**Applicant's Response to NRC Review Questions, Referencing Letter Dated July 7, 2005, from Magdalena R. Gryglak (Health Physicist, U.S NRC Region III), to Ray A. Carlson and Eric Ramsay (Radiological Physics Service, Inc.)**

**Today Dated: July 11, 2025**

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PURSUANT to guidance provided in NUREG-1556, Volume 18, Revision 1, "Consolidated Guidance about Materials Licenses: Program-specific Guidance about Service Provider Licenses" (August 2017), Radiological Physics Service Inc. herewith provides concise responses to NRC Region III questions. Expert radiological service providers offer commercial services to both specific and general licenses, ranging from low- to high-risk activities. Sealed source and device customers, including general licensees who receive and possess such byproduct radioactive material, may require expert commercial services to manage materials under specific licenses. In these unique situations, a service provider licensee is duly authorized by NRC to receive, possess, and handle radioactive materials under its license incident to performing specific services required by its customers. Under NUREG-1556, these services include servicing fixed gauges, and NRC authorizes such work under a specific license. The applicant has provided NRC Form 313. The following information is provided in response to the following NRC questions as a supplement to it previously submitted Form 313.

**NRC Review Questions:**

**Description/Construction**

**Q1.** Please provide RSO qualifications to work with higher activity sources (experience working with the type and quantity of material).

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**
The experience for the RSO, Ray Carlson, on license #13-32719-01 is for those isotopes as given on the license. The RSO has over 35 years working in the field of Radiological Physics and Nuclear medicine and is ABR certified in Medical Nuclear Physics, ABR Certified in Radiological Physics and ABMP Certified in Diagnostic Imaging. The RSO is not being requested to be an Authorized User for Kr85.

**Q2.** Please name an Authorized User to perform the new activity and the individual's qualifications (experience working with the type and quantity of material)

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**

The ONLY Authorized User will be Dr. Eric Ramsay, as named on NRC radioactive materials license 21-26253-01. For previous experience, attached are two older licenses which names Dr. Ramsay as RSO for licenses showing activities up to 13 Ci for Ir-192 (license #13-32719-01) and activities up to 1 Ci for all isotopes of atomic numbers 3-83 inclusive (broad scope license #21-12275-02). Dr. Ramsay is ABMP certified in Medical Physics with special competency in Radiation Oncology.

**Q3.** Please provide procedures to install the Kr-85 source into the device (please see section 8.10.1 of the guidance, which also discusses an agreement with the customer)

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**
Installation of the source box is coordinated with the customer site management team. Under supervision of Radiological Physics Service authorized user, installation of the Kr-85 Source Box is performed by an experienced, well-trained manufacturer's engineer with prior experience worldwide performing many source box installations in the same model thickness gauging equipment.

There are two options for delivery of the source to the customer site, either 1) the source is delivered pre-installed in the source box or 2) delivered separately in its own container to be installed into the source box which is delivered with the gauge unit.

Source Installation for Option 1:

1. Installation of Source into Source Box: The source is installed into the source box at the manufacture's site in China. The source box with the pre-installed source is sent to the customer site in the United States.
2. Place the Source Box into the Gauge: Open the Gauge unit cabinet door. Install the Kr-85 source box matching the Gauge unit equipment plugs with the source box plugs for proper alignment. Tighten screws and close the cabinet door.

Source Installation for Option 2:

Step 1. Pre-installation. The designated source box installation engineer dons designated protective clothing provided for source box installation. Protective clothing includes a lead suit, leaded gloves, and leaded eyeglasses. The beta-ray source box has been shipped to the customer site in a DOT Type A shipping package, a wooden box. The wooden box is brought to an unoccupied location with a circular area of 30 square meter radiation exclusion area, and the shielded pig containing the Kr-85 source is taken out of the shipping box and placed on a worktable.

Step 2. Removal of Sealing Plates. An Allen wrench is used to remove the side covers and the top protective film of the source box to be loaded.

Step 3. Setting the Source Rotation Configuration. Manually rotate the internal rotating structure of the β-ray source box to the designated start position. Apply supplied screws to

to secure the rotating position.

Step 4. Kr-85 Source Installation. Remove the Kr-85 source stopper from the beta-ray shipping pig to make sure the internal mounting spring is free and springy. Use provided remote tools. Remove the radioactive source from the lead cylinder and install the radioactive source inside the source box with the window side facing up. Retighten the source holder of the beta-ray source box to its original position.

