



PennState

Office of Physical Plant
Environmental Health and Safety
The Pennsylvania State University
6 Eisenhower Parking Deck
University Park, PA 16802

814-865-6391
Fax: 814-863-7427
www.ehs.psu.edu

December 9, 2016

Director, Office of Nuclear Security and Incident Response
U.S. Nuclear Regulatory Commission
Document Control Desk
11555 Rockville Pike
Rockville, Maryland 20852-2738

Re: License SNM-95
Docket: 070-0113

Subject: Response to Questions Regarding Subparts K and L Implementation

This letter is in response to informal questions raised by Mr. Christopher Ryder by email and telephone conversations regarding Penn State's implementation and compliance with 10 CFR Subparts K and L in connection with the SNM-95 license renewal application. With the number of individual components of these Subparts, I felt it best to respond formally by means of the Enclosure attached to this letter.

These responses included reference to specific groups within the radiation safety program at Penn State: the University isotopes Committee, Environmental Health and Safety, Radiation Safety Officer, and the Radiation Protection Office/Staff. The roles and responsibilities of each of these groups are detailed on pages 13-15 in the documents submitted to the Nuclear Regulatory Commission dated November 5, 2014 with the subject "Amendment to PSU license renewal application dated August 1, 2014."

Regards,

Mark E. Linsley, CHP, Radiation Safety Officer
Pennsylvania State University
6 Eisenhower Parking Deck
University Park, PA 16802
814-865-6391; mark@trgroupinc.com

CC: Maurine Claver, Director, Environmental Health and Safety
Yuanqing Guo, Assistant Radiation Safety Officer

Enclosure: Response to questions regarding renewal application of NRC License SNM-95

NSIRD
NMSSOI
NSIR
NMSS

Enclosure: Response to questions regarding renewal application of NRC License SNM-95

Informal question from phone conversations and/or emails with C. Ryder:

PSU is currently licensed for liquid fission products. How does PSU prevent internal exposures?

RESPONSE

Possession and use of radioactive material is in accordance with "The Rules and Procedures for Users of Radioactive Material at The Pennsylvania State University" document approved by the University Isotopes Committee (UIC). This document covers polices for the safe use of radioactive material and includes emergency procedures applicable to the users of this material.

In general, rooms authorized for the use of radioactive material are laboratories with sinks, benches, and fume hoods. Contamination survey meters are available for all laboratories using radioactive material other than tritium. Lab coats, protective eye wear, splash shields, and shielding are available wherever required. Facility requirements are commensurate with the radioactive material hazard and may including shielding and airborne activity control. The suitability of any particular laboratory and the requirements for special facilities and equipment for a given procedure are determined by Environmental Health and Safety and the UIC in the review of the experimenter's request to use radioactive material.

SUBPART—K: Waste Disposal

§ 20.2001 General requirements.

- (a) A licensee shall dispose of licensed material only--
- (1) By transfer to an authorized recipient as provided in § 20.2006 or in the regulations in parts 30, 40, 60, 61, 63, 70, and 72 of this chapter;
 - (2) By decay in storage; or
 - (3) By release in effluents within the limits in § 20.1301; or
 - (4) As authorized under §§ 20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.
- (b) A person must be specifically licensed to receive waste containing licensed material from other persons for:
- (1) Treatment prior to disposal; or
 - (2) Treatment or disposal by incineration; or
 - (3) Decay in storage; or
 - (4) Disposal at a land disposal facility licensed under part 61 of this chapter; or
 - (5) Disposal at a geologic repository under part 60 or part 63 of this chapter.

RESPONSE

Waste is disposed by Environmental Health and Safety in accordance with in-house procedures. Radioactive waste is collected by researchers in labeled plastic, metal, or fiberboard containers. Short-lived waste is segregated from long-lived waste by researchers. Waste containers are collected by and transported to Environmental Health and Safety facilities in accordance with Pennsylvania and DOT regulations, and stored for processing or decay. Appropriate shielding

is provided when applicable within laboratories and the storage facility. Waste is stored in areas secure from unauthorized removal.

