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September 4, 2015

Mr. Eric H. Reber
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
15545 Rockville Pike
Rockville, MD 20852

SUBJECT: Control No. 586654, Request for Additional Information, dated July 6, 2015

Dear Mr. Reber,

The purpose of this correspondence is to address your concerns expressed in the subject letter. See attachment.

Our consultant is International Radiation Safety Consulting, Inc. (IRSC). Its personnel are authorized to discuss our application with you on our behalf.

If you have any questions please call me at 508.553.6832 or email me at larry.fahey@thermofisher.com.

Sincerely,

Larry Fahey

Larry Fahey
Radiation Safety Officer

NMSS23

ITEM 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 FH 62 C14 series.

Response:
1. There are four (4) devices that fall under the FH62 C14 family
2. The terms "device and monitors" are referring to the same 4 instruments in the FH62 C14 family (See the table below. Reference SSDR NR-1234-D-101-E)

Description/ Monitor Type	Model FH 62 C14	Model 5030 SHARP	Model 5014i Beta	Model 5030i SHARP
Measurement	Beta Attenuation	Beta Attenuation and Light Scattering	Beta Attenuation	Beta Attenuation and Light Scattering
Optical Assembly	No	Yes	No	Yes (installed on the outside)
NSI board	No	Yes	Yes	Yes
Sample Delivery Tube	Standard Length	Modified Length	Modified Length	Modified Length

ITEM 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.

Response: Should read "Carbon-14, 100 microcuries (maximum)"

ITEM 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.

Response: The U.S. Postal Service shows our address as being 27 Forge Parkway, Franklin, MA 02038-3135. This is the address from which we are requesting to distribute products. Also all device labels will include this correct address.

ITEM 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.

Response: This is an encapsulated disc check source and it highly unlikely that there will be any degradation of the source material over the useful life of the product.

ITEM 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.

Response: See the dose calculations report prepared by Paul Steinmeyer for the FH 62 C14 Series included with this response

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ITEM 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.

Response: These devices have been distributed for approximately 10 years, there were approximately 4909 devices sold and there are currently 4500 units in service. To date, there has not been any contamination issues or over exposures related to this product reported.

This history demonstrates 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.

ITEM 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.

Response: See the dose calculations report prepared by Paul Steinmeyer for the FH 62 C14 Series included with this response.

International Radiation Safety Consulting, Inc.

Dose Calculations:
Thermo Environmental Instruments
FH 62 C14 Series
100μCi ^{14}C

Doses to Various Critical Groups
Based on NUREG 1717 Methodology

Thermo Environmental Instruments
27 Forge Parkway
Franklin, Massachusetts 02038

Prepared by:
K. Paul Steinmeyer, RRPT
Senior Health Physicist
30 Basket Shop Road
Columbia, CT 06237

A. Introduction

This document contains dose calculations to support an application for a license to distribute airborne particle detectors, each containing 100 µCi of ^{14}C. Calculations have been performed in this report for ^{14}C sources using the NUREG-1717 methodology.

B. Radioactive Material Contained

Isotope: Carbon-14, in solid form.
Total Activity: 100 µCi total per unit
Half-life: 5,730 years
Daughter isotope: N-14 (stable)

Thermo is licensed for 7 mCi total of ^{14}C. Therefore, the absolute maximum number of units that might be in Thermo's possession at one time is

$$\frac{7\ \text{mCi}}{1} \times \frac{1000\ \mu\text{Ci}}{\text{mCi}} \times \frac{\text{device}}{100\ \mu\text{Ci}} = 70 \text{ devices.}$$

The maximum number of these devices that could reasonably be expected to be in the licensed facility at any one time is twenty (20).

C. External Dose Potential—Normal Use, Disposal, Distribution

1. Photon Radiation

Bremsstrahlung photon emissions from an intact device will be negligible. This is confirmed in NUREG-1717[1] on page 2-182, Table 2.13.2 footnote f, which states that for ^{14}C the "Radionuclide does not emit significant intensities of photons with energies of about 0.1 MeV or greater, and external dose is not estimated in these cases (see Section 2.13.4.1.3)."

