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March 26, 2014

Justin A. Vazquez
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
11555 Rockville Pike
Rockville, MD 20852

RE: Reply to Letter Dated February 27, 2014
Request for Additional Information
Application for Exempt Device Registration
and
Distribution License
Docket No. 030-38702

Dear Mr. Vazquez,

Enclosed is our response to your letter dated February 27, 2014. For your convenience we have listed your questions with our answers.

If you have any questions please call me at 970.407.0426 or email me at phil@hivizsights.com

Sincerely,

Phillip Howe
CE

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Index of Attachments

Attachment A Series 1 - F01 Front Sights: Requested drawings for the Series 1 gunsights

Attachment A Series 1 - R01 Rear Sight: Requested drawings for the Series 1 gunsights

Attachment B Night Sight Data Sheet: Requested Table Cross-Referencing to Drawings

Attachment C Night Sights Exploded: Revised drawing correctly referring to "HZ" as the distributor

Attachment C Series 1 Text on Sights: Revised drawing correctly referring to "HZ" as the distributor

Attachment D Front Rear Photo: Revised image correctly referring to "HZ" as the distributor

Attachment D Rear Sight Photo: Revised image correctly referring to "HZ" as the distributor

Attachment E Form HZ-COC Certificate of Conformance: Requested Certificate of Conformance

Attachment F Questions from NRC: Requested Supplemental Dose Calculations

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Northpass, LLC Applications dated October 7, 2013 and October 9, 2013 Information Needed for Registration of Gunsight Series 1 and for Exempt-Distribution License

A. Questions Regarding Registration Certificate Application Request

Northpass, LLC application dated October 7, 2013, contained insufficient information as required by 10 CFR 32.210 and described in the relevant guidance document NUREG-1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration." Specific deficiencies include:

1. In your application, the sealed sources to be used in gunsight Series 1 are: mb microtec "Model 400 Series" (listed in Registration Certificate NY-1271-S-101-S), and SRB Techologies "Model MH, RH" (listed in Registration Certificate NC- 585-S-102-S). Please list the exact models numbers of sealed sources to be used from mb microtec. Registration Certificate NY-1271-S-101-S. Please note that Registration Certificate NY-1271-S-101-S lists six different models of sources (400/1, 400/2, 400/3, 400/4, 400/5 and 400/6). If all the models will be used for gunsights Series 1, please state so.

Hi-Viz sights will use mb microtec 400/1 sources.

2. Please provide engineering drawings for all 10 models of gunsight Series 1. The engineering drawing provided in Attachment E did not indicate the model of gunsights in Series 1. For example, clarify how a drawing designation such as "Dovetail Sight" corresponds to the models listed in Appendix B.

Enclosed as Attachment A are the requested drawings for the Series 1 gunsights. Note that we are requesting the gunsights be approved within a range of dimensions. Enclosed as Attachment B is a cross-reference table further clarifying the range of dimensions of gunsights within each model. The radionuclide, activity, source model, and materials of construction will remain the same across all Series 1 models. We request the flexibility to produce products within this range of dimensions without applying for an amendment to our exempt distribution license or device registration.

3. In your application, you stated that "gunsights are labeled with the Manufacturer Marking 'HV,' the letters 'H3' to indicate that the product contains tritium and an indication of the year of manufacturer, for example '13' for 2013." You also stated that Attachment F contained labeling information of the product. Please note that the information provided in Attachment F and also as shown

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on the drawings in Attachment E is inconsistent with your statement. Specifically, you stated that the device will be labeled with the Manufacturer Marking "HV," and Attachments E and F indicated that Manufacturer Marking is "VIZ", "HZ" or "HI." Please clarify this discrepancy.

We have finalized our decision to label all models as "HZ." Enclosed as Attachment C are revised drawings correctly referring to this labeling.

4. Please address the labeling requirements for each of the different models as required in 10 CFR 32.25(b). Guidance on labeling is available in Section 10.4 of Volume 3 of the NUREG-1556 series; please include information on the description of the labeling of the product, including information contained on the label, materials of construction of the label, and how and where the label is attached.

All labels will be laser etched into the metal creating permanent marking. No adhesive labels will be used. See Attachment D for the location of the labels.

5. In accordance with the guidance in NUREG-1556, Volume 3, Section 10.6, "Radiation Profiles," please include the maximum radiation levels around the product when it contains the maximum allowable quantity of each nuclide, or combination of nuclides for each model. Please include the maximum radiation levels on the surface of the product, at 5 cm, 30 cm, and 100 cm (2.0 in., 11.8 in., and 39.4 in.) from the product, and how the levels were measured/determined. If the measurements read background level, please state so.

