Information needed in order to renew FLIR exempt-distribution license 41-25639-01E

A. Questions concerning the items covered by 10 CFR 32.14 and 32.15

1. Please provide details of chemical and physical form of, and maximum quantity in each product, as required by 10 CFR 32.14(b)(1).

2. Please provide details of construction and design of each product, as required by 10 CFR 32.14(b)(2).

3. Please provide the method of containment or binding of the radioactive byproduct material in the product, as required by 10 CFR 32.14(b)(3).

4. Procedures for and results of prototype testing are required by 10 CFR 32.14(b)(4) to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions to be encountered in normal use of the product. Please provide these procedures and describe the prototype testing performed on the product.

5. Please describe the quality control procedures to be followed in the fabrication of production lots of the product and provide a description of the quality standards the product will be required to meet, as required by 10 CFR 32.14(b)(5).

6. Please describe the proposed method of labeling or marking each unit and its container with the identification of the manufacturer or initial transferor and the byproduct material in the product, as required by 10 CFR 32.14(b)(6).

7. As stated in 10 CFR 32.14(c), each product will contain no more than the quantity of byproduct material specified for that product in 10 CFR 30.15. Please provide the quantity of byproduct material specified for your product.

8. Please describe how the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling, as required by 10 CFR 32.14(d).

9. As stated in 10 CFR 32.15(a)(1), each person licensed under 10 CFR 32.14 shall maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product. Please describe your quality assurance practices in the manufacture of the part or product, or the installation of the part into the product.

10. As stated in 10 CFR 32.15(a)(3), each person licensed under 10 CFR 32.14 shall visually inspect each unit in inspection lots. Any unit that has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit. Please describe how you shall visually inspect each unit in inspection lots for defects.

11. As stated in 10 CFR 32.15(c), no person licensed under §32.14 shall transfer to other persons for use under 10 CFR 30.15 or equivalent regulations of an Agreement State any defective part or product. Please describe how you shall prevent transfer to other persons for use under 10 CFR 30.15 or equivalent regulations of an Agreement State any defective part or product.

B. Questions concerning the items covered by 10 CFR 32.18 and 32.19

1. 10 CFR 32.18(b) requires that the byproduct material not be contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being. Please confirm that this requirement will be met.

2. 10 CFR 32.18(c) requires that the byproduct material be in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution. Please provide the form in which the byproduct material will be distributed, and confirm that the byproduct material will not be incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

3. 10 CFR 32.18(d) requires the applicant to submit copies of prototype labels and brochures, and that the Commission approve such labels and brochures, in order to demonstrate compliance with 32.19(c) and (d). Please provide copies of the labels on the immediate container of check sources, and the accompanying brochure, if any, that may be distributed along with the byproduct material.

4. 10 CFR 32.19(a) requires that no more than 10 exempt quantities set forth in 10 CFR 30.71, Schedule B shall be sold or transferred in any single transaction (an individual exempt quantity may be composed of fractional parts so that the sum does not exceed unity). Please confirm that no more than 10 exempt quantities set forth in 10 CFR 30.71, Schedule B shall be sold or transferred in any single transaction.

5. 10 CFR 32.19(b) requires that each quantity of byproduct material set forth in 10 CFR 30.71, Schedule B shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 10 CFR 30.18. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour. Please describe how you shall meet the requirements of 10 CFR 32.19(b).

6. 10 CFR 32.19(c) requires that the immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and quantity of radioactivity, and (2) bears the words "Radioactive Material." Please describe and provide a sample or copy of the labels you plan to use in meeting this requirement.

7. 10 CFR 32.19(d) requires, in addition to the labeling information required by paragraph (c) of this section, the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words "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"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material. Please describe and provide a sample or copy of the labels and/or brochures you plan to use in meeting this requirement.