



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

December 22, 2011

Docket No. 03036438
Control No. 576518

License No. 37-30850-01

Doyle Terry Stout
President and Radiation Safety Officer
Gamma Irradiator Service
337 Distillery Hill Road
Benton, PA 17814

SUBJECT: GAMMA IRRADIATOR SERVICE, REQUEST FOR ADDITIONAL
INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO
LICENSE, CONTROL NO. 576518

Dear Mr. Stout:

This is in reference to your facsimile dated December 9, 2011 requesting to amend Nuclear Regulatory Commission License No. 37-30850-01 with a revised Radiation Safety Manual including revised Operating and Emergency Procedures. Item 4 of the NRC's Confirmatory Action Letter 1-11-001 dated October 20, 2011, requested this information to be submitted to the NRC. In order to continue our review, we need the following additional information:

1. The cover page of your facsimile indicates that the Radiation Safety Manual is a confidential document. The NRC cannot withhold this document unless you follow the instructions in 10 CFR 2.390. Otherwise, this document will be marked publicly available in our Agency-wide Documents Access and Management System (ADAMS).
2. Please remove all personally identifiable information (PII) from your submission. PII refers to information that can be used to identify or contact a person uniquely and reliably or can be traced back to a specific individual (i.e., a person's name in combination with any of the following information, such as relatives' names, postal address, personal e-mail address, home or cellular telephone number, personal characteristics, Social Security number (SSN), date or place of birth, mother's maiden name, driver's license number, bank account information, credit card information, or any information that would make the individual's identity easily discernible or traceable). The NRC does not need this information to process your request. Please remove all PII from your resubmission.
3. Step 3 in your ALARA Procedure indicates that the training shall consist of a mock-up (if possible). Please include in your Operating Procedures for high-risk activities (i.e., source loading, source reloads, and source transfers, etc.) that a mock-up or dry run will be completed prior to undertaking all high risk activities to ensure that all personnel involved understand their roles and responsibilities. In your 30-day response to the October 8 event, your root cause flow chart indicated that there was a lack of communications and that the procedure did not clearly identify who has what duties and when to perform those duties. A mock-up or dry run will ensure proper communications

and identify who has what roles and responsibilities.

4. The first sentence in Section 5.0 of your Radiation Safety Manual indicates that each individual qualified to perform non-routine maintenance on irradiators shall be qualified by 40 hours of Health Physics and a minimum of 8 hours of hands-on for each model of device to be worked on. Please insert the words “calibrators and self-shielded” before the word “iradiator” because the NRC has only authorized you to perform service on calibrators and self-shielded irradiators. You are not authorized to perform service on panoramic, open air collimators, or 10 CFR Part 36 pool irradiators.
5. Section 5.2 describes the contents of the initial training, but 10 CFR Parts 21 and 30 are missing from the list of regulations that should be included in this training. Part 21 discusses defects and reports of noncompliance. Part 30 is titled rules of general applicability to domestic licensing of byproduct material and includes reporting requirements. Please add 10 CFR Parts 21 and 30 to the initial training course.
6. Section 6.1 of your Radiation Safety Manual indicates that there is annual refresher training, but Section 5 does not describe the contents for the annual refresher training. Please provide a description of the annual refresher training course. Appendix H of NUREG-1556, Volume 18, “Program Specific Guidance About Service Provider Licenses”, dated November 2000 indicates that Authorized Users should take refresher training annually.
7. Section 6.0 of your Radiation Safety Manual is titled “Responsibilities of customer and service provider,” but does not include documentation to clearly differentiate the roles and responsibilities of the customer and the service provider. Please make sure that you establish a written agreement between the service provider and your customer specifying which licensed activities shall be performed under the customer’s license and supervision, and which licensed activities shall be performed under your supervision pursuant to your NRC service provider license. The agreement shall include a commitment by the service provider and customer to ensure safety, and any commitments by the service provider to help the customer clean up the temporary job site if there is an accident. A copy of this agreement shall be maintained and available for inspection.
8. The first sentence in Section 6.1 of your Radiation Safety Manual fails to include the requirement for all personnel working under Gamma Irradiator Service license to be monitored for radiation exposure with a TLD or film badge. A whole body dosimeter is required because of the high activity sources you work with when servicing calibrators and self-shielded irradiators.
9. Section 6.1 contains the following sentence: “Personnel working on all devices shall have a calibrated and operational survey meter in the area at all times.” In your 30-day response to the October 8 event, your root cause flow chart indicated that a meter failed and a second meter was not monitoring dose rates at top of cask when tool was removed. It is imperative to personnel safety that calibrated and operational survey meters are used in a high radiation fields. Please rephrase your sentence to indicate that personnel working on all devices shall use a calibrated and operational survey meter in

the area at all times.

