



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001**

May 19, 2016

CSECO
ATTN: Doug Broadwell
Operations Manager
875A Island Dr. #356
Alameda, CA 94502

**SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING CSECO EXEMPT
DISTRIBUTION LICENSE APPLICATION AND SEALED SOURCE AND
DEVICE REGISTRATION CERTIFICATE APPLICATION**

Dear Mr. Broadwell:

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Campbell/Harris Security Equipment Company (CSECO) application dated March 31, 2016, Agencywide Documents Access and Management System (ADAMS) accession no. ML16103A398, which is a re-submission of the applications for an exempt distribution license dated April 1, 2015, and a sealed source and device safety evaluation dated June 11, 2015. You have also provided responses to the NRC's requests for additional information dated July 29 and September 23, 2015, concerning your original application. The staff has determined that additional information is needed. In order to continue with our review, please address the issues listed in the enclosure.

Any correspondence regarding your application should reference the control number specified below. Please submit the requested information within 30 days of the date of this letter. If we have not received complete information within 30 days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in Title 10 of *Code of Federal Regulations* (10 CFR) 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

D.Broadwell

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If you have questions regarding your exempt distribution license application, please contact me at (301) 415-5608, or by email at Eric.Reber@nrc.gov. For questions regarding your application for a Sealed Source and Device registration certificate, please contact Tomas Herrera at (301) 415-7138, or by email at Tomas.Herrera@nrc.gov.

Sincerely,

/RA/

Eric H. Reber
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-38916
Mail Control No. 590618

D. Broadwell

-2-

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Sincerely,

Eric H. Reber
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
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Office of Nuclear Material Safety
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Docket No. 030-38916
Mail Control No. 590618

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ADAMS Accession No: ML16134A355

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Eric Reber	DMiller for Lisa Pope	Shirley Xu	Tomas Herrera
DATE	05/16/2016	05/19/2016	05/19/2016	05/19/2016
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	
NAME	THerrera for Maria Arribas-Colon	Hipolito Gonzalez	Eric Reber	
DATE	05/19/2016	05/19/2016	05/19/2016	

OFFICIAL RECORD COPY

Doug Broadwell
Operations Manager
CSECO
030-38916

A. REQUEST FOR ADDITIONAL INFORMATION REGARDING EXEMPT DISTRIBUTION
LICENSE AND SEALED SOURCE AND DEVICE REGISTRATION (SSD) CERTIFICATE

1. The legal name of your corporation will be listed on your prospective exempt distribution license and Sealed Source and Device registration certificate. For clarity, the name(s) that you do business under may also be added to the license.

The applicant name provided in your application is "A&A Harris Ent. Inc. dba Campbell/Harris Security Equipment Company aka CSECO."

Please spell out the legal name of your corporation without abbreviations.

2. Several pages of your application were marked, "Confidential Information, Submitted under 10 CFR 2.390 as Trade Secrets." To withhold this information from public disclosure, you must follow the procedures in Title 10 of *Code of Federal Regulations* (10 CFR) 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1). To date, you have not met the document marking and affidavit requirements for withholding from public disclosure the pages marked, "Confidential Information, Submitted under 10 CFR 2.390 as Trade Secrets."

B. REQUEST FOR ADDITIONAL INFORMATION REGARDING EXEMPT DISTRIBUTION
LICENSE

1. The regulations in 10 CFR 32.30(a) state that an application for a specific license to initially transfer for sale or distribution devices containing byproduct material for use under 10 CFR 30.22 will be approved if the applicant satisfies the general requirements of 10 CFR 30.33. However, the requirements in 10 CFR 30.33(a)(2) and (3) do not apply to an application for a license to transfer byproduct material in such industrial devices manufactured, processed, or produced under a license issued by an Agreement State.

You have submitted a copy of your current State of California license (License No. 4147-01); however, this license does not authorize the manufacture, processing, or production of the devices that are the subject of your exempt distribution license application and your Sealed Source and Device registration certification request. Please provide a copy of your current State of California license that authorizes the manufacture, processing, or production of the K9 series of portable density gauges that will be distributed for use by license-exempt persons under 10 CFR 30.22.

Enclosure

2. The regulations in 10 CFR 32.30(b) state that an application for a specific license to manufacture, process, produce, or initially transfer for sale or distribution devices containing byproduct material for use under 10 CFR 30.22 or equivalent regulations of an Agreement State will be approved if the applicant submits sufficient information relating to the industrial devices to demonstrate that the device will meet the safety criteria set forth in 10 CFR 32.31.

- a. The regulations in 10 CFR 32.30(b)(6) state that an applicant should submit information about the maximum external radiation levels at 5 and 30 centimeters from any external surface of the device, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

In your application, you have provided three sets of radiation level measurements for your device: (1) a listing of four measurements made with the shutter closed and open in the Radiation Profile section, (2) two tables showing measurements that were provided in response to Item C.17 of the U.S. Nuclear Regulatory Commission's (NRC) letter dated July 29, 2015, and (3) two tables showing measurements that were provided in response to Item B.1.a of the NRC's letter dated September 23, 2015. These three sets of measurements provide conflicting information about the radiation levels produced by your devices. Furthermore, the number of measurements and the distances at which the measurements were made vary among the different sets of survey results.

