UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

September 28, 2022

Mr. James F. Center
Radiation Safety Officer
Western Michigan University
Office of the Vice President for Research and Innovation
1903 W Michigan Ave.
Kalamazoo, MI 49008

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING THE RENEWAL OF RADIOACTIVE MATERIALS LICENSE FOR WESTERN MICHIGAN UNIVERSITY, NRC LICENSE NO. 21-03336-10

Dear Mr. Center:

Our office has reviewed Western Michigan University's (your) U.S. Nuclear Regulatory Commission (NRC) April 19, 2022 letter, April 15, 2022 NRC Form 313 application, and supporting information regarding the renewal of your Materials License No. 21-03336-10. As we discussed via telephone on September 27, 2022, upon review, our office has determined that additional information is needed to complete our review. Your renewal application is available electronically from the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession No. ML22110A071. The NRC's ADAMS is accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

In accordance with our conversation, please provide the following additional information:

1. In Subitem Nos. 6.B. through 9.B. of the most recent amendment to your license, cesium-137 was authorized for use in Troxler Model 3216 and CPN Model 503 DR portable gauges. However, only the americium-241 sources were listed in the application. We have noted that this is consistent to the most current sealed source and device registry information for those devices.
   Please confirm that no cesium-137 sealed sources were possessed for use in the Troxler Model No. 3216 or CPN Model No. 503 DR gauges, under your license.

2. For the authorization to use americium-241 sealed sources in Troxler and CPN portable gauges, we have noted that only the overall possession limit of 4 sources and 180 millicuries total are indicated under ITEM 5 – Radioactive Material, Subitem No. A, to your application.
   As discussed, please provide the following clarifications regarding your use of americium-241 sealed sources:

   a. maximum possession limit per sealed source, to be authorized under this item; and
   b. maximum number of sources & gauges for each of the Troxler and CPN models; and
   c. If the maximum possession limit for CPN differs from Troxler, the maximum possession limit for each model.

3. For the authorization to use nickel-63 and tritium foil or plated sources, as listed under ITEM 5 – Radioactive Material, Subitem Nos. E and F, to your application, only overall possession limits, by radionuclide, are indicated. In addition, we have noted that in Subitem Nos. 6.L. through 9.L. of the most recent amendment to your license, one or more nickel-63 sealed sources – up to 10 millicuries total – were authorized for possession and storage only in a Shimadzu Model 15A device. **Please provide the following clarifications and supporting information regarding your use of nickel-63 and tritium foils and sealed sources:**

    a. maximum possession limit per foil or plated source, to be authorized under each of these items; and
    b. an indication as to whether the sources previously authorized in Subitem Nos. Nos. 6.L. through 9.L. of the most recent amendment to your license have been disposed; or otherwise are being used under the license; and
    c. If applicable, the final disposition information (confirmation of receipt and final leak test results) for all nickel-63 sources removed from the license.

4. In accordance with our phone conversation, for the authorization to use polonium-210 sealed sources, as listed under ITEM 5 – Radioactive Material, Subitem No. H, to your application, we understand that any such sources are currently in storage, pending disposal. **As discussed, if the polonium-210 source authorized use is limited to storage, pending disposal, please provide the following clarifications:**

    a. Confirmation that the purpose of use for polonium-210 is limited to storage pending disposal; and
    b. A description of plans to store and dispose polonium-210, under the license.

5. In Subitem Nos. 6.J. through 9.J. and 6.K. through 9.K. of the most recent amendment to your license, a plutonium-beryllium source in a neutron howitzer, together with associated activation products, was authorized for laboratory experiments and student instruction. We have noted that no request for an authorization for the neutron howitzer was included in the application.
   To remove the plutonium-beryllium source authorization, as well as the authorization for associated activation products, from your license, please provide the following clarifications and supporting information:

    a. Confirmation that these materials were never possessed or used under the license; or
    b. An indication that the omission was inadvertent and a request to retain these sources on the license; or
    c. Final disposition information for each item, which should include: (i) the last date on which the source was used, under the license; (ii) the date on which the source was disposed or transferred; (iii) a history of leaking sources, if any; (iv) the company or individual to which the sources were transferred, for final disposition, including license number, if applicable; (v) a letter or other document confirming that any described waste disposal or transferred source was received; and (vi) final leak test results for each sealed source, or waste container survey, as applicable.

6. The application was unclear as to whether the sealed sources & devices will be used in accordance with the applicable sealed source & device registry certificate.
   Please confirm that uses for each source and device will be in accordance with the SSDR, or provide additional details the use of the licensed material.

