

Smiths Detection 2202 Lakeside Boulevard Edgewood, Maryland 21040, USA T: +1 410 612 4000 F: +1 410 510 9496 www.smithsdetection.com

September 16, 2013

Ms. Margie Kotzalas, Chief, Licensing Branch DMSSA, FSME - Mail Stop T-8E24 U.S. Nuclear Regulatory Commission 11545 Rockville Pike Rockville, MD 20852

Re: Request for Special Exemption to Demonstrate
Handheld Radioisotope Identification Devices (RIIDs)

Ms. Kotzalas:

Smiths Detection Inc. manufactures and sells security equipment that helps users to detect explosives, chemical and biological agents, radiological / nuclear threats, weapons and contraband. The company's products are widely used in airports, ports and borders, government buildings, and critical infrastructure facilities as well as by the police, security details, military personnel, and emergency responders. The RadSeeker radioisotope identification product contains a sealed Sodium-22 source of 5.4 or 16.2 nanocuries, depending on model, as an internal gain stabilization source. Technical specification sheets are included with this letter in Attachment A.

Even though the instruments are approved for distribution to persons exempt from regulation NRC RAM license (06-24000-01E). All Smiths Detection personnel are required to operate under the company's specific RAM license conditions and regulation, even with regard to operating a finished RadSeeker product at a customer location. Smiths Detection is looking for a method to allow its sales and marketing functions the same latitude offered to the end users of these products. For example, the job of our sales and marketing functions is to effectively demonstrate and educate customers regarding a given instrument's capability. This activity of giving a demonstration requires no greater risk than the exempt end user experiences in normal use of these devices after they have purchased it. During such activities, Smiths Detection personnel only use the device as it is intended to perform their role of demonstrating the instruments.

Smiths Detection believes the requirements to file for reciprocity for its personnel to travel to customer locations, conferences and trade shows to give demonstrations, to be

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unnecessarily burdensome. Smiths Detection is seeking a special exemption that will allow its personnel to perform end-user activities, such as demonstrations, without having to file reciprocity. This would allow them the ability to take possession of these devices as an exempt person. Please see the following rational statement included on the following pages.

We are open to other potential solutions that provide relief from the administrative burden while at the same time achieving the goals of the regulatory requirements and to ensure public safety. To that end we would welcome an opportunity to meet with NRC personnel to discuss this request for a Special Exemption or any other possibilities which might exist. Thank you for your consideration if you have any questions or would like additional information please do not hesitate to contact me.

Respectfully submitted,

Gary Shelton

Senior Radiation Safety Officer

CC: E.J. Prior, Compliance Counsel

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The NRC requires:

Licensees who request exemptions to regulations must demonstrate that the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. The request shall include:

- Exemption and why it is needed;
- Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested;
- Alternative methods for complying with the regulation and why they are not feasible.

Synopsis:

Smiths Detection manufactures products that contain radioactive sealed sources under NRC RAM license 06-31431-01. The products have been deemed safe for use without any special measures or precautions, including licensing to the end user, distribution allowed by NRC license 06-24000-01E. The NRC requires that the sources and products be listed on a specific license for possession, manufacturing, and distribution. The specific license conditions allow for temporary jobsites within the license jurisdiction, but does not allow for Smiths Detection personnel to travel with these devices or possess and operate them outside the license jurisdiction without filing for reciprocity. This has created a hardship, since the demonstration and training of the detection products require employees to possess and use the detection systems as intended at hundreds of customer locations, trade shows, and other establishments within all of the United States jurisdictions. The detection systems here are highly specialized and state of the art technology. Smiths Detection customers require a true demonstration of the capabilities and operating parameters to allow a more informed decision.

Smiths Detection is requesting an exemption to 10 CFR 30.34(c) and any agreement state equivalent. 10 CFR 30.34(c) states "Each person licensed by the Commission pursuant to the regulations in this part and parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part and parts 31 through 36 and 39 of this chapter shall carry with it the right to receive, acquire, own, and possess byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of part 71 of this chapter."

Smiths Detection is requesting that employees using these specific devices, as endusers and in the manner in which the products are intended to be used, be exempt from the above regulation, and to have the ability to possess, and use as intended, the RadSeeker, that it manufactures as the end user. Request for Special Exemption September 16, 2013 Page 4 of 5

The RadSeeker to be used under this exemption is used in threat detection and screening technologies for military, transportation, homeland security and resilience applications. They apply multiple technologies to quickly identify radiological and nuclear materials.