2. Particle Radiation

a. Carbon 14 (^{14}C) decays to stable Nitrogen-14 (^{14}N) by emitting a negative beta particle. No direct photon (gamma) radiation occurs during this transformation. The E_{max} energy of this beta particle is 0.156 MeV (156 keV) and the E_{av} energy is 0.049 MeV (49 keV)[2]. The yield of this transformation is 1.0. Note that beta particles with energies near the average energy are the ones most likely to actually be emitted. At energies greater than and less than E_{av} the probability of emission (yield) decreases. Particles emitted at the endpoint energy are rare. See Figure 1.

[1] U.S. Nuclear Regulatory Commission. "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials." NUREG-1717. Washington, D.C., June 2001.
[2] Kocher, David C. "Radioactive Decay Data Tables." U.S. Department of Energy, DOE/TIC-11026.

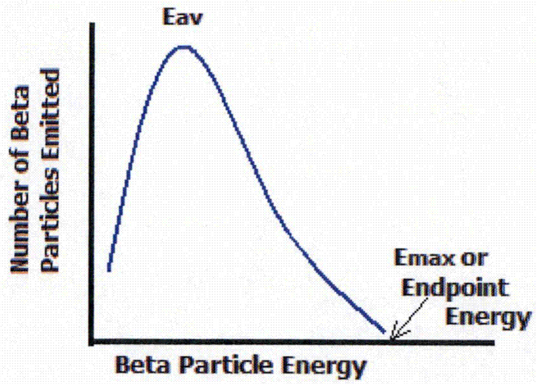

Figure 1. Typical beta particle energy distribution curve.

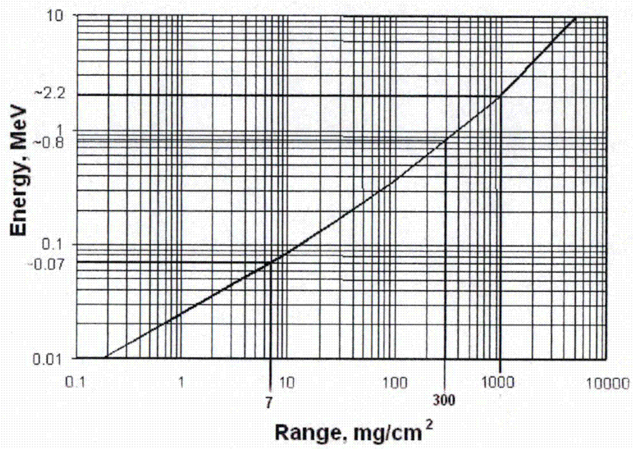

Figure 2. Beta particle range-energy curve showing threshold energies for shallow (7 mg/cm²), lens or eye (300 mg/cm²) and deep (1000 mg/cm²) dose equivalents.

Inspection of the Beta Particle Range-Energy Curve (above) from the Health Physics and Radiological Health Handbook[3] shows that a ^{14}C beta particle at the maximum particle energy (with a yield approaching zero) can penetrate a density-thickness of 7 mg/cm^2 (the nominal density-thickness of the upper layer of the epidermis (the *stratum corneum* or dead skin cell layer), so some shallow dose equivalent might be expected if the source were removed from its housing. There would be *no* deep dose (DDE) delivered to any person from the ^{14}C particle emissions.

[3] After Schleien, Bernard "The Health Physics and Radiological Health Handbook," Revised Edition, copyright 1992, p. 184.

3. External Dose for Distribution Workers and Members of the Public

The radioactive source is fixed within a housing that is in turn positioned inside a metal case. Intact sources within these devices, during normal use and distribution, will deliver no measurable dose to any person. The presence of one or many of these devices will not increase the dose above the non-detectable level. There is no reason for any distribution worker or member of the public to access the unshielded source. Warnings are provided to preclude this.

4. External Dose to End Users

Assumptions:

a. Dose rates at various distances in air (no attenuation) are given in the table below.