7. The license omitted specific location-of-use information for each sealed source.
   For the authorizations for each of the portable gauges, the fixed gauges, the gas chromatograph electron capture detectors, and the americium-241 calibration/ standardization sources, please indicate the following location-of-use information:

   a. Buildings, floors, and room numbers where those sealed sources and devices may be used or stored, under the license, as known; and
   b. Facility diagram for each permanent storage and/or use location for the sealed sources & devices to be authorized for use in portable and fixed gauges, under the license. Each diagram should be drawn to scale and should show uses of areas above, below and adjacent to the use or storage location, sufficient to show security of the area, and to demonstrate an ability to meet public dose limits. If the use areas are limited to only a small number of rooms or floors of a designated building, it is unnecessary to provide a diagram of the entire building. If possible, please provide the room number and/or floor of the designated storage and use locations.

8. Regarding the removal of the Kohrman Hall from the license, the application indicated that no radioactive material was used there, under the license.
   In accordance with our conversation, please confirm that any records necessary for decommissioning of Kohrman Hall, including radioactive materials use history prior to 2003, if any, will be maintained under your NRC License No. 21-03336-09.

9. Regarding the removal of McCracken Hall from the license, the application indicated that final surveys were conducted, that two sealed sources were used there under the license, and removed, and that final closeout surveys were conducted.
   Please provide the clarification and supplemental information, as applicable:

   a. Confirmation that any records necessary for decommissioning of McCracken Hall, including radioactive materials use history prior to the initial issuance of NRC License No. 21-03336-10, if any, will be maintained under your NRC License No. 21-03336-09;
   b. History of materials use in McCracken Hall, under the license; and
   c. For any sealed sources other than the krypton-85 and the cesium-137 sources, referenced on pages 1 to 2 of your letter, that were used in McCracken Hall, under NRC License No. 21-03336-10, if any, final disposition information, including (i) the last date on which the source was used, under the license; (ii) the date on which the source was disposed or transferred; (iii) a history of leaking sources, if any; (iv) the company or individual to which the sources were transferred, for final disposition, including license number, if applicable; (v) a letter or other document confirming that any described waste disposal or transferred source was received; and (vi) final leak test results for each sealed source, or waste container survey, as applicable.

10. Regarding Training & Experience Criteria described in ITEM 8 – Training for Individuals Working in or Restricted Areas – to your application, training did not address specific training expected of portable and fixed gauge users. Additional specific training expected for portable gauge users is described in Section 8.8.1, “Authorized Users,” and Appendix C to NUREG 1556, Volume 1, revision 2, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses,” pp. 8-9 and C-1 to C-2. Additional specific training expected for portable gauge users is described in Section 8.7.2, “Authorized Users,” and Appendix D to NUREG 1556, Volume 4, revision 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses,” pp. 8-10 and D-1 to D-2.

Please provide the following additional information regarding the training criteria for portable and fixed gauge authorized users:

a. Confirmation that, prior to authorization, under the license, each individual authorized to independently use portable gauges will have completed either:

   i. A portable gauge manufacturer's course for users, either including or together with hands-on training use of portable gauges; or

   ii. A training course that meets the criteria in NUREG 1556, Vol. 1, rev. 2, Appendix C:

      (1) Course Content (minimum 1.5 to 2 hours each of):
         - radiation safety and regulatory requirements, emphasizing practical subjects important to safe use of the gauge; radiation versus contamination; internal versus external exposure; concepts of time, distance, and shielding to minimize exposure; control and surveillance of gauges; location of the sealed source within the portable gauge; inventory; recordkeeping; incidents; licensing and inspection by the regulatory agency; need for complete and accurate information; employee protection; and deliberate misconduct; and
         - practical training, to include portable gauge theory, operating procedures, emergency procedures, security, maintenance, and transportation procedures; and field training emphasizing radiation safety, including dry runs of setting up and making measurements with the gauge, controlling and maintaining surveillance over the portable gauge, performing routine cleaning and lubrication, packaging and transporting the gauge, storing the gauge, and following emergency and security procedures

      (2) Course Examination, requiring prospective gauge users to achieve at least a 70-percent score on a 25- to 50-question written test, which should include:
         - an emphasis on radiation safety of portable gauge storage, security of gauges while on jobsites, use, sealed source location, maintenance, and transportation, rather than the theory and art of making portable gauge measurements; and
         - review of correct answers to missed questions with the prospective gauge user following the scoring of the test

      (3) Instructors, with a minimum training and experience of:
         - Successful completion of both a portable gauge user course; and an 8-hour radiation safety course or radiation safety officer training course
         - Documentation of 8 hours of hands-on experience with portable gauges

b. Confirmation that, prior to authorization, under the license, each individual authorized to independently use fixed gauges will have completed either:

   i. A fixed gauge manufacturer's or distributor's course for users, either including or together with hands-on training use of fixed gauges; or

ii. A training course that meets the criteria in NUREG 1556, Vol. 4, rev. 1, Appendix D:

