SUBORDER

NIST S 7201.01

Approval Date: 02/10/2021
Effective Date:[1] TBD

Ionizing Radiation Safety – Radioactive Material at NIST Gaithersburg

National Institute of Standards and Technology
U.S. Department of Commerce

Directive Owner:
Chief Safety Officer

[1] For revision history, see Appendix A.

1. PURPOSE

This suborder delineates the requirements, roles, responsibilities, and authorities necessary for the full and effective implementation of NIST Order 7201.00 as it applies to RAM at NIST Gaithersburg.[2, 3]

2. BACKGROUND

NIST Order 7201.00 delineates the requirements, roles, responsibilities, and authorities necessary for the full and effective implementation of NIST Policy 7200.00 as it applies to RAM and ionizing-radiation-producing machines at NIST. This suborder pertains to RAM at NIST Gaithersburg. Other suborders pertain to RAM at NIST Boulder and to ionizing-radiation-producing machines at NIST Gaithersburg and at NIST Boulder.

3. APPLICABILITY

a. This suborder applies to NIST employees and associates at NIST Gaithersburg whose duties involve potential exposure to radiation from the permitted radioactive material and activities in 3b.

b. Permitted radioactive material and activities:

(1) The acquisition, use, transfer, distribution, and disposal of the form and quantities of RAM specified in NRC Form 374 for the current version of NIST's radioactive materials license SNM-362;

(2) The distribution of the form and quantities of RAM specified in NRC Form 374 for the current version of 19-23545-01E;

(3) The acquisition, use, transfer, and disposal of RAM specified as a GL;

(4) The acquisition, use, transfer, and disposal of the form and quantities of RAM permitted under the exemptions in 10 CFR Parts 30 and 40;

(5) Off-site use of RAM specified in NRC Form 374 for the current version of SNM-362; and

(6) Production of incidentally activated radioactive material from operations of a particle-beam accelerator or neutron-generating device (non-reactor).

[2] Terms and acronyms are defined in Sections 5 and 6, respectively.
[3] This suborder does not apply to any activities conducted under the auspices of NRC reactor license TR-5.

c. Prohibited activities:

(1) Intentional administration of radiopharmaceuticals or intentional direct exposures of human or live animal subjects;

(2) Environmental tracer studies involving the willful and direct release of radioactive material;

(3) Intentional operation of a particle-beam accelerator to produce radioactive material for its radioactive properties;

(4) Acquisition of SNM of Moderate Strategic Significance; and

(5) Aggregation of RAM resulting in NIST possessing SNM of Moderate Strategic Significance.

4. REFERENCES[4]

a. NIST Policy 7200.00, Ionizing Radiation Safety

b. NIST Order 7201.00, Ionizing Radiation Safety – RAM and Ionizing-Radiation-Producing Machines

c. NIST Ionizing Radiation Safety Committee (IRSC) Charter

d. NRC License SNM-362

e. NRC License 19-23545-01E

f. NIST S 7101-24_Incident Reporting and Investigation

g. NRC Confirmatory Order EA-09-142 (NRC Inspection Report 030-03732/2008-001, NRC Investigation Report 4-2008-062), March 1, 2010

h. NUREG 1556, Consolidated Guidance About Materials Licenses, Volumes 5, 6, 7, 8, 11, 17, and 21

i. NUREG 1516, Management of RAM Safety Programs at Medical Facilities

j. Federal Register / Vol. 72, No. 189 / Monday, October 1, 2007

[4] Unless explicitly stated otherwise, each reference pertains to the most recent published version.

k. 10 CFR 2, 19, 20, 21, 30, 31, 32, 33, 36, 37, 40, 61, 70, 71, 72, 73, 74, and 110

l. 49 CFR 170 – 189

m. NIST S 7101-21_Personal Protection Equipment

n. NIST S 7101-04_Safety and Health Requirements for Minors

o. NIST S 7101-02_Employee Reporting of Unsafe or Unhealthful Working Conditions

p. NIST Suborder 7101.59, Chemical Hazard Communication

5. DEFINITIONS

Definitions common to all NIST ionizing-radiation-safety programs are provided in NIST Order 7201.00. Definitions specific or applicable to this suborder are:

a. **19-23545-01E** – A NRC license to manufacture, process, produce, package, repackage, or transfer quantities of byproduct material for commercial distribution to persons exempt pursuant to 10 CFR 30.18 or the equivalent regulations of an Agreement State.

b. **ALARA** – An acronym for "As Low As is Reasonably Achievable", which means making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits in 10 CFR 20 as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

c. **Allegation** – A declaration, statement, or assertion of impropriety or inadequacy associated with NRC-regulated activities, e.g., unsafe practices or potential violations of **RSP** requirements, the validity of which has not been established.

d. **Alternate Supervised-User Supervisor** – A **Source User** with the additional responsibility and authority to provide task-specific training and **direct supervision** of a **Supervised User** as an alternate to the primary **Supervised-User Supervisor**, when designated to do so by the **Supervised-User Supervisor**.

e. **Acquisition** – The process which results in **RAM** being procured or otherwise physically possessed by a NIST employee or associate at NIST Gaithersburg.[5] It does not indicate NIST's ownership status of the **RAM**.

f. **Annually** – At least once each year with an interval not to exceed 15 months.

g. **Authorized Source Use** - The documented approval, including hazards review and conditions or limitations for the use of a **RS# Source,** which has been submitted via a **NIST-364** and modified by **NIST-365**s. The Authorized Source Use for each source can be found in the RSIMS database under the sections Authorizations and Radiological Hazards and Supplemental Controls.

h. **Authorized Use Permit** (used synonymously with **Permit**) **–** The documented approval of a proposed experimental activity utilizing **RAM** under the **SNM-362** license. The **Permit** will contain the SNM-362 types and quantities of RAM that may be used, the Source-Use protocols, the RAM facilities, and the Source Users, as well as engineering and administrative controls based on a Safety Evaluation. Subsequent authorization under a NIST-364 or NIST-365 is required to commence work.

i. **Authorized Use Permit Administrator** – A Source User that has been approved by their Division Chief and the RSO who has the responsibility to oversee the **Authorized Use Permit Request** and the **Authorized Use Permit Amendment Requests** for a particular **Permit**.

j. **Authorized Use Permit Amendment Request** – A document developed by an OU, with assistance from **RSD,** to amend a **Permit**. The **Permit** modifications are approved when an **Authorized Use Permit Amendment Request** is approved by the **RSO** pursuant to the approval by the **IRSC** of a **Safety Evaluation** of the **Authorized Use Permit Amendment Request** performed by an **IRSC-approved RSO designee.**

k. **Authorized Use Permit Request** – A document developed by an OU, with assistance from **RSD,** to define the activities and conditions of a new **Permit**. The **Permit** is created when an **Authorized Use Permit Request** has been approved by the **RSO** pursuant to the approval by the **IRSC** of a **Safety Evaluation** of the **Authorized Use Permit Request** performed by an **IRSC-approved RSO designee.**

[5] NIST O 7101.00, Occupational Safety and Health Management System, defines an "associate" as an individual conducting work at a NIST workplace who (a) is not a NIST employee, (b) is not required to conduct work in accordance with their own employer's NIST-accepted safety plan, and (c) has signed an agreement to comply with NIST and sponsoring Organizational-Unit administrative requirements, including safety requirements.

l. **Biennially** – At least once every two years with an interval not to exceed two and one-half years.

m. **Byproduct Material** –

(1) Any RAM (except SNM) yielded in or made radioactive by exposure to the radiation incident to the process of producing or using SNM;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its **source material** content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(3) Any discrete **source** of radium-226, or any material that has been made radioactive by use of a particle-beam accelerator, that is produced, extracted, or converted after extraction for use in a commercial, medical, or research activity; and

(4) Any discrete **source** of naturally occurring **RAM**, other than **source material**, that:

(a) Has been determined by the NRC, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, would pose a threat similar to the threat posed by a discrete **source** of radium-226 to the public health and safety or the common defense and security; and

(b) Is extracted or converted after extraction for use in a commercial, medical, or research activity.

n. **Category 1 Quantity of RAM** – A quantity of RAM meeting or exceeding the Category 1 threshold in Table 1 of Appendix A to 10 CFR 37. **Category 1 quantities of RAM** do not include the RAM contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

o. **Category 2 Quantity of RAM** – A quantity of **RAM** meeting or exceeding the Category 2 threshold but less than the Category 1 threshold in Table 1 of Appendix A to 10 CFR 37. **Category 2 quantities of RAM** do not include the **RAM** contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

p. **Controlled-Access Area** – Any temporarily or permanently established area which is clearly demarcated, access to which is controlled, and which affords isolation of the material or persons within it.

q. **Declared Pregnant Worker** – A worker who has voluntarily informed the **RSO**, in writing, of their pregnancy and the estimated date of conception. The declaration remains in effect until the **declared pregnant worker** withdraws the declaration in writing or is no longer pregnant.

