

**Office of
Research
Economic
Development**

April 4, 2022

Ms. Mary Muessle
Director, Division of Radiological Safety & Security
US Nuclear Regulatory Commission, Region IV
1600 East Lamar Boulevard
Arlington, TX 76011

**Research Integrity
and Compliance**

RE: Response to Apparent Violations in NRC Inspection Report 030-01176/2021-001

To all concerned:

Please find attached our written response to *Apparent Violations in NRC Inspection Report 030-01176/2021-001; EA-22-001*, dated 3/7/2022, stemming from the NRC announced inspection on November 17, 2021. We used NRC Information Notice 96-28 as a template for what to include in identifying the root causes and corrective actions to be taken.

As the Interim Vice President of Research, I would like to thank you all, and, in particular Dr. Janine Katanic, for the thorough evaluation of our program. We all feel strongly that it is important to be compliant with well-considered and well-established radiation safety protocols and NRC regulations. As such, we are working diligently to address all identified issues and look for ways we can improve our program.

We would like to acknowledge the willingness of Dr. Katanic to work through this with us by way of conference and reconciliation. She is a very thorough and detailed inspector who clearly outlined the required corrections and was pleasant and easy to work with.

Please do not hesitate to reach out to our office should you require additional information.

Sincerely,



Diana G. Hulme
Interim Vice President of Research & Economic Development
University of Wyoming

cc:

Dr. Ken Sims, Professor of Isotope Geology, Chair Radiation Safety Committee
Diana G. Hulme, Interim VP Research & Economic Development
Dr. Carolyn Brandt, Director of Research Integrity & Compliance
Jim Herrold, Radiation Safety Officer
Dr. Kevin Shimkus, Research Compliance Manager

**Animal Care & Use
Conflict of Interest
Drones
Export Control
Human Subjects
Research Misconduct**

Old Main 305/308
Dept. 3355
1000 E. University Ave.
Laramie, WY 82071
Phone: (307) 766-5353
Fax: (307) 766-2608

Biological Safety

101 Wyoming Hall
Dept. 4305
1000 E. University Ave.
Laramie, WY 82071
Phone: (307) 766-2723
Email: mjd@uwyo.edu

Radiation Safety

102 Wyoming Hall
Dept. 4305
1000 E. University Ave.
Laramie, WY 82071
Phone: (307) 766-2638
Email: herrold@uwyo.edu

[uwyo.edu/research/
compliance](http://uwyo.edu/research/compliance)

I. APPARENT VIOLATION 030-01176/2021-001-01: Failure to establish administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations. (10 CFR 33.13(c)(3))

A. The licensee's administrative procedures failed to assure:

1. Control of procurement and use of byproduct material.
2. Completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of facilities and equipment, training, and experience of the Authorized User (AU), and the operating or handling procedures.
3. Review, approval, and recording by the RSC of safety evaluations of proposed uses prepared in accordance with 10 CFR 33.13(c)(3)(ii) prior to use of the byproduct material.