Please indicate which survey results fulfill the requirement in 10 CFR 32.30(b)(6) to provide such information. Also, please confirm that the indicated survey results are measurements for a device containing the maximum amount of radioactive material requested in your application.

- b. The regulations in 10 CFR 32.30(b)(10) state that an applicant should submit information about the proposed methods of labeling or marking the device and its point-of-sale package to satisfy the requirements of 10 CFR 32.32(b).

You have not provided information concerning the labeling or marking of the point-of-sale package for your devices.

Please provide information about the proposed methods of labeling or marking the point-of-sale package that satisfies the requirements of 10 CFR 32.32(b).

3. The regulations in 10 CFR 32.31(a)(2) require that an applicant must demonstrate that the device is designed and will be manufactured so that it is unlikely that the external radiation dose in any 1 year, or the committed dose resulting from the intake of radioactive material in any 1 year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from disposal of the quantities of units likely to accumulate in the same disposal site will exceed 10 μ Sv (1 mrem).

In your application, you have addressed disposal procedures for your devices; however, you have not provided information that meets the requirement of 10 CFR 32.31(a)(2).

In your response, please provide information that demonstrates that your devices are designed and will be manufactured so that It is unlikely that the external radiation dose in any 1 year, or the committed dose resulting from the intake of radioactive material in any 1 year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from disposal of the quantities of units likely to accumulate in the same disposal site will exceed 10 μ Sv (1 mrem).

4. The regulations in 10 CFR 32.31(b) require that an applicant for a license under 10 CFR 32.30 shall demonstrate that, even in unlikely scenarios of misuse, including those resulting in direct exposure to the unshielded source removed from the device for 1,000 hours at an average distance of 1 meter and those resulting in dispersal and subsequent intake of 10^{-4} of the quantity of byproduct material, a person will not receive an external radiation dose or committed dose in excess of 100 mSv (10 rem), and, if the unshielded source is small enough to fit in a pocket, that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv (200 rem).

In your application, you have provided some information about how your devices would respond to accident conditions including fires, and you have provided radiation survey information concerning dose rates produced by radioactive sources that are present in intact devices; however, you have not provided information that specifically complies with the requirements of 10 CFR 32.31(b).

- a. In your response, please provide information that demonstrates that a person directly exposed to the unshielded source removed from the device for 1,000 hours at an average distance of 1 meter will not receive an external radiation dose in excess of 100 mSv (10 rem).
- b. In your response, please provide information that demonstrates that the dose to a person resulting from the intake of 10^{-4} of the quantity of byproduct material in a single source will not result in a committed dose in excess of 100 mSv (10 rem).
- c. In your response, please provide information that demonstrates that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter that would result from carrying an unshielded source in a pocket for 80 hours would not exceed 2 Sv (200 rem).

C. REQUEST FOR ADDITIONAL INFORMATION REGARDING SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

1. NRC Question No. 11 (in Section C) of the NRC's request for additional information dated July 29, 2015, requested the following: "Provide an engineering drawing specifically indicating the location of the source within the rotor." In CSECO's response to the NRC postmarked August 27, 2015, CSECO stated the following: "Below are drawings showing the relative position of the source in the rotor and its location in the unit as a whole. Because of the availability of our CAD consultant, we will supply a drawing specifically showing the source location in the rotor by September 15."

The subsequent drawings supplied by CSECO did not include this information. Please provide the drawings requested.

2. CSECO provided copies of the "General Operating Manual" for the K910B and K910G Buster devices. The NRC requested that CSECO provide a final version of the manuals for the devices that will be distributed as exempt products. The NRC has identified information in both manuals that could lead to confusion for the end users. For example:
 - Page 19 in both manuals reference a source activity of 100 μCi when the maximum activity that CSECO has requested is 10 μCi .
 - Page 20 references a 100 μCi (3.7 MBq) source.
 - Page 21, Section 3.3.2, as an exempt product, the end users would not be required to contact the nearest public health or emergency services in the event of an accident. Please consider revising this section.
 - Page 24, Section 7, if approved as an exempt product the CSECO devices would no longer be generally licensed. There are no transfer requirements for the end user.
 - Page 24, Section 8, as an exempt product there are no requirements for the end user to report the transfer of the devices. There are no special disposal requirements for exempt products.
 - Page 25, the label references a 100 μCi (3.7 MBq) source; the maximum activity source that CSECO has requested is 10 μCi . Please adjust accordingly.

Please perform a thorough review of the operating manuals for the K910B and K910G Buster devices. For example, the manual contains dated information and information regarding the devices as generally licensed devices. Inaccurate information could be confusing to the end users. Please resubmit a copy of both operating manuals and ensure that they have been updated to reflect that the devices will be distributed as exempt products.