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

July 6, 2015

Thermo Fisher Scientific, Inc.
ATTN: Larry Fahey
Radiation Safety Officer
Environmental Instruments Division
27 Forge Parkway
Franklin, MA 02038

SUBJECT: THERMO FISHER SCIENTIFIC, INC. REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL

Dear Mr. Fahey:

This refers to your license renewal application request dated April 10, 2015. In your cover letter you write that there have been no changes since Amendment No. 01, Corrected Copy (2) was issued. Please note that Amendment No. 02 of your license was issued on November 29, 2010, and this amendment added Model 5014i Beta and Model 5030i SHARP to your license.

In order to continue our review, we need the following additional information.

1. In section 1.0 Introduction of your application you list four devices in the FH62 C14 series that are to be considered during the renewal of your license. You also write, [italics added for emphasis] "In this application, these *three* monitors will be referred to as the "FH 62 C14 Series Monitors". The radioactive source, source housing, source housing mounts and all other aspects of the radioactive source are identical in *both* Models."

   Please clarify these seemingly contradictory statements regarding the devices, models and monitors that you wish to distribute under your license. Specifically, please clarify (1) how many and which devices and (2) how many and which monitors, are within the FY 62 C14 series.

2. In section 1.0 Introduction of your application you write that each device contains "Carbon-14 (100 µµmaximum)".

   Please clarify the meaning of "µµ" in this context.

3. In items 2 and 3 of the NRC Form 313 submitted with your application you write that your street address is 27 Forge Parkway, Franklin, MA 02038. The air monitor label and point of sale label in Appendix D of your application indicate that your address is 27 *West* Forge Parkway, Franklin, MA 02038. Furthermore, the "Regulatory Label" in Item 4.2.12 of your application does not include your entire street address. Also, Amendment No. 02 and Amendment No. 01, Corrected copy (2), of your license list your address in different ways.

In light of this conflicting information, please confirm your mailing address and the address from which you are requesting to distribute products. Please also confirm that all device labels will include the correct address.

4. 10 CFR 32.26(b)(3) requires an applicant for a license under 10 CFR 32.26 to submit information about changes in chemical and physical form that may occur during the useful life of the product.

   In item 4.2.5 of your application you provide information about the nature of the material in your devices and indicate that they are designed to operate within a secure weatherproof and tamper resistant shelter under normal ambient conditions. However, you did not directly address changes in chemical and physical form that may occur during the useful life of your products.

   In your response, in accordance with 10 CFR 32.26(b)(3), please submit information about changes in chemical and physical form that may occur during the useful life of your products.

5. 10 CFR 32.27(a) requires an applicant for a license under 10 CFR 32.26 to demonstrate that the product is designed and will be manufactured so that in normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in 10 CFR 32.28.

   In Item 4.3.1 of your application you write that your products would meet the requirements in 10 CFR 32.27(a), but you provide no basis for this conclusion.

   In your response, please provide detailed information that demonstrates that the safety criteria in 10 CFR 32.27(a) will be met for your devices. In developing your response for this item and items 4 and 5 of this letter, you may wish to review section 2.12, Gas and Aerosol Detectors, of NUREG-1717, which provides further information concerning the safety criteria in 10 CFR 32.27.

6. 10 CFR 32.27(b) requires an applicant for a license under 10 CFR 32.26 to demonstrate that the product is designed and will be manufactured so that it is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

   In section 4.3.2 or your application you write that your products would meet the safety criteria in 10 CFR 32.27(b); however, you provide no basis for this conclusion. You also write that users of the devices are instructed not to attempt to access the source.

   Please provide a detailed response that demonstrates that the safety criteria in 10 CFR 32.27(b) will be met for your devices. In developing your response, you should consider that your products are distributed to persons that are exempt from regulatory

requirements and as such, recommendations to users regarding their use should not be considered in the development of the information that you provide.

7. 10 CFR 32.27(c) requires an applicant for a license under 10 CFR 32.26 to demonstrate that the product is designed and will be manufactured so that in use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in 10 CFR 32.28, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in 10 CFR 32.28. Also, 10 CFR 32.26(b)(14) requires that applicants submit information relating to a determination that the probabilities with respect to the doses referred to in 10 CFR 32.27(c) meet the criteria of that paragraph.

   In section 4.3.3 of your application you state that your devices will meet the safety criteria in 10 CFR 32.27(c) and state that Thermo Fisher Scientific, Inc. has implemented a program for the safe handling, recycling, storage and disposal of the sources in your devices; however, you provide no basis for your conclusion regarding the safety criteria in 10 CFR 32.27(c). Furthermore, the procedures you describe only apply to disposal at your facility.

   Please provide a detailed response that demonstrates that the all of the safety criteria in 10 CFR 32.27(c) will be met. You should include the results of radiation surveys and calculations, as well as assumptions upon which your conclusions are based. You should specifically include information relating to your determination that the probabilities with respect to the doses referred to in 10 CFR 32.27(c) meet the criteria of that paragraph. In developing your response, you should consider that your products are distributed to persons that are exempt from regulatory requirements and as such, recommendations to users regarding the return of products to your facility for reuse or disposal should not be considered in the development of the information that you provide.

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 renewal application.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in 10 CFR 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390 (b)(1).

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/reading-rm/adams.html.

Any correspondence regarding this renewal application should reference control number 586654. If you have any questions, you may contact Eric H. Reber at (301) 415-5608, or by electronic mail at Eric.Reber@nrc.gov.

Sincerely,

/RA/

Eric H. Reber
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-36808
Mail Control No. 586654
License No. 20-23922-01E

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Sincerely,
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Eric H. Reber
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SUNSI Review Complete: E. Reber
After declaring this document "An Official Agency Record" it **will** be released to the Public.

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DATE	07/02/2015		07/02/2015		07/02/2015		07/02/2015	

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