r. **Direct Supervision** – Relative to a **Supervised User**, a term meaning that the **Supervised-User Supervisor** shall be available for consultation within a reasonable amount of time commensurate with the need for consultation, based on the proficiency of the **Supervised User** and the hazards and risks associated with the task being performed.

s. **Radiation Facility Owner (RFO)** – A Source User that has been approved by their Division Chief and the RSO to manage access to a **RAM Facility** and to act as a liaison to the RSD.

t. **GL (General License)** – A license provided by regulation that grants authority to a **person** for certain activities involving **byproduct material**, **source material**, or **SNM** and is effective without the filing of an application with the NRC or the issuance of a licensing document to a particular **person**. See 10 CFR 31, 40, and 70, and the applicable license for authorizations, limitations, and restrictions.

u. **GL Device** – A device typically used to detect, measure, gauge, or control the thickness, density, level, or chemical composition of various items and that is governed by a **GL**. Examples of such devices are gas chromatographs (detector cells), density gauges, fill-level gauges, and static elimination devices.

v. **RSD (Radiation Safety Division)** – The group of health physics staff members at NIST located organizationally in the Office of Safety, Health, and Environment (OSHE).

w. **Incident –** For the purposes of the suborder, an unplanned event in which any of the following, individually or in combination, occurred or had a plausible likelihood of occurring: internal exposure to radiation, excessive external exposure to radiation, spill of **RAM**, release of **RAM** to the environment.

x. **Incidentally-Activated RAM** – Material that becomes radioactive when a particle-beam accelerator is operated for purposes other than the deliberate production of RAM for use in a commercial, medical, or research activity.

y. **Ionizing Radiation** – Sometimes referred to hereafter as “radiation”, alpha particles, beta particles, gamma rays, x rays, neutrons, high-energy electrons, high-energy protons, and other particles capable of producing ions when they impinge on or penetrate matter.

z. **IRSC (Ionizing Radiation Safety Committee)** – An official NIST standing committee that reports to and assists the NIST Director in the oversight of the operations and activities of all NIST ionizing-radiation-safety programs except for the ionizing-radiation-safety program under NRC Reactor License TR-5.

aa. **IRSC-Approved RSO Designee** (used synonymously with **IRSC-Approved Designee)** – An individual requested by the **RSO** and approved by the **IRSC** who, once approved, may be designated by the **RSO** to carry out **IRSC**-specified functions on behalf of the **RSO**.

bb. **Licensed RAM** – As used herein, **byproduct material**, **source material**, and **SNM** that is acquired, used, transferred, or disposed of under **SNM-362** or as a **GL device**. A term also used synonymously with **licensed source**.

cc. **Licensed Source** – A term used synonymously with **licensed RAM.**

dd. **LC RAM (Limited Control RAM) –** RAM that is:

(1) **Byproduct material** exempted under 10 CFR 30;

(2) Unimportant quantities of **source material** as per 10 CFR 40.13;

(3) **RAM** such as that described in 10 CFR 31.8, 10 CFR 40.22, and 10 CFR 70.19 that is not part of a **GL device**;

(4) **Incidentally-Activated RAM**; or

(5) Any other **RAM** determined by the RSO to warrant some degree of control for **RSP** purposes that is not covered elsewhere in this suborder.

ee. **Nationally Tracked Source** – A sealed **source** containing a quantity of any **RAM** greater than or equal to **Category 1 quantities of RAM** or **Category 2 quantities of RAM**. In this context only, a sealed **source** is defined as **RAM** that is sealed in a capsule or closely bonded in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

ff. **NCNR HP (NIST Center for Neutron Research Health Physics)** – The group of health physics staff members located organizationally in the NIST Center for Neutron Research.

gg. **NIST-364** – A term synonymously with **source acquisition and use request**.

hh. **NIST-365** – A term used synonymously with **source-use change request**.

ii. **Non-RS# Source** – Any **SNM-362 RAM** that has not been assigned a **RS#**.

jj. **NSO (NIST Security Officer)** – The individual responsible for managing the NIST security program, including, but not limited to, coordination of law enforcement operations and investigations with the DOC Office of Security, in accordance with the requirements of NIST's NRC licenses and applicable Federal, State, and local regulations.

kk. **NUREG** – A NRC technical report designation.

ll. **Occupational Dose** – The dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to **RAM** from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other **person**. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered **RAM**, from voluntary participation in medical research programs, or as a member of the public.

mm. **Particle-Beam Accelerator** (used synonymously with **Accelerator**) – Any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

nn. **Permit** – A term used synonymously with **authorized use permit.**

oo. **Permit administrator** – A term used synonymously with **authorized use permit administrator**.

pp. **Person** – (1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department of Energy, except that the Department of Energy shall be considered a **person** within the meaning of the regulations in this part (10CFR part 20) to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing.

qq. **Public Dose** – The dose received by a member of the public from exposure to radiation or to **RAM** released by a licensee, or to any other **source** of radiation under the control of a

licensee. **Public dose** does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered **RAM** and released under 10 CFR 35.75, or from voluntary participation in medical research programs.

rr. **Radiological Hazard Assessment** –

(1) A delineation of the radiological hazards and maximum potential exposures presented by the RAM associated with a specific activity or set of activities; and

(2) The identification of any activity-specific regulatory or RSP requirements related to posting, dosimetry, monitoring, leak testing, etc.

ss. **Radiological Hazard Mitigation Plan** – A document specifying the proactive and real-time measures that must be implemented to reduce the risks associated with the hazards delineated in a **radiological hazard assessment** to acceptable levels, including engineering and administrative controls, personal protective equipment, and activity-specific emergency procedures.

tt. **RAM (Radioactive Material)** – Material permitted at NIST Gaithersburg under **SNM-362**, a **GL**, or as **LC RAM**.

uu. **RAM Facility** – A building, room, or area that has been approved by the **RSO** as being suitable for the purpose of using or storing **sources** or for the operation of a particle-beam accelerator or neutron-generating device.

vv. **RAM Shipper** – An individual who packages, labels, manifests, and ships **RAM** in accordance with applicable DOT, NRC, U.S. Postal Service, IATA, and RSP requirements.

ww. **Reportable Quantity of SNM** – **SNM** in a quantity totaling 1 g or more of contained U-235, U-233, or plutonium. For reporting purposes, fractional quantities of 0.5 g or more are to be rounded up to the next whole unit.

xx. **RS#** – For the purpose of accountability, an alpha-numeric identifier assigned by **RSD** to **SNM-362 RAM** that exceeds the quantities specified in the **RSP**[6] or to a **GL device**.

yy. **RS# Source** – **SNM-362 RAM** or a **GL device** that has been assigned a **RS#**.

[6] Based on Appendix C of 10 CFR 20, as modified in SE-0005, *Selected Low-Risk Uses*.

zz. **RSI (Radiation Safety Instruction)** – A procedure or set of procedures implemented by **RSD** to ensure that specific requirements of the **RSP** are met.

aaa. **RSO (Radiation Safety Officer)** – The individual, meeting the requirements of the NRC, who is responsible for managing the **RSP**, including all aspects of the utilization of **sources** under the **RSP**, in accordance with the requirements of NIST's NRC licenses; applicable Federal, State, and local regulations; and this suborder.

bbb. **RSP (Radiation Safety Program) – As used herein, the program at NIST Gaithersburg** for controlling the receipt, possession, use, distribution, transfer, and disposal of **SNM-362 RAM**, **GL devices**, and **LC RAM** in such a manner that the total dose to an individual, including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation, does not exceed the standards for protection against radiation prescribed in applicable regulations. The **RSP** comprises the following elements, implementation of which will result in all applicable regulatory and license requirements being met:

(1) This suborder and all supporting suborder-specific directives, including procedures, guidance, and notices;

(2) All required tools, including **RSIs**, training, forms, instructions, and information-management systems; and

(3) Any documented experimental procedures required by this suborder and any supporting suborder-specific directive.

ccc. **Safety Evaluation** – A documented evaluation by an **IRSC-approved RSO designee** of the radiological hazards associated with the proposed experimental activities presented via an **Authorized Use Permit Request** or via an **Authorized Use Permit Amendment Request**.

ddd. **Sealed Source** – **RAM** that is permanently encased, for its intended use and expected lifetime, in a capsule or closely-bonded solid form designed to prevent leakage or escape of the **RAM**.

eee. **Security Zone** – Any temporary or permanent area determined and established for the physical protection of **Category 1 quantities of RAM** or **Category 2 quantities of RAM**.

fff. **SGI (Safeguards Information)** – A special category of sensitive unclassified information that must be protected (see 10 CFR 73.2). For the purposes of this suborder, SGI concerns the physical protection of **SNM of low strategic significance** or **SNM of moderate strategic significance**.

ggg. **SGI-M (Safeguards Information-Modified Handling)** – The designation or marking applied to SGI that the NRC has determined requires handling requirements modified from the specific SGI handling requirements that are applicable to **SGI** needing a higher level of protection.

hhh. **SNM (Special Nuclear Material)** –

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the NRC determines to be **SNM**, but not including **source material**; or

