leidos

10 March 2014

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Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs

SUBJECT: RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

REFERENCE CONTROL NUMBER 582208

This letter provides the information requested in your letter dated February 14, 2014 regarding the license renewal package for our Exempt Distribution License No. 04-23909-01E.

"Review the documents submitted to the NRC in the past to determine if the information is up to date and accurately represents the current licensed activities and products. Identify in the application, by date, those documents that are applicable and those that are out-of-date or superseded, and indicate any changes necessary to reflect the current program."

Amendment 5 dated February 12, 2009, of the license lists the following documents:

**Application dated October 20, 2003**

The initial application submitted to the Commission contained five attachments: 1) various SAIC licenses, 2) ISO certification and Quality Manual, 3) drawings for the initial list of products, 4) drawings for individual source holders, and 5) equipment operations manuals.

*Application*

Items 1, 3 through 6 and items 12 and 13 of the application dated 19 September 2013 supersedes the corresponding items on the application dated 20 October 2003. Item 2 (Name and Address of Applicant) has changed since the application dated 19 September 2014 was submitted. The SAIC Board of Directors changed the name of the company to Leidos, Inc. effective 28 September 2013. A letter was delivered to the Commission on 20 September 2013 requesting that the licensee name on 04-23909-01E be changed accordingly. This letter, which contains the information required by NUREG 1556 Volume 8 Appendix F, is attached for reference.

*Attachment 1*

Attachment 1 of the application dated 20 October 2013 contained 1) amendment 106 of our California Radioactive Materials License 2290-37, 2) amendment 8 of our California Radioactive Material License 6504-37GL, and 3) the Canadian license (09602-2-03) of our Exploranium subsidiary based in Mississauga, Ontario, Canada. These documents have been superseded as follows:

California Radioactive Material License 2290-37 is currently at amendment 135 (attached) dated 8 October 2013. The application dated 19 September 2013 contained amendment 134. Amendment 135 only changes the name of the licensee to Leidos, Inc. from Science Applications International Corporation (SAIC). California Radioactive Material License 6504-37GL is currently at amendment 16. This license was not included in the application dated 19 September 2013 as it is used only to distribute the VACIS line of non-intrusive inspection systems. Canadian license 09602-2-03 is at amendment 4 and was not included in the application dated 19 September 2013. We no longer have a possession license in Canada as all equipment manufacturing that took place at our Canadian subsidiary has been transferred to our California facility. This Canadian license is only for service US CBP VACIS equipment on Canadian soil.

*Attachment 2*

Attachment 2 of the application dated 20 October 2003 contained a copy of our ISO 9001:1994 certificate and revision J of our quality assurance manual (QAM-100). These documents have been superseded by the ISO 9001:2008 certificate and updated quality manual contained in the 19 September 2013 application.

*Attachment 3*

Attachment 3 of the 20 October 2003 application contained a list of instruments with installed check sources and a drawing/description of the installation. The instruments listed were:

- PDR-1S Dosimeter Reader
- PELAN (Pulsed Elemental Analysis Using Neutrons)
- GR-130/GR-135 and ARIS Isotope Identifiers
- GR-820 Airborne Gamma Spectrometer
- GR-320 Portable Gamma Spectrometer

Only the GR-135 Isotope Identifier is currently in active production. All others have been discontinued. The application dated 19 September 2013 included updated drawings for the GR-135 Isotope Identifier which superseded those in the application dated 20 October 20003.

*Attachment 4*

Attachment 4 of the 20 October 2003 application contained examples of check source holders for sources that are not installed in equipment/instruments.

The drawing 87044 in the 20 October 2003 application remains unchanged and is still valid. Drawing 93635 has been updated to revision A from revision 0. The only change between these revisions is the Exploranium name on the label has been changed to SAIC. The revision A of this drawing was included in the 19 September 2014 application.

*Attachment 5*

Attachment 5 of the 20 October 2003 application contained the User's Manual for the GR-135 Isotope Identifier. This document was identified as Part Number 87316-1 Revision 3. This document has been superseded by document 426657-001 Revision D which is attached to this letter.