10. Section 8.10.6 of NUREG-1556, Volume 18 indicates that each licensee must develop, implement, and maintain operating and emergency procedures. Section 6.1 of your Radiation Safety Manual discusses irradiator relocation, but does not describe in detail the operating procedures and the tools necessary to accomplish this activity. In addition, the procedure should include emergency procedures that might be encountered for this activity (i.e., if the unit falls or topples over, if the source becomes dislodged, if the rigging fails, etc.).
11. Missing from Section 6 of your Radiation Safety Manual are the Operating and Emergency Procedures for preventive maintenance activities and source loads, reloads, and source transfers. Section 8.10.6 of NUREG-1556, Volume 18 requires service providers who perform specific operations involving sealed sources such as inspection and maintenance of devices, and removal and replacement of sealed sources, to include appropriate procedures and instructions for these operations in the applicant's operating and emergency procedures; or to provide a commitment to follow the manufacturer's procedures for inspection, maintenance, source exchange, and operations that involve access to the sealed source(s) and safety systems, if applicable. Section 8.10.9 of NUREG-1556 Volume 18 requires applicants seeking authorization to perform non-routine maintenance to submit specific procedures for review. Your Radiation Safety Manual did not provide any operating or emergency procedures for these activities.
12. The title of Section 6.2 of your Radiation Safety Manual is limited to self-shielded irradiators, but should also include calibrators and a description of calibrators since you have serviced calibrators at various facilities over the years.
13. Sections 6.3 and 6.4 of your Radiation Safety Manual should be removed because your license is limited to servicing of self-shielded irradiators and calibrators that have been registered either with the USNRC under 10 CFR 32.210 or with an Agreement State.
14. Section 6.5 of your Radiation Safety Manual is titled Emergency Procedures. You state that non-routine work such as source transfer or reloading of sources will require a separate ALARA Review Document to address ALARA, and detailed step by step procedures with hold points incorporated into the reload or source transfer procedure, specific to the device being worked on. But you did not provide a generic emergency procedure to show the hold points for these high risk activities. Please develop emergency procedures for anticipated scenarios; such as, but not limited to the following:
 - Over-exposure event
 - Unshielded and/or dislodged source
 - Improper packaging identified during receipt survey of new sealed sources
 - Doses in excess of public dose limits in unrestricted areas
 - Stuck source
 - Leaking source
 - Device topples over during relocation
 - Off-scale survey meter or Off-scale personal dosimeter
 - Alarming dosimeter

- Irradiator or calibrator fails to function as designed (i.e. safety interlocks not working, evidence of tampering, etc.)

Your emergency procedure(s) should be able to respond to a variety of events such as described above. In your 30-day response to the October 8 event, your root cause flow chart indicated a variety of reasons that caused three individuals to be over-exposed. You can take into account your root cause analysis and factor that into your generic emergency procedure.

15. Section 6.5 of your Radiation Safety Manual has the following sentence: "Exits and low dose rate areas that can be moved into shall be identified." Please re-word for clarity.
16. Section 6.5 of your Radiation Safety Manual indicates that in the event of an emergency, you will immediately withdraw to a low dose area, block access or lock doors, develop a recovery plan with long reach tools and document actions. Then you will notify facility Radiation Safety Officer (RSO). Emergency Procedures should include a step to re-assess everyone's dose, the dose rates in the area, and to stop all work before proceeding. A recovery plan is necessary, but should never be executed prior to notifying the RSO. It is imperative that the recovery plan takes into account who will participate, the possibility that a Planned Special Exposure (PSE) might need to be established in accordance with 10 CFR 20.1206, and that all notifications have been made to all regulatory agencies. Please revise this section to include step-by-step procedures with hold points to ensure personnel safety is a priority.
17. Section 7.0 of your Radiation Safety Manual indicates that dose rate instruments should be capable of measuring dose rates from 0.1 mrem/hr to 1 rem/hr. However, the October 8, 2011, source loading job you were working had dose rates that exceeded 1 rem/hr. You should have instrumentation that is capable of detecting doses from unshielded sources that you might encounter. Section 8.10.2 of NUREG-1556 Volume 18 discusses radiation survey instrumentation and might be helpful in formulating your response.
18. Section 7.2 of your Radiation Safety Manual indicates that instruments used in the field should have an alarm or audible sound to alert the service personnel if a change in condition occurs. Please rephrase to indicate that instruments used in the field must have an alarm or audible sound to alert the service personnel if a change in condition occurs. As noted in your 30 day report, your alarming dosimeters were the first indication that the source was exposed. Had the two survey meters been operating, they too should have alerted you prior to the source being exposed.
19. Section 8.0 of your Radiation Safety Manual states that "any violation of the license will be noted with recommendations and corrective actions." Please rephrase to include any violation of the license, NRC regulations, NRC Orders, NRC Confirmatory Action letter and any other commitments will be noted with recommendations and corrective actions and a time frame as to when compliance will be achieved as required by 10 CFR 2.201.
20. In Section 6.1 of your Radiation Safety Manual you indicate that personnel may use a self-reading dosimeter or electronic dosimeter, but in Section 9.0 you also identify the

