



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

July 21, 2021

Paige Pryse
Radiation Safety Officer
PQ Corporation
1101 Quartz Rd.
Clarksville, IN 47129

Dear Ms. Pryse:

This letter is in reference to the application dated May 18, 2021, signed by Dan Davin, Plant Manager, requesting the renewal of U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-32825-01.

The NRC's guidance document for your type of license, which I refer to throughout this letter as "the guidance", is NUREG-1556, Volume 4, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses." The latest revision was published on July 2016 and is accessible at: <https://www.nrc.gov/docs/ML1618/ML16188A048.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.

Please revise and resubmit your application using Appendix B, "Suggested Format for Providing Information Requested in Items 5 through 11 of U.S. 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 8.7.1, "Radiation Safety Officer," of the guidance identifies that the Radiation Safety Officer (RSO), is responsible for the oversight of licensed operations. The RSO must have sufficient organizational authority and management prerogative to enforce appropriate radiation protection rules, standards, and practices.

To formally establish the organizational authority of your office, please submit a current Delegation of Authority signed by a management representative. A model Delegation of Authority is provided in Appendix C, "Typical Duties and Responsibilities of the Radiation Safety Officer," of the guidance.

3. Section 8.7.1, "Radiation Safety Officers," of the guidance identifies that licensees must notify the U.S. NRC and obtain a license amendment before making changes in the designation of the RSO responsible for the radiation safety program.

In your application, you stated the following: "Before obtaining licensed materials the proposed RSO will have successfully completed the training described in Criteria in the section 'Individuals Responsible for Radiation Safety Training and Experience - Radiation Safety Officer' in NUREG-1156 Vol 4. Before being named as RSO future RSOs will successfully complete the training described in the criteria referenced above and within 30 days of naming a new RSO, we will submit the new RSO's name to NRC to include in our license."

Your statement is not acceptable as a license amendment is needed before making changes in the designation of the RSO. Please revise and resubmit your application with a statement confirming that a change in the designated RSO will be made only after obtaining a license amendment.

4. Section 8.7.2, "Authorized Users," of the guidance identifies that Authorized Users (AUs) must have adequate training and experience in the use of fixed gauging devices.

The "Response from Applicant" section of the guidance states that one of the following should be provided:

- The statement: "Before using licensed materials, authorized users will have successfully completed one of the training courses described in the 'Criteria' part of the section titled, 'Authorized Users' in NUREG-1556, Volume 4, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses'; or
- A description of the training and experience for proposed AUs.

In your application, you stated the following: "Before using licensed materials the authorized users will have successfully completed the training described in the training section NUREG-1556."

This is not an acceptable response because it does not refer to the current revision of the guidance. Please submit an acceptable response as specified in the guidance.

5. Section 8.9, "Item 9: Facilities and Equipment," of the guidance describes the regulations and criteria for facilities and equipment.

The "Response from Applicant" section of the guidance states that one of the following should be provided:

- The statement, "We will ensure that the location of each fixed gauge meets the criteria in Section 8.9, 'Facilities and Equipment,' in NUREG-1556, Volume 4, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses'; or
- Confirmation that the fixed gauge is secured to prevent unauthorized removal or access and submittal of specific information demonstrating that the proposed conditions will not impact the safety or integrity of the source or device (address any instances where the proposed conditions exceed any conditions listed in the SSD registration certificate.)

Your application does not provide information relevant to demonstrating that your facilities and equipment are adequate to protect health and to minimize danger to life or property.

Please revise and resubmit your application providing an acceptable response as specified in the guidance or provide alternative procedures.

6. Section 8.10.3, "Material Receipt and Accountability," of the guidance, identifies that licensed material 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 fixed gauging devices;
- 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; and
- Update transactions in the National Source Tracking System (NSTS) and perform an NSTS annual inventory reconciliation, if applicable.

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

- 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."

In your application, you stated the following: "Physical inventories will be conducted at intervals not to exceed six months to account for all sealed source and devices received and possessed under the license."

Your response is not complete because your response does not also identify how you ensure accountability of licensed materials at all times. Please provide a complete and acceptable response.

7. Section 8.10.4, "Occupational Dose," of the guidance, states that licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure as necessary.

The "Response from Applicant," section of the guidance specifies that that one of the following should be provided:

- 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."

Your application does not identify how you will evaluate and monitor occupational dose. Please revise and resubmit your application providing an acceptable response. You may refer to Section 8.10.4 and Appendix G, "Dosimetry-Related Guidance," of the guidance for additional information.

8. Section 8.10.6, "Operating, Emergency, and Security Procedures," of the guidance, states that applicants must develop, implement and maintain adequate Operating, Emergency & Security (OE&S) Procedures. In addition, copies of the OE&S Procedures must be provided to all gauge users and the procedures should be posted or otherwise made available at each location of use.

The NRC permits greater flexibility when licensing certain types of fixed gauging devices. For each fixed gauging device that is requested, if one or more of the following safety conditions are met, the applicant need not submit the OE&S Procedures for NRC review during the licensing process:

- the air gap between the radiation source and detector of the device is less than 45 centimeters [18 inches];
- the air gap of the device would not allow insertion of a 30-centimeter [12-inch] diameter sphere into the radiation beam of the device without removal of a barrier;
- the radiation dose rate in the radiation beam of the device at 45 centimeters [18 inches] from the radiation source with the device shutters, if any, in the open position does not exceed 1 mSv per hour [0.1 rem per hour]; and
- entry into vessels (e.g., bins, tanks, hoppers, or pipes) with a gauge installed is not necessary under any foreseeable circumstances and is prohibited

The "Response from Applicant," section of the guidance specifies that that one of the following should be provided:

- If the gauge meets one or more of the safety conditions, provide the statement, "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 Licensees'; or
- If the gauge does not meet any of the safety conditions, provide your operating, emergency, security, and lock-out (if applicable) procedures.

Your application neither provides your OE&S Procedures nor commits to develop, implement, maintain, and distribute OE&S Procedures meeting the criteria in Section 8.10.6 of the guidance.

Please revise and resubmit your application providing an acceptable response. You may refer to Section 8.10.6 and Appendix H, "Operating, Emergency and Security Procedures," of the guidance for additional information.

9. 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 states, "Leak tests will be performed at regular intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration certificate." Though, your procedures fail to provide procedures addressing the collection and analysis of leak test samples. Further, your application does not address the retention of leak test records.

As indicated in the "Response from Applicant," area of this section, you may revise 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 in Appendix I of NUREG-1556, Volume 4, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed 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."
10. Section 8.10.8, "Maintenance," of the guidance identifies that licensees should routinely clean and maintain gauges according to the manufacturer's or distributor's written recommendations and instructions. Though, specific authorization by the NRC or an Agreement State is required to perform nonroutine maintenance and repair of fixed gauges.

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

For routine maintenance, submit one of the following:

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

For nonroutine operations, submit one of the following:

- the statement: "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”; or

- a request to perform this work “in-house,” using the information in Appendix J of this NUREG to support the request.

Your application states, “Maintenance will be performed according to manufacturer’s or distributor’s instructions.” This is not a complete response as it does not address nonroutine operations.

Please revise and resubmit your application providing a complete response. You may refer to Section 8.10.8 and Appendix J, “Information Needed to Support Applicant’s Request to Perform Nonroutine Operations.”

In accordance with Title 10 of the *Code of Federal Regulations* (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. 13-32825-01
Docket No. 030-38447
Control No. 626855