



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

September 10, 2021

Kyle Geise
Manager Test Lab
City of Fort Wayne
200 East Berry Street
Fort Wayne, IN 46802

Dear Mr. Geise:

This letter is in reference to your application dated August 12, 2021, requesting the renewal of U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-16526-02.

The NRC's guidance document for your type of license, which I refer to throughout this letter as "the guidance", is NUREG-1556, Volume 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses." The latest revision was published on June 2016 and is accessible at: <https://www.nrc.gov/docs/ML1617/ML16175A375.pdf>.

Upon review of your application, I identified the following areas requiring additional or clarifying information:

1. NRC Form 313, "Application for Materials License," indicates that the license application should be prepared following the instructions provided in the current volume of NUREG-1556, "Consolidated Guidance About Materials Licenses."

Your application was not prepared in accordance with the most recent revision of the guidance and did not adequately address all required items. Therefore, you may revise and resubmit your application using Appendix B, "Suggested Format for Providing Information Requested in Items 5 through 11, of the U.S. NRC Nuclear Regulatory Commission Form 313," from the guidance.

Additional items in this letter address the specific areas in which additional or clarifying information is requested. Further information regarding completion of the license application may be found in Section 8, "Contents of an Application," of the guidance.

2. Section 8.3, "Address(es) where Licensed Material will be Used or Possessed," of the guidance and Item 3 of the NRC Form 313, "Application for Materials License," require that you specify all address(es) where licensed materials will be used or possessed. For portable gauge applicants, it is also common for "temporary job sites" to be included in the request.

Item 3 of your license application does not identify if you intend to continue using your portable gauging devices at temporary job sites.

Please revise and resubmit your application identifying in Item 3 of the application if you wish to continue using licensed material at temporary job sites. If seeking continuing authorization to use temporary job sites, the guidance identifies that the address may be stated as, "temporary jobsites anywhere in the U.S. where the NRC maintains jurisdiction."

3. Section 8.5.1, "Sealed Sources and Devices," and Section 8.6, "Item 6: Purpose(s) for Which Licensed Material Will Be Used," of the guidance states that applicants must provide information regarding the radioactive material requested and the intended purpose of use. This should include the following:
- identification of each radionuclide and nominal activity for each portable gauge;
 - identify the manufacturer (or distributor) and model number of each type of portable gauging device;
 - state the number of each type of portable gauging device requested;
 - provide a description of the use of the portable gauging devices; and
 - list the activity per source and the maximum activity per gauge being requested, which must not exceed the maximum activity listed in the approved certificate of registration issued by the NRC or by an Agreement State.

Your application did not provide all required information.

Please revise and resubmit your application providing complete information for Items 5 and 6, "Materials To Be Possessed and Proposed Uses." Identify all requested radionuclides and specify the activity per source and the total activity for each radionuclide required for use with the requested CPN International Division of InstroTek, Inc., Model MC Series PORTAPROBE portable gauging devices.

4. Section 8.8.1, "Authorized Users," of the guidance, states that individual gauge users must have adequate training and experience in the use of portable gauging devices. Acceptable training and experience may include either:
- the completion of a portable gauge manufacturer's course for users and hands-on training in the use of portable gauges; or
 - an equivalent course that meets the criteria in Appendix C of the guidance.

The "Response from Applicant," section of the guidance, specifies that either of the following responses may be provided:

- the statement, "Before using licensed materials, authorized users will have successfully completed one of the training courses described under "Criteria" in the section titled "Training for Individuals Working in or Frequenting Restricted Areas" in NUREG-1556, Volume 1, Revision 2, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses.'"; or
- provide a description of the training for proposed authorized users.

Your application states: "All authorized users are trained, have certifications." Your response is not acceptable as it lacks a clear commitment to having users complete a portable gauge manufacturer's course and hands-on training in the use of portable gauging devices or an equivalent course meeting the criteria in Appendix C of the guidance.

Please submit an acceptable response. For additional information, please refer to Section 8.8, "Item 8: Training for Individuals Working In or Frequenting Restricted

Areas,” and Appendix C, “Criteria for Acceptable Training Courses for Portable Gauge Users,” of the guidance.

5. Section 8.9, “Facilities and Equipment,” of the guidance identifies that applicants must provide a facility diagram for each permanent portable gauge storage location.

Your application did not include a facility diagram or drawing of your facility.

Please revise and resubmit your application for license renewal providing a facility diagram depicting all information relevant to public dose and security as discussed in Sections 8.10.5, “Public Dose,” and 8.10.6, “Operating, Emergency, and Security Procedures.”

Identify all entrances and points of access, rooms, uses of the rooms, the location of the gauge storage area and its distance from occupied work areas. Also, describe and label all adjacent areas to your facility (parking lot, neighboring buildings, streets, etc.). If your facility is a multistory and/or multitenant building, identify all floors and their uses, including areas occupied by other tenants. If the gauges are stored in a cabinet or similar container, submit a diagram and description of the container.

Please do not submit blueprints or copies of blueprints. Simple, hand – drawn diagrams are best.

As depicted in Figure 8-4, “Storing Gauges,” of Section 8.10.5 of the guidance, gauges should be stored away from occupied areas. Further, Title 10 Code of Federal Regulations (10 CFR) §30.34(i) requires that portable gauges must be secured against unauthorized removal using a minimum of two independent physical controls that form tangible barriers.

6. Section 8.10.2, “Radiation Monitoring Instruments,” of the guidance specifies that licensees should possess, or have access to, radiation monitoring instruments, which are necessary to protect health and minimize danger to life or property, especially in circumstances related to incidents involving gauges at construction sites.