(2) Any material artificially enriched by any of the foregoing, but not including **source material**.

iii. **SNM of Low Strategic Significance** –

(1) Less than an amount of **SNM of moderate strategic significance** but more than 15 g of U-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope) or 15 g of U-233 or 15 g of Pu or the combination of 15 g when computed by the equation, g = (g contained U–235) + (g Pu) + (g U–233); or

(2) Less than 10,000 g but more than 1,000 g of U-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U–235 isotope); or

(3) 10,000 g or more of U-235 (contained in uranium enriched above natural but less than 10 percent in the U–235 isotope).

jjj. **SNM of Moderate Strategic Significance** –

(1) Less than a formula quantity of **SNM of strategic significance** but more than 1000 g of U-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope), or more than 500 g of U-233 or Pu, or in a combined quantity of more than 1000 g when computed by the equation, g = (g contained U-235) + 2 (g U-233 + g Pu); or

(2) 10,000 g or more of U-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope).

kkk. **SNM-362** – A NRC license authorizing acquisition, use, transfer, and disposal of any chemical or physical form of the byproduct material specified in the license, but not exceeding quantities specified in the license, for purposes authorized by the license.

lll. **SNM-362 RAM** – **Byproduct material**, **source material**, and **SNM** that is acquired, possessed, used, transferred, or disposed of under **SNM-362**.

mmm. **SNM-362 Source** – A term used synonymously with **SNM-362 RAM**.

nnn. **Source** – A term used synonymously with **RAM**.

ooo. **Source Acquisition and Use Request (NIST-364)** – A NIST form or RSIMS database request that is submitted to initiate the acquisition and/or registration process of **SNM-362 RAM** or a **GL Device** and to request approval of its use under a **Permit**. A **Source Acquisition and Use Request** is approved by the **RSO**, is authorized by the Division Chief, and will define the **Authorized Source Use** for the **Source**.

ppp. **Source Custodian** – A **Source User** who has been approved in writing by the **RSO** and the **IRSC** to carry out additional responsibilities for control and accountability of licensed **RAM**.

qqq. **Source Material** –

(1) Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; and

(2) Ores that contain, by weight, one-twentieth of 1 percent (0.05 percent), or more, of uranium, thorium, or any combination of uranium and thorium.

(3) **Source material** does not include **SNM**.

rrr. **Source User** –

(1) For **SNM-362 RAM**, an individual who has been approved in writing by the **RSO** and the **IRSC** to use **SNM-362 RAM** based on his or her education, experience, and training.

(2) For **GL devices**, an individual who has been approved by the **RSO** to use a **GL device** based on his or her training.

sss. **Source-Use Change Request (NIST-365)** – A NIST form that is used to modify the **Authorized Source Use** of a **RS# Source**. The modifications to the **Authorized Source Use** are approved when the **Source-Use Change Request** is approved by the **RSO** and is authorized by the Division Chief.

ttt. **SUNSI (Sensitive Unclassified Non-Safeguards Information)** – Information that is generally not publicly available and that encompasses a wide variety of categories, such as proprietary information, personal and private information, or information subject to attorney-client privilege.

uuu. **Supervised User** – An individual who has been authorized to carry out specific protocols under the **direct supervision** of a **Source User**.

vvv. **Supervised-User Supervisor** – A **Source User** with the additional responsibility and authority to provide **direct supervision** of a **Supervised User**.

www. **Waste Management Plan** – Plan that describes the radioactive waste to be generated in the conduct of an activity and how those wastes will be staged safely for disposal and ultimately disposed of.

6. ACRONYMS

a. ALARA – As Low As is Reasonably Achievable

b. AMD – Acquisitions Management Division

c. CFR – Code of Federal Regulations

d. CSO – Chief Safety Officer

e. DOE – Department of Energy

f. DOT – Department of Transportation

g. ESO – Emergency Services Office

h. GL – General License or Generally Licensed

i. RSD –Radiation Safety Division

j. IATA – International Air Transport Association

k. IRSC – Ionizing Radiation Safety Committee

l. LC RAM – Limited Control Radioactive Material

m. NCNR HP – NIST Center for Neutron Research Health Physics

n. NIST – National Institute of Standards and Technology

o. NMMSS – Nuclear Materials Management and Safeguards System

p. NRC – Nuclear Regulatory Commission

q. NSTS – National Source Tracking System

r. NUREG – Nuclear Regulatory Commission (a NRC technical report designation)

s. NSO – NIST Security Officer

t. OSHE – Office of Safety, Health, and Environment

u. OSY – Department of Commerce Office of Security

v. OU – Organizational Unit

w. RAM – Radioactive Material

x. RFO – Radiation Facility Owner

y. RS# – SNM-362 Source Number

z. RSI – Radiation Safety Instruction

aa. RSO – Radiation Safety Officer

bb. RSP – Radiation Safety Program

cc. SNM – Special Nuclear Material

dd. SGI – Safeguards Information

ee. SGI-M – Safeguards Information-Modified Handling

ff. T&R – Trustworthy and Reliable or Trustworthiness and Reliability

gg. TEDE – Total Effective Dose Equivalent

hh. SUNSI – Sensitive Unclassified Non-Safeguards Information

7. RADIATION SAFETY PROGRAM REQUIREMENTS

This section provides general requirements pertaining to RAM at NIST Gaithersburg followed by requirements specific to SNM-362 RAM, GL devices, and LC RAM.

a. Program Requirements – General

(1) NIST shall develop, document, and implement a RSP commensurate with the scope and extent of SNM-362 and 19-23545-01E; the March 1, 2010 NRC Confirmatory Order; the terms and conditions of applicable GLs; and all other requirements, including those applicable to LC RAM, necessary to ensure safety of personnel, protection of the environment, and regulatory compliance.

(a) The RSP shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public from licensed and unlicensed radioactive material ALARA.

(b) Facilities and equipment shall be adequate to protect health and minimize danger to life or property. They shall minimize the possibility of contamination and keep exposures to workers and the public ALARA.

(c) It shall be demonstrated by review by RSD of dosimetry results and other appropriate means that exposures to individuals, including members of the public, are maintained ALARA.

(d) Individuals whose assigned duties involve the use of or exposure to RAM at NIST Gaithersburg shall be subject to monitoring and audits by the NRC, the IRSC, the RSO, RSD personnel, and others.

b. Program Requirements – SNM-362 RAM

(1) License Amendments and Changes

Requests for license amendments, including requests for license exemptions and requests for additional information, shall be authorized by the IRSC prior to their submittal to the NRC.

(2) Transfer of Ownership or Control of Licensed Activities

Applications to transfer ownership or control of licensed activities shall be reviewed for completeness and accuracy by the IRSC and authorized by the NIST Director prior to their submittal to the NRC.

(3) RAM Use Locations

(a) The use, possession, and storage of SNM-362 RAM at any location on or off the NIST Gaithersburg site shall be approved by the RSO and authorized by the appropriate line management, in accordance with the requirements of this suborder.

(4) SNM-362 RAM Form, Quantities, and Purpose of Use

(a) The form, quantities, and purposes of use of SNM-362 RAM authorized at the NIST Gaithersburg site are restricted to those specified in NRC Form 374 for the most recent version of SNM-362.

(b) The activities listed in Section 3c are prohibited.

(c) Official information on the form and quantity of SNM-362 RAM authorized at the NIST Gaithersburg site shall be made available by the RSO as necessary to other NRC or Agreement-State licensees.

(5) Individuals Responsible for the RSP

Roles and responsibilities shall be allocated to ensure safe operations and compliance with regulatory and license requirements. These shall include:

(a) The NIST Director, who has ultimate responsibility for:

i. Ensuring the implementation and maintenance of an effective RSP;

ii. Ensuring proper allocation of resources for the RSP; and

iii. Providing direction on issues involving ionizing radiation safety and regulatory and license compliance within the context of the RSP;

(b) The CSO, who has responsibility for ensuring the maintenance of the RSP;

(c) An IRSC, which has responsibility for:

i. Overseeing the effectiveness of the implementation and maintenance of the RSP and providing the NIST Director with independent advice on matters concerning ionizing radiation safety;

ii. Reviewing the results of internal and external audits and annually assessing the performance of aspects of the RSP;

iii. Recommending actions to the NIST Director as necessary on issues involving ionizing radiation safety and regulatory and license compliance within the scope of the RSP;

iv. Evaluating the adequacy of resources for the RSP and recommending changes to the NIST Director;

v. Reviewing and approving safety evaluations of authorized use permit requests and authorized use permit amendment requests; and

(d) An RSO, who has responsibility for:

i. Serving as the manager of, and NRC point of contact for SNM-362 and 19-23545-01E; and

ii. Maintaining the RSP.

(6) Posting and Labeling

(a) It shall be ensured by RSD that postings required by 10 CFR 19 appear in a sufficient number of places to permit individuals engaged in NRC-licensed or regulated activities to observe them on the way to or from any particular licensed- or regulated-activity location to which the regulation applies, shall be conspicuous, and shall be replaced if defaced or altered.

