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April 14, 2015

Sean Chapel, President
IRSC, Inc.
7 Cabot Pl., 3rd Floor
Stoughton, MA 02072 USA

Dear Sean,

Here are my responses to NRC's request for additional information, dated April 9, 2015. I note that there is no Mail Control number on this NRC letter.

Missing Information

1. 10 CFR 32.22(a)(2)(iv) requires the applicant to submit information pertaining to the solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2) (iii) and (xii) of this section.

The following statement appears in Section 5 on page 4 of the application:
"Tritium is soluble in water, but contact between tritium and water is not anticipated."
Please state the extent to which elemental gaseous tritium is soluble in water and in body fluids.

1. Answer. Tritium is very soluble in water and body fluid. In internal dosimetry, the concentration of the tritium in the urine is assumed to equal the concentration in the soft tissues of the body.[1] This is confirmed in numerous references.[2,3,4] Also, the ALI value for 3H in 10 CFR 20 Appendix B applies to all forms of the isotope: "Gas (HT or T_2) Submersion: Use above values as HT and T_2 oxidize in air and in the body to HTO."

2. 10 CFR 32.23(b) requires the applicant to demonstrate that "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

[1] Radiation Information Network's Tritium Information Section. Idaho State University, Pocatello, Idaho. http://www.physics.isu.edu/radinf/tritium.htm.
[2] International Commission on Radiation Protection Publication 30. (1979) *Limits for the Intakes of Radionuclides by Workers*. Oxford: Pergamon Press, ICRP, Part 1; Ann. ICRP.
[3] International Atomic Energy Agency.(1982) *Safe handling of Tritium: Safety Series No. 34*. Vienna. IAEA.
[4] NUREG 0938. (1992) "*Information For Establishing Bioassay Measurements and Evaluation of Tritium Exposure*". Washington, DC. NRC. http://pbadupws.nrc.gov/docs/ML1306/ML13060A351.pdf

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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."

Attachment I, "Dose Calculations: Gaseous Tritium Light Sources for Gun Sights (Revision 1)," appear to provide sufficient information and calculations to demonstrate that this requirement can be met; however, it appears that no statement to this effect is provided. Please provide this statement or indicate where it can be found in your application.

2. Answer. This wording was added to the report.

Accident Scenario Doses

The remaining questions concern the assumptions made in Attachment I.

Section D of Attachment I states that Armson is licensed for 200 Ci of ^{3}H, which (at 160mCi per set of sights) converts to 1,250 sets, and therefore that this is the maximum number of gun sights that might be in Armson's possession. Dose calculations for accident scenarios are based on the assumption that at any given time they are actually in possession of 80% (i.e., 1,000) of this "maximum number" of sight sets, with 800 sets located in a warehouse, 200 sets in the production area, and 200 sets that might be in transit to sellers in a single vehicle.

You considered six scenarios:

1) Dose to a warehouse worker and to a firefighter extinguishing a fire in a manufacturer's warehouse containing 800 sets (assumes that 5% (40) of the sets are destroyed in the fire).
2) Dose to firefighters extinguishing a tractor trailer fire, with the trailer containing 200 devices (assumes that 10% (20) of these sets are destroyed in the fire).
3) Dose to firefighters extinguishing a fire in an end use facility, assumed to be a private residence and containing 3 gun sights (assumes 100% destroyed).
4) Catastrophic release from crushing of a set of gun sights in a small repair shop (assumes 100% destroyed).
5) An accident involving the crushing of a set of gun sights in a home (assumes 100% destroyed).
6) A shipping accident in a storeroom or cargo-handling area involving the crushing of a shipment of 1000 gun sight sets (assumes 100% destroyed).

3. What is the basis for the assumption that Armson is "actually in possession of 80% of the maximum number" of gun sights (measured in curies) it is licensed to possess at any given time?

3. Answer. The postulated doses resulting from these scenarios have been recalculated assuming 100% release in all cases.

4. What is the basis for the assumption of 5% destroyed in scenario 1 and 10% destroyed in scenario 2? (If these are considered to be upper bounds, please explain why.)

