IONIZING RADIATION SAFETY – RADIOACTIVE MATERIALS AT NIST-BOULDER

NIST S 7201.02
Approval Date: 02/10/2017
Effective Date:[1] 02/10/2017

Table of Contents

[1] For revision history, see Appendix A.

1. PURPOSE

a. This suborder establishes the requirements of an operational radiation safety program necessary for the implementation of NIST Order 7201 as it applies to the acquisition, use, and disposition of radioactive material (RAM) at NIST Boulder. The main goal of the program is to permit the beneficial use of radioactive materials for research and development purposes while ensuring doses are maintained as low as is reasonably achievable (ALARA).

b. This suborder establishes:

(1) Program elements;

(2) Roles of individuals and their corresponding responsibilities;

(3) Authorities necessary for fulfilling responsibilities; and

(4) A standard of accountability.

c. This suborder describes the "what's required" and "who's responsible" for the program. The implementation (the "how to") of this program is accomplished through various documents such as a radiation safety manual, procedures, instructions, guideline, *etc.*

2. BACKGROUND

a. As a federal organization, NIST is subject to the authority of the Nuclear Regulatory Commission (NRC) regulations regarding radioactive materials written in Title 10, Code of Federal Regulations (CFR).

b. The acquisition, use, and disposition of licensed radioactive material is authorized by the issuance of a specific license or granted through a general license. NIST Boulder is eligible for both types of licenses. Licensed material is used in accordance with a specific license; generally-licensed materials and other materials are used in accordance with applicable regulations.

c. NIST may revise radiation safety program procedures without submitting an application for license amendment provided that:

(1) The changes are approved by the Radiation Safety Officer (RSO) in writing;

(2) The appropriate licensee staff members are provided training in the revised procedure(s) prior to implementation;

(3) The changes are in compliance with the NRC regulations and the license; and

(4) The changes do not degrade the effectiveness of the program. **[LC20A Item 10]**

(a) Program requirements imposed on the use of specifically-licensed material by NRC Materials License 05-03166-06 are emphasized by the format "[License Condition # and in some cases specific sections]" (e.g., LC20A Item 10 means License Condition 20A. Application dated April 28, 2015 (ML15156B315) Item 10 Radiation Safety Program) since the condition may be more restrictive than regulation.

3. APPLICABILITY

This suborder applies to activities conducted under specific licenses applicable to NIST Boulder or involving generally-licensed or non-specially-licensed RAM regulated by the NRC.

4. REFERENCES

a. Code of Federal Regulations, Energy Title 10, Chapter 1, various parts.

b. Code of Federal Regulations, Protection of Environment Title 40, as applicable.

c. Code of Federal Regulations, Transportation Title 49, as applicable.

d. NRC Materials License(s), current.

e. U.S. NRC Consolidated Guidance About Materials Licenses (NUREG-1556).

f. NIST O 7201.00, Ionizing Radiation Safety – Radioactive Material and Ionizing-Radiation-Producing Machines.

g. U.S. NRC Regulatory Guide 8.13 Instruction Concerning Prenatal Exposure.

h. U.S. NRC Regulatory Guide 8.29 Instruction Concerning Risks from Occupational Radiation Exposure.

i. ANSI N323-1978 Radiation Protection Instrumentation Test and Calibration.

j. National Council on Radiation Protection and Measurements (NCRP) Report No. 127 Operational Radiation Safety Program.

5. APPLICABLE NIST OCCUPATIONAL SAFETY AND HEALTH DIRECTIVES

a. NIST S 7101.20: *Work and Worker Authorization Based on Hazard Reviews*.

b. NIST S 7101.23: *Safety Education and Training Program*.

c. NIST S 7101.24: *Incident Reporting and Investigation*.

d. NIST S 7101.04: *Safety and Health Requirements for Minors*.

