (among others) for research and development and for educational purposes is a category of actions which the NRC has determined does not individually or cumulatively have a significant effect on the human environment and thus, no environmental assessment or environmental impact is required. In Item 9 of the LRA, Unsealed Source Radiation Facilities, of its application, NIST states that gaseous and liquid effluents, if any, will be within 10 CFR Part 20 limits and will be subject to appropriate effluent monitoring and controls. For example, any laboratory operations determined to have significant potential for exceeding 10% of the 10 CFR 20, Appendix B, Table 2, release limitations shall be monitored on an as needed basis, and liquid effluents collected in holding tanks will be sampled to assure compliance with 10 CFR Part 20, Appendix B, limits prior to any release to the sanitary sewer. Accordingly, the NIST license renewal falls within a category of actions that does not require the preparation of an EA.

III. CONCLUSION

The NRC staff concludes that the information provided by NIST in its LRA provides reasonable assurance that an adequate level of safety will be maintained for operations during the proposed license renewal term. The staff concludes that the LRA meets the requirements of 10 CFR 70.23, "Requirements for the Approval of Applications," and that the proposed operations at NIST will not have an adverse impact on the public health and safety, the common defense and security, or the environment. The staff further concludes that NIST will continue to meet the applicable requirements in 10 CFR Parts 19, 20, 30, 32, 36, 40, 51, 70, 73, and 74, as discussed in this SER.

The NRC staff therefore approves the NIST request to renew the SNM license for a 10 year period, in accordance with the LRA commitments and subject to the license conditions specified in this SER which NIST has agreed to and which are incorporated in the renewed license.

IV. PRINCIPAL CONTRIBUTORS

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V. REFERENCES

U.S. Nuclear Regulatory Commission and National Institute of Standards and Technology Correspondence

1. NIST Exemption Request – May 20, 1998 - ADAMS Accession No. ML101020120
2. TAR Response, Medical Nuclear Safety to NMSS/FCSS – July 12, 1999 - ADAMS Accession No. ML101020673
3. NRC Response to NIST Request for Exemptions – November 23, 1999 - ADAMS Accession No. ML993350644
4. NIST Response to Increased Controls Order EA-05-090 – December 13, 2005 - ADAMS Accession No. ML060050350
5. NRC Inspection of NIST for Increased Controls Order – June 13, 2007 - ADAMS Accession No. ML071860616

6. NRC Letter and Safety Inspection Report – June 29, 2007 – ADAMS Accession No. ML071510198
7. NIST License Renewal Application – June 29, 2007 - ADAMS Accession No. ML071930318
8. NRC LRA acknowledgment receipt – August 3, 2007 - ADAMS Accession No. ML072080154
9. NIST Decommissioning Funding Submittal – August 23, 2007 - ADAMS Accession No. ML072540614).
10. NIST Response to Receipt of Increased Controls Order EA-07-905 - ADAMS Accession No. ML081220338
11. NRC RAI – February 1, 2008 - ADAMS Accession No. ML080110155
12. NIST RAI Response – February 29, 2008 - ADAMS Accession No. ML080780064
13. NIST Revision 1 of the LRA – February 29, 2008 - ADAMS Accession No. ML080780065
14. NIST Designation of T&R Official – May 22, 2008 - ADAMS Accession No. ML081700621
15. NIST Decommissioning Cost Estimate (DCE) RAI response – August 31, 2009 - ADAMS Accession No. ML092810475
16. NRC RAI on DCE – February 18, 2010 - ADAMS Accession No. ML13155A524
17. EA-09-142, Confirmatory Order – March 1, 2010 - ADAMS Accession No. ML ML100601095
18. NIST RAI Response as DCE Revision 3 – June 16, 2010 - ADAMS Accession No. ML101930392
19. NIST Revision 2 of the LRA – June 24, 2010 - ADAMS Accession No. ML101930393
20. NRC Inspection for Increased Controls – July 21, 2010 - ADAMS Accession No. ML102350114
21. NRC RAI's to NIST DCE – November 30, 2010 - ADAMS Accession No. ML103210269
22. NIST Response to DCE RAI – December 14, 2010 - ADAMS Accession No. ML 12158A201
23. NIST Revision 3 of the LRA – March 23, 2011 - ADAMS Accession No. ML110940239
24. NRC Letter and Safety Inspection Report – October 28, 2011 – ADAMS Accession No. ML113050207