Distance	rad/h	rad/min
1.0 cm	124.1	2.1
2.0 cm	25	0.4
15.2 cm	0.013	0.0002
20.0 cm	0.0005	--

Figure 3. Dose Rate[4] from a 100 μCi isotropic point source of ^{14}C.

There is no reason for any end user to access the unshielded source. Warnings are provided to preclude this.

b. The range for 156 keV beta particles in two materials used in the construction of the source holder is given in the table below.

Material	Range (cm)
Aluminum	9E-3
Iron	3E-3

Figure 4. Range of ^{14}C E_{max}-energy beta particles in aluminum and iron.

A thickness of material that exceeds the range of a given energy beta particle will attenuate all betas of that energy. This absorbed energy will be converted to *bremsstrahlung*. The photon energy will be roughly 1/3 of the beta energy, dependent on the absorbing medium. Photon energy is best characterized by using 1/3 the average particle energy, or $\frac{49 \text{ keV}}{3} = 16$ keV. These low-energy photons will then be absorbed to a large extent by the remaining thickness of the aluminum and steel that make up the source housing.

[4] After Michigan State University, Department of Radiology (http://www.ehs.msu.edu/radiation/programs_guidelines/radmanual/appendix_carbon_14.pdf)

Conclusion

External radiation dose to all exposed individuals and groups is within the specified guideline values. Internal doses, presuming no leakage, should be negligible and certainly less than 1 mrem per year for an individual and less than 10 mrem per year to handlers and distributors of these devices. This fulfills the requirements of 10CFR 32.23 and 10 CFR 32.24.

Therefore, 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 II of the table in § 32.24.

Also, in normal use and disposal of a single exempt unit, 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 1 mrem.

It follows, then, that there will be no dose greater than 15 mrem to the skin or extremities.

Finally, ^{14}C has no specific target organ, so no single body organ will exceed a dose of 3 mrem.

D. Internal Dose Potential—Normal Use, Disposal, Distribution

Attributes of Carbon
Source: 100 μCi (MBq), one sealed source
Half-life: 5730 years
Melting Point: 3500.0 °C (6332.0 °F)
Boiling Point: 4827.0 °C (8720.6 °F)

1. Background Information
Firefighters[5] report that in structure fires temperatures are reached that soften steel to the point that it sags or bends from the weight of materials attached to it. The melting temperature of steel is approximately 1370°C (2500°F). This is far below the vaporization temperature of carbon, so the carbon component of this radioactive source is unlikely to produce respirable particles (caused by vaporization of the radioisotope and condensation of the vapor upon cooling) in a structure fire.

[5] Hebron (CT) Volunteer Fire Department, personal communication, November 8, 2006.

2. Incineration—Commercial Incinerator

Commercial incinerators[6] run at a burn temperature of 1427°C (2600°F). This is also far lower than the melting point of carbon, and well below its vaporization temperature, so the carbon component of this radioactive source is unlikely to produce respirable particles (caused by vaporization of the radioisotope and condensation of the vapor upon cooling) if one or more sources is inadvertently sent to a commercial incinerator.

3. Calculation of Internal Dose from Incineration

Notwithstanding the evidence presented above, this calculation will estimate the internal dose to the persons most likely to receive the largest dose in the case of destruction and theoretical vaporization of one of these devices by fire.

Assumptions:

- A single unit is accidentally incinerated
- Fraction of C-14 vaporized and released[7] = 0.01% (0.0001)
  - 100 μCi × 0.0001 = 0.01 μCi
- Efficiency of emissions control equipment at the incinerator = 90%
  - Per cent (fraction) released = 10% (0.1)
- Combustion air flow rate = 120,000 $\frac{ft^3}{min}$
- Combustion time = 15 minutes

Calculating the concentration of aerosolized ^{14}C emitted during the burn:

$$0.01\mu\text{Ci} \times \frac{\text{min}}{120{,}000\,\text{ft}^3} \times \frac{1}{15\,\text{min}} \times \frac{1\,\text{ft}^3}{2.832\text{E}+4\,\text{cm}^3} = \frac{2\text{E}-13\,\mu\text{Ci}}{\text{cm}^3}$$

The most restrictive DAC for effluent concentrations is 3E-9 μCi/cm^3. The estimated concentration is 15,000 times smaller than this DAC.

