



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

July 29, 2015

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) exempt distribution license application dated April 1, 2015, and sealed source and device safety evaluation dated June 11, 2015. The staff has determined that additional information is needed. In order to continue with our review, please address the issues listed below.

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 you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

In accordance with 10 CFR 2.390 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).

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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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	07/21/2015	07/27/2015	07/27/2015	07/27/2015
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB		
NAME	Hipolito Gonzalez	Hector Rodriguez-Luccioni		
DATE	07/28/2015	07/29/2015		

OFFICIAL RECORD COPY

Doug Broadwell
Operations Manager
CSECO
030-38847

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

1. On the NRC form 313, under section 3, "Address where licensed material will be used or possessed," CSECO stated that this section is not applicable but that your physical address is 2209 Harbor Bay Parkway, Alameda, CA 94502. For exempt distribution licenses the address under section 3 is the address where the exempt devices will be distributed from. In your SSD application, under "Applicant" it identified two addresses: a mailing address and a physical address. Please provide the address where the device will be distributed from and where the device will be manufactured.
2. In your license and SSD application, CSECO stated that the devices used a sealed source of 0.37 MBq (10 μ Ci) or less of Ba-133 and you made a reference to the Sealed Source and Device registration certificate CA0207D101B. The sources registered under CA0207D101B have a maximum activity of 37 MBq (1 mCi) and 3.7 MBq (100 μ Ci). The SSD application also includes a tolerance of $\pm 10\%$ and the license application under the labeling section indicates that typically the activity of the source is 0.2775 MBq (7.5 μ Ci). The NRC only includes the maximum activity of the byproduct material in the registration certificate and the license. Please clarify the maximum activity of byproduct material in your device.
3. In your application, under "Condition of Use" you stated that the device was prototype tested in accordance with ANSI N538 (1979) and that it was assigned the classification ANSI-95-675-785-R2, however the application did not include the prototype test results.

The NRC may accept one of the following methods to demonstrate the product ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions: (1) testing a prototype of the product, (2) performing an engineering analysis, (3) operational history of the product, or (4) comparison to a similar or equivalent model previously reviewed and registered. Please note that Section 10.5 of Volume 3, Revision 1 of the NUREG-1556 series provide guidance on each of these methods.

As required under 10 CFR 32.30(b)(11) and 10 CFR 32.30(b)(12) please provide the procedures and results of prototype testing, or provide one of the other acceptable methods of prototype testing, of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use and disposal of the device.

4. As required under 10 CFR 32.30(b)(15) please provide a copy of CSECO's quality assurance program. The quality assurance program must ensure that: (a) the materials of construction and the final assembly meet the design specifications; (b) the final product is leak test; (c) a final radiation profile is performed, (d) a test that verifies the product operates as intended, including all safety functions is performed; and (e) a visual and mechanical inspection of components that are considered critical to safety or are expected to be susceptible to failure under extreme or unusual conditions must be performed. Please see NUREG-1556, Volume 3, Revision 1, Section 10.7, "Quality Assurance and Quality Control," for more information.

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. Please provide a copy of your current possession license from the State of California.
2. In your application dated April 1, 2015, you stated that the estimated annual sales of the device is 500 units and therefore the maximum total quantity of material for this level of sales is 18.5 MBq. You also stated that the actual quantity will probably be 13.9 MBq as your standard product uses 0.2775 MBq of material. Please provide the basis for your calculations, there seems to be an inconsistency. For your calculations use the maximum activity of byproduct material in your device.
3. In your application dated April 1, 2015, you stated that the estimated exposure to an individual using the device full time is from 15 to 20 $\mu\text{Sv}/\text{year}$. Assuming the technicians spend 15 minutes swapping electronics at a working distance of 30 cm they would receive a dose of 0.015 $\mu\text{Sv}/15$ minutes or 0.06 $\mu\text{Sv}/\text{hr}$. Please provide the basis for your calculations.
4. 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).
5. You submitted an affidavit dated June 26, 2015 to withhold proprietary information of the Application for Device Evaluation and Registration submitted in June 2015. Portions of your applications for the exempt distribution license dated April 1, 2015, were marked as proprietary information. The affidavit submitted in June cannot be used for the exempt distribution license application because it only reference the Application for Device Evaluation and Registration. In order for the NRC to withhold the information included in the exempt distribution license application from public disclosure, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate.