(b) Areas in which SNM-362 RAM is authorized to be used or stored shall be properly posted by RSD.

(c) Containers of SNM-362 RAM and items contaminated with SNM-362 RAM shall be labeled and marked by the OUs in accordance with regulatory requirements and in a manner adequate to inform any individual in the work area of the potential hazards.

(7) SNM-362 RAM Safety and Security Training

(a) Radiation-safety-awareness training on general radiation safety policy and procedures, and security requirements, shall be provided by RSD to all employees and associates entering on duty.[7]

(b) All Source Custodians, Source Users, Supervised Users, and associated Group Leaders and Division Chiefs shall receive initial and refresher radiation-safety and applicable RAM-security training provided by RSD in accordance with SNM-362 requirements and commensurate with the potential radiological health protection issues associated with their specific duties.

(c) All individuals approved to operate an irradiator subject to 10 CFR 36 criteria shall receive a safety review annually by RSD.

(d) ESO and OSY personnel shall receive annual or biennial training, as required, provided by RSD on how to respond to security, fire, and other monitored-alarm situations that fall within the purview of the RSP.

(e) All individuals involved in activities related to the shipping or receiving of SNM-362 RAM shall receive biennial training provided by RSD commensurate with their assigned duties.

(f) Evaluation by RSD of an individual's understanding of training material shall be by methods such as direct testing of knowledge, performance observations, personal interviews, and ALARA reviews.

(8) Security-Zone-Access Training

(a) All individuals whose assigned duties require unescorted access to a security zone or access to security-zone-related information shall receive initial and annual refresher training provided by RSD in accordance with 10 CFR Part 37.

(9) Controlled-Access-Area Training

[7] The Confirmatory Order issued by NRC to NIST on March 1, 2010 requires NIST to provide such training.

(a) All individuals whose assigned duties require unescorted access to a controlled-access area shall receive initial and annual refresher training provided by RSD in accordance with 10 CFR Part 73.

(10) SNM-362 RAM Facility Management and Control

(a) SNM-362 RAM facilities shall be approved by RSD for use based on the facility design and construction and any applicable hazard-mitigation and monitoring systems required to be available in the facility.

(b) SNM-362 RAM facilities shall be released by RSD from the requirements of the RSP only after it has been determined by appropriate monitoring as being suitable for unrestricted use.

(c) When a decision has been made to terminate all SNM-362 RAM use activities within a building, decommissioning of the building in accordance with NRC requirements shall be coordinated by RSD.

(11) Audit Program

(a) External Audits

i. External audits based on NUREG 1556 shall be commissioned by RSD at least annually, and the results shall be documented and reported to the IRSC.

(b) Internal Audits

i. Internal audits shall be implemented by the RSO to critically review the adequacy of compliance with RSP requirements, including NRC license requirements.

ii. Results of audits shall be submitted by the RSO to the IRSC as they become available.

(c) IRSC Reviews

i. Selected elements of the RSP shall be assessed annually by individuals designated by the IRSC.

(12) Radiological Instrumentation

(a) Calibrated survey instrumentation needed to conduct compliance-related monitoring, e.g., to conduct post-use contamination surveys, shall be made available to the OUs by RSD.

(b) All "in-service" instruments used for health and safety or regulatory compliance monitoring shall be routinely evaluated by RSD for functionality via a calibration and testing program.

(13) Occupational Dose

(a) Radiation dosimeters for monitoring external dose shall be issued by RSD to individuals pursuant to 10 CFR 20.1502(a), declared pregnant workers, and to those individuals entering a high or very high radiation area.

(b) Internal exposure monitoring shall be arranged by RSD and performed for those individuals subject to 10 CFR 20.1502(b).

(14) Public Dose

(a) Sources shall be used, transported, stored, and disposed in such a way that the total effective dose equivalent (TEDE) to members of the public will not exceed more than 1 mSv (100 mrem) in 1 calendar year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour.

(15) Radiological Monitoring

(a) Activities that could result in radiation exposures to workers or members of the public, or in releases to the environment, shall be adequately evaluated, monitored, and reviewed by RSD to determine potential hazards and to identify radiological conditions for radiation safety purposes.

(b) Semi-annual sealed-source leak testing shall be performed by RSD as specified in applicable SNM-362 conditions.

(16) SNM-362 RAM Acquisition, Accountability, and Administrative Control

(a) Authorized Use Permit

i. The use of SNM-362 RAM is covered under an authorized use permit. The permit is approved prior to the acquisition of the sources that will be used under the permit.

ii. A permit contains the purpose for the source use, the experimental protocols, the RAM facilities, the Source Users, the quantities and types of RAM that can be authorized under the permit, the waste management plan, and the radiological hazard mitigation plan. A permit also contains an attestation from the Group Leader and Division Chief indicating that the Source Users have the qualifications to ensure the safe conduct of the work.

iii. All permits are evaluated against the conditions in the SNM-362 license, the RSP, and general radiation safety standards prior to their approval.

iv. The permit administrator facilitates all permit requests and permit amendments and is the liaison to RSD in matters relating to the permit.

(b) Acquisition and Registration

i. Acquisition of SNM-362 RAM is authorized through a NIST-364. A NIST-364 contains the isotope and amount of the source, the experimental protocols, the RAM facilities, the Source Users, and the Permit.

(i) SNM-362 RAM received without this approved request shall be rejected and returned to the provider or held pending proper approval and authorization.

(ii) In order to approve the acquisition of SNM-362 RAM, the request cannot result in violations of the SNM-362 license including the possession limits of the license and must conform the conditions and limitations in the permit.

ii. Once the acquisition of the source is approved, the source is given a RS# and is registered in the RSIMS database.

(c) Authorized Source Use

i. How a source may be used is dictated by its authorized source use which is found in the RSIMS database and is listed individually for each source. This use is bounded by the conditions and limitations found in the permit and is listed specifically on NIST-364s and NIST-365s.

(i) When the NIST-364 is evaluated against the permit, a radiological hazard assessment is performed for the source. This will confirm the applicability of the permit for the request and will result in a source specific mitigation plan. This may include supplemental controls augmenting the conditions found in the permit.

(ii) A request may be made to change any of the authorizations for a source, including the Permit for the source via a NIST-365. The same evaluation that was done for the NIST-364 would be repeated which could change the radiological hazard assessment and mitigation plan for the source.

(d) SNM-362 RAM Accountability and Administrative Control

i. Procedures that delineate appropriate administrative controls relating to SNM-362 RAM accountability shall be maintained by RSD and implemented by RSD and the OUs.

ii. For RS# sources subject to the hazardous chemical list requirements of NIST Suborder 7101.59, Chemical Hazard Communication:

(i) The associated RS#-source inventory records maintained by RSD shall include the product identifiers referenced on the associated container labels/Safety Data Sheets; and

(ii) Current RS#-source inventory records are available through the online RSD database RSIMS

iii. The total amount of SNM-362 RAM shall be verified by RSD via an annual physical inventory conducted by the OUs

iv. It shall be verified by RSD upon receipt of SNM-362 RAM that the material received, as indicated in the shipping order and other documentation, is what was expected.

v. Procedures to ensure the proper relocation of SNM-362 RAM shall be maintained by RSD and implemented by the OUs and RSD.

vi. Procedures to ensure the proper transfer of SNM-362 RAM to other persons shall be maintained by RSD and implemented by the OUs and RSD.

vii. SNM-362 material transactions and balances subject to the provisions of 10 CFR 70 and NUREG BR-006 and BR-007 shall be reported by RSD to the NMMSS database.

viii. Transactions involving nationally-tracked sources shall be submitted by RSD to the NSTS.

(17) SNM-362 RAM Security

(a) Security procedures shall be maintained by the RSO and NSO and implemented by the OUs for SNM-362 RAM subject to 10 CFR 20.1801 and 1802; 37 and 73, and the SNM-362 Security Plan.

(b) SNM-362 RAM subject to 10 CFR Part 37 or 73 shall be secured from unauthorized access by an access-authorization program and by locked doors, cabinets, or similar measures when unattended.

(c) A T&R qualification program shall be administered by the NSO to authorize access to controlled-access areas; security zones; and SGI, SGI-M, and SUNSI related to such areas and zones.

(d) For on-site and in-transit physical protection of SNM of low strategic significance, the following requirements shall be met:

i. Minimize the possibility for unauthorized removal of SNM consistent with the potential consequences of such actions;

ii. Facilitate the location and recovery of missing SNM;

iii. Implement and maintain a physical-protections system that shall:

(i) Provide continuous monitoring and detection of unauthorized access or activities within controlled-access areas and security zones containing SNM;

(ii) Provide early detection of removal of SNM by any unauthorized individuals from controlled-access areas and security zones;

(iii) Ensure proper placement and transfer of custody of SNM; and

(iv) Provide for immediate assessments of, and responses to, indications of unauthorized access or activities within controlled-access areas and security zones containing SNM; and

iv. Implement and maintain an information protection system for SGI and SGI-M.