E. Accident Scenarios Considered

1. Licensed Quantity

Thermo is licensed for 7 mCi of ^{14}C, which (at 100 μCi per device) converts to 70 devices $\left(\frac{7{,}000\ \mu\text{Ci}}{100\ \mu\text{Ci/device}}\right)$.

a. Scenarios

For purposes of these calculations, five scenarios are considered, four of which involve fires. Fires are considered to be the most likely event that could potentially breech the protective structures containing the source.

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[6] Bridgeport RESCO, Bridgeport, CT. Personal communication with Vincent Langoni, Plant Manager.
[7] From NUREG 1717, Table A.1.1.

1. Dose to a warehouse worker and to a firefighter extinguishing a fire in a manufacturer's warehouse containing 70 devices. This scenario assumes that all the devices are destroyed in the fire, **7E+3 μCi = A**;
2. Dose to firefighters extinguishing a tractor trailer fire, with the trailer containing 20 devices[8]. This scenario assumes that all of these sets are destroyed in the fire, **2E+3 μCi = A;**
3. Dose to firefighters extinguishing a fire in an end use facility containing 3 devices. All three devices are assumed to be destroyed in the fire releasing **3E+2 μCi = A.**
4. Catastrophic release from crushing of one (1) unit in a small repair shop, releasing **1E+2 μCi = A.**
5. A shipping accident in a storeroom or cargo-handling area involving the crushing of a shipment of 20 units, releasing 20 units $\times \frac{100\ \mu\mathrm{Ci}}{\mathrm{unit}}$ = **2E+3 μCi = A.**

b. *Exposure Times Estimated During Accidents*

NUREG 1717 does not provide guidance on how long it takes to put out a fire in the various scenarios described. We therefore used what our best judgment told us was the worst *credible* case, not the worst *possible* case. All the times used below, we believe, meet that criterion.

a. The 5-minute exposure time presumption in the worker scenarios estimates that these people evacuate the premises when the fire alarm sounds or when the fire is discovered. It is unlikely to take any of these individuals more than 5 minutes to proceed to the nearest exit and stop any exposure that might have resulted from the accident.
b. The 2-hour exposure time for firefighters extinguishing a fire in a 100' x 100' x 9' high warehouse recognizes that this is not a very large structure, it is all on one level, and it is unlikely that there is a basement. Based on my limited personal experience[9] 2 hours would be more than enough time to put out a fire of this size.
c. The 0.5-hour time applies to firefighters extinguishing a fire in a tractor-trailer (10' x 40') and in a small repair shop (6.6' x 10' x 10' high). Thirty minutes is ample time to extinguish a fire in an enclosure of this size.

2. *Internal Dose Potential–Accidents*

a. *Instantaneous Airborne Concentration (C) in an Accidental Release*

$$C = \frac{Q}{V k t}\left(1 - e^{-kt}\right) \qquad \textbf{(1)}$$ [10]

[8] This number was supplied by Thermo.
[9] 3-day firefighter training school, attended twice in 3 years.
[10] NUREG-1717, page A.1-1, equation 1.

And

Q = RF x A **(2)**[11]

Where, from above:

Scenario	Enclosure	A (µCi)
1	Warehouse 1	7E+3
2	Tractor Trailer	2E+3
3	End use	3E+2
4	Sm Repair Shop	1E+2
5	Warehouse 2	2E+3

Table 1. Total amount of radioactive material involved in each scenario.

b. Calculate Quantity Released (Q)

Q = RF x A **(3)**

Where:

Q = quantity (µCi) released

RF = fraction of radioactive material released as respirable size particles (0.01% or 0.0001 for particulate sources[12]) and

A = total amount of radioactive material involved in a fire.