Any radioactive waste which cannot be held for disposal by the decay-in-storage program is transferred to a facility licensed to receive, treat, and/or dispose of radioactive waste. Long-lived waste is stored in a secure area prior to transfer to a licensed broker for disposal. The waste is packaged in accordance with broker instructions and the requirements of the final licensed disposal site prior to shipment.

§ 20.2002 Method for obtaining approval of proposed disposal procedures.

A licensee or applicant for a license may apply to the Commission for approval of proposed procedures, not otherwise authorized in the regulations in this chapter, to dispose of licensed material generated in the licensee's activities. Each application shall include:

- (a) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; and
- (b) An analysis and evaluation of pertinent information on the nature of the environment; and
- (c) The nature and location of other potentially affected licensed and unlicensed facilities; and
- (d) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this part.

RESPONSE

Not Applicable.

The Licensee does not foresee the need for any alternative disposal method than that already approved. Should the need arise, the Licensee will submit a request to the Commission for approval of a proposed procedure in accordance with § 20.2002.

§ 20.2003 Disposal by release into sanitary sewerage.

- (a) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:
 - (1) The material is readily soluble (or is readily dispersible biological material) in water; and
 - (2) The quantity of licensed or other radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in table 3 of appendix B to part 20; and
 - (3) If more than one radionuclide is released, the following conditions must also be satisfied:
 - (i) The licensee shall determine the fraction of the limit in table 3 of appendix B to part 20 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in table 3 of appendix B to part 20; and

- (ii) The sum of the fractions for each radionuclide required by paragraph (a)(3)(i) of this section does not exceed unity; and
 - (4) The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 5 curies (185 GBq) of hydrogen-3, 1 curie (37 GBq) of carbon-14, and 1 curie (37 GBq) of all other radioactive materials combined.
- (b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in paragraph (a) of this section.

RESPONSE

Liquid waste may be discharged to the public sanitary sewer system in accordance with 10 CFR 20.2003 and 10 CFR 20.2007. Disposals are kept within the limits of 10 CFR 20.2003. Liquid waste that is not suitable for drain disposal, due to solubility considerations or hazardous chemical constituents, may be shipped to an outside vendor for final disposal. Alternatively, the liquid waste may be solidified and shipped for waste disposal.

§ 20.2004 Treatment or disposal by incineration.

- (a) A licensee may treat or dispose of licensed material by incineration only:
- (1) As authorized by paragraph (b) of this section; or
 - (2) If the material is in a form and concentration specified in § 20.2005; or
 - (3) As specifically approved by the Commission pursuant to § 20.2002.
- (b) (1) Waste oils (petroleum derived or synthetic oils used principally as lubricants, coolants, hydraulic or insulating fluids, or metalworking oils) that have been radioactively contaminated in the course of the operation or maintenance of a nuclear power reactor licensed under part 50 of this chapter may be incinerated on the site where generated provided that the total radioactive effluents from the facility, including the effluents from such incineration, conform to the requirements of appendix I to part 50 of this chapter and the effluent release limits contained in applicable license conditions other than effluent limits specifically related to incineration of waste oil. The licensee shall report any changes or additions to the information supplied under §§ 50.34 and 50.34a of this chapter associated with this incineration pursuant to § 50.71 of this chapter, as appropriate. The licensee shall also follow the procedures of § 50.59 of this chapter with respect to such changes to the facility or procedures.
- (2) Solid residues produced in the process of incinerating waste oils must be disposed of as provided by § 20.2001.
 - (3) The provisions of this section authorize onsite waste oil incineration under the terms of this section and supersede any provision in an individual plant license or technical specification that may be inconsistent.

RESPONSE

Not Applicable.

The University will not process or dispose of radioactive material on site by means of incineration.

§ 20.2005 Disposal of specific wastes.

- (a) A licensee may dispose of the following licensed material as if it were not radioactive:
- (1) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and
 - (2) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.
- (b) A licensee may not dispose of tissue under paragraph (a)(2) of this section in a manner that would permit its use either as food for humans or as animal feed.
- (c) The licensee shall maintain records in accordance with § 20.2108.