6. DEFINITIONS

a. **ALARA** (acronym for "as low as is reasonably achievable") - Making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part 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 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.

b. **Ancillary Personnel** – Individuals who are not actively fulfilling the role of an AU or SU but whose assigned duties involve potential exposure to radiation and/or radioactive material.

c. **Authorized User** (sometimes referred to as the Principal Investigator (PI)) – The NRC-approved individual who is assigned primary responsibility for the safe use and handling of specifically-licensed RAM they have been approved to possess.

d. **Becquerel** (Bq) – The SI unit of radioactivity, corresponding to one disintegration per second.

e. **Byproduct material** –

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(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 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or any material that:

(a) Has been made radioactive by use of a particle accelerator; and

(b) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

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

(a) The Commission, 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, determines 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) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

f. **Committed Dose Equivalent** ($H_{T,50}$) – The dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

g. **Controlled area** – An area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

h. **Curie** (Ci) – A unit of radioactivity equal to 3.7×10^{10} disintegrations per second.

i. **Declared pregnant woman** – A woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in

effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

j. **Discrete source** – A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

k. **Dose or radiation dose** – A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this section.

l. **Dose equivalent (HT)** – The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

m. **Effective dose equivalent (HE)** – The sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factors (WT) applicable to each of the body organs or tissues that are irradiated (HE = ΣWTHT).

n. **Embryo/fetus** – The developing human organism from conception until the time of birth.

o. **Exposure** – Being exposed to ionizing radiation or to radioactive material.

p. **Extremity** - Hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

q. **Gray** – The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads).

r. **High radiation area** – An area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

s. **Individual** – Any human being.

t. **Individual monitoring** –

(1) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(2) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

(3) The assessment of dose equivalent by the use of survey data.

u. **Individual monitoring devices** (individual monitoring equipment) - Devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

v. **Internal dose** – That portion of the dose equivalent received from radioactive material taken into the body.

w. **Ionizing Radiation Safety Committee** (IRSC) – A body chartered by the NIST Director to assist the Director and RSO in managing the radiation safety program.

x. **License** – A license issued under the regulations in parts 30 through 36, 39, 40, 50, 60, 61, 63, 70, or 72 of this chapter.

y. **Licensed material** - Source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the Commission.

z. **Licensee** – The holder of a license.

aa. **Limits** (dose limits) – The permissible upper bounds of radiation doses.

bb. **Member of the public** – Any individual except when that individual is receiving an occupational dose.

cc. **Minor** – An individual less than 18 years of age.

dd. **Monitoring** (radiation monitoring, radiation protection monitoring) – The measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

ee. **NRC** – The Nuclear Regulatory Commission or its duly authorized representatives.

ff. **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 radioactive material 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 radioactive material and released under § 35.75, from voluntary participation in medical research programs, or as a member of the public.

gg. **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 shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), 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.

hh. **Planned special exposure** – An infrequent exposure to radiation, separate from and in addition to the annual dose limits.

ii. **Public dose** – The dose received by a member of the public from exposure to radiation or to radioactive material 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 radioactive material and released under § 35.75, or from voluntary participation in medical research programs.

jj. **Rad** – The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

kk. **Radiation** (ionizing radiation) – Alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing

ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

ll. **Radiation area** – An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

mm. **Radiation Safety Officer** – An individual nominated by NIST and approved by the NRC who is responsible for managing the radiation safety program. See NUREG Series 1556 for the minimum RSO qualifications.

nn. **Rem** – The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem=0.01 sievert).

oo. **Residual radioactivity** – Radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 10 CFR part 20.

pp. **Responsible Person** – The individual who is assigned sole responsibility for the safe use and handling of generally-licensed or non-specifically-licensed RAM regulated by the NRC.

qq. **Restricted area** – An area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

rr. **Sievert** – The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv=100 rems).

ss. **Site boundary** – The line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

tt. **Source material** –

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

(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. Source material does not include special nuclear material.