(18) SNM-362 RAM Safe Use and Emergency Procedures

(a) Safety measures, including radiological hazard assessments, radiological hazard mitigation plans, and ALARA considerations, shall be integrated into all facets of

work planning and execution and delineated in authorized use permit requests and authorized use permit amendment requests submitted by the OUs to RSD.

(b) Safety evaluations of authorized use permit requests and authorized use permit amendment requests shall be performed by the RSO and reviewed, approved, and recorded by the IRSC.

(c) Authorized use permit requests and authorized use permit amendment requests shall be approved by the RSO pursuant to IRSC approval of their associated safety evaluations.

(d) SNM-362 RAM may only be used by, or under the direct supervision of, Source Users approved by the IRSC.

(e) SNM-362 RAM may be used only after RSO approval and OU authorization of source-acquisition and use requests and source-use change requests determined by the RSO to be permitted under specific permits.

(19) Safety Rights and Stop Work[8]

(a) A safety-conscious work environment shall be maintained where personnel feel free to raise safety concerns, e.g., concerns about unsafe work practices or potential violations of RSP requirements, without fear of retaliation, intimidation, harassment, or discrimination.

i. Documented procedures shall be implemented and maintained by NIST for employees and associates to raise safety concerns, and for documenting, investigating, and addressing such concerns.

ii. Documented procedures shall be implemented and maintained by NIST for employees and associates to report allegations of retaliation, intimidation, harassment, or discrimination in response to their raising safety concerns, and for documenting, investigating, and addressing such allegations.

(b) Documented procedures shall be implemented and maintained by NIST for employees and associates to stop immediately any operation that presents an imminent danger to the health or safety of NIST employees, associates, visitors, or the public.

[8] The requirements in this subsection are met elsewhere in NIST's occupational safety and health management system (Safety Rights and Responsibilities, Employee Reporting of Unsafe Working Conditions, and Stop Work). These requirements are not addressed in Section 8, ROLES AND RESPONSIBILITIES.

(20) SNM-362 RAM Transportation and Shipping

(a) SNM-362 RAM shall be transported off site only by individuals listed in requests approved by the RSO and authorized by the Division Chief responsible for the RAM.

(b) SNM-362 RAM shall be shipped only to parties authorized to receive such RAM under an NRC or Agreement-State license, as a distribution under the Exempt Distribution license under 10 CFR 110.23, or as a DOE Exempt transfer.

(c) SNM-362 RAM to be shipped off site must be packaged and labeled by SNM-362 RAM shippers in accordance with applicable DOT, NRC, U.S. Postal Service, and IATA requirements.

(21) Radioactive Waste Management

(a) Considerations, including ALARA, related to the generation and management of radioactive waste shall be included in all permits.

(22) Incident Response

(a) Documented procedures for responding to the following events shall be maintained by RSD and implemented as necessary:

i. Activity-specific incidents, including unplanned internal exposures, excessive external exposures, spills, and unplanned environmental releases;

ii. Incidents that restrict access to or compromise the security of facilities;

iii. Loss of control or theft of SNM-362 RAM; and

iv. Other events that require special intervention, e.g., by Source Users, RSD staff members, or emergency-response personnel.

(23) Incident Reporting and Investigation for Incidents within the Purview of the RSP

(a) Incidents shall be reported and investigated in accordance with the NIST Incident Reporting and Investigation suborder with "immediate notification incidents" replaced by "radiological incidents that require reporting to the NRC or other external agencies"; such incidents shall be investigated by the RSO and, when the security of radioactive material is involved, the NSO/OSY

(b) The adequacy of incident investigations of radiological incidents that require reporting to the NRC or other external agencies, and of the associated corrective and preventive actions, shall be reviewed by the IRSC.

(24) Notifications

(a) Notifications and evaluations of theft, loss, incidents, and overexposures shall be made by the RSO to the NRC in accordance with 10 CFR 20.1906, 20.2201-2207, and 30.50.

(b) Notifications that a facility, activity, or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, or that a facility, activity, or basic component supplied to such facility or activity contains defects that could create a substantial safety hazard, shall be made by the RSO to the NRC in accordance with 10 CFR 21.

(25) Reports

(a) A list of routine and non-routine reports required by the NRC and other regulatory agencies shall be maintained by RSD, and such reports shall be submitted to the NRC by the RSO after approval or concurrence by the IRSC, as necessary.

(b) A report documenting RSP program actions, radiological monitoring activities, dosimetry trends, and other program metrics shall be submitted annually by the RSO to the IRSC and by the IRSC to the NIST Director.

(26) Compliance with RSP Requirements

(a) The following information shall be communicated by RSD as required to individuals with responsibilities in the RSP:

i. NIST is subject to inspections by Federal entities. Inspectors for these entities have the right and authority to evaluate the regulatory compliance aspects of all individuals and facility operations under the purview of the RSP.

ii. Individuals with assigned duties in the RSP are subject to monitoring and audits by the NRC, the IRSC, the RSO, RSD, and others.

iii. Findings resulting from inspections, monitoring, and audits may result in suspension or termination of participation in the RSP and of access to SNM-362

RAM facilities. Failure to comply with RSP requirements may result in disciplinary action.

iv. Violations of requirements, including failure to provide information to the NRC that is complete and accurate in all material respects, have the potential for civil and criminal penalties.[9]

(b) Procedures for holding individuals accountable for non-compliance with RSP requirements shall be maintained by the RSO and implemented by the RSO and others as necessary. These procedures shall include but not limited to provisions for suspending or terminating participation in the RSP and prohibiting access to SNM-362 RAM facilities.

(27) Documents and Recordkeeping

(a) Procedures for controlling documents associated with managing the RSP shall be maintained and implemented by the RSO.

(b) Procedures for ensuring that RSP records are retained until license termination or as otherwise specified in applicable regulations, NRC license requirements, or NIST directives shall be maintained and implemented by the RSO.

c. Program Requirements – GL Devices

(1) GL Device Acquisition and Registration

(a) Acquisition of GL devices shall be authorized by the pertinent Division Chief within the requesting OU only after the RSO has approved the associated source acquisition and use request (NIST-364).

(b) Once the acquisition of the GL device is approved, the GL device is given a RS# and is registered in the RSIMS database.

(2) GL Device Use

(a) The use of GL devices is covered by the permit for generally licensed devices.

[9] The Confirmatory Order issued by NRC to NIST on March 1, 2010 requires NIST to incorporate language to this effect into the RSP.

(b) The specifics of how a GL device may be used is dictated by its authorized source use which is found in the RSIMS database and is listed individually for each source. This use is bounded by the conditions and limitations found in the permit.

(c) A request may be made to change any of the authorizations via a NIST-365.

(d) GL devices shall be used only by individuals who have completed the training provided by RSD and been authorized by their Division Chiefs.

(3) Accountability and Administrative Control

(a) The GL devices possessed at NIST Gaithersburg shall be verified via an annual physical inventory.

(b) GL devices shall not be abandoned.

(c) The information included with GL devices about the NRC's requirements for the user shall be followed.

(d) If applicable, leak testing shall be performed.

(4) Transfer and Shipping

(a) No GL device shall be transferred to an off-site recipient without prior authorization by RSD.

(b) The NRC shall be notified by RSD of the transfer of any GL devices from NIST to another party in accordance with the requirements of 10 CFR 31.5 and 10 CFR 30.6.

(c) GL devices shall only be transferred (for disposal or to obtain a replacement device) to a person holding a specific license pursuant to 10 CFR Part 30 and Part 32, such as the device manufacturer or licensed waste broker.

(d) GL devices to be shipped off site must be packaged and labeled by RAM shippers in accordance with applicable DOT, NRC, U.S. Postal Service, and IATA requirements.

(5) Disposal

(a) No GL devices shall be disposed of without prior authorization by RSD.

d. Program Requirements – LC RAM

(1) Acquisition

(a) RSD shall be notified by the OU prior to the acquisition of LC RAM for the purpose of verifying as proper the designation of the RAM as LC RAM and assisting the OU in verification that any applicable quantity limits, such as those specified in 10 CFR 30.18 and 10 CFR 40.22, are not exceeded.

(2) Accountability and Administrative Control

(a) For radiological decommissioning purposes, RSD shall be notified by the OU prior to the acquisition of LC RAM of the locations in which the LC RAM will be used or stored and of any changes to such locations.

(b) RSD shall maintain a current list of the locations in which LC RAM is used or stored.

(c) Any instructions and precautions provided by the manufacturer shall be followed by the user.

(3) Disposal

(a) RSD shall be notified by the OU prior to the disposal of any LC RAM to assist in proper disposal.

8. ROLES AND RESPONSIBILITIES

Roles and responsibilities common to all NIST ionizing-radiation-safety suborders can be found in NIST Order 7201.00.

This section provides general roles and responsibilities pertaining to RAM at NIST Gaithersburg followed by roles and responsibilities specific to SNM-362 RAM, GL devices, and LC RAM.

