



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
2100 RENAISSANCE BOULEVARD, SUITE 100  
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

June 28, 2012

Docket No. 03038547  
Control No. 577472

License No. 19-31474-01

Peter Wallace  
Radiation Safety Officer  
Smiths Detection Ijamsville  
9639 Dr. Perry Road, Suite 101N  
Ijamsville, MD 21754

SUBJECT: SMITHS DETECTION IJAMSVILLE, REQUEST FOR ADDITIONAL  
INFORMATION CONCERNING APPLICATION FOR NEW LICENSE,  
CONTROL NO. 577472

Dear Mr. Wallace:

This is in reference to your letter dated May 1, 2012 (ADAMS Accession No. ML12136A488), requesting to obtain a Nuclear Regulatory Commission License. In order to continue our review, we need the following additional information:

1. Your application should have been signed by a management representative rather than the Radiation Safety Officer (RSO). Please submit a NRC Form 313 (Appendix B of NUREG-1556 Volume 18, "Consolidated Guidance About Materials Licensees: Program Specific Guidance About Service Provider Licensees.") signed by a management representative. The manager's signature is an indication that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.
2. Your application did not follow the guidance published for service providers. Please resubmit your application using the guidance in NUREG-1556, Volume 18. You can photocopy and complete Appendix C in NUREG-1556, Volume 18 as part of your response. The Appendices also contain procedures that are acceptable to the NRC and may be used to submit your response.
3. Please note that page 2 of your radiation protection program is missing. The page numbers go from page 1 to page 3.
4. Please provide the facsimile number for your office such that we can have in our records.
5. Please provide a corporate organization chart and a radiation safety organization chart.

6. Section 1.4 of your radiation protection program discussed areas that would be reviewed as part of the annual audit. You may want to consider adding a review of your Operating and Emergency procedures, a review of your license and a review of security of radioactive materials. Appendix I of NUREG-1556, Volume 18 has a sample audit checklist that you might find helpful.
7. Section 2 of your radiation protection program describes the RSO's duties. The RSO should also have the authority to terminate unsafe practices and activities jeopardizing the safety of workers, the public, or environment.
8. Section 2.5 of your radiation protection program stated: Insure that all devices containing sealed sources have been leak tested within 6-months prior to their use. Please confirm that these devices should be leak tested every 6 months. You may want to delete the words "prior to use."
9. Section 3.3 of your radiation protection program stated: Participate in radiation safety training as requested by the RSO. However in Section 12 you indicate that personnel will undergo radiation safety training prior to assuming duties and as an annual refresher. Appendix H of NUREG-1556 Volume 18 may be helpful when re-writing your response regarding training.
10. Section 3.6 of your radiation protection program indicates that personnel shall wear disposable gloves at all times when working with radioactive materials and use respiratory protection when necessary. At the end of this section, in bold lettering, you state that "The statements in Item 3 regarding appropriate protective measures would be in the unusual case of a damaged device where damage to the IMS cell was possible and contamination was possible." However in Section 8 the procedure for handling a damaged source does not indicate that your personnel shall don gloves or respiratory protection nor does it indicate that a "Caution Radioactive Material" label shall be applied to the plastic bag containing the damaged device. Please provide a copy of your respiratory protection program and revise Section 8 when you elaborate on your emergency procedures.
11. Section 7 of your radiation protection program discusses leak testing. In section 7.1.1 you indicate that an outside laboratory may be used, but in section 7.1.3 you indicate that you will analyze the leak test using a liquid scintillation counting technique. We will need to know if you will only collect leak test samples or if you will collect and analyze leak tests samples. Appendix O of NUREG-1556 Volume 18 may be helpful in developing your response.
12. Section 10.3.7 of your radiation protection program does not mention the specific section of 49 CFR. Please check to see if you were referring to 49 CFR 173.441 and 173.443.
13. Section 12.2.2 of your radiation protection program indicated that training at another facility can be used to meet this requirement if a review of this Radiation Protection Program is provided. Please note that your company policies and the way you handle the radioactive material may differ and we strongly encourage you to train personnel in a consistent manner. Appendix H of NUREG-1556 Volume 18 may be helpful in developing your response.

