



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

March 1, 2022

Robert Newton, CHP
Technical Specialist - RPO
DTE Energy
Fermi 2, AIB M-32
6400 N. Dixie Hwy.
Newport, MI 48166

Dear Mr. Newton:

This letter is in reference to your application dated October 20, 2021, requesting the renewal of U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-02335-09.

The NRC's guidance document for your type of license 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 NRC Web site 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. Section 8.2, "Item 2: Name and Mailing Address of Applicant," indicates that the legal name of the applicant's corporation or other legal entity be identified in the license application.

Your application identifies your company's legal name as *DTE ENERGY*. A recent check with the Michigan Department of Licensing and Regulatory Affairs' Corporations Division was not successful in confirming your company's active registration as *DTE ENERGY*.

A business registration was located for the legal entity identified as *DTE ENERGY COMPANY*.

Please clarify if your company's complete legal name is *DTE ENERGY COMPANY*. Otherwise, please provide the complete legal name under which your company is actively registered.

2. Section 8.5.1, "Sealed Sources and Devices," states that your application should specify the radionuclide and nominal activity of each fixed gauging device and identify the number of each type of fixed gauge requested.

Your license application requests continuing authorization to possess and use the following fixed gauging devices for level measurement:

- Ohmart Corporation Model SHRH-A; and
- Ohmart Corporation Model SHRM-PA

Please identify the total number and activity for each of the requested fixed gauging device models. In addition, please identify the activity per source and the number of sources per device.

3. Section 8.7.1, "Radiation Safety Officer," of the guidance identifies that the appointed Radiation Safety Officer (RSO) must have adequate training and experience. Additional training is required for RSOs in programs that perform non-routine operations.

The application includes a request to designate you as the RSO. Though, the request did not provide complete documentation of your training and experience with fixed gauging devices, which should include supervised hands-on training and experience and instruction related to the performance of non-routine operations.

Acceptable training and experience include completion of a manufacturer/distributor's course or an equivalent, including supervised hands-on training and experience and instruction in performance of non-routine operations. Please state whether you have had this required training and provide documentation of the completion of this training. In addition, please provide a course outline detailing the subjects covered in the course and the name and title of the course instructor(s).

4. Section 8.7.2, "Authorized Users," of the guidance identifies that authorized users tasked with performing non-routine operations must be provided additional training and experience with fixed gauging devices.

Your application requests the removal and appointment of additional authorized users listed in Condition 17.A. of your license. Though, your request does not provide documentation of their training and experience with fixed gauging devices, which must include instruction in the performance of non-routine operations.

Clarify your request for the removal and addition of authorized users identified in Condition 17.A. of your license. Include documentation of each proposed authorized user's training and experience with fixed gauging devices.

5. Section 8.10.8, "Maintenance," of the guidance specifies that a request to perform non-routine operations "in-house," should use the information in Appendix J, "Information Needed to Support Applicant's Request to Perform Nonroutine Operations," to support the request.

Your license previously authorized your company to perform non-routine operations, including the installation, relocation and removal of fixed gauging devices. Your request to add additional authorized users to Condition 17.A. of your license suggests that you would like to retain continuing authorization to perform non-routine operations.

If applicable, revise your selection in Item 10.8, "Radiation Safety Program – Maintenance," of your application and provide applicable procedures and commitments to support your request to perform non-routine operations in-house. Refer to Appendix J, "Information Needed to Support Applicant's Request to Perform Nonroutine Operations," of the guidance for additional information.

6. 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 all information relevant to demonstrating that your facilities and equipment are adequate to protect health and to minimize danger to life or property. In particular, your application does not address whether the location(s) where your fixed gauging devices are installed adhere to the "Conditions of Normal Use," and "Limitations and/or Other Considerations of Use," specified in the associated Sealed Source & Device (SS&D) Registration Certificate for your fixed gauging devices.

Please expand upon your statement provided in Item 9, "Facilities and Equipment," of your application to address all criteria indicated in Section 8.9 of the guidance.

7. Section 8.10.3, "Material Receipt and Accountability," of the guidance, identifies that licensed material must be tracked "from cradle to grave" 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 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."

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.

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.

Your application commits to developing, implementing, maintaining and distributing OE&S Procedures meeting the criteria in Section 8.10.6, "Operating, Emergency, and Security Procedures," of the guidance, with an alternative procedure in lieu of the performance of periodic testing of the on-off mechanism (shutter) and indicator, if any.

Your alternative procedures identify that confirmation of the proper operation of the shutter will be confirmed by verifying the expected annunciation of the on-off indicator located in the control room. Please provide the following additional or clarifying information:

- Identify the minimum frequency of operation of the shutter;
 - Clarify if the annunciator is a fail-safe design;
 - Describe the signal produced by the annunciator when the shutter is in the OPEN (ON) or CLOSED (OFF) position (e.g., continuous light indication); and
 - Identify the actions to address the suspected failure of the annunciator.
9. Section 8.13, "Item 13: Certification," specifies that a representative of the legal entity filing the application must sign and date the [NRC Form 313, "Application for Materials License."](#) The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant (i.e., a certifying official).

You signed the submitted application for license renewal. Though, your title is not recognized as that of a certifying official (e.g., President, Chief Executive Officer or Manager).

Therefore, please revise and resubmit the application bearing the signature of a certifying official. For additional information, you may refer to Chapter 3, "Management Responsibility," of the guidance.

In accordance with Title 10 Code of Federal Regulations §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 20 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. 21-02335-09
Docket No. 030-10445
Control No. 628983