



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

February 5, 2015

Trung Tu
Radiation Safety Officer
Scion Instruments
3500 West Warren Avenue
Freemont, CA 94538

**SUBJECT: SECOND REQUEST FOR ADDITIONAL INFORMATION REGARDING SCION
INSTRUMENTS (FORMERLY BRUKER DALTONICS) AMENDMENT
REQUEST**

Dear Mr. Tu:

This letter refers to your response letter dated January 19, 2015, Agencywide Documents Access and Management System (ADAMS) Accession No. ML15021A053, which responds to our first request for additional information dated January 8, 2015 (ADAMS Accession No. ML15005A202). In reviewing your letter, we find additional information is required to complete our review. In the enclosure to this letter, we have summarized the information that needs to be submitted.

We will continue our review upon receipt of this information. If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your amendment request. Any correspondence regarding your application should reference the Mail Control number specified below.

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. 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 of NRC's "Rules of Practice," 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, please contact me at (301) 415-6004 or by email at Hector.Rodriguez-Luccioni@nrc.gov. Any questions regarding the sealed source and device registration should be directed to Celimar Valentin-Rodriguez at (301) 415-7124 or by email at Celimar.Valentin-Rodriguez@nrc.gov.

Sincerely,

/RA/

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

Docket No. 030-38672
Mail Control No. 585536
License No. 04-35093-01E
Registration Certificate No. NR-1385-D-101-E

Enclosure: As Stated

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Docket No. 030-38672
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Enclosure: As Stated

ADAMS Accession No.: ML15022A366

OFFICE	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB
NAME	Hector Rodriguez-Luccioni	Shirley Xu	Celimar Valentin-Rodriguez	Lymari Sepulveda	Tomas Herrera	Hipolito Gonzalez	Hector Rodriguez-Luccioni
DATE	01/22/2015	01/28/2015	01/29/2015	02/03/2015	02/03/2015	02/05/2015	02/05/2015

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Trung Tu
Radiation Safety Officer
Scion Instruments

Additional Information Request Regarding Exempt Distribution License and Sealed Source and Device Registration

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 our first request for additional information, dated January 8, 2015, we requested 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). In your response letter dated January 19, 2015, you stated that Techcomp USA, DBA Scion Instruments will use a durable, adhesive label fixed to the external surface of the ECD unit, another label affixed to the external surface of the GC, and a label fixed to the external surface of the "point of sale package." Your response also included examples of the labels. We reviewed your labels and some information required by 10 CFR 32.32, "Conditions of licenses issued under §32.30: Quality control, labeling, and reports of transfer," is missing. Please provide methods of labeling or making the device and its point-of-sale package so that:
 - a. Each item has a durable, legible, readily visible label or marking on the external surface of the device containing:
 - i. The following statement: "CONTAINS RADIOACTIVE MATERIAL";
 - ii. The name of the radionuclide(s) and quantity(ies) of activity;
 - iii. An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and,
 - iv. Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information).
 - b. The external surface of the point-of-sale package has a legible, readily visible label or marking containing:
 - i. The name of the radionuclide and quantity of activity;
 - ii. An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and,
 - iii. The following or a substantially similar statement: "THIS DEVICE CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NUCLEAR REGULATORY COMMISSION SAFETY CRITERIA IN 10 CFR 32.31. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

Enclosure