



February 12, 2024

U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Vanessa Cox, Project Manager
Materials Safety and Licensing Branch
Division of Material Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
Vanessa.Cox@nrc.gov

Reference: License No. 06-15099-03E
Docket No. 030-36154
Mail Control No. 637316

Subject: MIRION TECHNOLOGIES (CANBERRA), INCORPORATED REQUEST FOR
ADDITIONAL INFORMATION CONCERNING RENEWAL FOR EXEMPT
DISTRIBUTION LICENSE NUMBER 06-15099-03E

In reply to the USNRC email message received on February 1, 2024, where the USNRC received our responses to the requested additional information on January 25, 2024.

The ISOXSRCE Check Source Fixture Assembly and the FC2B Calibration Check Assembly are not new products as the former Canberra Industries (and now Mirion Technologies (Canberra), Inc.) has been offering these assemblies for over twenty (20) years.

As required by 10 CFR 30.20, Mirion Technologies (Canberra), Inc. has reported the distribution of the Eu-155 1 μ Ci source and the Na-22 1 μ Ci source in the ISOXSRCE Check Source Fixture Assembly under 10 CFR 32.18.

As required by 10 CFR 30.20, Mirion Technologies (Canberra), Inc. has reported the distribution of the 8 μ Ci Cs-137 source in the FC2B Calibration Check Assembly under 10 CFR 32.14 for use under 10 CFR 30.15 (a) (9).

We are adding these two (2) specific assemblies mentioned above to the distribution license 06-15099-03E since they were not included in the last renewal process (over ten (10) years ago) by the former RSO.



- Provide prototype testing procedures and results. Provide acceptable prototype labels and brochures.

Mirion Technologies (Canberra), Inc. does not have any prototype testing procedures and results, or prototype labels or brochures since these devices were created over twenty (20) years ago, but we do have User's Manuals available.

See Attachment # 10 for the ISOXSRCE Check Source Fixture Assembly User's Manual number 9231598C.

See Attachment # 11 for the FC2B Calibrator User's Manual number 9240318F.

- Provide quality control procedures.

Mirion Technologies (Canberra), Inc. follows the guidelines described in our Quality Control manuals submitted as Attachment # 5 (Meriden) and Attachment # 6 (Oak Ridge) to the USNRC on January 25, 2024.

The Meriden production department follows the ISOXSRCE Assembly drawing number B-35393 submitted as Attachment # 2 to the USNRC on January 25, 2024.

The Oak Ridge production department follows the FC2B Work Instruction document # MIL-WRK-222 submitted as Attachment # 4 to the USNRC on January 25, 2024.

- Provide methods of labelling on the product and container with the identification of the manufacturer or initial transferor and the byproduct material.

Refer to the ISOXSRCE Check Source Fixture Assembly drawing # B-35393 submitted as Attachment # 2 to the USNRC on January 25, 2024, for locations of labels showing the Fixture Assembly serial number and the source serial number which show Mirion Technologies (Canberra), Inc. and address.

The label on the source disk identifies the isotopes in the disk and refer to Attachment # 7 submitted to the USNRC on January 25, 2024, for an example of the typical label attached to the ISOXSRCE Check Source Fixture Assembly.

For FC2B Field Calibrator Assembly, refer to the drawing # 39103 for an example of the Radiation Label submitted as Attachment # 8 to the USNRC on January 25, 2024.

Refer to drawing # 40154 for an example of the Nameplate label submitted as Attachment # 9 to the USNRC on January 25, 2024, for information on product labelling.



- Provide the radiation levels and method of measurement.

Mirion Technologies (Canberra), Inc. took measurements on the surface and at 12 inches away using a gamma radiation survey meter on both the ISOXSRCE Check Source Fixture and the FC2B Field Calibrator Assembly.

Refer to Attachment # 12 for the Radiation Levels for the ISOXSRCE Check Source Fixture Assembly.

Refer to Attachment # 13 for the Radiation Levels for the FC2B Field Calibrator Assembly.

- Provide evidence that each product will contain no more than the quantity of byproduct specified for that product in Title 10 of the Code of Federal Regulations (10 CFR) Section 30.15.

Refer to Attachment # 14 for an example of the typical source data certificate as evidence of the source activity supplied with each FC2B Field Calibrator Assembly is no more than one (1) exempt quantity for each source as specified in 10 CFR 30.15.

Refer to Attachment # 15 for an example of the typical source data certificate as evidence of the source activities supplied with each ISOXSRCE Check Source Fixture Assembly is composed of fractional parts of Eu-155 and Na-22 of the exempt quantities in 10 CFR 30.71, Schedule B, and the sum of the fractions do not exceed unity.

- Provide a statement of intended use of the product and that the product would not be incorporated in any food; beverage; cosmetic; drug; or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

Refer to Attachment # 16 for document number RSP-011-1, Radioactive Shipping Notification, for the statement of intended use of the product and that the product would not be incorporated in any food; beverage; cosmetic; drug; or other commodity or product designed for ingestion or inhalation by, or application to, a human being as per 10 CFR 32.19(d).

Should you have any questions, please do not hesitate to contact the undersigned at 203-639-2462 or at tschwager@mirion.com.

Sincerely,
Mirion Technologies (Canberra), Inc.

Mr. Terrence W. Schwager
Radiation Safety Officer



Enclosed Attachments:

NOTE: Attachments numbers 1 through 9 were submitted to the USNRC on January 25, 2024

10. ISOXSRCE Check Source Fixture Assembly User's Manual number 9231598C.
11. FC2B Calibrator User's Manual number 9240318F.
12. Radiation Levels for the ISOXSRCE Check Source Fixture Assembly.
13. Radiation Levels for the FC2B Field Calibrator Assembly.
14. Example of typical source data certificate as evidence of the source activity supplied with the FC2B Field Calibrator Assembly
15. Example of typical source data certificate as evidence of the source activities supplied with each ISOXSRCE Check Source Fixture Assembly
16. RSP-011-1, Radioactive Shipping Notification