



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

May 24, 2022

Janelle K. Baier
Quality Manager
Holcim (US) Inc.
1435 Ford Ave.
Alpena, MI 49707

Dear Ms. Baier:

This letter is in reference to your application dated February 14, 2022, requesting the renewal of U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-25823-01.

The U.S. NRC's guidance document for your type of license, which I refer to below as "the guidance", is NUREG-1556, Volume 4, Rev. 1, dated July 2016, "Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Fixed Gauge Licenses." This guidance is available on the U.S. NRC's website 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 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 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. Title 10 of the *Code of Federal Regulations* (10 CFR) §30.32(g)(1) and Section 8.5.1, "Sealed Sources and Devices," of the guidance, require the license application identify the radionuclide and activity for each requested sealed source and device, the manufacturer's (or distributor's) name, model number, and the number of gauges for each model.

Your application does not identify the requested sealed source and device manufacturer's (or distributor's) name, model number and the number of gauges requested.

Please resubmit your application providing the following information, as applicable:

- manufacturer (or distributor) name and model number for each requested fixed gauging device or material analyzer;

- list of compatible sealed source manufacturer (or distributor) names and model numbers to be authorized for use with each requested device;
- maximum activity per source and number of sealed sources per device; and
- total number of each type of fixed gauging device you are seeking authorization to possess and use.

3. Section 8.7.2, “Authorized Users,” of the guidance identifies that Authorized Users 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 Authorized Users.

Your application does not address the provision of training to Authorized Users.

Please resubmit your application providing an acceptable response as specified in the guidance.

4. 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 Sealed Source & Device (SS&D) Registration Certificate.)

Your application identifies that the location of each gauge is compatible with the “Conditions of Normal Use,” specified in the associated SS&D Registration Certificate. Though, this statement does not satisfy all criteria specified in Section 8.9 of the guidance.

This statement should be expanded to also include a reference to the “Limitations and/or Other Considerations of Use,” section of the SS&D Registration Certificate. You may also choose to resubmit your application including the statement indicated in the “Response from Applicant,” section of the guidance.

5. 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 license identifies that you possess radiation detection instruments appropriate for detecting gamma emitting radionuclides. Though, your application does not identify if you also possess, or have access to, a radiation detection instrument suitable for detecting neutron-emitting radionuclides, including the californium-252 radionuclide used in your Thermo Gamma Metrics Model 2000 and SABIA Model X1 Prompt Gamma Neutron Activation Analyzers. This does not satisfy the criteria specified in Section 8.10.2 of the guidance. A response, satisfying the criteria, is needed.

As indicated in the "Response from Applicant," area of Section 8.10.2, you may revise and resubmit your application providing either of the following:

- the statement: "Surveys according to 10 CFR 20.1501 will be performed by a person specifically authorized by the NRC or an Agreement State to perform these surveys."; or
 - the statement: "We will use radiation survey instruments that meet the criteria in Section 8.10.2, 'Radiation Monitoring Instruments,' in NUREG-1556, Volume 4, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses,' and one of the following three choices:
 - "Each radiation survey meter will be calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform radiation survey meter calibrations."; or
 - "We will implement the model radiation survey instrument calibration program in Appendix F, 'Model Radiation Survey Instrument Calibration Program,' in NUREG-1556, Volume 4, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses.'"; or
 - "We will submit alternative calibration procedures for NRC review."; or
 - submit a description of an alternative method to perform radiation surveys according to 10 CFR 20.1501.
6. Section 8.10.4, "Occupational Dose," of the guidance states that applicants must evaluate the potential occupational exposure of all workers and monitor occupational exposure when appropriate.

As indicated in the "Response from Applicant," area of the guidance, please provide one 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."

According to Appendix G, "Dosimetry-Related Guidance," of the guidance, licensees should review evaluations periodically and revise them as needed. They should check assumptions used in their evaluations to ensure that the assumptions are up-to-date and accurate. Considerations for performing a reevaluation include changes in occupancy factors, personnel handling practices, new gauges containing sources of different activities, different radionuclides or different cleaning and lubrication procedures.

Your application referred to a previous evaluation, which was based on personnel dosimetry monitoring data collected from 1997 through 2007. You should consider if this previous evaluation may require an update.

7. 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.

Your application does not provide adequate OE&S Procedures. Your procedures should address all of the following subject areas, as applicable.

Components for Fixed Gauging Device OE&S Procedures

- A. Instructions for using gauges in accordance with the manufacturer or distributor's instructions.
- B. Routine cleaning, inspection and maintenance of the gauges in accordance with the manufacturer's recommendations and instructions.
- C. Instructions for testing each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or as specified in the Sealed Source & Device (S&SD) Registration Certificate.
- D. Tag-out / Lock-Out Procedures that are adequate to ensure that no individual or portion of an individual's body can enter the radiation beam.
- E. Handling and using sources of radiation so that exposures are maintained as low as reasonably achievable and no individual is likely to be exposed to radiation doses in excess of the standards established in 10 CFR Part 20, Subpart C.
- F. Maintaining accountability of radiation sources and gauging devices.
- G. Methods and occasions for conducting radiation surveys.
- H. Methods and occasions for locking and securing sources of radiation.
- I. Personnel monitoring and the use of personnel monitoring equipment.
- J. Minimizing exposure to individuals in the event of an accident involving sources of radiation.
- K. Notifying proper personnel in the event of damage, loss, theft, or accident involving sources of radiation.
- L. Shipping, receiving and opening packages containing sealed sources.

For each gauge that is requested, if one or more of the following safety conditions are met, you need not submit your OE&S Procedures for review:

- 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]; or
- entry into vessels (e.g., bins, tanks, hoppers, or pipes) with a gauge installed is not necessary under any foreseeable circumstances and is prohibited

As indicated in the “Response from Applicant,” area of the guidance, please provide one of the following:

- If the gauge meets one or more of the safety conditions specified above, 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 Licenses.’”; or
- If the gauge does not meet any of the safety conditions specified above, provide your Operating, Emergency & Security Procedures and Lock-Out / Tag-Out Procedures.

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. 21-25823-01
Docket No. 030-30142
Control No. 630092