Key information regarding the RadSeeker CL/CL/CS Handheld Radioisotope Identifiers:

- a. The RadSeeker is a rugged, state-of-the-art handheld radioisotope detector and identifier. The RadSeeker was specifically designed to meet the U.S. Department of Homeland Security (DHS) mission requirements for a next-generation system capable of detecting and identifying varied nuclear threats.
- b. The RadSeeker DL/CL contains a 5.2 nCi (nanoCurie) sealed Na-22 source that is used for stabilization of the gamma detector. The RadSeeker CS is similar and contains a 16.4 nCi Na-22 source.
- c. The source activity is well below the requirement for a SSDR. The source is sealed, encapsulated, and further mounted inside an aluminum box internal to the RadSeeker which would require special tools to open.
- d. The external exposure rate is background; emission from the source is not detectable external to the device.
- e. The exemption would allow for Smiths personnel to possess and operate RadSeeker as a normal user throughout the United States, allowing them to perform such business as demonstrating and training emergency personnel and other customers.

Summary

Licensees who request exemptions to regulations must demonstrate that the exemption is authorized by law.

These products are approved for distributed to people exempt to regulation.

Will not endanger life or property or the common defense and security, and is otherwise in the public interest.

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The purpose of these products is for the common defense and security of our homeland, further they have passed the rigors of approval for distribution to persons exempt from regulation.

Exemption and why it is needed

The tight tracking of 30-40 of these units around the country while thousands of them are legitimately distributed to exempt persons with no regulatory burden will serve no purpose else to tie up Federal, State, and Smiths Detection resources that can be better used for the public good. The administration of thousands of reciprocity filings for all Sales/Marketing visits, will really serve no purpose to anyone.

Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested. The scope of the special exemption request is very specific only applying to Smiths Detection US personnel using these specific devices in an end-user capacity. The limited purpose and use of only preapproved, exempted-distribution devices pose no increase in risk to the public.

Alternative methods for complying with the regulation and why they are not feasible Smiths Detection has explored the following methods for performing these business functions related to these exempt-distribution devices:

- 1. Specific license in each jurisdiction in the U.S.
 - a. Requires an office of agent in each location
 - b. Requires additional license-mandated training of all employees, who would only be using the devices as an end-user, while actual end users have no such training requirement.
 - c. Questionable if using Federal, State and Smiths Detection resources to administer this process would be in the best public interest.
 - d. Major expense to all parties involved to serve no gain in public safety or security.
- 2. Reciprocity filings for each customer site
 - a. Questionable if using Federal, State and Smiths Detection resources to administer this process would be in the best public interest.
 - b. Additional training burden as in (1) above.
 - Major expense to all parties involved to serve no gain in public safety or security.
 - d. Delays in helping agencies to get the tools to protect the U.S. from terror threats.



RadSeeker[™]

HANDHELD RADIOISOTOPE IDENTIFIER



Feature Highlights

- Advanced spectrum processing and identification algorithms for superior identification accuracy
- Continuous automatic stabilization, no field calibration required
- Fully ruggedized to survive 3ft drop, extreme operating temperatures and water spray
- Simplified user interface takes the guesswork out of spectral interpretation
- Designed to meet/exceed all ANSI N42.34 (2006) requirements

The RadSeeker is a handheld, portable, rugged and highly accurate radioisotope detector and identifier. The RadSeeker was specifically designed to meet the Department of Homeland Security (DHS) mission requirements for a next-generation system capable of detecting and identifying nuclear threat materials.

The RadSeeker offers superior identification capabilities that are based on Symetrica's Discovery Technology™. This technology couples advanced spectrum processing and identification algorithms with a choice of highly sensitive 1.5" x 1.5" Lanthanum Bromide (LaBr₃) or 2" x 2" Sodium lodide (Nal) detectors resulting in superior accuracy which is unique and exclusive to Smiths Detection. This sophisticated detector system is capable of resolving complex masking scenarios and exceeds all ANSI N42.34 (2006) requirements for the identification of bare, shielded and multiple isotopes.

The RadSeeker is easy to use while supplying the operator with quick, simple, specific information for threat assessment. Applications include Customs inspection, border protection, emergency response, and radiological facilities/personnel monitoring.

RadSeeker and Cargo Inspection

The RadSeeker can be used during a search or screening scenario in order to detect radioactive sources and then clearly identify whether the radioactive material uncovered is harmless naturally occurring radiation or a more dangerous source, such as special nuclear materials or those consistent with a "dirty bomb". For each source identified the RadSeeker provides a risk assessment describing the source as innocent or a threat, removing all the guess work from the operator.