uu. **Special nuclear material** –

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

vv. **Supervised User (SU)** – An AU-approved individual who is authorized to use an AU's specifically-licensed RAM. As the name implies, the SU is under the supervision of the AU who is responsible for the particular RAM.

ww. **Survey** – An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

xx. **Total Effective Dose Equivalent (TEDE)** – The sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

yy. **Unrestricted area** – An area, access to which is neither limited nor controlled by the licensee.

zz. **Waste** – Those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

aaa. **Week** – Seven (7) consecutive days starting on Sunday.

bbb. **Whole body** - For purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

ccc. **Year** – The period of time beginning in January used to determine compliance with the provisions of this part. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

7. ACRONYMS

a. ALARA – As Low As is Reasonably Achievable.

b. ANSI – American National Standards Institute.

c. AU – Authorized User.

d. CDE – Committed Dose Equivalent.

e. CFR – Code of Federal Regulations.

f. DOT – Department of Transportation.

g. IRSC – Ionizing Radiation Safety Committee.

h. LSC – Liquid Scintillation Counter.

i. NCRP - National Council on Radiation Protection and Measurements.

j. NIST – National Institute of Standards and Technology.

k. NRC - Nuclear Regulatory Commission.

l. NUREG – NRC Technical Report Designation (Nuclear Regulatory Commission).

m. NVLAP - National Voluntary Laboratory Accreditation Program.

n. RAM – Radioactive material.

o. Reg. Guide – NRC Regulatory Guide.

p. RSO – Radiation Safety Officer.

q. SI – Système International d'Unités.

r. SU – Supervised User.

s. TEDE – Total Effective Dose Equivalent.

8. REQUIREMENTS

NIST is required as a licensee to develop, document, and implement a radiation protection program commensurate with the scope and extent of specifically licensed activities and sufficient to ensure compliance with the provisions of 10 CFR 20.

To ensure compliance NIST shall use, to the extent practical, engineering controls and procedures based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA.

Except as specifically provided otherwise in NRC Materials License 05-03166-06, NIST shall conduct its program in accordance with the statements, representations, and procedures contained in the license. The U.S. NRC's regulations shall govern unless the statements, representations, and procedures in the license application and correspondence are more restrictive than the regulations. **[LC 20]**

SPECIAL CIRCUMSTANCES:

1) **RAM that is not specifically-licensed is not typically subject to a specific license or the requirements of a written radiation protection program unless required by regulation.**

2) **Therefore, RAM (e.g., generally-licensed material of devices, "exempt quantities" of byproduct material, small quantities of source material, etc.) not listed on a specific license is managed on a case-by-case basis in accordance with applicable regulations and is only subject to the requirements in this suborder when specifically applicable.**

3) **Responsible Persons designated by official first-level supervisors shall ensure regulatory and program compliance for their RAM that is not specifically-licensed, inform the RSO of receipt, use, and storage locations, and transfer the RAM in**

accordance with regulatory requirements. If disposal is permitted, it is to be transferred to the RSO for proper disposal.

The following elements are required in this program and are implemented through various documents (e.g., radiation safety manual, procedures, instructions, guideline, etc.). Each element is addressed separately below:

a. Radiation Safety Training;

b. Radiation Monitoring Instruments;

c. Radiological Surveys;

d. Material Receipt, Accountability, and Security;

e. Safe Use of Radionuclides and Emergency Procedures;

f. Occupational Dose;

g. Transportation;

h. Waste Management;

i. Program Review;

j. Notifications and Reports; and

k. Recordkeeping.

a. Radiation Safety Training

(1) Qualified Instructors **[LC 20A Item 8C]**

(a) The RSO and Authorized Users (AUs) are qualified by default for providing radiation safety training.

(b) Other instructors may be approved at the discretion of the RSO.