The maximum radiation dose rate level around the product at 5 cm, 30 cm, and 100 cm (2.0 in., 11.8 in., and 39.4 in.) is at background levels. These are calculated values. It is not possible for the low energy beta particles to penetrate the glass of the source, nor can they penetrate the housing of the gunsight

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6. As part of the Quality Assurance (QA) program, in accordance with the guidance in NUREG-1556, Volume 3, Revision 1, Section 10.7, "Quality Assurance and Quality Control," please confirm that your QA program includes the following:

- **Full design conformity in accordance with the statements and commitments submitted in support of the application (including materials, dimensions within stated tolerances, manufacturing methods, assembly methods, labeling),**

- **What the final leak testing measurements are, and**

Final inspections, such as all units or statistical samples, are tested for proper operation of all safety features.

All units produced will be in compliance with our QA procedures.

We have initiated a lot wipe testing procedure of 42 units per 1000 produced. Gunsights have no moving parts to test. It would not be practical to conduct firing tests for units produced.

Each batch will be inspected for acceptable illumination by a 5% random sampling as specified in our QA manual.

Enclosed as Attachment E is a certificate of conformity which we intend to include with large volume shipments (>100 units).

B. Questions Regarding Exempt-Distribution License Application

Your application dated October 9, 2013 does not sufficiently address the requirements in 10 CFR 32.22, "Self-Luminous Products Containing Tritium, Krypton-85 or Promethium-147: Requirements for License to Manufacture, Process, Produce, or Initially Transfer," and described in the relevant guidance document NUREG-1556, Volume 8, "Program-Specific Guidance about Exempt Distribution Licenses."

1. **In accordance with 10 CFR 32.22(a)(2)(iii), please indicate any changes to the chemical and/or physical form of the byproduct material that may occur during the useful life of the devices. If there are no anticipated changes that will occur, please state so explicitly.**

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High purity H-3 is used in source production. There is no expected change in the physical form of the material during the product's useful life.

2. **In accordance with 10 CFR 32.22(a)(2)(iv), you must discuss the solubility in water and body fluids of the forms of the byproduct material used in your device. You have provided a statement in Item 5 of your application, and a reference to an external source. Please provide in more explicit detail an explanation pertaining to the solubility of tritium gas in water and body fluids.**

Once inhaled or ingested tritium gas rapidly oxidizes in the body into tritiated water, which is soluble in water and bodily fluids. It moves relatively quickly through the body and has a short biological half life of 10-12 days.

3. In accordance with 10 CFR 32.22(a)(2)(vi), you must provide the maximum radiation levels at 5 and 25 centimeters from any external surface of the product and the method of measurement. While in Attachment J, "Dose Calculations," you have indicated that the eternal dose rates are negligible, you have not discussed the radiation levels (i.e., exposure levels). Please provide this information.

Both the exposure rate and the dose rate are at background levels.

4. In accordance with 10 CFR 32.22(a)(2)(ix), please indicate the length of the expected useful life of the product.

In the original application we had listed the product life as 12 years, based upon the half-life of tritium. We have since revised it to 10 years as this is more of an industry standard.

5. In accordance with 10 CFR 32.23(a), you must demonstrate that, in normal handling/storage of either a single device or of multiple devices, it is unlikely that the external radiation dose in any 1 year, or the dose commitment resulting from the intake of radioactive material in any 1 year, will exceed, for a given individual, the doses specified in either Column I or Column II, respectively, of the table in 10 CFR 32.24. In Attachment J, "Dose Calculations," you indicate in the "Conclusion" section on Page 2 that "….[i]nternal dose, at a leak rate of 10 ppb/g, should be negligible and certainly less than [these limits]" Please explain how you arrived at this conclusion.

Please see Attachment F for our response.

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6. In accordance with 10 CFR 32.23(c), you must demonstrate that in the use and disposal of a single device, or in the handling and storage of typical quantities of multiple devices, 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 doses specified in Column III of the table in 10 CFR 32.24, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the doses specified in Column IV of that table.

Please see Attachment F for our response.

a. In Attachment J, "Dose Calculations," Selection D, "Accident Scenarios Considered," for Scenarios 1 and 2, you assume that 5 percent and 1 percent of devices, respectively, are destroyed in the conceived fire conditions. Please explain why these particular percentages were selected and why the probability of these scenarios is considered to be "low." Furthermore, please explain why the probability of Scenarios 4 and 5 are considered to be "low," and why the probabilities of Scenarios 3 and 6 are considered to be "negligible."

Please see Attachment F for our response.

b. In Attachment J, "Dose Calculations," Selection E, "Internal Dose Potential," Subsection 2, "Inhalation Intake and Dose" (Page 6), you have calculated the individual intake for the scenarios considered using Equation 4 from Appendix A of NUREG-1717 (Page A.1-2). However, instead of considering the average concentration during the period of individual exposure, you have used the values for instantaneous air concentration at the time t=1 h in your calculations. Please provide corrected calculations, incorporating the time-averaged value for air concentration over the period of time in which each considered individual is exposed.

Please see Attachment F for our response.