References to "Division Chiefs" and "Group Leaders" should be interpreted as "or equivalent" for those OUs without Division Chiefs or Group Leaders, respectively.

a. Roles and Responsibilities – General

(1) CSO:

(a) Approve this suborder and all changes thereto; and

(b) Approve all suborder-specific directives and changes thereto;[10] and

(c) Ensure that general radiation-safety-awareness training is incorporated into the NIST general safety training provided to all employees and associates entering on duty.

(2) RSO:

(a) Maintain the RSP;

(b) Review NRC proposed rule changes and other communications and incorporate the results of those reviews into the RSP as necessary to permit ongoing regulatory compliance;

(c) Approve individuals who, once approved, may be designated by the RSO to carry out specified functions on behalf of the RSO; and

(d) Provide, as needed, advice and assistance on radiological safety matters to individuals whose assigned duties involve the use of, or exposure to, RAM.

(3) RSD Chief:

(a) Ensure that RSD staff members carry out their responsibilities.

(4) RSD Staff Members:

(a) Support the RSO and OUs in carrying out their responsibilities.

(5) All Those with Roles in the RSP:

(a) Ensure compliance with all applicable RSP requirements, including RAM security requirements, within their areas of responsibility;

i. Carry out all role-specific responsibilities delineated in RSP program elements that support this suborder, e.g. documented procedures;

(b) Identify to the RSO, and when appropriate, their own management, any issues that have, or may have, ALARA, radiation-safety, or RAM security regulatory-compliance implications, and provide assistance in the resolution of such issues;

[10] As per NIST O 7101.00, Occupational Safety and Health, the CSO has the authority to delegate to the Deputy CSO, subordinate line managers, and other OSHE employees the authorities necessary to carry out CSO responsibilities, provided that such delegations are not inconsistent with other OSH directives.

(c) Cooperate fully with NRC and RSP representatives conducting inspections, monitoring, audits, and investigations; and

(d) Provide information to the NRC that is complete and accurate in all material respects.

b. Roles and Responsibilities – SNM-362

(1) NIST Director:

(a) Authorize applications to transfer ownership or control of licensed activities and submit such applications to the NRC.

(2) IRSC:

(a) Review and approve changes to procedures previously approved by the NRC and incorporated into SNM-362 when:

i. The changes are in accordance with regulatory requirements, will not change license conditions, and will not decrease the effectiveness of the program;

ii. The changes are documented;

iii. Provisions for training are made prior to implementation;

(b) As necessary, evaluate the adequacy of resources for the RSP and recommend changes to the NIST Director;

(c) Maintain documented procedures for IRSC review and approval of Source Users and safety evaluations of authorized use permit requests and authorized use permit amendment requests;

(d) Approve requests for individuals to serve as Source Users;

(e) Approve requests for Source Users to serve as Source Custodians based on their successful completion of the required radiation-safety training;

(f) Review, approve, and record safety evaluations of authorized use permit requests and authorized use permit amendment requests;

(g) Review for completeness and accuracy and authorize or not the submittal of Applications for License Amendment, responses to Requests for Additional Information, Licensee Event Reports, and responses to Notices of Violation;[11]

(h) Review for completeness and accuracy applications to transfer ownership or control of licensed activities prior to the submittal of such applications to NIST Director;

(i) For the following types of events, review the adequacy of the investigations, their conclusions, and actions to preclude recurrence, and track those actions to completion:

i. NRC-reportable occurrences;

ii. NRC-identified violations of RSP requirements;

iii. Self-identified apparent violations of RSP requirements that could be characterized by the NRC as Severity Level I, II, or III violations; and

iv. Any incidents identified to the IRSC by the RSO that have, or may have, adverse impacts on ALARA, radiation safety, or regulatory compliance;

(j) Annually review the performance quality of operations in one or more areas of the RSP, document the results of those reviews, and track and report to the NIST Director on the actions taken;

(k) Review the results of internal and external audits of the RSP and ensure resolution of all reported findings and apparent violations;

(l) On an as-needed basis, specify RSO duties that must be performed by the RSO or an IRSC-approved RSO designee; and

(m) Approve individuals, proposed by the RSO, who, once approved, may be designated by the RSO to carry out IRSC-specified RSO duties on behalf of the RSO.

(3) IRSC Chair:

(a) Ensure that the IRSC operates in accordance with the IRSC charter; and

[11] The Confirmatory Order issued by NRC to NIST on March 1, 2010 required NIST to incorporate language to this effect into the RSP.

(b) Sign RSP documents requiring IRSC approval, signifying such approval.

(4) RSO:

(a) Serve as the manager of, and NRC point of contact for, SNM-362 and 19-23545-01E;

(b) Establish and track metrics indicating the status of the RSP and report these to the IRSC, NIST management, and the NRC as required;

(c) Assist the IRSC in the performance of its duties, including providing timely information to the IRSC on issues and incidents with potentially significant adverse impacts on ALARA, radiation safety, or regulatory compliance;

(d) Propose to the IRSC the approval of individuals who, once approved by the IRSC, may be designated by the RSO to carry out IRSC-specified functions on behalf of the RSO;

(e) Maintain a list of IRSC-approved RSO designees and the RSO duties they are approved to carry out;

(f) Perform radiological hazard assessments to support of the development by the OUs of authorized use permit requests and authorized use permit amendment requests;

(g) Perform safety evaluations of authorized use permit requests and authorized use permit amendment requests;

(h) Approve authorized use permit requests and authorized use permit amendment requests thereby approving of the Permit pursuant to IRSC approval of safety evaluations of those requests;

(i) Approve NIST-364s or NIST-365s, respectively, pursuant to:

i. Determining that acquisitions of SNM-362 RAM will not result in possession limits being exceeded, the requested source use will not result in license conditions being violated, and the requested source use is permitted by the permit referenced by the NIST-364; and

ii. Documenting the **source**-specific maximum dose, dose rate, **source** containment (e.g., sealed, unsealed), emissions, leak-test requirements, radiotoxicity level, and any supplemental **Source-User** requirements, e.g., finger ring, electronic dosimeter; and any **source**-specific requirements for **RSD** staff;

(j) Approve SNM-362 RAM facilities for use based on the facility design and construction and the hazard-control and monitoring systems required to be available in the facility;

(k) Release SNM-362 RAM facilities from the requirements of the RSP after it has been determined by appropriate monitoring that they are suitable for unrestricted use;

(l) When a decision has been to terminate all SNM-362 RAM use activities within a building, ensure that the building is decommissioned in accordance with NRC requirements;

(m) Ensure that areas in which SNM-362 RAM is used or stored are properly posted;

(n) Ensure that SNM-362 radiation-safety and RAM-security training is made available to those who require it based on their assigned duties;

(o) Ensure that individuals requiring SNM-362 radiation safety or RAM-security refresher training are notified when training is due;

(p) Ensure that records of SNM-362 radiation-safety and RAM-security training are maintained;

(q) Submit requests to the IRSC for individuals to serve as Source Users based on their education, experience, and training;

(r) Submit requests to the IRSC for Source Users to serve as Source Custodians based on their successful completion of the required radiation-safety training;

(s) Approve requests for individuals:

i. To serve as Supervised Users based on their successful completion of the required radiation-safety training and attestations by their Division Chiefs and Group Leaders that their qualifications and the direct supervision to be provided have been evaluated and determined to be adequate to ensure safe conduct of the work;

ii. To serve as Supervised-User Supervisors and Alternate Supervised-User Supervisors;

(t) Ensure that internal audits of selected RSP requirements are conducted to identify RSP issues and initiate, recommend, provide, verify, and report to the IRSC on the implementation of corrective and preventive actions;

(u) Evaluate reports of safety hazards that imply the existence of defects or items of non-compliance with NRC regulations and report the results to the IRSC;

(v) Ensure that appropriate radiological monitoring instrumentation is available to RSD staff members as needed;

(w) Provide the OUs with appropriate radiological monitoring instrumentation needed to conduct compliance-related monitoring;

(x) Ensure that all "in-service" instrumentation used for health and safety or regulatory compliance monitoring is subjected to a calibration and testing program;

(y) Establish appropriate requirements for monitoring known and potential radiological hazards;

(z) Maintain procedures for the acquisition of SNM-362 RAM meeting the requirements of Section 7, SNM-362 RAM Acquisition, Accountability, and Administrative Control;

(aa) Maintain procedures to ensure the accountability of the current inventory of SNM-362 sources;

(bb) Maintain a current inventory of RS# sources;

(cc) For RS# sources subject to the hazardous chemical list requirements of NIST Suborder 7101.59, Chemical Hazard Communication:

i. Include the product identifiers referenced on the associated container labels/Safety Data Sheets in the associated RS#-source inventory records; and

ii. Make current RS#-source inventory records available upon request.