RESPONSE

Liquid scintillation counting (LSC) waste is collected by and transported to Environmental Health and Safety facilities in accordance with Pennsylvania and DOT regulations, and stored for processing or decay. It is disposed in a manner commensurate with its chemical and radiological content. Short lived LSC waste with half-lives less than or equal to 120 days is held until it is no longer radioactive then disposed of as non-radioactive liquid chemical waste through the university's chemical waste disposal program.

Liquid scintillation counting waste containing Special Nuclear Material with half-lives greater than 120 days is stored in a secure area prior to being transferred to a radioactive waste broker licensed to receive, treat, and/or dispose of radioactive waste. The waste is packaged in accordance with broker instructions and the requirements of the final licensed disposal site prior to shipment.

The licensee does not dispose of tissue under paragraph (a)(2) of this section in a manner that would permit its use either as food for humans or as animal feed.

The licensee maintains all records of radioactive waste disposal in accordance with § 20.2108.

§ 20.2006 Transfer for disposal and manifests.

- (a) The requirements of this section and appendix G to 10 CFR Part 20 are designed to--
- (1) Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility (as defined in Part 61 of this chapter);
 - (2) Establish a manifest tracking system; and
 - (3) Supplement existing requirements concerning transfers and recordkeeping for those wastes.
- (b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to 10 CFR Part 20.
- (c) Each shipment manifest must include a certification by the waste generator as specified in section II of appendix G to 10 CFR Part 20.

(d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in section III of appendix G to 10 CFR Part 20.

(e) Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in § 20.1003 intended for ultimate disposal at a land disposal facility licensed under part 61 of this chapter must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to this part.

RESPONSE

Any radioactive waste which cannot be held for disposal by the decay-in-storage program is transferred to a facility licensed to receive, treat, and/or dispose of radioactive waste. The licensed radioactive waste broker generates the NRC's Uniform Low-Level Radioactive Waste Manifest prior to shipment. The licensee maintains copies of the NRC manifest in accordance with record retention requirements.

§ 20.2007 Compliance with environmental and health protection regulations.

Nothing in this subpart relieves the licensee from complying with other applicable Federal, State, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of under this subpart.

RESPONSE

Through the review and oversight of the University's Environmental Health and Safety Office, the Licensee conducts its entire waste disposal program in accordance with all local, state, and federal regulations.

§ 20.2008 Disposal of certain byproduct material.

(a) Licensed material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in §20.1003 may be disposed of in accordance with part 61 of this chapter, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under part 61 of this chapter, must meet the requirements of § 20.2006.

(b) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in § 20.1003, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

RESPONSE

Any radioactive waste which cannot be held for disposal by the decay-in-storage program is transferred to a facility licensed to receive, treat, and/or dispose of radioactive waste. Long-lived waste is stored in a secure area prior to transfer to a licensed broker for disposal. The waste is packaged in accordance with broker instructions and the requirements of the final licensed disposal site prior to shipment.

SUBPART—L: Records

§ 20.2101 General provisions.

(a) Each licensee 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 part.

(b) In the records required by this part, the licensee may record quantities in SI units in parentheses following each of the units specified in paragraph (a) of this section. However, all quantities must be recorded as stated in paragraph (a) of this section.

(c) Notwithstanding the requirements of paragraph (a) of this section, when recording information on shipment manifests, as required in § 20.2006(b), information must be recorded in the International System of Units (SI) or in SI and units as specified in paragraph (a) of this section.

(d) The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

RESPONSE

With the exception of transportation records, the Licensee maintains all records required by this part using the traditional units of curie, rad, rem, including multiples and subdivisions as appropriate. Radioactive material transported or delivered to a carrier for transport is in accordance with 25 PA Code 230, "Packaging and Transport of Radioactive Material," and all applicable U.S. Department of Transportation regulations in accordance with the provisions of 10 CFR Part 71.