B. CORRECTIVE ACTION STEPS:

1. Complete and thorough review of the circumstances that led to the violation.

- a) The University of Wyoming (UW) Radiation Safety Committee (RSC) met on 12/9/2021 to discuss the apparent violations identified by the NRC Region IV inspector on 11/17/2021, and to set a path towards correcting the violations.
- b) A subcommittee of the RSC was established (consisting of the Radiation Safety Officer (RSO), RSC Chair, one representative from UW Administration and one authorized principal user of byproduct material) to investigate the circumstances leading to the violations.
 - (1) A table was created, documenting the core issues, sub-categories, assignments, and completion dates. This table of actions taken was provided to the NRC inspector on 12/1/2021 (ADAMS Accession No. ML22045A950), and again on 2/28/2022.
 - (2) The subcommittee met via Zoom six times between 12/16/2021 and 2/28/2022 to discuss corrective actions ensuring control of procurement and use of byproduct material.
- c) A subcommittee of the RSC (consisting of the RSO, RSC Chair, one representative from UW Administration and two authorized principal users of byproduct materials) met several times in February 2022, to make improvements to the Radiation Safety Program Annual Audit process and to conduct the audit for FY 2021.
 - (1) The revised audit process includes full reviews of management oversight by the RSC, the execution of duties by the RSO, and new, renewed, amended, and closed radiation permits.
 - (2) The RSC subcommittee physically inspected current authorized usage and storage areas of licensed radioactive material.
 - (3) In addition to the audit of past performance, the audit report will contain action items for 2022 based on findings from the NRC and the subcommittee.
 - (a) These action items will become the RSO's goals and objectives for his 2022 performance evaluation.
 - (4) The full report of the RSC Audit subcommittee will be presented for discussion by the full RSC at their next scheduled meeting, April 11, 2022.

2. Identify the root causes of the violations. Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violations.

a) Root cause:

- (1) The RSC and RSO lacked adequate formal processes or procedures for performing necessary actions associated with permits.
 - (a) Current procedures for reviewing and approving radioactive material permits had been reviewed by the RSC and approved by the NRC during the renewal of UW's NRC license in 2019. However, procedures did not specify the steps in the process assigned to the RSO and the RSC.
 - (b) The permit application, renewal and amendment forms were updated and approved by the RSC in 2020. However, these forms did not specifically address the issues requested by the NRC inspector.
 - (c) The RSO routinely used a J.L. Shepherd & Associates Model 28-6 instrument calibrator to perform calibrations of radiation survey instruments. The RSO conducted informal training for the calibration procedures, but did not develop, implement, or maintain written operating and emergency procedures.

(2) Corrective actions and dates of full compliance:

(a) *Full compliance achieved on 12/9/2021:*

- (i) The forms for permit amendment applications were modified by the RSO to include information and instructions requested by the NRC inspector.
 - (a) Instructions for completing the form, specifying what constitutes the need for a new amendment application vs. an amendment.
 - (b) Statement on amendment form above signature that, "All conditions of my original permit not changed by approved amendments will apply."
- (ii) The amendment form was approved by the RSC via email prior to use for approvals documented by the RSC meeting minutes for 12/9/2021.

(b) *Anticipated full compliance in June 2022:*

- (i) The RSC subcommittee reviewed permit application protocols from other university institutions to make improvements to UW's permitting policies and procedures.
- (ii) The UW Radioactive Materials Safety Plan, RSC Control Functions and Radiation Safety Standard Operating Procedures (SOPs) are being modified to specify processes for permit applications, renewals, and amendments.
 - (a) RSC procedures will include safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the Authorized User (AU), and the operating or handling procedures.
 - (b) The SOPs will include "check lists" for the RSO and RSC to ensure compliance with the permitting procedures.
- (iii) The revised documents will be on the agenda for discussion and approval by the RSC at their meeting in June 2022.