Step 5. Restore the Rotating Source to its OFF Position. Manually remove the screw that secures the position of the rotary source box; after unscrewing, the rotary source box will automatically reset to the closed state. Reinstall the source box side panels and top protective film.

Step 6. Place the Source Box into the Gauge. Open the Gauge unit cabinet door. Install the Kr-85 source box matching the Gauge unit equipment plugs with the source box plugs for proper alignment. Tighten screws and close the cabinet door.

**Q4.** Emergency procedure (Section 8.10.1 provides a summary of emergency scenarios, which may include high dose rate alarm; leaking source; stuck source; radioactive spill; natural phenomena, such as fire, earthquake, and tornados; medical emergency; contaminated or injured individual; inhalation or ingestion due to aerosolized contamination; radiation overexposure; unshielded source; device malfunction; device toppled over or damaged; activation of a safety or security alarm; lost or missing radioactive material, and transportation accident involving the transport of licensed material.

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**

Emergency scenarios have been evaluated by the manufacturer. For the installation given in Option 1, the only scenario considered likely is a dropped source. Should this occur, the source is easily located due to its size.
For the installation given in Option 2, one scenario has been considered potentially likely: an emergency procedure may be anticipated for a dropped Kr-85 source box. The response is to pick up and inspect the source box to ensure that the window has not been compromised (the sealed source has already been tested against the dropped source scenario). The following emergency scenarios have both extremely low risk and low probability: High dose rate alarm (the source is a pure-beta Kr-85 source); leaking source (leak testing not required for Kr-85 gauge sources); radioactive spill (source is a gas element and does not spill); natural phenomena (highly unlikely during the short installation period); contaminated or injured individual (highly unlikely); inhalation or ingestion due to aerosolized contamination (noble gas not an inhalation hazard and source not ingestible); radiation overexposure (unlikely due to protective wear and pure beta source handling, and Radiological Physics Services will monitor area radiation levels); device malfunction (device is designed and tested against malfunctions); lost or missing source material (not likely during the short installation procedure); source security (locked

cabinet, closed source position not accessible to operators and company personnel); and transportation accident after arrival at site (source box is permanently installed into nonmobile equipment). The manufacturer's risk analyses and 12 years of installation experience with many hundreds of similar devices have not shown a history of similar incidents of concern.

For device malfunction, the manufacturer will be responsible for correction including return of the source to the manufacturer if required.

For a transportation accident where the package containing the sealed source becomes damaged, the source package will be returned to the manufacturer.

If the source is missing with no explanation, this is reported to the NRC. For a mis-delivered source, the tracking information provided by the delivery company will be used to determine the location of the source and to have it delivered to the customer site.

**Q5.** Please provide procedures for commissioning of the device.

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**

Commissioning and start-up are performed by the manufacturer's experienced and trained engineer. The manufacturer's Operation Manual was previously submitted to NRC-Headquarter as part of the original Sealed Source and Device Registration application. The Operation Manual describes all start-up checks and daily checks needed to ensure proper gauge operation. The trained manufacturer's engineer also trains the customer employees who will operate the equipment.

**Q6.** Please provide procedures for transportation, receipt of Kr-85 sources and packaging, if sources are returned to manufacturer, at temporary job sites and accountability of material.

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**

The Kr-85 sealed source is transported by the manufacturer to the customer facility by air freight in approved DOT Type A containers in conformance will all DOT requirements and procedures. Radiological Physics Service Inc. will oversee receipt, opening, and installation procedures and associated quality assurance functions, including source inventory and tracking for NRC reporting, as required under the license.

"We commit to follow the Quality Assurance and Quality Control Program described in letters dated April 15, 2025, and June 17, 2025, referenced in the Sealed Source and Device Registry certificate no. NR-1521-D-101-G."

**Q7.** Please provide procedures to ensure the Kr-85 sources are secured during receipt, storage, installation, and operation.

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**

(1) During receipt and storage. The Kr-85 source will be secured on the customer property in a designated storage location until installation into the gauging equipment. The customer facility features security provisions (locked areas, security cameras, security personnel) onsite to ensure source protection prior to installation.
(2) During installation and operation. The installation procedure will be performed by the manufacturer's experienced and trained engineer with oversight by Radiological Physics Service Inc. authorized user (radiological physicist). During operation, the Kr-85 sealed source will be maintained in a locked cabinet in a location not accessible to company employees or others (as usual for other installations).