25. NRC Availability of Environmental Assessment and Finding of No Significant Impact – April 13, 2012 – ADAMS Accession No. ML113110291
26. NIST Response to RAIs – August 14, 2012 – ADAMS Accession No. ML12229A384
27. NIST Acceptance of License Condition 12 – August 27, 2012 – ADAMS Accession No ML12241A042
28. NRC RAI's to NIST - September 10, 2012 – ADAMS Accession No. ML12255A114
29. NIST RAI Response - October 25, 2012 – ADAMS Accession No. ML12313A127
30. NRC RAIs to NIST – November 8, 2012 - ADAMS Accession No. ML12314A256
31. NIST RAI Response November 16, 2012– ADAMS Accession No. ML12331A270
32. NIST Requested Revision to RAI Response dated November 16, 2012 – December 18, 2012 - ADAMS Accession No. ML12354A396
33. NIST Response to Security Issues Related to Transportation – December 26, 2012 - ADAMS Accession No. ML12363A443
34. NIST Request for Continued Exemption to Part 36.23(b) and (c) – March 5, 2013 - ADAMS Accession No. ML13073A025
35. NRC RAI for Physical Security and Transportation – May 6, 2013 - ADAMS Accession No. ML13119A053
36. NIST RAI Response and Revision 4 to LRA – June 5, 2013 - ADAMS Accession No. ML13165A099
37. NIST E-mail Regarding Continuance of Exemptions – June 18, 2013 - ADAMS Accession No. ML13169A141
38. Meeting Summary – July 16, 2013 - ADAMS Accession No. ML13203A060
39. NSIR Safety Evaluation Report – July 24, 2013 – ADAMS Accession No. ML13203A042
40. Email NIST Re: 10 CFR 36.27(a) – August 19, 2013 - ADAMS Accession No. ML1323A171

Regulatory References

1. Part 2, Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders;
2. Part 19, Notices, Instructions and Reports to Workers: Inspection and Investigations;
3. Part 20, Standards for Protection against Radiation;

4. Part 21, Reporting of Defects and Noncompliance;
5. Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material;
6. Part 32, Specific Domestic Licensing to Manufacture or Transfer Certain Items Containing Byproduct Material
7. Part 33, Specific Domestic Licenses of Broad Scope for Byproduct Material;
8. Part 36, Licenses and Radiation Safety Requirements for Irradiators;
9. Part 40, Domestic Licensing of Source Material
10. Part 50, Domestic Licensing of Production and Utilization Facilities;
11. Part 51, Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;
12. Part 70, Domestic Licensing of Special Nuclear Material;
13. Part 71, Packaging and Transportation of Radioactive Material;
14. Part 73, Physical Protection of Plants and Materials; and
15. Part 74, Material Control and Accounting of Special Nuclear Material.

Guidance and Standards References

1. (NRC, 1983) U.S. Nuclear Regulatory Commission, Regulatory Guide 5.59, "Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance," February 1983.
2. (NRC, 1999) U.S. Nuclear Regulatory Commission, NUREG-1556 Volume 11 "Consolidated Guidance about Materials Licenses – Program Specific Guidance about License of Broad Scope."
3. (ANSI/ANS, 1997) ANSI/ANS 8.3, "Criticality Accident Alarm System (CAAS)," 1997 (Reaffirmed in 2003).
4. (NRC, 2010) U.S. Nuclear Regulatory Commission, NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," May 2010.
5. (NFPA, 2003) NFPA 801, "Standard for Fire Protection for Facilities Handling Radioactive Material," 2003.
6. NFPA 101, "Life Safety Code."
7. (NFPA) 70, "National Electrical Code."
8. (ANSI/ANS, 2007) ANSI/ANS 8.23, "Nuclear Criticality Accident Emergency Planning and Response," 2007.