

THERMOFISHER SCIENTIFIC LETTER DATED MAY 31, 2019
REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the ThermoFisher Scientific (ThermoFisher) letter dated May 31, 2019 and has determined that additional information is needed. In order to continue with our review, please address the issues listed below.

1. Exempt Distribution License

The information related to review of your exempt distribution license application is required by Title 10 of the *Code of Federal Regulations*, (10 CFR) Part 32, Sections 30.20, 32.26, 32.27, 32.28, 32.29, and 32.210 and is described in the relevant guidance document NUREG-1556, Volume 8, titled "Program-Specific Guidance about Exempt Distribution Licenses," available on the NRC public web site (<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/>).

Please provide the information required by the regulations. These regulations apply to companies that import products as well as those that manufacture products within the United States. Note that it is the applicant's responsibility to confirm the validity of all information.

1. Please provide the following information required in 10 CFR 32.26(b)(8): Total quantity of byproduct material expected to be distributed in the product annually. In your renewal application dated April 10, 2015, you estimated the following:

100 - FH-62-C14 instruments totaling 10 millicuries of C14
137 - SHARP 5030 instruments totaling 13.70 millicuries of C14
75 - 5014i Beta instruments totaling 7.5 millicuries of C14
20 - 5030i Sharp instruments totaling 2.0 millicuries of C14

Please provide a revised estimate for the above models (if needed) and an estimate for the new model 5028i.

2. Please provide us with a copy of your Massachusetts possession license. Please note that an exempt distribution license cannot be issued until you have provided a copy of the possession license in your response to us.

2. Sealed Source and Device Registration

1. The table on Page 2 of your application lists two weights and two voltages for Model 5028i. Please discuss any differences between the two Model 5028i configurations.
2. Please confirm that the Measurement Head Channel A Assembly (Part Number CIC0001420), included in your application, is the same source holder depicted in Attachment 1 of NR-1234-D-101-E.
3. Please discuss how ThermoFisher will avoid corrosion of the measurement heads due to the use of stainless steel and brass.
4. Please confirm that ThermoFisher will label Model 5028i according to the requirements in 10 CFR 32.29(b).
5. Please confirm that Model 5028i will meet the external radiation doses and dose commitments according to 10 CFR Paragraph 32.26(b). Please provide updated radiation profiles for the increased maximum activity.

Enclosure

6. Please provide prototype testing for Model 5028i that verifies that the product design will maintain its integrity when subjected to conditions of normal use and likely accident conditions. As stated in NUREG-1556, Vol. 3, Rev. 2, the NRC accepts one of the following methods of prototype testing: (1) testing of a prototype of a product; (2) engineering analysis; (3) operational history of the product; or (4) comparison to a similar or equivalent model previously reviewed and registered.