- (iv) The RSO will make corrections, finalize the documents, and have them posted on the Radiation Safety web page (anticipated completion June 2022).
- (c) ***Anticipated full compliance on 5/1/2022:***
 - (i) On 1/27/2022 the RSO prepared a Word template for a printed version of the AU permit license that includes the following information:
 - (a) Permit Number and AU Name.
 - (b) “The above-named person is authorized to receive, possess and use the following licensed radioactive materials in accordance with initial approval, amendments and renewals approved by the UW Radiation Safety Committee”
 - (c) Approval Date, Expiration Date, Initial Permit Date, and Amendment Dates,
 - (d) Permitted Isotope, Compounds & Source Manufacturer/Model, Source Type, Possession Limit and Unit.
 - (e) Permitted Building and Room Number
 - (ii) The template will be presented to the RSC for comments and approval at their meeting on 4/11/2022.
 - (iii) The RSO will work with the developers of EHS Assistant (On Site Systems) to create the forms in the database.
 - (iv) The RSO will print forms for the current AUs, to be distributed to AU’s and posted in labs and/or storage areas by 5/1/2022.
- (d) ***Anticipated full compliance by August 2022:***
 - (i) By August 1, 2022, the RSO will develop written operating and emergency procedures for the use of the J.L. Shepherd Model 28-6 survey instrument calibration source.
 - (ii) The RSO will develop a formal training program for the full survey instrument process by August 1, 2022.
 - (iii) Before instrument calibrations are performed (next due 8/25/2022), the RSO will train participants, following the written procedures, and document the training in the EHS Assistant software.
- b) **Root cause:**
 - (1) For expediency, the RSO sometimes handled permit-related matters informally, without bringing them to the RSC’s attention.
 - (a) The RSO did not always pay close attention to details or devote sufficient time relating to the permitting process.
 - (b) There are no written guidelines on when permit-related actions can be addressed by the RSO vs. bringing them to the RSC.
 - (2) **Corrective actions and dates of full compliance:**
 - (a) In discussions with the NRC and RSC Chair, the RSO verbally adopted the policy that all permit-related actions will not be handled without approval by the RSC (via email, if needed) and documentation in the RSC minutes.
 - (b) Responsibilities for revising the permit and audit procedures were distributed among RSC subcommittee members to allow the RSO to concentrate on other compliance issues.
 - (i) ***Anticipated full compliance in June 2022:*** Formal procedures

describing the steps and duties in the permitting process will be specified in Radiation Safety Plans and SOPs, as stated above.

- (ii) ***Full compliance achieved on 12/9/2021:*** Revised permit amendment forms were approved by the RSC on December 9, 2021 and were used to formally authorize the permit limits and transfer of radioactive sources from the unauthorized and retired users to the RSO.

(c) ***Full compliance achieved on 12/7/2021:***

- (i) The RSO modified the sealed source procedures and checkout log to include a column for the location of intended use.
- (ii) The modified forms were posted at the RMMC and emailed to remote UW authorized use facilities on 12/7/2021.

c) **Root cause:**

- (1) When permit changes were informally approved, or when the NRC license was amended, the licensee did not take commensurate action to document or reflect these changes in the licensee's radiation safety program documents.
 - (a) Without formal written procedures, the RSO did not always put permit changes on the meeting agendas for RSC approval.
 - (b) Without a "check list" of required tasks, the RSO did not always follow through to update NRC license and permit changes in the database and paper files.
 - (c) The RSC did not inspect the Radiation Safety filing systems as part of the annual audit process.

(2) **Corrective actions and dates of full compliance:**

- (a) ***Full compliance achieved on 12/9/2021:*** NRC license amendments and permit changes made since November 2021 have been documented in RSC minutes, and in Radiation Safety databases and files.
- (b) ***Full compliance achieved February 2022:*** The RSC Annual Audit process was modified to look at all permit activities that have occurred.
- (c) ***Anticipated full compliance in June 2022:*** Written procedures will include a "check list" of important steps, and specify that changes in permitting and NRC license will be reflected in RSC minutes and both electronic databases and paper files.

d) **Root cause:**

- (1) The licensee did not enter the certain NRC license possession limits and certain radioactive source information into the proprietary software (EHS Assistant) correctly.

(2) **Corrective actions and dates of full compliance:**

- (a) ***Full compliance achieved on 3/10/2022:*** License line number 6.O was added to EHS Assistant per License Amendment 50 (corrected copy) dated 3/10/2022.
- (b) ***Anticipated full compliance in June 2022:*** The missing AU permit limit and possession of Ra-226 will be corrected through a formal permit application and approval by the RSC in June 2022.
- (c) ***Full compliance achieved on 3/15/2022:*** The RSO's permits have been corrected in EHS Assistant to specify authorized use(s) of licensed materials, including storage and instrument calibration.
 - (i) The use location and units of possession limits (in mCi) have also been

corrected in EHS Assistant.