**Letter dated February 18, 2004**

This letter added the IM239 air monitor for the Navy and the Small CAD chemical agent detector. This letter is no longer valid and should be removed from the license. The IM-239 development was transferred to another division of the corporation and is no longer maintained or developed under this license. The Small CAD chemical agent detector has been discontinued by the June 7, 2006, letter (see below).

**Letters dated April 26, 2005 and July 22, 2005**

This letter was an amendment request to allow the distribution of the GR-820 Airborne Spectrometer with an installed exempt Cesium 137 check source and three uninstalled check sources (one exempt Cesium 137, one Thorium check source and one Uranium check source) that would be used to validate system performance.

This letter was followed by a letter from the Commission dated May 31, 2005, request additional information. The letter dated July 22, 2005, was in response to the Commission's request for additional information.

These letters are no longer valid and should be removed from the license. The GR-820 Airborne Gamma Spectrometer has been discontinued.

**Letters dated December 2, 2005 and January 30, 2006**

This letter (December 2, 2005) was to amend the license to allow the distribution of the GR-820 Airborne Spectrometer and to take credit for prototype testing of the installed source by the source

manufacture. The amendment request was followed up with an email from the Commission indicating that such prototype testing by the source manufacturer was "not sufficient."

The follow-up letter (January 30, 2006) provided the results of manufacturer prototype testing of the source mounted in the GR-820 Airborne Spectrometer.

These letters are no longer valid and should be removed from the license. The GR-820 Airborne Gamma Spectrometer has been discontinued.

**Letter dated January 9, 2009**

This letter issued a clarification relative to the check sources distributed as exempt quantities per 10 CFR 32.18 that are not installed in equipment. Typically these check sources are shipped with the equipment but there can be cases where the source would be distributed without the equipment; for example, to replace a previously distributed source that was shipped with the equipment.

This letter is still applicable to the license as there may be cases where sources are shipped by themselves without an accompanying piece of equipment.

**Letter dated June 7, 2006**

This letter requested to remove the Small CAD (SCAD) device from the license. This letter is no longer valid and should be removed from the license. The Small CAD Chemical Agent Detector has been discontinued.

**Letter dated May 22, 2007 and email dated July 18, 2007**

This series of documents requested the addition of SAIC facilities in Vista, California and San Diego, California to the list of authorized distribution locations and the eventual decommissioning of or Rancho California location.

This letter and email are no longer valid and should be removed from the license. The address in items 2 and 3 of the 19 September 2013 application is the only address associated with this license. As noted above and in the attached letter, the name of the corporation has been changed to Leidos, Inc. from Science Applications International Corporation (SAIC).

"The attachment to your application contains the following statement: 'Information contained herein is SAIC proprietary information and is made available to you as required for our Material License renewal. This information is submitted in confidence and its disclosure to you is not intended to constitute public disclosure or authorization for disclosure to other parties.' Please be aware that you may request that certain portions of your submittal to the NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390."

A revised supplemental information package is attached to this letter. It 1) removes the stated statement about proprietary information, 2) removed sections that relate to items 7 through 11 of the application, 3) updates the information to addresses weakness identified in your letter dated 14 February 2014, and 4) changes the corporate name to Leidos from SAIC.

C.1 "Title 10, Code of Federal Regulations, Section 32.14(b)(5) requires that quality control procedures be followed in the fabrication of production lots of the product and a description of the quality standards the product will be required to meet. Your application discusses the Quality Assurance Program, but does not appear to specifically address quality control procedures or the quality standards that product will be required to meet. Please describe the quality procedures to be followed in the fabrication of production lots of the product and provide a description of the quality standards the product will be required to meet."

The quality control procedures that are followed in the manufacturing of production lots of the product are:

- SOP-0047 Electrostatic Discharge Program
- SOP-0065 Internal Material Handling and Packaging Standard
- MGWI-0056 Part Marking and Identification Standard

As necessary:

- SOP-0004 Control of Nonconforming Material
- PDWI-0144 Production Rework and Repair Process

Note that these documents related to only the docking station element of the GR-135 product as it is the element that contains the byproduct material.