Continued overleaf

RadSeeker

RadSeeker and Emergency Response

In an emergency situation, radiological response teams can quickly and accurately determine whether or not a source is present and the level of threat it represents. The built-in wireless capabilities which

include both WiFi 802.11 and satellite phone interface provide those in a remote command center easy access to information such as the threat identified, source spectra and the location of the device/operator.

In a situation that is deemed unsafe to send a responder down range the RadSeeker can be placed mechanically while monitoring and controlling the device from a safe distance.

Technical Data

General Specifications

Radiation detection

Identification performance

Library Stabilization Energy range Alarm indications Battery

Environmental and safety

Protection Dimensions (WxLxH) Weight Connectivity Display Locator

Accessories included

Configurations

Radiation detection technologies

Dose rate range

High sensitivity detection alarms/alerts indicate gamma or neutron radiation above background; user-adjustable thresholds. Performance exceeds ANSI N42.34 (2006) requirements

Exceeds all ANSI N42.34 (2006) requirements for bare, shielded, multiple and masked isotopes. Active background

updates improve identification performance

Easily extensible library with 41 radionuclide's classified according to ANSI N42.34 (2006)

Automatic energy stabilization (eliminates the need for field calibration)

25 keV - 3MeV (Gamma)

Audio, visual, earphone, vibrator, discrete ultra-bright LEDs for alarm indication on rear of system Smart lithium ion battery (UL Approved); 8+ hours (normal operating conditions with 150+ IDs). Battery

rechargeable in unit or desktop charger

Operating temperature range: -32°C (-25°F) after warm-up to 50°C (122°F); shock and vibration: ANSI N42.34 (2006); drop: 91.44 cm (3 ft) onto 5.1 cm (2") plywood covered concrete; safety: UL 61010-1; EMC: ANSI

N42.34 (2006), humidity: 3-98% relative humidity, non-condensing at 35°C (95°F) Fresh water resistant, splash proof, dust and sand proof, IP65 (ANSI/IEC 60529) 17.8 x 30.5 x 11.4cm (7" x 12" x 4.5") – small bumpers CS 2.4 kg (5.2 lbs), CL 2.2kg (4.8 lbs)

Wireless 802.11b/g/n, serial USB, ethernet and satellite phone connectivity available via RF modem

High contrast, high resolution (428 x 272 pixels) color Organic Light Emitting Diode (OLED)

Global Positioning System (GPS) - provides the longitude and latitude of the system throughout the screening

process and at time identification was made

. Transportation case, sling with strap, additional battery pack, AC power adapter, 12v DC car adapter, desktop battery charger, USB cables, USB headphone adapter, SAT phone adaptor, set of large bumpers, screwdriver (for

changing bumpers), manuals, PC software installation CD

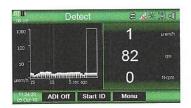
RadSeeker CS (Commercial Sodium Iodide)

2" x 2" Sodium Iodide (gamma spectrometer) Moderated ³He (neutron detector) 1urem/hr to 12mrem/hr (Cs-137)

RadSeeker CL (Commercial Lanthanum Bromide)

1.5" x 1.5" Lanthanum Bromide (gamma spectrometer) Moderated 3He (neutron detector) 1urem/hr to 20 mrem/hr (Cs-137)

Utilizing Symetrica's Discovery Technology, licensed exclusively to Smiths Detection



The display provides a historical graph of the intensity of the source. To the right of the history the real-time count rate and dose rate are shown constantly on every screen providing the much needed info to the user



This Identification screen displays a list of alarms. In the case where multiple radionuclides are identified, they are listed by priority. The isotope category is further provided as well as a threat assessment. Green for Innocent and Red for a Threat.



UNITED STATES NUCLEAR REGULATORY COMMISSION



Office of Federal and State Materials and Environmental Management Programs WASHINGTON, DC 20555 - 0001

August 12, 2013

Docket No. 030-38417 Mail Control 581328 License No.

06-24000-01E

Paul Del Visco Director of Operation Smiths Detection, Inc. 21 Commerce Drive Danbury, CT 06810-4131

SUBJECT:

SMITH DETECTION. LICENSE AMENDMENT

Dear Mr. Visco:

Enclosed please find U. S. Nuclear Regulatory Commission (NRC) Exempt Distribution License No. 06-24000-01E, Amendment # 03. As requested, the models of sealed sources under License Item #7 were changed, and a new use was added to License Item #11 under License Condition. Please review the enclosed documents carefully and be sure that you understand all the conditions. If there are any errors or questions, please contact me so that appropriate corrections, or answers, may be provided.