§ 20.2102 Records of radiation protection programs.

(a) Each licensee shall maintain records of the radiation protection program, including:

- (1) The provisions of the program; and
- (2) Audits and other reviews of program content and implementation.

(b) The licensee shall retain the records required by paragraph (a)(1) of this section until the Commission terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph (a)(2) of this section for 3 years after the record is made.

RESPONSE

The Licensee maintains all records of the radiation protection program as required under 10 CFR § 20.2102. Examples of some of the records maintained include:

- *Radiation safety committee minutes*
- *Requests for approval to use licensed material*
- *Training: radiation worker, transportation, security, etc.*
- *Annual radiation protection program reviews*
- *Licenses*
- *Radiation Authority (Nuclear Regulatory Commission; Pennsylvania Department of Environmental Protection Bureau of Radiation Protection) audits, inspections, and reports of the licensee's programs*

§ 20.2103 Records of surveys.

(a) Each licensee shall maintain records showing the results of surveys and calibrations required by §§ 20.1501 and 20.1906(b). The licensee shall retain these records for 3 years after the record is made.

(b) The licensee shall retain each of the following records until the Commission terminates each pertinent license requiring the record:

(1) 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. This includes those records of 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 required under the standards for protection against radiation in effect prior to January 1, 1994; and

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose. This includes those records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose required under the standards for protection against radiation in effect prior to January 1, 1994; and

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to § 20.1703(c)(1) and (2). This includes those records showing the results of air sampling, surveys, and bioassays required under the standards for protection against radiation in effect prior to January 1, 1994; and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to January 1, 1994.

RESPONSE

The Licensee maintains records showing the results of surveys and calibrations required by §§ 20.1501 and 20.1906(b). Examples of some of the records maintained include:

- *Instrument calibrations*
- *Material receipt, inventory, leak checks, and disposal*
- *Dosimetry*
- *Internal and external occupational exposure evaluations*
- *Public dose evaluations including those from effluents*
- *Radiological surveys*
- *Records required for decommissioning*

§ 20.2104 Determination of prior occupational dose.

(a) For each individual who is likely to receive an annual occupational dose requiring monitoring under § 20.1502, the licensee shall determine the occupational radiation dose received during the current year.

(b) Prior to permitting an individual to participate in a planned special exposure, the licensee shall determine—

- (1) The internal and external doses from all previous planned special exposures; and
- (2) All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

(c) In complying with the requirements of paragraphs (a) or (b) of this section, a licensee may—

- (1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;
- (2) Accept, as the record of cumulative radiation dose, an up-to-date NRC Form 4, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and
- (3) Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee) by telephone, telegram, electronic media, or letter. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(d) The licensee shall record the exposure history of each individual, as required by paragraphs (a) or (b) of this section, on NRC Form 4, or other clear and legible record, including all of the information required by NRC Form 4.4 The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing the NRC Form

(e) If the licensee is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee shall assume—

- (1) In establishing administrative controls under § 20.1201(f) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
- (2) That the individual is not available for planned special exposures.

(f) The licensee shall retain the records on NRC Form 4 or equivalent until the Commission terminates each pertinent license requiring this record. The licensee shall retain records used in preparing NRC Form 4 for 3 years after the record is made. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

RESPONSE

The Licensee determines the current and prior occupational radiation dose records for each individual likely to receive an annual occupational dose requiring monitoring under §20.1502. Historically, only reactor staff personnel meet this requirement.

§ 20.2105 Records of planned special exposures.

(a) For each use of the provisions of § 20.1206 for planned special exposures, the licensee shall maintain records that describe--

- (1) The exceptional circumstances requiring the use of a planned special exposure; and
- (2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and
- (3) What actions were necessary; and
- (4) Why the actions were necessary; and
- (5) How doses were maintained ALARA; and
- (6) What individual and collective doses were expected to result, and the doses actually received in the planned special exposure.

(b) The licensee shall retain the records until the Commission terminates each pertinent license requiring these records.

RESPONSE

Not Applicable.