(2) Acceptable Training Methods **[LC 20A Item 8C]**

(a) Attending qualified instructor training sessions;

(b) Reading materials provided by qualified instructors;

(c) Computer-based training approved by a qualified instructor;

(d) Watching Radiation Safety video presentations approved by a qualified instructor;

(e) Attending training provided by other NIST staff or outside vendors approved by the RSO or an AU;

(f) Attending radiation safety related seminars as approved by the RSO or an AU; or

(g) Other means at the discretion of the RSO or an AU.

(3) Notices, Instructions, and Reports to Workers (10 CFR 19) Training **[LC 20A Item 8B]**

(a) All individuals who in the course of employment are likely* to receive, in a year, an occupational dose in excess of 100 mrem shall be instructed in the following in a manner commensurate with potential radiological health protection problems present in the workplace:

i. The storage, transfer, or use of radiation and/or radioactive material.

ii. The health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed.

iii. The applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material as well as the expectation that the individual shall comply with said regulations and license conditions.

iv. Their responsibility to report promptly to the RSO any condition which may lead to or cause a violation of NRC regulations and licenses, or potential unnecessary exposure to radiation and/or radioactive material.

v. The appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material.

vi. The radiation exposure reports which workers may request pursuant to 10 CFR 19.13.

***NOTE**: When determining the likelihood of occurrence, consider assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility.

(4) Content of Training **[LC 20A Item 8C]**

(a) Training shall be of sufficient content and length to ensure the compliant, safe use and handling of RAM. **[LC 20A Item 8C]**

(b) NUREG 1556 Volume 7, Appendix J should be used as a guide for selecting training topics.

(c) Training should include the following elements as applicable:

i. Radiation Protection Principles;

(i) ALARA Policy and Practices;

ii. Characteristics of Ionizing Radiation;

iii. Units of Radiation Dose and Quantities;

iv. Proper Selection and Use of Radiation Detection Instrumentation;

v. Biological Hazards of Exposure to Radiation (with respect to the scope of source use):

(i) Declared Pregnant Woman Policy; and

(ii) Minors in NIST Laboratories Policy;

vi. Acquisition and Disposition of RAM;

vii. Accountability and Control of RAM;

(i) Posting and Labeling of RAM;

viii. Hands-on Use of Radioactive Material;

ix. Emergency Response; and

x. Dosimetry.

(d) Ancillary Personnel may not need extensive training, however, the following is the minimum they shall receive:

i. Radiation hazards they may be exposed to:

(i) Declared Pregnant Woman Policy; and

(ii) Minors in NIST Laboratories Policy;

ii. Response to Radiological Postings;

iii. The appropriate precautions necessary to keep exposure ALARA;

iv. Acquisition and Disposal of RAM;

v. Emergency Response; and

vi. Recognition of events which requires informing the RSO.

(e) General Employee & Associate Orientation

i. Overview of radiation safety policies and procedures:

(i) ALARA;

(ii) Recognition and Response to Radiological Postings; and

(iii)Emergency Response;

ii. Acquisition and Disposal of RAM.

(5) Assessment of Training **[LC 20A Item 8C]**

(a) Training shall be assessed by written or verbal testing, except in the case of the RSO being self-taught, in which no assessment will be performed.

(b) A test will be considered successfully completed with a score of at least 80%.

(c) Additional assessments may be used to demonstrate proficiency in practical applications (*e.g.*, instrument use in accordance with operating manual).

(6) Frequency of Training for Personnel **[LC 20A Item 8C]**

(a) Before assuming duties with, or in the vicinity of, radioactive materials or radiation.

(b) Conditional training circumstances at the discretion of the RSO or an AU.

i. Whenever there is a significant, applicable change in duties, regulations, or the terms of the license.

ii. Behavioral or "for-cause" retraining.