Please be advised that you must conduct your program involving radioactive materials in accordance with the conditions specified in your NRC license, representations made in your license application, and other rules, regulations, and orders of the U.S. Nuclear Regulatory Commission, now or hereafter in effect, to include the following:

 Comply with applicable NRC regulations in 10 CFR Part 30, "Rules of General Applicability to domestic Licensing of Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; and other applicable regulations.

NOTE: Licensees authorized to distribute or initially transfer products containing byproduct material must also possess a valid possession license issued either by NRC or an Agreement State(s) which authorizes possession and use of byproduct material.

- Distribute only those products containing radioactive material which are specifically authorized in your license.
- Notify NRC in writing within 30 days of any change in mailing address.
- 4. Request and obtain appropriate amendments if you plan to change control or ownership of your organization, change locations of distribution of products containing radioactive material, or make any other changes in your program which are contrary to the license conditions or representations made in your license application and any supplemental correspondence with NRC.

- 5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You should receive a reminder notice approximately 60 days before the expiration date. Continued distribution of products containing radioactive material after your license expires is a violation of NRC regulations.
- In accordance with 10 CFR 30.36, request termination of your license if you plan to permanently discontinue activities involving distribution of products containing radioactive material.

You will be periodically inspected by NRC. Failure to conduct your program in compliance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action(s) against you. This could include issuance of a notice of violation; proposed imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG-1600).

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

If you have any questions, you may contact me at (301) 415-7640, or electronic mail: Shirley.Xu@nrc.gov.

Sincerely.

Shirley S. Xu, Licensing Branch

Division of Materials Safety and

State Agreements

Office of Federal and State Materials and Environmental Management Programs

Enclosure: License Number 06-24000-01E

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U.S. NUCLEAR REGULATORY COMMISSION

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Amendment No. 03

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified

| below. | | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| Licensee | | In accordance with letter dated | |
| | | July 2, 2013 | |
| Smiths Detection | | License number 06-24000-01E is amended in its entirety to read as follows: | |
| 2. 21 Commerce Drive | | 4. Expiration date March 31, 2021 | |
| Danbury, Connecticut 06810-4131 | | 5. Docket No. 030-38417 | |
| • | | Reference No. | |
| | | | |
| Byproduct, source, and/or special nuclear material | 7. Chemical and/or | physical form 8. | Maximum amount that licensee may possess at any one time under this license |
| A. Sodium 22 | A. Sealed Sources (Eckert & A. Not applicable Ziegler Isotopes Model SKRB (See Condition 10) 17540/18147) | | |
| | Ä. | 5 | |
| 9. Authorized use: | | 8 3 8 8 8 | |
| Pursuant to 10 CFR 32.14, "Certa distribute RadSeeker, a Hand Po 0.016 microcuries of Sodium-22, equivalent provisions of the regul | rtable Radiation De to persons exempt | etector System (HPRD from licensing pursua | S), containing not more than |

CONDITIONS

- 10. This license does not authorize possession or use of licensed material.
- A. The licensee is authorized to distribute only from its facilities located at: 21 Commerce Drive, Danbury, Connecticut.
 - B. The licensee is authorized to use the devices for instruction and training purposes at customer's facilities and trade shows.
- 12. The licensee shall submit periodic material transfer reports as specified in 10 CFR 32.16.

| NRC FORM 374A | PAGE 2 OF 2 PAGES |
|---------------------------------------|--------------------------------------|
| | License Number 06-24000-01E |
| MATERIALS LICENSE SUPPLEMENTARY SHEET | Docket or Reference Number 030-38417 |
| | Amendment No. 03 |

- 13. Except as specifically provided otherwise by this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated January 31, 2011 (ML110410368);
 - B. Email with attachments dated March 14, 2011 (ML110750422);
 - C. Letter dated June 20, 2011 (ML111801400);
 - D. Letter dated October 14, 2011 (ML112971569).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: August 12, 2013

By:_____Shirley/S. Xu

Licensing Branch

Division of Materials Safety and State Agreements

Office of Federal and State Materials and Environmental Management Programs

Washington, DC 20555

From: (865) 738-1029 Keith Leiter II Smiths Detection 3202 Regal Drive

Alcoa, TN 37701

Origin ID: GKTA



SHIP TO: (301) 415-5477

BILL SENDER

Ms Margie Kotzalas, Chief, Lic Branch **U.S. Nuclear Regulatory Commission** 11545 Rockville Pike DMSSA, FSME-Mail Stop T-8E24 ROCKVILLE, MD 20852

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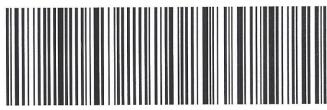
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