Since the RF =1, the values for Q equal the values for A (above).

Scenario	Enclosure	# Devices	A (µCi)	Q (µCi)
1	Warehouse 1	70	7E+3	0.7
2	Tractor Trailer	20	2E+3	0.2
3	End use	3	3E+2	0.03
4	Sm Repair Shop	1	1E+2	0.01
5	Warehouse 2	20	2E+3	0.2

Table 2. Total amount of radioactive material released in each scenario.

c. Calculate Instantaneous Airborne Concentration (C)

$$C = \frac{Q}{V k t}\left(1 - e^{-kt}\right) \qquad \textbf{(4)}$$

Where:

Q = released quantity (µCi)

[11] NUREG-1717, page A.1-2, equation 3.

[12] Release fraction (RF) = 0.01% (NUREG-1717 Table A.1.1).

V = volume (m^3) into which activity is released[13] (see table 1 below)
k = ventilation rate (see table 1 below)
t = time over which C is averaged. A time of 1 hour is used for this calculation.
$(1 - e^{-(1)(1)}) = (1 - 0.37) = 0.63$

$$C_{WH-1} = \frac{0.7}{(3000)(1)(1)}\,(1 - e^{-(1)(1)})$$
$$= 2.3E - 4\,(0.63) = 1.5E - 4\ \mu Ci/m^3$$

$$C_{TT} = \frac{0.2}{(87)(1)(1)}\,(1 - e^{-(1)(1)})$$
$$= 0.0023\,(0.63) = 1.4E - 3\ \mu Ci/m^3$$

$$C_{End} = \frac{0.03}{(450)(1)(1)}\,(1 - e^{-(1)(1)})$$
$$= 6.67E - 5\,(0.63) = 4.2E - 5\ \mu Ci/m^3$$

$$C_{Shop} = \frac{0.01}{(18)(1)(1)}\,(1 - e^{-(1)(1)})$$
$$= 0.00055\,(0.63) = 3.5E - 4\ \mu Ci/m^3$$

$$C_{WH-2} = \frac{0.2}{(3000)(4)(1)}\,(1 - e^{-(4)(1)}) \qquad \text{see footnote}^{14}$$
$$= 1.67E - 5\,(0.98) = 1.63E - 5\ \mu Ci/m^3$$

Type of Enclosure	**Q** (μCi)	L x W x H (m)	Floor area (m^2)	Volume **(V)** (m^3)	Ventilation Rate **(k)** (volume/h)	**C** Instantaneous air conc (μCi/m^3)
Warehouse-1	7E+3	30.5 x 30.5 x 3.66	9.3E+2	3,000	1	1.5E-4
Tractor trailer	2E+3	13.7 x 2.35 x 2.7	32	87	1	1.4E-3
End use	3E+2	186 m^2 x 2.44	186	450	1	4.2E-5
Small Repair Shop	1E+2	2 x 3 x 3	6	18	1	3.5E-4
Warehouse-2	2E+3	30.5 x 30.5 x 3.66	9.3E+2	3,000	4	1.63E-5

Table 3. Assumed attributes of relevant enclosure volumes; instantaneous airborne concentrations.

[13] From NUREG-1717 Table A.1.2.
[14] Ventilation rate for a storeroom or cargo handling area (k) = 4, in accordance with NUREG 1717 Table A.1.2.

3. Inhalation Intake–Accidents

During a fire, an individual's intake from inhalation of airborne radioactive material (μCi) is given by

$$\mathbf{I_{Inh} = C \times BR \times t,} \qquad \mathbf{(5)}$$

Where t = time of exposure (h),

BR = breathing rate (m^3/h) = 1.2 m^3/h[15]

C = average concentration of airborne radioactive material ($\mu Ci/m^3$) over time, t.