(c) Refresher Training.

i. Annually:

(i) Authorized Users; and

(ii) Responsible Persons.

ii. Biennially

(i) Supervised Users (SUs); and

(ii) Ancillary Personnel.

b. Radiation Monitoring Instruments

(1) NIST will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG 1556, Vol. 7 dated December 1999. **[LC 20A Item 10A]**

(2) At a minimum, NIST shall possess, or have access to, the following or equivalent **[LC 20A Item 10A]:**

(a) An ion chamber dose rate meter;

(b) A pancake Geiger Mueller detector calibrated in counts per minute;

(c) An alpha detector calibrated in counts per minute; and

(d) A Liquid Scintillation Counter (LSC).

(3) Instruments and equipment used for quantitative radiation measurements (*e.g.*, dose rate and effluent monitoring) shall be calibrated periodically for the radiation measured in accordance with ANSI N323-1978.

c. Radiological Surveys

(1) NIST shall make or cause to be made, surveys of areas, including the subsurface, that:

(a) May be necessary for compliance with the regulations in 10 CFR 20; and

(b) Are reasonable under the circumstances to evaluate:

i. The magnitude and extent of radiation levels;

ii. Concentrations or quantities of residual radioactivity; and

iii. The potential radiological hazards of the radiation levels and residual radioactivity detected.

(2) NIST shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 20.1301.

(3) NIST shall survey the facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG 1556, Vol. 7, dated December 1999. **[LC 20A Item 10E]**

(4) Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such intervals specified in the certificate of registration issued by the U.S. NRC under 10 CFR 32.210 or by an Agreement State. **[LC 14A]**

(5) Sealed sources and detector cells designed to emit alpha particles shall be tested at intervals not to exceed 3 months. **[LC 14B]**

(6) Sealed sources and detector cells shall be tested for leakage prior to use unless accompanied by a satisfactory leak test by the previous owner in the last 6 months (3 months for primarily alpha emitters) **[LC 14C]**

(7) The following sealed sources and detector cells need not be tested **[LC 14D]**

(a) Those containing 100 μCi (3.7 MBq) or less of beta- and/or gamma-emitting radioactive material;

(b) Those containing 10 μCi (370 KBq) or less of alpha-emitting radioactive material;

(c) Those containing only H-3 (tritium);

(d) Those containing only material with a half-life of 30 days or less; or

(e) Those containing only gaseous radioactive material.

(8) Sealed sources need not be leak tested if they are in storage **AND** are not in use. However, when the source is removed from storage for use or transfer and has not been tested within the required interval, the source shall be leak tested prior to use or transfer. **[LC 14E]**

(9) No sealed source shall be stored for a period of more than 10 years without being tested for leakage. **[LC 14E]**

(10) The leak test shall be capable of detecting the presence of 0.005 μCi (185 Bq) of radioactive material on the test sample. **[LC 14F]**

(11) Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by NIST or by other persons specifically licensed by the U.S. NRC or an Agreement State to perform such a service. **[LC 14G]**

d. Material Receipt, Accountability, & Security

(1) Possession and use of specifically-licensed material is limited to the license conditions of license 05-03166-06. **[LC 6, 7, 8, & 9]**

(2) Possession and use of generally licensed material is limited to the applicable general license.

(3) Possession and use of non-specifically licensed material is limited to the applicable regulation(s).

(4) NIST shall use written procedures for ensuring that material is properly received and opened. **[LC 20A Item 10B]**

(5) Packages (if identified as radioactive material) shall be inspected by receiving personnel and secured in a locked enclosure reserved for radioactive material until they are retrieved by the RSO for monitoring. **[LC 20A Item 9A]**

(6) NIST shall ensure monitoring of the external surfaces of a package containing licensed material as indicated in the table below (presumes package is received during normal working hours. If received outside of normal working hours, monitor the package within 3 hours of the beginning of the next work day):