- (d) **Full compliance achieved on 3/15/2022:** All permits for Am-241/Be gauging devices have been corrected in the authorized use field of EHS Assistant to specify the possession of specific manufacturer and model of device, and the usage location (i.e., temporary job sites in NRC jurisdiction).
- (e) The RSO conducted a thorough review of records in the EHS Assistant database to confirm that all license limits are current with License Amendment 50 (corrected copy) dated 3/10/2022.
- (f) **Full compliance achieved on 3/29/2022:**
 - (i) Corrected permit limits for the RSO's possession of Cs-137, Pu-239 and Th-230 were formally approved by the RSC on 3/29/2022 and documented in the RSC minutes.
 - (ii) The RSO's permit limits for Cs-137, Pu-239 and Th-230 permit limits were corrected in EHS Assistant to be within permit and NRC license limits.

II. APPARENT VIOLATION 030-01176/2021-001-02: Failure to own and possess byproduct material except as authorized in a specific license. (10 CFR 30.3(a))

- A. Title 10 CFR 30.3(a) requires, in part, that no person shall own or possess byproduct material except as authorized in a specific license issued in accordance with the regulations in 10 CFR Chapter I.
 - 1. Specifically, the licensee possessed an approximately 18.4 mCi Am-241 wire source, which was not authorized to be possessed under 6.B. to 9.B., or 6.D. through G. to 9.D. through G., of NRC license No. 49-09955-10, Amendment 48, dated January 14, 2020.

B. CORRECTIVE ACTION STEPS:

- 1. **Complete and thorough review of the circumstances that led to the violation.**
 - a) The RSO researched previous NRC licenses held by UW to find out how long the Am-241 source had been in its possession without being specifically listed.
 - (1) Licenses prior to and including Amendment 42 (which expired on 7/31/2009) allowed up to 2 curies of Am-241 sealed sources. However, as noted below, this particular "homemade" Am-241 source does not meet the definition of a sealed source.
 - (2) Amendment 43 (which expired 12/31/2019) only allowed the authorized use of Am-241 in portable gauging devices.
 - (3) Amendment 48 (which expires 1/31/2035) lists the gauging devices by model number.
 - b) The RSO borrowed a radioisotope identifier from the State of Wyoming Department of Homeland Security on 11/22/2021 and confirmed that the source was indeed Am-241.
 - c) The RSO contacted the person who was UW RSO from 1973-1976, but he could not provide any more information. The person who was RSO from 1977-1992 is no longer living.
 - d) The RSO obtained measurements and pictures of the source on 12/8/2021 in order to register the source with the Off-Site Recovery Program (OSRP).