Type of Enclosure	Avg. Concentration (C) ($\mu Ci/m^3$)	Breathing Rate (BR) (m^3/h)	Intake μCi t = 0.083 hour (5 min) Worker	Intake μCi t = 2 hour Firefighter[16] w/o SCBA (with SCBA)	Intake μCi t = 0.5 hour Firefighter[10] w/o SCBA (with SCBA)	Intake μCi t = 1 hour Firefighter[10] w/o SCBA (with SCBA)
Warehouse-1	1.5E-4	1.2	1.5E-5	3.6E-4 (3.6E-8)	--	--
Tractor trailer	1.4E-3	1.2	1.4E-4	--	8.4E-4 (8.4E-8)	--
End use	4.2E-5	1.2	4.2E-6	--	--	5E-5 (5E-9)
Small Repair Shop	3.5E-4	1.2	3.5E-5		2.1E-4 (2.1E-8)	--
Warehouse-2	1.63E-5	1.2	1.6E-6	3.9E-5 (3.9E-9)		

Table 4. Calculated intakes due to fires for the various enclosure types, for workers as well as firefighters. Firefighter intakes in parenthesis account for SCBA use.

4. Inhalation Dose (Workers)–Accidents

Internal dose is calculated by comparing the calculated intake to the stochastic ALI for ^{14}C in Appendix B to 10 CFR 20. This ALI is 2E+3 μCi. Using proportionalities:

$$\text{E.g., } x_{WH-1} = \frac{5000 \text{ mrem}}{2\text{E}{+}3\ \mu\text{Ci}} = \frac{x \text{ mrem}}{3.6\text{E}{-}8\ \mu\text{Ci}}$$

[15] NUREG-1717, section A.1.5, last paragraph.

[16] Fire fighters are presumed to be wearing self-contained breathing apparatus (SCBA) that provides an assigned protection factor of 10,000 against airborne particles. Refer to 10 CFR 20 Appendix A (Facepiece, full; Pressure demand.

$$x_{WH-1}\ \frac{(3.6\text{E}-8\ \mu\text{Ci})(5000\ \text{mrem})}{2\text{E}+3\ \mu\text{Ci}} = 4\text{E}-5\ \text{mrem}$$

$$x_{TT}\ \frac{(8.4\text{E}-8\ \mu\text{Ci})(5000\ \text{mrem})}{2\text{E}+3\ \mu\text{Ci}} = 4\text{E}-4\ \text{mrem}$$

$$x_{End\ use}\ \frac{(5\text{E}-7\ \mu\text{Ci})(5000\ \text{mrem})}{2\text{E}+3\ \mu\text{Ci}} = 1\text{E}-4\ \text{mrem}$$

$$x_{Shop}\ \frac{(2.1\text{E}-8\ \mu\text{Ci})(5000\ \text{mrem})}{2\text{E}+3\ \mu\text{Ci}} = 9\text{E}-5\ \text{mrem}$$

$$x_{WH-2}\ \frac{(3.9\text{E}\ \mu\text{Ci})(5000\ \text{mrem})}{2\text{E}+3\ \mu\text{Ci}} = 4\text{E}-6\ \text{mrem}$$

Type of Enclosure	**Intake (µCi) t = 0.083 hour Worker**	**Worker Dose mrem**
Warehouse-1	2,689	**4E-5**
Tractor trailer	22,908	**4E-4**
Residence-1	67	**1E-4**
Small Repair Shop	558	**9E-5**
Warehouse-2	1,295	**4E-6**

Table 5. Calculated internal doses to workers due to inhalation.

5. Inhalation Dose (Firefighters)–Accidents

Internal dose is calculated by comparing the calculated intake to the stochastic ALI for ^{14}C in Appendix B to 10 CFR 20. This ALI is 2E+3 µCi; firefighters are presumed to be wearing self-contained breathing apparatus (APF = 10,000). Using proportionalities:

$$\text{E.g., } x_{WH-1} = \frac{5000\ \text{mrem}}{2\text{E}{+}3\ \mu\text{Ci}} = \frac{x\ \text{mrem}}{3.6\text{E}{-}8\ \mu\text{Ci}}$$

$$x_{WH-1}\ \frac{(3.6\text{E}-8\ \mu\text{Ci})(5000\ \text{mrem})}{2\text{E}+3\ \mu\text{Ci}} = 9\text{E}-8\ \text{mrem}$$

