



January 25, 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

Mirion Technologies (Canberra), Inc. provides the following in response to the USNRC's request for additional information on the letter dated November 16, 2023:

1. Provide a copy of Agreement State possession license.

Refer to Attachment #1 for the PDF copy of Mirion Technologies (Canberra), Inc., State of Tennessee Radioactive Materials License number R-01013-C25, Amendment # 78, expiration date of March 31, 2025.

2. Provide the details of construction and design of each product.

The radioactive sources are procured from authorized source manufacturers and the Ba-133, Cl-36, Cs-137, Co-60 and Sr-90 sources will be distributed as received from the source manufacturer without installation into any Mirion Technologies (Canberra), Inc. products.

Mirion Technologies (Canberra), Inc. office in Meriden CT installs a single disk containing 1 μ Ci each of Eu-155 and Na-22 into our ISOXSRCE Check Source Fixture Assembly that is used for detector calibrations at customers site.

Refer to Attachment # 2 for a PDF copy of drawing # B-35393, for details on the design of the ISOXSRCE Check Source Fixture Assembly.



Mirion Technologies (Canberra), Inc. office in Oak Ridge TN installs a single disk containing 8 μCi of Cs-137 into the FC2B Field Calibrator Assembly that is used for checking the calibration of the Personal Radiation Monitor at customer's site.

Refer to Attachment # 3 for a PDF copy of drawing # 39984, for details on the design of the FC2B Field Calibrator Assembly.

3. Provide the methods of containment or binding of the byproduct material in the product.

The source manufacturer's method of containment for the source disks uses epoxy to encapsulate the source material for a 100% seal.

For the ISOXSRCE Check Source Fixture Assembly the method of attachment of the source disk to the fixture is to use instant adhesive # 454.

Refer to the ISOXSRCE Check Source Fixture Assembly drawing # B-35393 provided in Attachment # 2.

For the FC2B Field Calibrator Assembly the method of attachment of the source disk to the assembly is to use Loctite EA 0151 epoxy.

Refer to the FC2B Work Instruction document # MIL-WRK-222 provided in Attachment # 4.

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

Both ANSI.N542 and ISO.2919 state that the design standards are not mandated but a series of tests are specified for which prototypes of new designs are subjected to testing for calibration sources greater than 30 μCi .

The sources in the fixture that we distribute are below 30 μCi each and we do not have any prototype testing procedures or results.

5. Provide quality control procedures.

See Attachment # 5 for the PDF copy of Mirion Technologies (Canberra), Inc. Quality Management System Policy Manual, QMS-M01, Revision O, Meriden CT facility.

See Attachment # 6 for PDF copy of Mirion Technologies (Canberra), Inc. Quality, Health & Safety (QHS) Management System (MS) Manual, MGT-MAN-001, Revision 18, Oak Ridge TN facility.



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

For the ISOXSRCE Check Source Fixture Assembly, refer to drawing # B-35393 provided in Attachment # 2 for information on product labelling and refer to Attachment # 7 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 in Attachment # 8 and refer to drawing # 40154 for an example of the Nameplate label in Attachment # 9 for information on product labelling.

7. Provide the radiation levels and method of measurement.

Radiation levels for the types of byproduct material listed on our license are not specified in 10 CFR 30.15.

8. 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.

For the Ba-133, Cl-36, Cs-137, Co-60 and Sr-90 radioactive sources, Mirion Technologies (Canberra), Inc. will distribute no more than one (1) exempt quantity for each source as specified in 10 CFR 30.15 to customers.

For the ISOXSRCE Check Source Fixture Assembly, it will be 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 shall not exceed unity.

9. 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.

Mirion Technologies (Canberra), Inc. provided the following information with each shipment of exempt quantities of radioactive materials as set forth in 10 CFR 32.19(d):

“Radioactive Material--Not for Human Use--Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not be Combined.”



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:

1. PDF copy of Mirion Technologies (Canberra), Inc., State of Tennessee Radioactive Materials License number R-01013-C25, Amendment # 78, expiration date of March 31, 2025.
2. PDF copy of drawing # B-35393, for details on the design of the ISOXSRCE Check Source Fixture Assembly.
3. PDF copy of drawing # 39984, for details on the design of the FC2B Calibration Check Assembly.
4. PDF copy of the FC2B Work Instruction document # MIL-WRK-222.
5. PDF copy of Mirion Technologies (Canberra), Inc. Quality Management System Policy Manual, QMS-M01, Revision O, Meriden CT facility
6. PDF copy of Mirion Technologies (Canberra), Inc. Quality, Health & Safety (QHS) Management System (MS) Manual, MGT-MAN-001, Revision 18, Oak Ridge TN facility
7. PDF copy of drawing for an example of the label for the ISOXSRCE Check Source Fixture Assembly.
8. PDF copy of drawing # 39103 for an example of the Radiation Label for the FC2B Assembly
9. PDF copy of drawing # 40154 for an example of the Nameplate label for the FC2B Assembly.