Package	Contents	Survey Type	Survey Time*
Labeled (White I, Yellow-II, Yellow-III)	Gas or Special Form, Greater Than Type A Quantity	Radiation Level	As soon as practicable, but not later than 3 hours after receipt of the package
Labeled (White I, Yellow-II, Yellow-III)	**NOT** Gas or Special Form, Greater Than Type A Quantity	Contamination & Radiation Level	As soon as practicable, but not later than 3 hours after receipt of the package
Labeled (White I, Yellow-II, Yellow-III)	Gas or Special Form, Less Than Type A Quantity	None	None
Labeled (White I, Yellow-II, Yellow-III)	**NOT** Gas or Special Form, Less Than Type A Quantity	Contamination	As soon as practicable, but not later than 3 hours after receipt of the package

Not Labeled	Licensed Material	None	None
Damaged	Licensed Material	Contamination & Radiation Level	As soon as practicable, but not later than 3 hours after receipt of the package

(7) NIST shall use written procedures for ensuring material accountability and security are implemented. **[LC 20A Item 10B]**

(8) Licensed material that is in a controlled or unrestricted area shall be stored and secured from unauthorized removal or access when not in use. [**LC 20A Item 9B]**

(9) Licensed material that is in use in a controlled or unrestricted area shall be controlled and under constant surveillance. **[LC20A Item 9C]**

(10) Physical inventories shall be conducted every 6 months, or at other intervals approved by the NRC, to account for all sealed sources and/or devices received and possessed under NRC Materials License No. 05-03166-06. **[LC 13 and 20A Item 10B]**

e. Safe Use of Radionuclides and Emergency Procedures

(1) NIST shall develop and implement procedures for the safe use of licensed material, including security of materials, and emergencies involving licensed material. **[LC 20A Item 10D]**

(2) Posting of notices to workers shall be in accordance with 10 CFR 19.11.

(3) Planned special exposures shall be in accordance with 10 CFR 20.1206.

(4) NIST shall conduct operations so that (1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, and (2) The dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 mSv) in any one hour.

(a) If NIST permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(5) Specifically-licensed material shall be stored or used only at NIST facilities located at 325 Broadway, Buildings 1, 23, and 81. **[LC 10]**

(6) Specifically-licensed material shall be used by, or under the supervision of, an Authorized User. **[LC 11]**

(7) Specifically-licensed material shall be used for the purposes approved by license 05-03166-06 **[LC 9A-E and LC 20A]**

(8) Sealed sources or detectors cells containing licensed material shall not be opened or sources removed from source holders. **[LC 15]**

(9) Licensed material shall not be used in or on human beings. **[LC 16]**

(10) NIST shall not offer licensed material for commercial distribution. **[LC 17]**

(11) NIST shall not use licensed material where activity is planned to be released to the environment. **[LC 19]**

f. Occupational Dose

(1) NIST shall do a prospective evaluation and determine that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or NIST will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program - Occupational Dose' in NUREG-1556, Vol. 7, dated December 1999. **[LC 20A Item 10C]**

(2) NIST shall implement radiation safety procedures which ensure doses are ALARA, but in any case do not exceed the following dose limits:

Type of Exposure	Regulatory Limits
Whole body, TEDE	5000 mrem/year
Sum of DDE and CDE to organ	50000 mrem/year
Skin or Extremity	50000 mrem/year
Lens of Eye	15000 mrem/year
Internal	1.0 ALI/year 10 mg/week soluble uranium
Embryo/Fetus*	500 mrem/gestation period
Member of the Public	100 mrem/year

*See Reg. Guide 8.13 and 8.29 for additional information.

(3) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with 10 CFR 20 or with conditions specified in a license must be processed and evaluated by a dosimetry processor:

(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

g. Transportation

(1) NIST may transport licensed material only in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material". **[LC 18]**

h. Waste Management

(1) NIST will use the model waste procedures published in Appendix T to NUREG 1556, Vol. 7, dated December 1999 to manage waste disposition. **[LC 20A Item 11]**

(2) NIST shall use contamination minimization techniques to reduce the generation of radioactive waste.

i. Program Reviews (Audits)

(1) The licensee shall periodically (at least annually) review (audit) the radiation protection program content and implementation to ensure the following:

(a) Compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license; and

(b) Occupational doses and doses to members of the public are ALARA.