- (1) The disposal request was approved by the RSC on 12/9/2021 and sent to OSRP on 12/23/2021.
 - (2) OSRP suggested lifting the source (loosely placed in a steel pipe shield) and looking underneath for a source registration number.
 - (a) The RSO did this on 3/14/2022. During the procedure, the RSO wore personal dosimetry and used a pressurized ion chamber (Ludlum 9DP) to measure dose. He also followed the precautions of time, distance and shielding to keep dose as low as reasonably achievable.
 - (b) A registration number from the UW Property Office was on the bottom of the source, but no registration number. The UW Property Office was contacted, but their records do not go back that far in their database.
2. **Identify the root causes of the violations. Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violations.**
- a) **Root cause:**
- (1) The homemade Am-241 “wire” source has been incorrectly designated by the UW Radiation Safety Office as a “sealed source” for as long as the current RSO has been employed at UW (as Assistant RSO from 1984-1992, as RSO from 1993 to the present).
 - (a) Whenever the NRC license was renewed since 1993, this incorrect designation on the license was not noted by the RSO, RSC or previous NRC inspectors.
 - (b) UW failed to specifically list the homemade 20 mCi Am-241 source by manufacturer and model number when requesting renewal of license 49-09955-10 on 12/13/2019.
 - (c) Note: Throughout that time, the source has been locked in secure storage. It has been inventoried and leak tested every six months, and records have been provided to the RSC and NRC inspectors for review. It has never shown removable contamination above permissible limits.
 - (2) **Corrective actions and dates of full compliance:**
 - (a) ***Full compliance achieved on 3/10/2022:***
 - (i) An amendment request to add the “homemade” 20 mCi Am-241 source to UW’s license (and to correct the address of the UW Regulated Materials Management Center) was approved by the RSC on 12/9/2021.
 - (ii) The amendment request was sent by the RSC Chair to the NRC Region IV Licensing Branch on 12/10/2021. (ADAMS Accession No. ML22061A094)
 - (iii) NRC License Amendment 50 to include authorization for a 20 mCi Am-241 “sealed source” was issued on 3/3/2022. (ADAMS Accession No. ML21350A170)
 - (iv) The RSO noticed that this designation of a “sealed source” is incorrect, and is told by the NRC Region IV Inspections Branch on 3/8/2022 that the amendment must be corrected.
 - (v) On 3/10/2022 the request for a corrected license amendment (designating it as a “wire” source) was approved by the RSC and

emailed to the NRC Region IV Licensing branch.

- (vi) The corrected NRC License amendment 50 was issued on 3/10/2022, correctly authorizing the possession of Am-241, up to 20 mCi as Wire, for storage only in preparation for disposal.
- (i) The RSC formally approved the RSO's permit application for the possession of up to 20 mCi of Am-241 as a wire source for storage on 3/29/2022.

III. APPARENT VIOLATION 030-01176/2021-001-03: Failure to ensure that each container of licensed material bears a durable, clearly visible label that must provide sufficient information to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures. (10 CFR 20.1904(a))

A. Specifically, the container containing 18.4 millicurie (decayed) Am-241 wire source did not have durable, clearly visible label that provided sufficient information, such as:

- 1. an estimate of the quantity of radioactivity, the date for which the activity is estimated, and radiation levels to permit individuals handling or using the container, or working in the vicinity of the container, to take precautions to avoid or minimize exposures.

B. CORRECTIVE ACTION STEPS:

1. Complete and thorough review of the circumstances that led to the violation.

- a) The RSC Chair inspected the storage at the Regulated Materials Management Center (RMMC), including sealed source and waste storage. He spoke with the RSO and the RMMC manager about the issues raised by the NRC inspector and asked questions.
- b) The RSO reviewed the inventory of UW byproduct material and identified all sources that are not exempt from labeling in 10 CFR 20.1905.
 - (1) Whereas all sources included labeling containing the isotope, activity, and date (including the Am-241 wire source, which was labeled on 12/8/2021), the labels or posting did not include the radiation levels or other precautions for safe handling.

2. Identify the root causes of the violations. Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violations.

a) **Root cause:**

- (1) The RSO did not pay sufficient attention to individual labels of radioactive materials when they were deteriorated or contained insufficient information.
 - (a) The RSC did not inspect radioactive storage and usage facilities and question whether the labeling was adequate.

(2) **Corrective actions and dates of full compliance:**

(a) ***Full compliance achieved on 3/28/2022:***

- (i) The Am-241 wire source and cylinder were labeled with isotope, activity and date on 12/8/2021.
- (ii) On 3/14/2022 the RSO created tags with spaces to enter isotope, activity, date, serial number, radiation levels (surface, 30 cm, 1 meter), removable contamination and precautions for safe handling.
- (iii) On 3/14/2022 the RSO measured the radiation levels of the Am-241 source, the Cs-137 calibration source, and other sources in the RMMC

storage. The radiation levels and other information were entered on the tags, which were attached to the source containers.

(iv) On 3/28/2022, the RSO measured and verified labeled sources in other locations on UW campus to ensure regulatory compliance.