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

General

1. In your application, under "Model Number" you provided "K910" however throughout the application the device is referred to as the "K910G Buster". Please clearly identify the correct model number.
2. In your application, under "Condition of Use," CSECO referred to the K9 family of Portable Gamma Detectors. Please clarify whether CSECO intends to register a series of devices or if CSECO only intends to register the Model K910G as an exempt device. If CSECO intends to register a series of devices, please provide a description of the devices, along with a description of differences between those devices and the K910G detector. A table format is preferred.

Description of Product/Construction

3. Provide a detailed description of the construction of the product as well as the use and function of the Model K910G device. This may be similar to the description in CSECO's registration certificate CA-0207-D-101-B.
4. Based on the information provided, it is our understanding that when the button that is pressed to rotate the source to the exposed position is released, the source will return to the shielded position. Please confirm that our understanding is correct. If not, please provide a description on how the source will return to the shielded position.
5. In your application, drawing number RDK9-002-D is labeled as "K910B – External". However, the label of the device in drawing number RDK9-002-D references the Model K910G BUSTER. Clarify if the drawing for Model K910B is identical to the Model K910G that CSECO is seeking to register.
6. Since CSECO is seeking registration for the Model K910G device as an exempt product, please provide a description of any tamper resistant features that would prevent access to or removal of the Ba-133 radioactive source.
7. In your application, you stated that "The source capsule is glued into the 0.125" diameter 0.20" deep counter-bore." Please describe the type of glue that CSECO will use to attach the source capsule to the rotor. In addition please describe any other features that would prevent the source capsule from becoming dislodged from the rotor.
8. In your application, under "Condition of Use" you stated that the source capsules have the ANSI N542-1977 classification 77C44222. Please provide the manufacturer(s) of the sealed source(s) and the sealed source model(s) that will be used in the Model K910G device.
9. In your application, under "Product Construction" you stated that "the shutter mechanism has an automatic spring return to close the shutter." Based on the information provided, it is

our understanding that once the button to open the shutter is released, the shutter will return to the closed position. Please confirm that the shutter cannot be locked in the open position.

10. Please discuss whether there is the potential for corrosion between unlike materials used in the construction of the Model K910G device.
11. Provide an engineering drawing specifically indicating the location of the source within the rotor.
12. 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.

Labeling

13. In your application under "Labeling," you provided a sample label for the Model K910G device. Please provide the dimensions for the labeling as well as confirming the colors that will be used.
14. The label provided in your application, indicated that the device would contain 100 μCi or less. In your application, you indicated that the activity for the Model K910G is 10 μCi or less of Ba-133. Please provide a copy of the final label indicating the correct device activity.

Conditions of Use

15. Please describe the actions to be taken when the product reaches the end of its working life.
16. Please provide the maximum allowable temperature, vibration, and shock during use, handling, storage, and transport.

Radiation Profile

17. In your application, under "Radiation Profile" you provided the measure maximum exposure at 5 cm and 30 cm. Please the type of survey instrument, the date that the surveys were taken, and the calibration date of the instrument. In addition please provide the survey measurements at the surface of the gauge and 100 cm from the gauge (with the shutter open and with the shutter closed), or provide justification why the surveys were not taken at those distances.

Installation

18. From the drawings in your application, there does not appear to be an opening for the radiation beam. Please confirm our understanding.

Accompanying Documentation

19. Please provide final copy of the user manual that is provided to your customers for the Model K910G device.