(2) NIST should use the model program review forms published in Appendix H to NUREG 1556, Vol. 7, Revision 1, dated February 2018, to perform program reviews. However, if the forms are not sufficient for a particular review it may be modified in full or part.

j. Notifications and Reports

(1) Radiation exposure data for an individual, and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, shall be reported to the individual as specified in 10 CFR 19.13.

(2) NIST shall inform an individual, in writing, of the dose from a planned special exposure within 30 days of the exposure as specified in 10 CFR 20.1206 and 20.2204.

(3) NIST shall submit a written report to the Administrator of the Region 4 NRC Office within 30 days following any planned special exposure, informing the NRC that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 10 CFR 20.2105.

(4) If a leak test reveals the presence of 0.005 μCi (185 Bq) or more of removable contamination **[LC 14F]**:

(a) The source shall be immediately removed from service; and

(b) A report shall be filed with the NRC in accordance with 10 CFR 30.50(c)(2).

k. Recordkeeping

(1) NIST shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this program.

(a) NIST may include SI units in parentheses following the standard units.

(b) Shipping manifests for waste are an exception in that SI units are required to be used; the standard units above may follow in parentheses.

(2) All records must be legible throughout the specified retention period.

(3) Records of the radiation safety program, including provisions of the program, shall be retained until the NRC terminates the license requiring the records.

(4) Records of audits and other reviews of program content and implementation shall be retained for 3 years after the record is made.

(5) Records showing the results of surveys and calibrations shall be retained for 3 years after the record is made.

(6) Records showing the transfer of licensed material shall be retained for 3 years after the transfer date.

(7) The following records are to be retained until the NRC terminates the license requiring the records:

(a) Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

(b) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

(c) Records showing the results of air sampling, surveys, and bioassays;

(d) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment; and

(e) Records sufficient to demonstrate compliance with the dose limit for individual members of the public.

(8) Records of the conduct of a planned special exposure shall be in accordance with 10 CFR 20.2105.

(9) Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and identifier such as model number, and the date of the inventory. **[LC 13 & 20A Item 10B]**

(10) Records of leak test results shall be kept in units of μCi and shall be maintained for 3 years. **[LC 14H]**

9. RESPONSIBLITIES

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

NOTE: *A person may delegate the authority of their position to other individuals in order to perform tasks that are necessary to meet program requirements unless a task is prohibited as*

non-delegable. In any case, the person retains the responsibility (a.k.a. burden) for ensuring the task is successfully accomplished.

a. Line Management (as it applies within their subordinate organizational body)

(1) Managers are responsible for ensuring that resources are authorized and properly allocated to sufficiently support radiological compliance and safety;

(2) Supervisors and managers are responsible for supporting the RSO, Responsible Persons, and Users in those instances when it is necessary for those individuals to assert authority; and

(3) Official first-level supervisors are responsible for designating Responsible Persons for non-specifically-licensed RAM.

b. Radiation Safety Officer

(1) Ensuring compliance with NRC and Department of Transportation (DOT) regulations and the conditions of material licenses by developing, managing, and enforcing a written radiation safety program;

(2) Complying with, and ensuring, applicable NIST policies and other directives are incorporated into the written radiation safety program;

(3) Providing health physics services within capabilities of the Boulder Safety, Health, and Environment Division;

(4) Submitting NRC License Applications, Applications for License Amendment, responses to Requests for Additional Information, Licensee Event Reports, and responses to Notices of Violation to the IRSC to review for completeness and accuracy;

(5) Notifying the NRC of radiological incidents in accordance with the applicable regulations; and

