



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

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

JAN 09 2020

Michael Matthews  
Director Environmental, Health and Safety  
Plastatech Engineering, Ltd.  
725 Morley Drive  
Saginaw, MI 48601

Dear Mr. Matthews:

A request for additional information was sent to you on November 7, 2019, in reference to your request to amend U.S. NRC Materials License #21-26714-01. A copy of this request is enclosed for your reference. A response was requested by December 7, 2019. To date, your response has not been received.

To continue the review of your amendment request, please submit a written response to this letter by January 24, 2020. Failure to respond by this date may result in your request being abandoned.

To expedite the licensing process, you may fax your response to (630) 515-1078. If you have any questions or require clarification on any of the information stated above, please do not hesitate to contact me at (630) 829-9737 or [Jason.Kelly@nrc.gov](mailto:Jason.Kelly@nrc.gov).

In accordance with Title 10 of the *Code of Federal Regulations* Section 2.390 of the U.S. Nuclear Regulatory Commission's (NRC) "Rules of Practice," a copy of this letter and enclosures will be 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 <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in black ink, appearing to read "Jason M. Kelly", is written over a horizontal line.

Jason M Kelly, MPH  
Health Physicist  
Materials Licensing Branch

License No. 21-26714-01  
Docket No. 030-34117  
Control No. 616867

Enclosure(s): As Stated



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

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2443 WARRENVILLE RD. SUITE 210  
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**NOV 07 2019**

Michael Matthews  
Director of Environmental Health and Safety  
Plastatech Engineering, Ltd.  
725 Morley Drive  
Saginaw, MI 48601

Dear Mr. Matthews:

This letter is in reference to your request dated October 29, 2019, for an amendment to your Radioactive Material License #21-26714-01. Upon review of your request, I identified the following areas requiring additional or clarifying information:

1. As the designated Radiation Safety Officer (RSO), you will be responsible for the oversight of licensed operations on a day-to-day basis. You must be provided with sufficient organizational authority and management prerogative to enforce appropriate radiation protection rules, standards, and practices. To formally establish the organizational authority of your office, submit a delegation of authority signed by a management representative (e.g., President, Chief Executive Officer or Plant Manager).
2. Your request refers to the completion of prior training for the Fixed Gauging Devices used by your company. Please include documentation of your completion of the manufacturer/distributor's Radiation Safety Training Course or an equivalent course.
3. In support of your appointment as RSO, I recommend that you review the enclosed copy of Appendix C, "Typical Duties and Responsibilities of the Radiation Safety Officer," from the U.S. Nuclear Regulatory Commission's NUREG-1556, Volume 4, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses."

Note that your management must afford you adequate time to perform your duties, which includes identifying and putting a stop to unsafe operations. This requires you to be available to periodically observe licensed operations. As this item is only advisory, no specific response is necessary or required.

4. A review of your license authorizations in Items 6, 7, 8 and 9, revealed some open-ended license authorizations that are no longer typically authorized. Upon issuance of the amended license, I need to modify your license authorizations to more closely align with your required licensed authorizations.

## 4. (Continued)

To that end, please provide the following information concerning your required license authorizations in Items 6, 7, 8 and 9:

- Identify each radionuclide and nominal activity in each fixed gauge.
- Identify the manufacturer (or distributor) and model number of each type of fixed gauge.
- State the number of each type of fixed gauge requested.
- Provide a description of the use of the gauges.
- Confirm that the activity per source and maximum activity per gauge will not exceed the maximum activity listed in the approved certificate of registration issued by the NRC or by an Agreement State.

I identified that Item 9.A. authorizes a Betacontrol of America Model MK 1.0 Transmission Gauge. Depending upon the activity required, it appears that this gauge model may be authorized with either the Institute National de Radioelements Model 700-052.002 or 700-052.004 Sealed Source or the QSA Global, Inc., Model KAC.D1 or KAC.D3 Sealed Source. To update your license, I will need you to identify the applicable Sealed Sources, Maximum Number and Activity of each Sealed Source and the Authorized Use of the Gauging Devices.

