



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001
September 23, 2015

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

SUBJECT: SECOND 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) letter dated August 27, 2015, Agencywide Documents Access and Management System (ADAMS) accession no. ML15244A522, which is a partial respond to our first request for additional information dated July 29, 2015 (ADAMS accession no. ML15202A043). 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 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, "Public inspections, exemptions, requests for withholding," 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/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

D.Broadwell

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If you have any questions regarding the Sealed Source and Device Registration you can contact Tomas Herrera at (301) 415-7138 or by email at Tomas.Herrera@nrc.gov. For questions related to the exempt distribution license, please contact me at (301) 415-6004 or email at Hector.Rodriguez-Luccioni@nrc.gov.

Sincerely,

/RA/

Hector Rodriguez-Luccioni, Ph.D.
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-38847
Mail Control No. 587152

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Docket No. 030-38847
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OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Hector Rodriguez-Luccioni	Shirley Xu	Tomas Herrera	Maria Arribas-Colon
DATE	09/15/2015	09/17/2015	09/18/2015	09/21/2015
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB		
NAME	Hipolito Gonzalez	Hector Rodriguez-Luccioni		
DATE	09/23/2015	09/23/2015		

OFFICIAL RECORD COPY

Doug Broadwell
Operations Manager
CSECO
030-38847

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

1. In your response to NRC Question A.3, you stated: “The product has been sold and in use for over 25 years and even though run over by trucks and the tracks of bulldozers and dropped many times, there has never been any failure in the containment and integrity of the radioactive source and shutter mechanism. This should qualify under item 3 above: ‘operation history of the product’.”

In your response you indicated that the product has been sold and in use for 25 years, however you did not indicate the number of detectors, or if the product in use for 25 years is exactly the same as the product you are trying to register. Please provide the number of detectors that have been distributed over the 25 year period and in your response please confirm that the device is identical that the one you are requesting to register (if this is the case). If the device it is not identical, please delineate the differences.

2. In your response to NRC Question A.4, you provided three documents: Unit Leak Testing, Final QA, and Incoming Inspection. These documents are procedures that ensure that the detectors meet certain criteria. However, these procedures do not constitute a Quality Assurance program. Please provide a copy of CSECO’s quality assurance program.

B. REQUEST FOR ADDITIONAL INFORMATION REGARDING EXEMPT DISTRIBUTION LICENSE

This information is required by 10 CFR 32.30, “Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.”

1. In your response to NRC Question B.3, you stated that the average exposure at 30 cm is 0.05 $\mu\text{Sv/hr}$ and you referenced the table you provided to answer NRC Question C.17. Please clarify the following:
 - a. In your original application dated April 1, 2015, under 32.30 b-6 you provided the maximum exposures with the shutter closed and open for 5 cm and 30 cm. The values provided in your original application do not match the values provided in the radiation profile table in letter dated August 27, 2015. Please clarify which values are correct.
 - b. After reviewing the radiation levels provided in your answer to NRC Question C.17, we noticed that some radiation levels with the shutter closed are higher than the radiation levels with the shutter open. Please provide an analysis explaining why some radiation levels are higher with the shutter closed than with the shutter opened.

2. In your response to NRC Question B.5, you stated that you decided to waive the request to withhold from public disclosure per 10 CFR 2.390 information provided in your application dated April 1, 2015. All the diagrams (blue prints) under Appendix A of your application dated April 1, 2015 have a "Proprietary" statement. Since you waived the request for proprietary information please submit the diagrams without the "Proprietary" statement.

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

1. In your response to NRC Question C.1, you stated: "The correct description should be the 'K9 Family of Portable Gamma Detectors'. All units in this family use the same enclosure and shutter mechanism. Currently we have the K910B which utilizes a 10 μ Ci source and PMT/Crystal detector, and the K910G which utilizes a 7.5 μ Ci source and SiPM/Crystal detector."

Based on this response it is our understanding that CSECO intends to register a series of products and identified as the "K9 Series". The K9 Series will include two device models, the K910B and K910G, and the only differences are the source activity (10 μ Ci and 7.5 μ Ci respectively) and the type of detector used (PMT and SiPM Crystal detectors respectively). Please confirm if our understanding is correct. If there are any more differences between the two models, please provide the differences in a table format.

2. In your response to NRC Question C.8, regarding the source manufacturer and model number you stated: "The manufacturer is Eckert & Ziegler Isotope Products model BA3390200110UA."

Please note that we are unable to find this specific model in our database of approved sources. However, we noted that the current CSECO registration certificate, CA-0207-D-101-B identifies a source model A3902 distributed by Isotope Products Laboratories (now Eckert & Ziegler). Please confirm whether this is the correct source model that will be used in the K9 Series of devices. If the source model is different please identify the registration certificate number for the source.

3. In your response to NRC Question C.13, you provided a label for the Model K910G detectors, please confirm that the K910B device will have a unique label, to differentiate between the two models.
4. In your response to NRC Question C.19 you provided the "General Operating Manual" for the K910B device. We noted that this version of the manual was for the devices registered under CA-0207-D-101-B. Please provide a final version of the manual that will be distributed with the exempt versions of the devices that you are seeking approval to distribute.

D. QUESTIONS NOT ANSWERED FROM OUR FIRST REQUEST FOR ADDITIONAL INFORMATION DATED JULY 29, 2015.

This is a reminder of the questions that you requested an extension to respond back. Please respond to the following questions by September 30, 2015. If we have not received complete information regarding the questions below by September 30, 2015, we will consider your

application as having been abandoned by you. This is without prejudice to the submission of a complete application.

1. 10 CFR 32.31(a)(4) requires that applicants shall demonstrate that the device is designed and will be manufactured so that in use, handling, storage, and disposal of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, the probability is low that the containment, shielding, or other safety features of the device would fail under such circumstances that a person would receive an external radiation dose in excess of 5 mSv (500 mrem), and the probability is negligible that a person would receive an external radiation dose or committed dose of 100 mSv (10 rem) or greater. In your application you made reference to your response for 10 CFR 32.30(b)(14) which only gives the results under the circumstances of a fire. Please provide the results under all conditions stipulated in 10 CFR 32.31(a)(4).
2. Provide an engineering drawing specifically indicating the location of the source within the rotor.
3. Please provide an engineering drawing with the cross section of the device that demonstrates the mounting of the rotor assembly within the device. The drawing should list/identify the components within the device.
4. Please provide the maximum allowable temperature, vibration, and shock during use, handling, storage, and transport.