

From: [Torres, Roberto](#)
To: "Dan Fonseca"
Subject: RE: Request to amend item 9.B. of NRC license 49-08631-01 (docket 030-07474, mail control 625577)
Date: Wednesday, June 16, 2021 12:38:00 PM

Mr. Fonseca:

Please ask Ludlum to provide a sealed source and device registration certificate for Ludlum calibrator Model T1106 in accordance with NRC regulation 10 CFR 32.210. Without this registration certificate NRC regional staff cannot approve the device Ludlum calibrator Model T1106 in NRC license 49-08631-01 (Wyoming Office of Homeland Security). Below is link to regulation 10 CFR 32.210. Sealed source and device registration certificates are issued by NRC Headquarters staff (sealed source and device registration certificate team) or by an Agreement State (Texas, where Ludlum Headquarters is based).

<https://www.nrc.gov/reading-rm/doc-collections/cfr/part032/part032-0210.html>

For Ludlum to obtain a sealed source and device registration certificate, have Ludlum contact either Tomas Herrera in NRC Headquarters at tomas.herrera@nrc.gov (301-415-7138) or the State of Texas radiation control program (512-239-0493, fax 512-239-6466 or by email Ashley.forbes@tceq.texas.gov).

Thank you for your cooperation.

Roberto J. Torres, M.S.
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region IV
1600 East Lamar Boulevard
Arlington, TX 76011-4511
817-200-1189

From: Dan Fonseca <dan.fonseca@wyo.gov>
Sent: Wednesday, June 16, 2021 10:22 AM
To: Torres, Roberto <RobertoJ.Torres@nrc.gov>
Subject: [External_Sender] Re: [WARNING: MESSAGE ENCRYPTED]Attached is amendment 44 to NRC license

Roberto,
Good Morning! This is Dan Fonseca from the Wyoming Office of Homeland Security. We are currently taking the final steps to secure our new 400 millicurie cs137 source from J.L. Shepherd and due to the verbiage found in section 9 of our amended license we are running into issues. Under section 9 our license states that our source used for calibration will be placed into a J.L. Shepherd model 28-6 calibrator. We are not purchasing the model 28-6 calibrator, our new calibrator is from Ludlum. The model number of the Ludlum calibrator is T1106. The description is Calibration SRange Source Holder and the Ludlum part # is 4047-010-00. We need to make this change under section 9 so that we can move forward with this process. This range calibrator is what we were trained on by Ludlum when we

attended their Bench Technician course and it is a safer operation because it has multiple remote activator buttons located on the range table and (1) remote activator. These air activated actuators allow the individual performing the calibration to stay out of the radioactive field during the calibration process and they can remotely shut down the source when they have to approach the table to make adjustments on the devices. Please contact me as soon as possible so that we can get this addressed.

Regards,

Dan Fonseca
Radiation Program Manager
Wyoming Office of Homeland Security
5500 Bishop Blvd.
Cheyenne, Wy. 82002
dan.fonseca@wyo.gov
(307) 777-7197 (office)
(307) 421-0206 (cell)

"Leaders do not come pre-assembled.....They are forged by experience!"

On Thu, May 6, 2021 at 12:49 PM Torres, Roberto <RobertoJ.Torres@nrc.gov> wrote:

Mr. Fonseca:

Attached is amendment 44 to NRC license 49-08631-01 adding material and changing the RSO as requested. The passcode to open the security envelope containing amendment 44 and transmittal letter is the license expiration date. Please make copies for your records since no hard copies will be sent by regular mail at this time.

Thank you for your cooperation.

Roberto J. Torres
U.S. NRC Region IV

E-Mail to and from me, in connection with the transaction of public business, is subject to the Wyoming Public Records Act and may be disclosed to third parties.



Subpart D—Sealed Source and Device Registration

§ 32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the NRC for evaluation of radiation safety information about its product and for its registration.

(b) The request for review must be sent to the NRC's Office of Nuclear Material Safety and Safeguards, ATTN: SDDR by an appropriate method listed in § 30.6(a) of this chapter.

(c) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. Subpart A of this part includes specific criteria that apply to certain exempt products and subpart B includes specific criteria applicable to certain generally licensed devices. Subpart C includes specific provisions that apply to certain specifically licensed items.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

(f) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with—

(1) The statements and representations, including quality control program, contained in the request; and

(2) The provisions of the registration certificate.

(g) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

(1) Calibration and reference sources containing no more than:

(i) 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

(ii) 0.37 MBq (10 μ Ci), for alpha emitting radionuclides; or

(2) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

(i) The intended recipients are licensed under part 33 of this chapter or comparable provisions of an Agreement State; or

(ii) The recipients are authorized for research and development; or

(iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

(h) After the certificate is issued, the Commission may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Commission will complete its evaluation in accordance with criteria specified in this section. The Commission may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

[52 FR 27786, July 24, 1987, as amended at 60 FR 24551, May 9, 1995; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008; 77 FR 43695, Jul. 25, 2012; 79 FR 75739, Dec. 19, 2014]

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