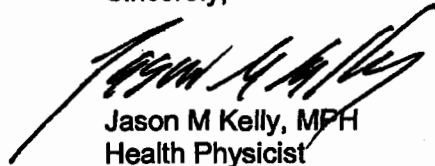
As a note, I identified that Item 9.B. errantly refers to an Eckert & Ziegler Isotope Products, Inc. (formerly Isotope Products Laboratories, Inc.) Model SIF.D1 Beta Source. Notations in the Inspection Report prepared by Edward F. Harvey, Inspector, following the August 26, 1996, inspection of your facility identify that these sources were used in two Thermo Fisher Scientific Model TFC-190 Beta Gauging Devices. Please confirm that this is the correct Manufacturer and Model Number for these gauging devices. Identify the Maximum Number, Activity and Authorized Use that you require license authorization to possess.

For your reference, the program specific guidance for your license is NUREG-1556, Volume 4, Rev. 1 dated July 2016. This guidance is available on the NRC Web site at: <https://www.nrc.gov/docs/ML1618/ML16188A048.pdf>

To continue the review of your amendment request, please submit a written response to this letter by December 7, 2019. Your response must be dated and signed by a licensee's representative and please reference Mail Control Number 616867 in the response. To expedite the licensing process, you may fax your response to (630) 515-1078. If you have any questions or require clarification on any of the information stated above, please do not hesitate to contact me at (630) 829-9737 or [Jason.Kelly@nrc.gov](mailto:Jason.Kelly@nrc.gov).

In accordance with Title 10 of the *Code of Federal Regulations* Section 2.390 of the U.S. Nuclear Regulatory Commission's (NRC) "Rules of Practice," a copy of this letter will be 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 <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in black ink, appearing to read "Jason M Kelly", is written over the typed name.

Jason M Kelly, MPH  
Health Physicist  
Materials Licensing Branch

License No. 21-26714-01  
Docket No. 030-34117

Enclosure(s): As stated

Enclosure

**APPENDIX C**  
**TYPICAL DUTIES AND RESPONSIBILITIES OF THE**  
**RADIATION SAFETY OFFICER**

## **TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER**

The radiation safety officer's (RSO's) duties and responsibilities (illustrated in Figure 8-2) typically include ensuring the following:

- Licensed activities that the RSO considers unsafe are stopped.
- Possession, installation, relocation, use, storage, routine maintenance, and nonroutine operations of fixed gauges are consistent with the limitations in the license, the Sealed Source and Device registration certificate(s), and the manufacturer's or distributor's recommendations and instructions.
- Individuals who use fixed gauges are properly trained.
- Radiation exposures are kept as low as is reasonably achievable (ALARA).
- Prospective evaluations are performed to demonstrate that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a) or that personnel monitoring devices are provided.
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- Up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed.
- Safety consequences of nonroutine operations are analyzed before conducting any such activities that have not been previously analyzed.
- Nonroutine operations are performed by the manufacturer, distributor, or person specifically authorized by the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State.
- Documentation is maintained to demonstrate, by measurement or calculation, that the dose to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in *Code of Federal Regulations* 10 CFR 20.1301, "Dose limits for individual members of the public."
- Fixed gauges are properly secured.
- Proper authorities are notified in case of accident, damage to, or malfunction of fixed gauges, fire, loss, or theft.
- Unusual occurrences involving the fixed gauge (e.g., malfunctions, accident, damage, theft) are investigated, cause(s) are determined, and appropriate corrective action(s) are identified, and corrective action taken.
- Audits are performed at least annually and documented, and corrective actions are taken.

- When the licensee identifies violation(s) of regulations or license conditions or program weaknesses, corrective action(s) are developed, implemented, and documented.
- Licensed material is transported in accordance with all applicable NRC and U.S. Department of Transportation requirements.
- Licensed material is disposed of properly.
- All required records are maintained.
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.
- Documents are posted as required by 10 CFR 19.11, "Posting of notices to workers," (10 CFR Part 19, license documents, operating procedures, NRC Form 3, "Notice to Employees,"), and 10 CFR 21.6, "Posting Requirements," (10 CFR Part 21 Section 206 of the Energy Reorganization Act of 1974, procedures adopted under Part 21), or a note is posted indicating where these documents can be examined.

**Model Delegation of Authority to Radiation Safety Officer**

**Memo To: Radiation Safety Officer**

**From: Chief Executive Officer**

**Subject: Delegation of Authority**

You, \_\_\_\_\_, have been appointed radiation safety officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission at any time. It is estimated that you will spend \_\_\_\_\_ hours per week conducting radiation protection activities.

\_\_\_\_\_  
Signature of Management Representative

\_\_\_\_\_  
Date

I accept the above responsibilities,

\_\_\_\_\_  
Signature of Radiation Safety Officer

\_\_\_\_\_  
Date

cc: Affected department heads