The quality control standards that the product is required to meet include the following:

- CISPR 11/EN 55011, Class A – Industrial, Scientific and Medical Equipment
- EN 50082-1:1997 – Electromagnetic Compatibility Requirements – Generic Immunity Standards – Residential, Commercial and Light Industry
- FCC Part 15, Subpart B, Class A – Unintentional Radiators
- IEC 1000-4-2/EN 61000-4-2 – Electromagnetic Compatibility Requirements, Part 2: Electrostatic Discharge Requirements

The docking station bears the CE mark and is designed to meet the safety, RFI, and EMI requirements in ANSI N42.34-2003 "American National Standard Performance Criteria for Hand-held Instruments for the Detection and Identification of Radionuclides."

C.2 "Title 10, Code of Federal Regulations, Section 32.14(d) requires that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in the product under the most severe conditions that are likely to en encountered in normal use and handling."

The information in the original application dated 20 October 2003, under a section labeled "Item 6" remains valid for the GR-135 docking station. The design and methods used to contain the byproduct material has not been altered. For completeness, the original application provided information that was applicable to multiple products; all but the GR-135 have been discontinued:

"When installed in equipment, such as the ... GR-135 ..., the check source material is left in its original manufactured sealed source containment. The sealed source is then placed inside a well and/or physically attached to a structural component of the internal instrument case, which is also sealed with case screws, or equivalent case closure mechanisms. See attachment 3 for information on the source installation location and method for each instrument. Should for any reason the source become dislodged from its normal secure position, the source would still remain closed inside the instrument case, and would not become detached from the equipment, unless the case was significantly damaged. Since the labels will be retained on the individual check sources, even of the case is breached, the source will be clearly identifiable as radioactive material. Release of the byproduct material to the environment was already evaluated as part of the original vendor's Exempt distribution license. No modifications are made to the source which would impact that assessment."

C.3 "Title 10, Code of Federal Regulations, Section 32.19(a) requires that no more than 10 exempt quantities set forth in Section 30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For the purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Section 30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity. Please describe how you shall prevent the sale and transfer of more than 10 exempt quantities in any single transaction."

See response to items C.4 below.

C.4 "Title 10, Code of Federal Regulations, Section 32.19(b) requires that each quantity of byproduct material set forth in Section 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Section 30.18 of this chapter. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millrem per hour. Please describe how you shall ensure that each quantity of byproduct material set forth in Section 30.71, Schedule B of this chapter shall be separately and individually packaged, with no more than 10 such packaged exempt quantities contained in any outer package for transfer, and such that the dose rate at the external surface of the outer package does not exceed 0.5 millirem per hours."

The check sources distributed under this license generally do not exceed 0.25 µCi of Cs-137. In order to meet the requirements contained in 10 CFR 32.19 (a) and (b), Leidos has written it's procedures to limit the number of GR-135 items per transaction to 10 (totaling 2.5 µCi).

Our internal procedure RS-01, Revision 7, dated 1 May 2012, titled "Preparing and Offering for Transport the GR-135 Series Instruments in Compliance with Hazardous Material Transport Requirements" states in part:

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6. Shipment of more than 1 Cs-137 check source by Air or Ground in US.....

6.1 Packaging

6.1.1 ***Determine the number of sources to be shipped in the consignment. No more than 10 sources may be shipped together in the same package/consignment.***

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Experience has shown that limiting the quantity of check sources to ten (totaling approximately 2.5 µCi) will ensure that the dose rate at the external surface of the outer package does not exceed 0.5 millirem per hours.

C.5 "Title 10, Code of Federal Regulations, Section 32.19(d) requires, in addition to the labeling information required by paragraph (c) of this section, that the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words "Radioactive Material – Not for Human Use – Introduction into Food, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not be Combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material. Please describe and provide a sample or copy of the label and/or brochure you plan to use in meeting this requirement.

The labels for the check sources are shown in Figure 4 of the supplemental information package. This label identifies the isotope and quantity of activity and shows the words "Radioactive Material" in accordance with 10 CFR 19(c).

The products user manual (attached), accompany each distribution, states the following in Appendix D. bold italicized to indicate the specific requirement.

**External Check Sources**

**Licensing Requirements**: Radioactive material contained in these sources is exempt from USNRC or US Agreement State licensing requirements as long as the unit is used and maintained in accordance with the manufacturer's instructions. For locations outside of the United States, users must verify all local license requirements with the applicable regulatory agency.

**Safe Handling**: Although quantities of radioactive material contained in these products are extremely small, the basic radiation protection principles of time, distance and shielding should be practiced as effective methods for minimizing exposure.