**Q8.** Please address and describe radiation safety measures during receipt, installation, and commissioning (equipment to handle material, personnel monitoring, ALARA, methods and frequency of performing radiation surveys during receipt, installation, and commissioning).

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**

Radiological Physics Service Inc. is a company experienced in radiation safety services and procedures for personnel protection and radioactive source management. The company will provide operational oversight to ensure radiation safety during Kr-85 source receipt, installation, and gauge commissioning. These services include radiological monitoring of conditions, personnel, and operations during procedures described above. These include assurance of proper safety equipment and resources, and radiation monitoring instrumentation and dosimetry. Monitoring will be continuous during source unpacking, accessing, installation, closure and commissioning, as needed to ensure adequate radiation safety.

**Q9.** Submit a description of an alternative survey method and frequency for demonstrating how to evaluate a radiological hazard.

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**

Radioactive material is not released, activity release and contamination is not an issue of concern for the Kr-85 sealed source, and leak testing is not required for Kr-85 registered sources used in gauging instruments. The primary radiological hazard associated with Kr-85 sealed source installation is external radiation exposure associated with beta-particle emission interactions with high-proton-number shielding materials, such as lead and stainless steel. Source installation procedures specifically direct the beta-emission fluence away from the source box installation specialist, and radiation protection is

afforded by source encapsulation, shielding of the source, and personnel protective equipment. The primary radiological hazard is monitored using portable survey instruments designed to monitor ambient x-ray and gamma radiation during the installation procedure. Specific installation steps described above include source retrieval from the shipping package, positional insertion into the source holder, securing the source, sealing the source box, placing the source box into the gauge, closing the cabinet, and commissioning quality assurance procedures. These steps are monitored to ensure that radiation exposures to the manufacturer's installation engineer and other observers do not exceed regulatory limits (10CFR20).

**Q10.** Please address maintenance of records (define responsibilities between service provider and distributor).

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**

The service provider is Radiological Physics Services Inc. This service provider will maintain records pertaining to radiological monitoring of source receipt, accessing, installation, and device commissioning, including personnel dosimetry records.

The distributor is Versant Medical Physics and Radiation Safety. Versant Medical Physics will provide source inventory, location, and status reports to NRC Region III in accordance with license requirements. The distributor will also provide NRC with status of sale and distribution of new sources and devices.

Q11. Please address routine maintenance and non-routine maintenance, if applicable.

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**

All routine and non-routine maintenance of the gauging device will be provided by the customer under a general license. Instrument maintenance is described in the Maintenance Manual provided to NRC with the SSDR certificate application. No maintenance will be performed inside the Kr-85 source box.

Q12. Please address waste disposal.

**RADIOLOGICAL PHYSICS SERVICE INC. RESPONSE:**

No radioactive waste will be generated. Used sources will be returned to the manufacturer after about 10-12 years of use.

Additionally:

" We will conduct surveys and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Section 8.10.4 of NUREG–1556,

Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

Ray A. Carlson

Ray A. Carlson, MS, RSO

Date 7/11/2025

## Martha Pavon

**From:** Magdalena Gryglak
**Sent:** Monday, July 14, 2025 11:02 AM
**To:** Martha Pavon
**Cc:** Tammy Tomczak; Sandy Pavon
**Subject:** FW: Re: Amendment Request to add new services for Radiological Physics Service, Inc. - NRC license no. 21-26253-01
**Attachments:** Response Letter to NRC.pdf; 665 647130 Additional Information.pdf

Good morning,

Please place in ADAMS.

Thank you

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**From:** Ray Carlson <rayacarlson@att.net>
**Sent:** Friday, July 11, 2025 11:31 AM
**To:** Magdalena Gryglak <Magdalena.Gryglak@nrc.gov>
**Cc:** Darrell Fisher <darrell.fisher@versantphysics.com>; Eric Ransay <eric.ramsay@versantphysics.com>
**Subject:** [External_Sender] Re: Amendment Request to add new services for Radiological Physics Service, Inc. - NRC license no. 21-26253-01

Dear Magdalena:

Please see the attached signed response letter.
Please note that the response to Q3 has changed based on information received from the manufacturer.
Ray Carlson