(dd) Provide instructions to the Source Custodians for maintaining inventory records of SNM-362 sources;

(ee) Report the inventory reconciliation of nationally tracked sources to NSTS in accordance with the requirements of 10 CFR 20;

(ff) Maintain procedures for meeting SNM-362 RAM-security requirements;

(gg) Report applicable SNM transactions to NMMSS in accordance with the requirements of 10 CFR 74;

(hh) Maintain procedures for implementing the controls necessary to minimize the possibility for unauthorized removal of SNM of low strategic significance and of Category 1 and Category 2 quantities of RAM;

(ii) Submit T&R determination requests to the OSY Reviewing Official after verifying and documenting that requested individuals have job-related duties that require unescorted access to controlled-access areas or security zones or that require their access to information related to such areas or zones;

(jj) Assist the Police Services Group and local law-enforcement agencies in any security-related incident response and in making necessary regulatory notifications;

(kk) Maintain procedures for protecting SGI, SGI-M, and SUNSI;

(ll) Provide appropriate monitoring for individuals whose assigned duties involve the use of or exposure to SNM-362 RAM;

(mm) Approve requests for individuals to transport SNM-362 RAM off the NIST-Gaithersburg site;

(nn) Notify the NRC of SNM-362 RAM thefts, losses, incidents, and overexposures in accordance with 10 CFR 20.1906, 20.2201-2207, and 30.50;

(oo) Notify the NRC of the following in accordance with 10 CFR 21:

i. That a facility, activity, or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954; or

ii. That a facility, activity, or basic component supplied to such facility or activity contains defects that could create a substantial safety hazard;

(pp) Investigate radiological incidents that require reporting to the NRC or other external agencies in accordance with the requirements in Section 7, Incident Reporting and Investigation;

(qq) Provide incident investigation reports, including required corrective and preventive actions, to the IRSC and responsible OU Director and Division Chief;

(rr) Communicate to the IRSC self-identified apparent violations of RSP requirements that could be characterized by the NRC as Severity Level I, II, or III violations;

(ss) Maintain procedures for holding individuals accountable for non-compliance with RSP requirements, including provisions for suspending or terminating participation in the RSP and prohibiting access to SNM-362 RAM facilities;

(tt) Maintain and implement procedures for controlling documents associated with managing the RSP; and

(uu) Maintain and implement procedures for ensuring that RSP records are retained until license termination or as otherwise specified in applicable regulations, NRC license requirements, or NIST directives.

(5) CSO

(a) Submit Applications for License Amendment, responses to Requests for Additional Information, Licensee Event Reports, responses to Notices of Violation, and other communications to the NRC after the IRSC has approved their submittal,

(6) IRSC-Approved RSO Designees:

(a) Once approved by the IRSC to perform specific RSO duties, perform those duties when designated to do so by the RSO.

(7) RSD Staff Members:

(a) Support NCNR HP staff members in carrying out their responsibilities;

(8) NCNR HP Staff Members:

(a) Implement the RSP in accordance with RSD procedures and other applicable documents.

(9) NSO:

(a) Maintain and implement physical-protection systems that:

i. Provide continuous monitoring and detection of unauthorized access or activities within controlled-access areas containing SNM-LSS and security zones containing Category 1 or Category 2 quantities of RAM;

ii. Provide early detection of unauthorized removal of SNM-LSS or Category 1 or 2 quantities of RAM from controlled-access areas or security zones; and

iii. Coordinate immediate assessments by OSY of indications of unauthorized access or activities or actual or attempted removals of SNM-LSS within controlled-access areas or security zones containing SNM-LSS or Category 1 or 2 quantities of RAM;

(b) Maintain and implement an access-authorization program that restricts access to controlled-access areas and security zones to authorized personnel only;

i. Remove individuals from the program when they leave NIST or their assigned duties no longer require access to controlled-access areas and security zones;

(c) Facilitate recovery of removed SNM-LSS or Category 1 or 2 quantities of RAM, in coordination with the Police Services Group and local law-enforcement agencies as necessary;

(d) Approve the security plan;

(e) Test the physical-protections system annually;

(f) Review the access-authorization program annually; and

(g) Maintain records of security-program activities that are suitable for inspection by regulatory agencies and auditors; and

(h) Submit T&R determination requests to the OSY Reviewing Official after verifying and documenting that requested individuals have job-related duties that require their access to information related to controlled-access areas or security zones.

(10) Police Services Group:

(a) Maintain a pre-arranged plan for response to an actual or attempted theft, sabotage, or diversion of Category 1 or 2 quantities of RAM;

(b) Respond without delay to indications of an actual or attempted unauthorized removal of SNM-LSS and/or Category 1 or 2 quantities of RAM; and

(c) Complete training annually on how to respond to security or other monitored-alarm situations that fall within the purview of the RSP.

(11) Fire Protection Group:

(a) Complete training annually on how to respond to fire and other monitored-alarm situations that fall within the purview of the RSP.

(12) OSY Reviewing Official:

(a) Implement and maintain a T&R qualification program for authorizing access to controlled-access areas; security zones; and information related to such zones and areas; and

(b) Conduct an annual review of the T&R qualification program.

(13) Office of Information Systems Management:

(a) Implement and maintain electronic encrypted systems for the protection of SGI, SGI-M, and SUNSI; and

(b) Ensure the secure destruction of electronic SGI, SGI-M, and SUNSI as necessary.

(14) OSHE IT Security Officer:

(a) Support the NIST IT Security Officer and the RSO in carrying out their IT-security-related responsibilities.

(15) AMD Chief:

(a) Ensure that AMD staff members involved in purchasing SNM-362 RAM complete the training specified by RSD on the applicable RSP requirements.

(16) Receiving Personnel:

(a) Complete training on the requirements for receiving SNM-362 RAM packages;

(b) Provide timely notification to RSD of SNM-362 RAM package receipt; and

(c) Provide immediate notification to RSD of SNM-362 RAM packages that are damaged or leaking or cannot be accepted.

(17) SNM-362 RAM Shippers:

(a) Complete RSD-specified training on the applicable DOT, NRC, U.S. Postal Service, IATA, and RSP requirements.

(18) OU Directors:

(a) Approve the submittal to RSD of authorized use permit requests;

(b) Approve the submittal to RSD of authorized use permit amendment requests that involve changes to the radiological hazard mitigation plan;

(c) Integrate the process delineated in this suborder for authorizing the use of SNM-362 RAM into documented experimental procedures for conducting hazard reviews and authorizing work and workers;[12,13] and

(d) Ensure accountability of all RS# and non-RS# sources within their respective OUs

(19) Division Chiefs and Group Leaders Together:

(a) Approve the submittal to RSD of authorized use permit requests and authorized use permit amendment requests;

(b) Ensure that SNM-362 RAM is not acquired or used prior to RSO approval and Division Chief authorization of a NIST-364;

(c) Submit requests to the RSO for individuals to serve as Source Users or Supervised Users based on their education, experience, and training;

(d) Submit requests to the RSO for Source Users to serve as Source Custodians based on their successful completion of the required radiation-safety training;

[12] The *Work and Worker Authorization Based on Hazard Reviews ("Hazard Review")* suborder requires OUs to implement and maintain documented procedures for conducting hazard reviews and authorizing work and workers based on the results of those hazard reviews.

[13] OU hazard reviews include the identification, assessment, and mitigation of all occupational safety and health hazards, not only those associated with RAM. The safety evaluations of authorized use permit and authorized use permit amendment requests result in requirements that must be integrated into those hazard reviews, and, hence, into OU procedures for authorizing work and workers.

(e) When Source Custodians terminate from NIST or will no longer be serving as Source Custodians, ensure that their source accountability responsibilities, are reassigned to one or more other Source Custodians;

(f) Manage the access to, and security of, their assigned SNM-362 RAM facilities;

(g) Serve as the managers for any assigned SNM-362 RAM facility issues (e.g., RSP audit corrective actions and facility work by Plant personnel); and

(h) Authorize the submittal of requests to the RSO for individuals to transport SNM-362 RAM from the NIST-Gaithersburg site.

(20) Division Chiefs:

(a) Authorize RSO-approved NIST-364s and NIST-365s;

(b) Ensure that Source Users and Source Custodians are aware of the terms and conditions of applicable permits and the authorized source use;

(c) Complete initial and refresher SNM-362 radiation-safety training and any applicable SNM-362 RAM-security training to carry out their responsibilities within the RSP;

(d) Ensure that the NSO is notified when individuals leave NIST or whose assigned duties no longer require access to controlled-access areas; security zones; or information related to such areas and zones;

(e) Approve submittals of the annual physical inventory of SNM-362 sources for their Divisions;

i. Ensure that all RS# and non-RS# SNM-362 sources within their Division facilities are properly accounted for, characterized, and documented;

(f) Ensure that radiological incidents occurring within their divisions are reported and investigated in accordance with the requirements in Section 7, Incident Reporting and Investigation;

(g) Ensure that initial incident reports and incident investigation reports are provided to the RSO; and

(h) Authorize RSO-approved requests for individuals to transport SNM-362 RAM off the NIST-Gaithersburg site.