**Use**: These devices should only be used as a method for verifying response of radiation measuring devices, and are to be used in accordance with manufacturer's instructions. These sources are not for human use, introduction into foods, beverages, cosmetics, drugs or medicines, or into products manufactured for commercial distribution. Exempt quantities should not be combined to increase the source activity.

**Storage**: All radioactive material should be securely stored when not in use.

**Disposal**: Per the USNRC, the sources contained in these devices may be disposed of in regular waste in the United States, without regard to their radioactivity, after the radioactive material warning labels have been removed or defaced from the device. However, users should verify compliance for additional transport and disposal restrictions of the source and device with all local regulations.

Respectfully,

Daniel Madson
Radiation Safety Officer

# Item 5 – Radioactive Material

## Element and mass number

Any isotope with atomic number 3-83 inclusive.

## Chemical or /or physical form

Sealed Sources

## Maximum amount which will be possess at any one time

Not applicable. The licensee will not possess under this license. Possession will be controlled by California Radioactive Material License 2290-37 (Attachment 1). The current amendment (134) states:

| 6. Nuclide | 7. Form | 8. Possession Limit |
|---|---|---|
| L. Any isotope with atomic number 3-83 inclusive | L. Sealed sources and foils | L. 300 sources not to exceed the exempt quantity limit for each isotope. |

# Item 6 – Purpose

The material will be used in conjunction with the radiation measuring devices produced and distributed by Leidos. Leidos produces and distributes various radiation measuring devices such as radioisotope identifiers and radioactive material detectors. To facilitate performance checking and field calibration of these devices, small exempt quantity sealed sources are required. These check sources may be delivered to persons exempt from licensing requirements, either:

- Attached to or installed in measuring devices or its associated accessories per 10 CFR 30.15 (an example being the GR-135 Isotope Identifier)
- Delivered with, but not installed in or attached to the devices per 10 CFR 32.18 (example being the AT-980 radiation portal monitor)

Leidos will not be manufacturing or producing any of the exempt sources for this purpose. All such sources will be obtained from a supplier with a valid US NRC exempt distribution license for the manufacture and distribution of the material. SAIC will not modify the source in any way. All manufacturers' labels will remain intact on the sources and will include the radiation warning symbol and/or the words "Radioactive Material" along with the isotope and associated activity. SAIC will only install in, attach to, or redistribute the sources with our radiation measuring devices to ensure that end users are provided a mechanism to validate the instruments response.

These sources are not to be contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or as an application to, human beings nor incorporated into any device for such purposes.

# Information Required for Specific Types of Distribution Licenses

## 9.1.3 Quality Assurance Program

Leidos has implemented a Quality Assurance (QA) program to provide control over all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the devices that contain byproduct material.

The QA program has been assessed by TUV America as compliant with the requirements of ISO 9001:2008. Copies of the current certificate and QA Manual are in Attachment 3. Note that the certificate shows an expiration date of 31 October 2013. A re-certification audit was conducted in June 2013 and re-certification was recommended. The new certificates have not yet been issued.

## 9.3 10 CFR 32.14: Certain Items Containing Byproduct Material

### 10 CFR 32.14

(b)(1) Chemical and physical form and maximum quantity of byproduct material in each product.

LeidosSAIC/Exploranium GR-135 Hand Held Radioisotope Identifier docking station contains a single Cs-137 0.25 µCi (9.25 kBq) Sealed Source.

(b)(2) Detail of construction and design of each product.

See SAIC drawing 426618 (Attachment 4). The source is placed into a holder in the docking station, label up.

The source is positions so that when a GR-135 is placed on the docking station the detector it is lined up with the source. The GR-135 will detect that it is in the docking station and enter into a stabilization routine – constantly monitoring and adjusting the system so that the 662 keV peak of the Cs-137 source shows up in the correct channel of the hand held unit.

(b)(3) The method of containment or binding of the byproduct material in the product

The source itself is distributed as exempt by the source manufacturer.

The Leidos/SAIC label is applied to the source. This label contains:

- The words "RADIOACTIVE MATERIAL"
- The Isotope (Cs-137))
- The activity in both µCi (0.25) and kBq (9.25)

- The name of the device manufacturer (SAIC)
- The date (month/year) of constructions


Figure 1 - Source in Holder

The source is placed into a holder which is attached to the docking station housing (Figure 1). A retaining ring is installed that holds the source within the housing (Figure 2).