Your application does not identify if you possess, or have access to, radiation monitoring instruments.

As indicated in the “Response from Applicant,” area of this section, please revise and resubmit your application providing either of the following:

- the statement: “We will either possess and use, or have access to and use, a radiation survey meter that meets the criteria in the section titled ‘Radiation Safety Program— Radiation Monitoring Instruments’ in NUREG–1556, Volume 1, Revision 2, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses,’ in the event of an incident”; or
- a description of an alternative procedure for determining source integrity after an incident involving the gauge.

7. Section 8.10.3, "Material Receipt and Accountability," of the guidance, identifies that licensed materials must be tracked "from cradle to grave" in order to ensure gauge accountability; identify when sealed sources/gauges could be lost, stolen, or misplaced; and ensure that possession limits listed on the license are not exceeded.

Licensees must do the following:

- maintain records of receipt, transfer, and disposal of gauges; and
- conduct physical inventories every 6 months (or at other intervals justified by the applicant and approved by the NRC) to account for all sealed sources.

Your application does not describe how you will ensure accountability of licensed materials at all times and does not commit to performing a physical inventory at intervals not to exceed 6 months.

As indicated in the "Response from Applicant," area of this section, please revise and resubmit your application providing either of the following:

- the statement: "Physical inventories will be conducted every 6 months or at other intervals approved by the NRC to account for all sealed sources and devices received and possessed under the license"; or
- a description and justification of an alternate frequency and/or procedure to account for all sealed sources and devices received and possessed under the license; and
- the statement: "We will develop, implement and maintain procedures for ensuring accountability of licensed materials at all times."

8. Section 8.10.4, "Occupational Dose," of the guidance identifies that licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure. When personnel monitoring is required, for all personnel dosimeters that require processing to determine the radiation dose, licensees must use dosimeters supplied by an NVLAP-approved processor.

Your application does not address how you will ensure compliance with the occupational dose limits specified in 10 CFR §20.1201, 10 CFR §20.1207 and 10 CFR §20.1208.

As indicated in the "Response from Applicant," area of this section, please revise and resubmit your application providing either of the following:

- the statement: "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a)"; or
- the statement: "We will provide and require the use of individual monitoring devices (dosimetry). All personnel dosimeters that require processing to determine the radiation dose will be processed and evaluated by a NVLAP-approved processor."

9. Section 8.10.6, "Operating, Emergency and Security Procedures," specifies that applicants must develop, implement, and maintain adequate Operating, Emergency and Security Procedures.

Your application did not address the development, implementation and maintenance of Operating, Emergency & Security Procedures.

Please revise and resubmit your application including a commitment to develop, implement and maintain adequate Operating, Emergency and Security Procedures. As applicable, provide one of the following with your response:

- the statement, "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
 - the statement, "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"; or
 - alternative procedures, and the statement, "Copies of these procedures will be provided to all gauge users and will be available at each jobsite."
10. Section 8.10.7, "Leak Tests," of the guidance identifies that the U.S. NRC requires testing to determine whether there is any radioactive leakage from the sealed source in the portable gauging device. Leak tests must be conducted by an organization licensed by the U.S. NRC or an Agreement State that does not exceed the maximum interval specified in the device's SS&D Registry Sheet. Licensees must also maintain records of leak test results.

Your application includes the following statement: "Gauges are leak tested 2 times a year, calibrated yearly." Though, your statement does not identify your procedures for arranging for, or performing, the analysis of collected leak test samples and maintaining records of leak test results. Further, your procedures commit to performing leak tests two times a year, which may be overly restrictive.

As indicated in the "Response from Applicant," area of this section, revise and resubmit your application providing one of the following:

- the statement, "Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device registration certificate. Leak tests will be performed by an organization licensed by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits and/or sample analysis services to other licensees and according to the kit supplier's instructions. Records of leak test results will be maintained"; or

- the statement, “We will implement the model leak test program published in Appendix I of NUREG–1556, Volume 1, Revision 2, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses.’ Records of leak tests will be maintained”; or
 - A description of the alternative equipment and/or procedures for determining whether there is any radioactive leakage from sources contained in gauges and the statement: “Records of leak tests will be maintained.”
11. Section 8.10.8, “Maintenance,” of the guidance identifies that licensees should routinely clean and maintain gauges according to the manufacturer’s written recommendations and instructions. Nonroutine maintenance or repair (beyond routine cleaning and lubrication) that involves detaching the source or source rod from the device, and any other activities during which personnel could receive radiation doses exceeding NRC limits, must be performed by the gauge manufacturer or a person specifically authorized by the NRC or an Agreement State.

Your application does not include applicable Maintenance Procedures.

As indicated in the “Response from Applicant,” area of this section, revise and resubmit your application providing a commitment regarding the performance of routine maintenance:

- the statement: “We will implement and maintain procedures for routine maintenance of our gauges according to each manufacturer’s written recommendations and instructions”; or
- alternative procedures for NRC review

Further, revise and resubmit your application providing a commitment regarding the performance of nonroutine maintenance or repair operations, including either:

- the statement: “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;” or
- a request to perform this work “in-house,” using the information in Appendix F of the guidance to support the request

In accordance with 10 CFR §2.390 of the NRC’s “Rules of Practice,” a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC’s Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

To continue review of your application, I request that you submit your response to this letter within 30 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, I encourage you to contact me at Jason.Kelly@nrc.gov or at (630) 829-9737.

Sincerely,

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

License No. 13-16526-02
Docket No. 030-29002
Control No. 628163