use of a PIC. Please indicate if a PIC is a pocket ion chamber. Please note that the NRC requires our licensees to provide dosimetry that is National Voluntary Laboratory Accreditation Program (NVLAP) approved and sensitive to the type of radiation to which you will encounter. Film badges should be replaced at intervals not to exceed one month, and thermoluminescent dosimeters (TLDs) or optically stimulated luminescence dosimeters (OSLs) at intervals not to exceed three months. An electronic dosimeter or PIC would be supplemental to the NVLAP-approved dosimetry. Section 8.10.4 of NUREG-1556 Volume 18 has information that might be helpful in formulating your response.

21. Section 9 of your Radiation Safety Manual discusses occupational dosimetry, but fails to address the use of extremity dosimeters for high risk activities such as source loads, reloads, source transfers, etc. As noted in your 30 day report, two personnel had extremity doses greater than 50 rem.
22. Section 6.1 indicates that a smear survey should be taken prior to service work, but Section 10.0 indicates that a leak test shall be taken during the job. Please clarify if the leak test/smear survey is taken before or during the service work. Section 8.10.8 of NUREG-1556 Volume 18 has information that might be helpful in formulating your response.
23. A sentence in Section 10.0 of your Radiation Safety Manual reads as follows: "Smears or swabs shall be taken in the area most likely to show contamination if the source was leaking or per manufacturer's recommendation." Section 8.10.8 of NUREG-1556, Volume 20 states, in part, that the licensee is expected to take the leak test sample according to the manufacturer. Please rephrase to read: "Smears or swabs shall be taken in the area most likely to show contamination if the source was leaking in accordance with the manufacturer's recommendation."
24. Section 10.0 of your Radiation Safety Manual indicates that a source is leaking if the measurement is greater than 0.005 microcuries or 11,100 dpm. License Condition 13.F of License No. 37-30850-01 states that the leak test shall be capable of detecting the presence of 0.005 microcuries of radioactive material. Appendix O of NUREG-1556 Volume 18 requires an instrument sensitive enough to detect 185 Bq (0.005 mCi) of the radionuclide of the sealed source. The NRC does not identify 11,100 dpm as a trigger level. Please eliminate the reference to 11,100 dpm.
25. Section 10.4 of your Radiation Safety Manual discusses receipt surveys but is not in compliance with 10 CFR 20.1906. Your procedure fails to include a check for degradation of package integrity, the time frame as to when a survey needs to be completed by, and the correct contamination and dose rate levels. Please revise your receipt survey procedures to comply with 10 CFR 20.1906 or indicate that the receipt survey will be performed by your customer. This distinction in duties should be addressed in the written agreement described in question 7 above.
26. Section 12.0 of your Radiation Safety Manual indicates that Gamma Irradiator Service will maintain records of repairs that use replacement parts. Appendix P of NUREG-1556 Volume 18 states that "*any non-manufacturer/non-distributor supplied replacement*

components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration. Licensees also need to ensure that, after maintenance or repair is completed, the sealed source/device is tested and functions as designed, before the unit is returned to routine use." Please include a statement that ensures replacement parts are in conformance with the parts that have been identified in the Sealed Source and Device registration and in agreement with the manufacturer's recommendation.

27. Your license specifies that you are authorized to service calibrators and self-shielded irradiators, but the Radiation Safety Manual you provided is generic in nature. Please revise your Radiation Safety Manual with the information requested above and tailor it to the specific calibrators and self-shielded irradiators you are authorized to service.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 576518. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5251.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

***Original signed by Stephen Hammann
for***

Kathy Modes
Senior Health Physicist
Decommissioning Branch
Division of Nuclear Materials Safety

cc:
Commonwealth of Pennsylvania
State of New Jersey
State of California

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