(1) Course Content, in the form of lectures, videos, computer-based sessions, or self-study lessons that emphasized practical subjects important to the safe use of the gauge including:
- Radiation safety and regulatory requirements, including radiation safety topics (radiation versus contamination, internal versus external exposure, biological effects of radiation, types and relative hazards of radioactive material possessed, as low as is reasonably achievable (ALARA) concept, use of time, distance, and shielding to minimize exposure, and location of sealed source within the gauge) and regulatory requirements (applicable regulations, license conditions, license amendments, and license renewals, locations of use and storage of radioactive materials, material control and accountability, annual audit of radiation safety program, transfer and disposal, recordkeeping, prior events involving fixed gauges, handling incidents, recognizing and ensuring that radiation warning signs are visible and legible, licensing and inspection by regulatory agency, need for complete and accurate information, employee protection, deliberate misconduct); and
- Practical Explanation of the Theory and Operation for Each Gauge Possessed by the Licensee, including operating, emergency, and security procedures, routine versus nonroutine maintenance, and lock-out procedures; and
- Supervised hands-on experience (on-the job training, under the supervision of an authorized user or the radiation safety officer) involving operating procedures, test runs of emergency procedures, routine maintenance, and lock-out procedures

(2) Training assessment, ensuring that proposed AUs are qualified to work independently with each type of gauge with which they may work. Management will ensure that proposed RSOs are qualified to work independently with and are knowledgeable of the radiation safety aspects of all types of gauges that may be possessed by the applicant

(3) Instructors, with a minimum training and experience of:
- Successful completion of both a fixed gauge manufacturer’s or distributor’s course for users, or equivalent; and an 8-hour radiation safety course or radiation safety officer training course
- Documentation of 8 hours of hands-on experience with fixed gauges

11. Regarding Radiation Safety Program details provided in ITEM 10 – Radiation Safety Program, information needed regarding the use of portable and fixed gauges was omitted from the license.
Accordingly, please confirm the following statements, or provide alternative information, as discussed during our phone conversation.

    a. Regarding Fixed Gauge Operating, Emergency, and Security; Maintenance; and Temporary Jobsites (Ref. NUREG 1556, Vol. 4, rev. 1, pp. 8-20 to 8-34):

        i. *Regarding operating, emergency & security procedures, if the gauge meets one or more of the safety conditions specified in "Discussion:"* "Operating, emergency, and security procedures will be developed, implemented, maintained, and distributed, and will meet the criteria in Section 8.10.6, 'Operating, Emergency, and Security Procedures' in NUREG–1556, Volume 4, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses.'

        ii. *For routine maintenance:* "We will implement and maintain procedures for routine maintenance of our gauges according to each manufacturer's or distributor's written recommendations and instructions."

        iii. *For non-routine maintenance:* "The gauge manufacturer, distributor, or other person licensed by the NRC or an Agreement State will perform nonroutine operations such as installation, initial radiation survey, repair and maintenance of radiological safety components, relocation, replacement, alignment, removal from service, and disposal of sealed sources."

        iv. *Confirming no use of fixed gauges at Temporary jobsites:* "We will not use fixed gauges at temporary jobsites."

    b. Regarding Portable Gauge Operating, Emergency, and Security; and Maintenance (Ref. NUREG 1556, Vol. 1, rev. 2, pp. 8-17 to 8-22):

        i. *Regarding operating, emergency & security procedures, either:*
            (1) "We will implement and maintain the operating, emergency, and security procedures in Appendix G to NUREG–1556, Volume 1, Revision 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses." Copies of these procedures will be provided to all gauge users and will be available at each jobsite." OR
            (2) "Operating, emergency, and security procedures will be developed, implemented, and maintained and will meet the criteria in section 8.10.6, "Radiation Safety Program—Operating, Emergency, and Security Procedures," NUREG–1556, Volume 1, Revision 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses." Copies of these procedures will be provided to all gauge users and will be available at each jobsite."

        ii. *For routine cleaning & lubrication:* "We will implement and maintain procedures for routine maintenance of our gauges according to each manufacturer's written recommendations and instructions."

iii. *For non-routine maintenance or repair operations that require detaching the source or source rod from the gauge:* "The gauge manufacturer, or other person licensed by the NRC or an Agreement State will perform nonroutine maintenance or repair operations that require detaching the source or source rod from the gauge."

Please provide a response via a signed and dated letter within 7 days (on or prior to October 5, 2022), as we discussed that you would be able to do. For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me at 630-829-9892.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room, at the NRC's ADAMS.

Sincerely,

Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2022.09.28 18:41:15 -05'00'

Sara A. Forster
Health Physicist
Materials Licensing Branch
Division of Radiological Safety & Security

Docket No.: 030-35835
License No.: 21-03336-10

Control No.: 630726

From:	Sara Forster
To:	Sandy Pavon; Martha Pavon
Cc:	Tammy Tomczak
Subject:	Additional Information Request re Western Michigan University renewal application, NRC License No. 21-03336-01, CN 630726
Date:	Friday, September 30, 2022 11:27:23 AM
Attachments:	CN630726.Lic21-03336-01 Request for Additional Information signed public.pdf

Good morning, Sandy & Martha:

Please find attached a request for information that was sent to the licensee, regarding the referenced action. Could you please add it to ADAMS and let me know the Accession number?

Thank you!

Sara