Figure 2 - Retaining ring attached

The outer plate is then placed over the source and internal electronics and secured with six screws. Two labels are applied; a duplicate of the label that was attached to the source (see above) and the nameplate for the docking stations (Figure 3). The nameplate label also contains the name, address and phone of the licensee.


Figure 3 - External (back view of Docking Station)

(b)(4) ... procedures for and results of prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product.

This product has been in distribution for over ten years, initially by Exploranium of Canada and then SAIC/Leidos. The prototype testing and the results are contained in the initial license application filed in 2003.

To date, SAIC has not been made aware of a single case were the byproduct material has become detached from the product with over 8000 units delivered.

(b)(6) The proposed method of labeling or marking each unit, and its container

The labeling of the GR-135 Docking Station is discussed above under (b)(3).

## 10 CFR 32.15

(a)(1) Maintain quality assurance systems in the manufacture of the part or product, or the installation of the part into the product, in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed products are capable of performing their intended functions.

Leidos' Quality Assurance system has been developed to be in compliance with ISO 9001:2008. In accordance with the ISO processes the QA system is regularly audit by qualified auditors of the licensee and external certification bodies.

(a)(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in the license issued under § 32.14, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

> The GR-135 Docking Station is a low volume product that is built to order. As such, each docking station goes through a complete inspection and will only be distributed if it is found to be in full compliance with SAIC procedures. Non-conforming products are repaired/reworked and retested to ensure full compliance prior to distribution.

(a)(3) Visually inspect each unit in inspection lots. Any unit which has an observable physical defect that could adversely affect containment of the byproduct material must be considered a defective unit.

> Complies. Each GR-135 Docking Station is inspected and only units with no observable defects that could adversely affect the containment of byproduct material are distributed.

(b) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State: (1) Any part or product tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria.

> Complies. Leidos will not transfer any docking station that was found defective under our ISO 9001:2008 Quality Assurance program.

(d)(1) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

> Complies. As stated above the actual byproduct material has a label with the manufacturers name and the actual docking station contains a nameplate with the manufacturers name and contact information.

## 10 CFR 32.16

Leidos will continue to file the required reports. A copy of the last report, submitted on January 28, 2013 is shown in Attachment 5. This report:

- Identifies the specific license [§32.16 (a)(1)]
- Indicate that the products are transferred for use under § 30.15 [§32.16 (a)(2)]
- Contains a description or identification of the type of each product and the model number(s) [§32.16 (b)(1)]
- The total quantity of the radionuclide for each product/model number [§32.16 (b)(2)]

- The number of units of each type of product transferred during the reporting period by model number. [§32.16 (b)(3)]
- The records of the transfer are maintains in our records management system at the place of manufacture.

## 9.5 10 CFR 32.18: Exempt Quantities

### 10 CFR 32.18

(b) The byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

Confirmed. The product material distributed under the license will not be "contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being."

(c) The byproduct material is in the form of processed ..., but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

Confirmed. The byproduct material is a sealed source obtained by a manufacturer that has a specific license to distribute them. Theses sealed sources are placed in an outer container (see drawings in attachment 6) and are not incorporated into any manufactured or assembled commodity, product, or device.

(d) The applicant submits copies of prototype labels and brochures.

Since the products have been available for distribution on the preceding license they are not prototype devices. The images below (figure 4) show the actual source with label.


Figure 4 – Labels

These devices are for the support (i.e.; calibration) of the GR-135 Isotope Identifier and the AT-980 Radiation Portal Monitors. They are options that may be included in the order but are not required. The information about the source option is not contained in the system brochure.

## 10 CFR 32.20

Leidos will continue to file the required reports. A copy of the last report, submitted on January 28, 2013 is shown in Attachment 7. This report:

- Identifies the specific license [§32.20 (b)(1)]
- Indicate that the products are transferred for use under § 30.18 [§32.20 (b)(2)]
- The total quantity of the radionuclide for each product/model number [§32.20 (c)]
- The records of the transfer are maintains in our records management system at the place of manufacture.