(21) Group Leaders:

(a) Approve the submittal to RSD of NIST-364s and NIST-365s;

(b) Periodically verify that sources are being used in accordance with the terms and conditions of applicable permits, NIST-364s and NIST-365s;

(c) Complete initial and refresher SNM-362 radiation-safety training and any applicable SNM-362 RAM-security training to carry out their responsibilities within the RSP; and

(d) Ensure that all RS# and non-RS# SNM-362 sources within their Group facilities is properly accounted for, characterized, and documented.

(22) Source Users:

(a) Use only those sources and carry out only those protocols for which they have been authorized and do so in accordance with the terms and conditions specified by the applicable NIST-364s and NIST 365s;

(b) Complete initial and refresher SNM-362 radiation-safety training and any applicable SNM-362 RAM-security training to carry out their responsibilities within the RSP;

(c) Protect against unauthorized use of, and access to, sources;

(d) Ensure that containers of SNM-362 RAM and items contaminated with SNM-362 RAM are labeled and marked in accordance with regulatory requirements and in a manner adequate to properly inform any individual in the work area of the potential hazards;

(e) Notify their Group Leader and the RSO of known occupational radiation exposures due to work at facilities other than those owned and operated by NIST;

(f) Obtain a favorable T&R determination prior to being granted unescorted access to a controlled-access area or security zone; and

(g) Obtain training and authorization from RSD prior to working unescorted in controlled-access areas.

(23) Source Custodians (in addition to their responsibilities as Source Users):

(a) Review and accept responsibility for SNM-362 sources as defined in NIST-364s and NIST-365s.

(b) Prior to permitting use of a source for which they are the Source Custodian, ensure that Source Users have been authorized to use the source with a NIST-364 or NIST-365;

(c) Coordinate with RSD transfers of SNM-362 RAM for which they are the Source Custodian to off-site entities or for disposal of waste;

(d) Maintain documented inventory records of source utilization, decay-corrected activity, transfer, distribution, and disposal of RS# and non-RS# sources, including any NMMSS and NSTS materials;

(e) Perform annual physical inventory verifications and reconcile records for RS# via the RSIMS database and non-RS# sources; and

(f) For Source Custodians of 10 CFR Part 36 regulated sources, conduct inspections annually of the operability of license-required access controls in coordination with the RSO.

(24) Authorized Use Permit Administrator

(a) Serve as the facilitator for the submission of an Authorized Use Permit Request by coordinating the scientific needs of the Source Users with the program requirements managed by RSD.

(b) Serve as the facilitator for the submission of an Authorized Use Permit Amendment Request coordinating the changes requested between the Source Users in the current Authorized Use Permit and with the program requirements managed by RSD.

(c) Serve as the liaison between Source Users and RSD in relation to the Authorized Use Permit including any Authorize Use Permit Requests and Authorized use permit Amendment Requests.

(25) Radiation Facility Owner (RFO):

(a) Serve as the primary point of contact for a RAM facility to the RSP.

(b) Ensure a radiation use facility is compliant with the requirements of the RSP and notifies management if corrective actions are needed.

(c) Manage access to a RAM Facility.

(26) Supervised-User Supervisors:

(a) Ensure that the identified job- or task-specific training and direct supervision prescribed in a permit are provided to their Supervised Users prior to and during work with SNM-362 RAM, as applicable.

(b) Designate an Alternate Supervised-User Supervisor if deemed needed and appropriate for the type of work.

(27) Alternate Supervised-User Supervisors:

(a) Carry out the responsibilities of Supervised-User Supervisors when delegated to do so by primary Supervised-User Supervisors.

(28) Supervised Users:

(a) Complete the required SNM-362 radiation-safety training, including training on their responsibilities as Supervised Users, provided by RSD;

(b) Follow the instructions of their Supervised-User Supervisor on the terms and conditions of applicable authorized source uses and authorized-source-use changes; and

(c) Use SNM-362 RAM only under the direct supervision of their Supervised-User Supervisor or their Alternate Supervised-User Supervisor.

c. Roles and Responsibilities – GL Devices

(1) RSO:

(a) Approve NIST-364s and NIST-365s related to GL devices;

(b) Provide appropriate training for Source Users and Source Custodians of GL devices;

(c) Approve requests for individuals to serve as Source Users or Source Custodians of GL devices;

(d) Perform activities needed to maintain safety and compliance for GL devices, including leak testing, coordination of shipping and disposal, and facility audits;

(e) Authorize all GL device transfers and disposals;

(f) Ensure that GL devices are shipped off site in accordance with applicable DOT, NRC, U.S. Postal Service, and IATA requirements; and

(g) Maintain procedures to ensure the accountability of the current inventory of GL devices.

(2) RSD Staff:

(a) Assign RS#s to GL devices whose acquisition has been approved by the RSO and authorized by the Division Chief on NIST-365s.

(3) Receiving Personnel:

(a) Complete training on the requirements for receiving GL devices;

(b) Provide timely notification to RSD of GL device package receipt; and

(c) Provide immediate notification to RSD of GL device that are damaged or leaking or cannot be accepted.

(4) Division Chiefs:

(a) Authorize NIST-364s and NIST-365s related to GL devices;

(b) Ensure that GL devices are not acquired prior to RSO approval and Division Chief authorization of a NIST-364;

(c) Submit requests to the RSO for individuals to serve as Source Users or Source Custodians of GL devices; and

(d) Approve submittals of the annual physical inventory for GL devices for their Divisions;

i. Ensure that all GL devices within their Division facilities are properly accounted for;

(e) Ensure that all GL device transfers and disposals are coordinated in advance with RSD.

(5) Group Leaders:

(a) Ensure that all GL devices within their Group facilities are properly accounted for; and

(b) Ensure that all GL device transfers and disposals are coordinated in advance with RSD.

(6) Source Users:

(a) Complete GL device radiation-safety training to carry out their responsibilities within the RSP;

(b) Obtain approval from the RSO and authorization from their Division Chief prior to acquiring or using GL devices.

(7) Source Custodians (in addition to their responsibilities as Source Users):

(a) Review and accept responsibility for GL devices as defined in NIST-364s and NIST-365s.

(b) Prior to permitting use of a GL device for which they are the Source Custodian, ensure that Source Users have been authorized to use the source;

(c) Coordinate all transfers and disposals of GL devices for which they are the Source Custodian in advance with RSD;

(d) Ensure that documented inventory records of source utilization, decay-corrected activity, transfer, and disposal of GL devices are maintained; and

(e) Perform annual physical inventory verifications and reconcile records for GL devices via the RSIMS database.

d. Roles and Responsibilities – LC RAM

(1) RSO:

(a) Advise OUs of the RSP requirements for LC RAM;

(b) Review all transfers and waste disposals of LC RAM prior to such transfers/disposals; and

(c) Maintain a current list of locations where LC RAM is used or stored.

(2) Division Chiefs:

(a) Ensure that RSD is notified prior to the acquisition of LC RAM;

(b) Provide RSD with the locations, and any changes to locations, in which the LC RAM will be used or stored;

(c) Ensure that users receive any instructions and precautions provided by the manufacturer; and

(d) Ensure that RSD is notified prior to the disposal of any LC RAM.

(3) Users:

(a) Follow any instructions and precautions provided by the manufacturer and any requirements of the RSP.

9. AUTHORITIES

For authorities common to all NIST ionizing-radiation-safety suborders, see NIST Order 7201.00.

The entities and individuals listed in Section 8 have the authority to carry out their assigned responsibilities. In addition:

a. IRSC:

(1) Review and concur on IRSC-selected elements of the RSP.

b. Source Custodians:

(1) Suspend access to, or use of, sources when there is a known or potential safety or regulatory compliance issue related to such access or use; and

(2) Direct source users to physically produce sources for source-inventory purposes.

10. ACCOUNTABILITIES

a. Disciplinary action and the suspension or termination of participation in the RSP and of access to RAM facilities may be applied, as appropriate, when assigned responsibilities are not carried out in a complete manner or when action or inaction leads to radiation-safety, RAM-security, or RSP-compliance issues.

b. Failure to comply with RSP requirements, including violations of NRC licenses and the failure to provide information to the NRC that is complete and accurate in all material respects, has the potential for civil and criminal penalties.[14]

11. DIRECTIVE OWNER

Chief Safety Officer

12. Appendices

A. Revision History

[14] The Confirmatory Order issued by NRC to NIST on March 1, 2010 requires NIST to incorporate language to this effect into the RSP.

Appendix A. Revision History

Revision #	Approval Date	Deployment Start Date	Effective Date	Description of Change
0	10/09/15	10/09/15	TBD	• Initial document
1	11/24/15	11/24/15	TBD	• Modified the inventory requirements and the responsibilities of the RSO for RS# sources to incorporate the hazardous chemical list requirements of NIST Suborder 7101.59, Chemical Hazard Communication in this suborder. • Clarified the requirements and roles and responsibilities with regard to LC RAM.
2	2/10/2021	3/2/2021	TBD	• Rename of the Safety Evaluation to an Authorized Use Permit • Create a permit administrator for each permit • Re-establish the Radiation Facility Owner • Re-establish that Source Custodians are approved by the IRSC • Re-establish the submission of documents to the NRC is done by the CSO • Other minor revisions