$$x_{TT}\ \frac{(8.4\text{E}-8\ \mu\text{Ci})(5000\ \text{mrem})}{2\text{E}+3\ \mu\text{Ci}} = 2\text{E}-7\ \text{mrem}$$

$$x_{End\ use}\ \frac{(5\text{E}-9\ \mu\text{Ci})(5000\ \text{mrem})}{2\text{E}+3\ \mu\text{Ci}} = 1\text{E}-8\ \text{mrem}$$

$$x_{Shop}\ \frac{(2.1\text{E}-8\ \mu\text{Ci})(5000\ \text{mrem})}{2\text{E}+3\ \mu\text{Ci}} = 5\text{E}-8\ \text{mrem}$$

$$x_{WH-2}\ \frac{(3.9\text{E}-9\ \mu\text{Ci})(5000\ \text{mrem})}{2\text{E}+3\ \mu\text{Ci}} = 1\text{E}-8\ \text{mrem}$$

Type of Enclosure	**Intake (µCi) t = 2 hours**	**Dose (mrem) t = 2 hours**	**Intake (µCi) t = 0.5 hour Firefighter**	**Dose (mrem) t = 0.5 hour**	**Intake (µCi) t = 1 hour Firefighter**	**Dose (mrem) t = 1 hours**
Warehouse-1	(3.6E-8)	**9E-8**	--	--	--	--
Tractor trailer	--	--	(8.4E − 8)	**2E − 7**	--	--
End use	--	--	--	--	(5E-9)	**1E-8**
Small Repair Shop			(2.1E-8)	**5E-8**		
Warehouse-2	(3.9E-9)	**1E-8**				

Table 6. Summary of calculated internal doses to fire fighters for various exposure times due to inhalation. Intakes in parentheses indicate that the APF for SCBAs (10,000) has already been accounted for.

6. *Ingestion Intakes–Accidents*

As shown above, the doses due to inhalation are very small. Even assuming that the possible ingested quantity in each accident was equivalent to the inhaled quantity, the potential dose might be doubled (since the oral ingestion ALI = the inhalation ALI). Even then, any potential dose would be very small when compared to the guideline values listed in 10 CFR 32.28.

F. Basis for "Low Probability" and "Negligible Probability" Decision

1. Footnote 1 to 10 CFR 32.23 admits that "The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made."

2. An exhaustive search of the internet for accidents or incidents involving airborne particle detectors failed to uncover any such accidents or incidents. Since these devices contain radioactive material it is reasonable to expect that any such incident anywhere in the world would receive extensive media coverage. There have been no such reports.
3. It appears that the safety record of these devices over a period of over 20 years[17] is exemplary. We believe that this excellent safety record justifies putting the probabilities of any of these incidents actually occurring into the "negligible probability" category.
4. These are subjective evaluations and are based on the best evidence available.

G. Effectiveness of the Containment

10 CFR 32.23(c) requires that it be "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."

These devices are ruggedly constructed and are designed to be used in industrial settings. Based on the long and successful history of these types of devices (cited in G above), Thermo believes that a significant reduction in the effectiveness of the containment of these devices is extremely unlikely.

H. Conclusion

Based on the above analyses, Thermo is confident in stating, and believes that all available evidence supports the conclusions that:

1. In normal use and disposal of a **single exempt unit**, 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 § 32.24 of this part (i.e., 1 mrem);

2. 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

[17] A patent application dated 1992 was located at http://www.google.com/patents/US5349844.

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 II of the table in § 32.24 (i.e., 10 mrem).

3. 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.

4. In use and disposal of a **single exempt unit**, or 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 III of the table in § 32.24 (i.e., 500 mrem), 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 IV of the table in § 32.24 (i.e., 15,000 mrem).

Based on the above evaluation, we believe that the airborne particle detector being submitted for exempt distribution is unlikely to deliver any significant doses to any person under any set of reasonable circumstances.

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