

From: Reber, Eric
To: ["doug@cseco.com"](mailto:doug@cseco.com)
Cc: [Xu, Shirley](#); [Herrera, Tomas](#)
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING CSECO EXEMPT DISTRIBUTION LICENSE APPLICATION AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE APPLICATION
Date: Friday, July 01, 2016 2:56:00 PM
Attachments: [CSECO_email_RAI.pdf](#)

Dear Mr. Broadwell,

Please see the attached file, which contains requests for additional actions by you concerning your license application and sealed source and registration certificate application, both dated March 31, 2016.

If you would like to discuss these matters by telephone, please feel free to contact me.

Regards,

Eric H. Reber
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Materials Safety Licensing Branch
Division of Material Safety, State, Tribal, and Rulemaking Programs
US Nuclear Regulatory Commission
Washington, DC 20555-0001
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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 your response letter dated June 15, 2016, which provided additional information in response to the NRC's letter dated May 19, 2016. The staff has determined that additional information is needed. In order to continue with our review, please address the following issues:

1. The regulations in 10 CFR 32.30(a) state, in part, 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. The regulation in 10 CFR 30.33(a)(2) provides one of the conditions for the approval of a specific license: the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. The regulation in 10 CFR 30.33(a)(3) provides another: the applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property. However, according to 10 CFR 32.30(a), 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."

In the NRC's letter dated May 19, 2016, you were requested to 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.

In response, you provided a copy of your State of California license that authorizes the distribution of generally licensed devices, i.e., State of California License No. 6156-01GL. This license is not applicable to the distribution of products to license-exempt persons and therefore does not and could not fulfil the requirement in 10 CFR 32.30(a) for "a license to transfer byproduct material in such industrial devices manufactured, processed, or produced under a license issued by an Agreement State."

The NRC has previously reviewed your State of California license that authorizes various activities related to gauges, i.e., State of California License No. 4147-01. This is the license that could be amended to satisfy the requirements in 10 CFR 30.33(a)(2) and (3). To satisfy the requirements in 10 CFR 30.33(a)(2) and (3), you should amend License No. 4147-01 so that it 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 or the regulations of an Agreement State, and provide a copy of the amended license to the NRC.

2. The following items concern the review of your application for a sealed source and device registration certificate:
 - a. Please provide a non-proprietary version of the drawing "K910B – External", including the overall dimensions of the K9 Series devices so that it may be included as an attachment to CSECO's registration certificate.
 - b. On page 19 of the K9B and K9G operations manuals under "Electronic Maintenance" the sample label references "10 lci" this appears to be a typographical error as the activity should be 10 μ Ci. Please provide corrected pages each of the user manuals.
 - c. On pages 26 and 27 of the K9B and K9G operations manuals under "EMERGENCY INVOLVING OBVIOUS DAMAGE TO THE BUSTER", "TRANSFER OF THE BUSTER TO A DIFFERENT USER", and "DISPOSAL" it states "Note: if the user is a "Specific Licensee", typically an institution that is licensed for other radioactive sources/devices then the user is subject to 10 CFR§20". Please note that the statement is inaccurate and could lead to confusion. The devices used under 10 CFR 30.22 are not subject to the requirements in 10 CFR Part 20, even if the user possess a specific license. Please delete the statement and provide corrected pages for the user manuals.

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 email. 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).

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,

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