4. Answer: We note that NRC does not take issue with the numbers of devices involved in Scenarios 2 through 5. We have recalculated Scenario 1 and 2 assuming 100% of the devices destroyed.

5. What is the basis for the assumption of an exposure time of 5 minutes, 2 hours, 0.5 hour, and 1 hour in the tables for inhalation intake?

5. Answer.

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 (resident) 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 applies to firefighters extinguishing a fire in a 100' x 100' x 9' high warehouse. 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[5] 2 hours would be more than enough time to put out a fire of this type.
c. The 0.5-hour time applies to firefighters extinguishing a fire in a tractor-trailer (10' x 40') and in a small watch repair shop (6.6' x 10' x 10' high). Thirty minutes is ample time to extinguish a fire in a room this size.
d. The 1-hour time applies to firefighters extinguishing a fire in a residence (2,000 ft^2 x 9' high). This is a relatively small dwelling and 1 hour was judged to be more than enough time to extinguish this fire.

[5] 3-day firefighter training school, attended twice in 3 years.

6. Scenario 6 assumes a much larger number of destroyed gun sights, which presumably was intended to provide an estimate of the upper bound on dose, but it is not clear why this number (1,000) was chosen. (Section 5 on page 4 of the application states that the estimated quantity of radioactive material to be distributed on an annual basis is about 1200 curies (44.4 TBq), which is about 7500 devices.) Given that Armson plans to distribute 7,500 gun sights per year, what is the basis for stating that the number that might accumulate in a storeroom or cargo-handling area is limited to 1,000?

6. Answer.

a. Scenario 6, a warehouse where somehow 1000 sets of gunsights are crushed and the entire quantity of ^{3}H is released, is intended to be an upper bound. NUREG 1717, section 2.14.5.5 Accidents and Misuse proposes the 1000 quantity, and this number was suggested in a letter from NRC dated November 14, 2014 (Mail Control No. 581174). We believe that this quantity is reasonable under the circumstances.
b. Since Armson's possession license is only for 200 Ci of ^{3}H (1,200 sets), the annual distribution of 7,500 sets does not apply to the accident dose analysis since that quantity will never be in Armson's possession at one time.

7. Section H, "Conclusion," of Attachment I, states: "Based on the information provided in this report, scenarios 1 through 5 are judged to have a low probability of occurrence. Scenario 6 is judged to have a negligible probability of occurrence based on the same information."

It does not appear that you have provided a basis for the "low" probability (1 in 10,000) or the "negligible" probability (1 in 1,000,000) of occurrence of any of the postulated accident scenarios. Instead, it appears that you have provided estimates of doses, and based on the magnitude of the doses, you concluded that since the maximum calculated dose according to any of the particular scenarios 1 through 5 is less than the value in Column III of the table in § 32.24, therefore the probability is low that the 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. Likewise, it appears that you concluded that since the maximum calculated dose according to scenarios 6 is less than the value in Column IV of the table in § 32.24, therefore the probability is negligible that the 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.

Given that the expected inventory of the product is relatively small, a more direct and convincing analysis could be to assume that all of the radioactive material in all of the units is released, and that all available radioactive material will be taken into the

body (or explain why it is not). If calculations based on such assumptions result in doses that do not exceed the appropriate values in the table in § 32.24, no further analyses would be necessary.

7. Answer.
   a. Basis for "Low Probability" and "Negligible Probability."
   An exhaustive search of the internet for accidents or incidents involving gaseous tritium light sources in the form of gun sights failed to uncover any such accidents or incidents. Since these sights 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.

   The first patent application that could be located for tritium-illuminated gun sights is dated May 13, 1990[6]. Therefore it appears that the safety record of these devices over a period of nearly 25 years 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.

   b. Calculations have been re-done to postulate 100% release of the ^{3}H from all devises involved in each incident. The numbers of sets of sights used in each scenario are the same as were used in the previous report.

Sincerely,

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Senior Health Physicist

[6] Appl. No.: 07/527,271**;** Inventor: Bindon, Glyn A. J. (Farmington Hills, MI); Filed: May 23, 1990.