The Licensee does not possess quantities of special nuclear material that could generate radiological conditions severe enough to require a planned special exposure evaluation.

§ 20.2106 Records of individual monitoring results.

(a) Recordkeeping requirement. Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to § 20.1502, and records of doses received during planned special exposures, accidents, and emergency conditions. These records must include, when applicable--

- (1) The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;
- (2) The estimated intake of radionuclides (see § 20.1202);
- (3) The committed effective dose equivalent assigned to the intake of radionuclides;
- (4) The specific information used to assess the committed effective dose equivalent pursuant to § 20.1204(a) and (c), and when required by § 20.1502;
- (5) The total effective dose equivalent when required by § 20.1202; and
- (6) The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) Recordkeeping frequency. The licensee shall make entries of the records specified in paragraph (a) of this section at least annually.

(c) Recordkeeping format. The licensee shall maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instructions for NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5.

(d) Privacy protection. The records required under this section should be protected from public disclosure because of their personal privacy nature. These records are protected by most State privacy laws and, when transferred to the NRC, are protected by the Privacy Act of 1974, Public Law 93-579, 5 U.S.C. 552a, and the Commission's regulations in 10 CFR part 9.

(e) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

(f) The licensee shall retain the required form or record until the Commission terminates each pertinent license requiring this record. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

RESPONSE

The licensee maintains records of doses received by all individuals for whom monitoring is or was required pursuant to § 20.1502. For individuals currently being monitored, records are updated annually. For individuals no longer requiring monitoring (inactive workers, retirees, etc.), records are maintained in perpetuity until the license is terminated at which time all records will be transferred to the appropriate regulatory authority. Records are maintained in clear and legible records containing all the information required by NRC Form 5. Records are protected from public disclosure. When received, records of a declaration of pregnancy are also maintained. All required records will be retained until the Commission or state radiation authority terminates each pertinent license requiring these records be maintained. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

§ 20.2107 Records of dose to individual members of the public.

- (a) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (see § 20.1301).
- (b) The licensee shall retain the records required by paragraph (a) of this section until the Commission terminates each pertinent license requiring the record.

RESPONSE

The Licensee maintains legible records in accordance with the requirements of this part. Records are maintained in hard-copy or digital formats. Evaluations of potential public dose are performed through direct measurement (surveys, air monitoring, dosimetry, etc.) and/or calculation. Records are maintained in locations and in a manner that safeguards record information and ensures records can be retrieved in a timely manner as needed. All required records will be retained until the Commission or state radiation authority terminates each pertinent license requiring these records be maintained.

§ 20.2108 Records of waste disposal.

- (a) Each licensee shall maintain records of the disposal of licensed materials made under §§ 20.2002, 20.2003, 20.2004, 20.2005, 10 CFR part 61 and disposal by burial in soil, including burials authorized before January 28, 1981.6
- (b) The licensee shall retain the records required by paragraph (a) of this section until the Commission terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination, are located in §§ 30.51, 40.61, 70.51, and 72.80 for activities licensed under these parts.

RESPONSE

The Licensee maintains records of the disposal of licensed materials made under §§ 20.2002, 20.2003, 20.2004, 20.2005, 10 CFR part 61 and disposal by burial in soil, including burials authorized before January 28, 1981. Examples of some of the records maintained include:

- *Shipment manifests*
- *Disposal/treatment certification from licensed processor*
- *Disposal via sanitary sewer*
- *Burial in soil made on-site prior to January 28, 1981*
- *NRC authorization for unrestricted use of the former burial site as approved in the letter from the NRC to Eva Pell, Ph.D., Vice President for Research, dated December 28, 1999 (Docket No. 030-00952; Control No. 124938).*

§ 20.2109 [Reserved]

RESPONSE

Not Applicable.

§ 20.2110 Form of records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

RESPONSE

The Licensee maintains legible records in accordance with the requirements of this part. Records are maintained in hard-copy or digital formats. Records are maintained in locations and in a manner that safeguards record information and ensures records can be retrieved in a timely manner as needed.