14. Section 13.2 of your radiation protection program indicates that you will provide bi-annual radiation safety refresher training, but Section 12.2.4 indicates an annual refresher training program. An annual refresher training program is acceptable.
15. Section 9 of your application indicated that “at no time does Smiths Detection Ijamsville handle source material. Please note that the NRC defines source material in 10 CFR Part 40. *Source Material* means: (1) Uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of: (i) Uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material. You may opt to replace the word “source” with “licensed.”
16. In Section 6 of your application, you requested to repair and service IONSCAN, Sabre, Sabre EXV, Sabre Centurian, Sabre Centurian II, Sentinel II, APD 2000 and MMTD devices. Sealed Source and Device Registration (SSDR) NR-0163-D-102-E identifies IONSCAN Series, IONSCAN DT Series, Sabre Series, Sabre Centurion Series and Sentinel Series. SSDR MD-0263-D-102-G lists a variety of Ion Mobility Spectrometers (IMS) including the APD 2000. Please confirm that these are the SSDRs related to the sources and devices you intend to repair and service. If there are other SSDRs, please provide their registration number(s).
17. In Section 6 of your application you requested to repair and service the above mentioned devices, but that you would not open IMS cells. Please elaborate on the types of repair and service you wish to perform. For example, installation and removal of IMS cell into and out of devices or equipment, radiation surveys, leak tests, IMS cell exchange, IMS cell relocation, IMS cell transfer, IMS cell disposal, routine maintenance, non-routine maintenance, packaging, transportation, etc..
18. Please provide the names, training and experience for proposed Authorized Users so that we can list them on the license as being able to conduct licensed activities at temporary job sites.
19. Ensure that your Radiation Protection Program addresses the following topics for licensed activities in NRC jurisdiction:
  - Development and implementation of an ALARA program.
  - Description of equipment and facilities adequate to protect personnel, the public and the environment.
  - Confirmation that licensed activities are conducted only by individuals qualified by training and experience.
  - Development and maintenance of written operating and emergency procedures.
  - Implementation of an audit program to ensure that, at least annually, the radiation safety program is reviewed.
  - Description of organization structure and individuals responsible for ensuring day-to-day oversight of the radiation safety program.
  - Establishment and management of a radiation safety and decommissioning

- records system.
  - Methods or procedures for preventing the release of contaminated material and equipment.
  - Methods or procedures for preventing personnel contamination. Radiation safety procedures and the authorized users responsibilities unique to each type of service operation requested in the application.
  - Radiation safety procedures.
  - Equipment, techniques, and corresponding radiation safety procedures associated with providing services involving either sealed sources or unsealed materials.
20. Specify the radiation detection instruments that you have available. Include the type (low energy gamma scintillator, etc) and number of instruments available, the types of radiation detected, the range (milliroentgens per hour or counts per minute), and the intended use (monitoring, surveying, assaying or measuring). Appendix J of NUREG-1556, Volume 18 addresses radiation monitoring instrument specifications and may be helpful in developing your response. Provide the frequency for calibrating your survey instruments. Survey instruments should be calibrated at least annually (every 12 months).
21. Please confirm that you will either perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or that you will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 18. Appendix L of NUREG-1556 Volume 18 addresses prospective evaluations and may be helpful in developing your response.
22. Please provide your operating and emergency procedures and ensure that they address the following for licensed activities conducted in NRC jurisdiction at temporary job sites, as tailored to your needs (i.e., as applicable):
- a) Procedure for obtaining an agreement with customers outlining the responsibilities of both the customer and service provider, when performing service operations at a customer's facility
  - b) Instructions for handling and using licensed materials at temporary job sites.
  - c) Instructions for maintaining security during storage and transportation.
  - d) Instructions to keep licensed material under control and immediate surveillance during use.
  - e) Steps to take to keep radiation exposures ALARA.
  - f) Steps to maintain accountability during use.
  - g) Steps to control access to work sites.
  - h) Steps to take and whom to contact when an emergency occurs.
  - i) Methods and occasions for conducting radiation surveys, including surveys for detecting contamination.
  - j) Procedures to minimize personnel exposure during routine use and in the event of an incident.
  - k) Methods and occasions for locking and securing stored licensed materials.
  - l) Procedures for the implementation and adherence to good health physics practices while performing service operations:
  - m) Minimization of distance to areas, to the extent practicable, where licensed

- materials are used and stored.
- n) Maximization of survey frequency, within reason, to enhance detection of contamination.
  - o) Separation of radioactive material from explosives.
  - p) Personnel monitoring, including bioassays, and the use of personnel monitoring equipment.
  - q) Transportation of licensed materials to temporary job sites, packaging of licensed materials for transport in vehicles, and physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal.
  - r) Procedures for picking up, receiving, and opening packages containing licensed materials, in accordance with 10 CFR 20.1906 at temporary job sites.
  - s) Instructions for maintaining records in accordance with the regulations and the license conditions.
  - t) Procedures for identifying and reporting to NRC defects and noncompliance as required by 10 CFR 21.21(a) of this chapter. See Table 8.4 in NUREG-1556 Volume 18, which describes the typical incident notifications required by NRC regulations.
  - u) Procedures and actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments.
  - v) Instructions for the proper storage and disposal of radioactive waste at temporary job sites.

Please tailor your responses to those activities you will conduct at temporary job sites where the NRC maintains jurisdiction. Since your address is located in Maryland, an Agreement State, the NRC does not have jurisdiction at your facility. However the NRC has jurisdiction in non-Agreement States. Section 10.1.1 references Maryland regulations. Please remove all references to Maryland regulations and provide answers based on work in NRC jurisdiction.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://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. 577472. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5251.

Please note that the Region I Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

USNRC – Region I  
2100 Renaissance Blvd, Suite 100  
King of Prussia, PA 19406-2713

P. Wallace

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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 Kathy Modes***

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

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**SUNSI Review Complete: KModes**

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