(6) Ensuring that the Ionizing Radiation Safety Committee (IRSC) is informed of the posting of any RAM-related reports to the NIST Incident Reporting and Investigation System.

c. Authorized Users

(1) Supervising the use of the radioactive material they manage;

(2) Ensuring that radioactive materials used in his or her particular lab or area are used safely and according to regulatory and program requirements;

(3) Ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA;

(4) Ensuring that they and their users have adequate and appropriate training to provide reasonable assurance that they will use licensed material safely, including maintaining security of, and access to, licensed material, and respond appropriately to events or accidents involving licensed material; and

(5) Ensuring that ancillary personnel have adequate and appropriate training to provide reasonable assurance that they will maintain their doses ALARA, follow posted instructions, and respond appropriately to radiological events.

d. Supervised Users

(1) Following current approved radiation safety procedures.

e. Ancillary Personnel

(1) Following current approved radiation safety procedures.

f. Ionizing Radiation Safety Committee

(1) Reviewing NRC License Applications, Applications for License Amendment, responses to Requests for Additional Information, Licensee Event Reports, and responses to Notices of Violation for completeness and accuracy, and advise the NIST Director as necessary, prior to their submittal to the NRC;

(2) For the following types of events, reviewing the adequacy of the investigations and actions to prevent recurrence, and reporting to the NIST Director on their completion:

(a) NRC-reportable occurrences involving radioactive material;

(b) NRC-identified violations of radiation safety program requirements;

(c) Self-identified apparent violations of radiation safety program requirements that could be characterized by the NRC as Severity Level I, II, or III; and

(d) Any events identified to the IRSC by the RSO that have, or may have, adverse impacts on ALARA, radiation safety, or regulatory compliance; and

(3) Reviewing the results of program reviews (audits) and tracking and reporting to the NIST Director on the resolution of all reported findings and apparent violations; and

(4) Assisting the RSO upon request from the RSO.

g. Responsible Persons

(1) Supervising the use of the radioactive material they manage;

(2) Ensuring that radioactive material used in their particular lab or area are used safely and according to regulatory and applicable program requirements;

(3) Ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA;

(4) Ensuring that they and their users have adequate and appropriate training to provide reasonable assurance that they will use licensed material safely, including maintaining security of, and access to, licensed material, and respond appropriately to events or accidents involving licensed material; and

(5) Ensuring that ancillary personnel have adequate and appropriate training to provide reasonable assurance that they will maintain their doses ALARA, follow posted instructions, and respond appropriately to radiological events.

10. AUTHORITIES & ACCOUNTABILITIES

"The key to an effective [radiation protection] program is the formal delegation of authority to competent staff members." – NCRP Report No. 127

a. Special Delegation of Authority

(1) The RSO, AU, SU, and Responsible Person roles are delegated the authority of the NIST Director to ensure the safe and compliant use of RAM. This power ***is not*** limited by organizational boundaries, roles, positions, or employment statuses.

(a) Line management will support these roles in those instances where it is necessary for them to assert authority.

i. If any radiological dispute arises, the RSO is the final arbiter.

b. Accountability

(1) Each individual fulfilling a role in this program is accountable for their conduct. Depending on the circumstances, the consequences for inappropriate behavior may progressively escalate (e.g., peer coaching, re-training, suspension or revocation of RAM use).

(a) Personnel actions may be initiated by line management.

(b) Civil or criminal actions may be taken depending on circumstances.

11. DIRECTIVE OWNER

a. Chief Safety Officer

12. APPENDICES

A. Revision History

Appendix A. Revision History

Revision No.	Approval Date	Deployment Start Date	Effective Date	Brief Description of Change; Rationale
0	02/10/17	NA	02/10/17	None – Initial document
1	04/17/18	NA	04/17/18	• Added responsibility for the IRSC to review the results of internal and external audits of the Boulder radioactive materials program and tracking and reporting to the NIST Director on the resolution of all reported findings and apparent violations;