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

February 28, 2017

North Pass, Ltd. DBA HIVIZ Shooting Systems
ATTN: Mr. Phillip Howe
Chief Executive Officer
620 S Adams St.
Laramie, WY 82070

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, NORTH PASS, LTD. DBA HIVIZ SHOOTING SYSTEMS AMENDMENT REQUEST DATED DECEMBER 27, 2016

Dear Mr. Howe:

This letter is in response to your application dated December 27, 2016, requesting amendments to your Exempt Distribution License No. 49-35121-01E and Sealed Source and Device Registration Certificate NR-1382-D-101-E.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter you will find the list of the questions and items not addressed in your application.

Please be aware that upon your request, proprietary information submitted to the U.S. Nuclear Regulatory Commission (NRC) may be withheld from public disclosure. To do this, you must follow the procedures in Title 10 of the *Code of Federal Regulations* (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).

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Any correspondence regarding your amendment application should reference Control Number 592709.

If you have any questions, please contact Tomas Herrera at (301) 415-7138, or by e-mail at Tomas.Herrera@nrc.gov regarding the Sealed Source and Device Registration, and Richard Struckmeyer at (301) 415-5477, or by e-mail at Richard.Struckmeyer@nrc.gov regarding the Exempt Distribution License.

Sincerely,

/RA/

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Materials Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-38863
License No. 49-35121-01E

Enclosure:
Request for Additional Information

REQUEST FOR ADDITIONAL INFORMATION, NORTHPASS, LTD. DBA HIVIZ SHOOTING SYSTEMS AMENDMENT REQUEST DATED DECEMBER 27, 2016

DATE: February 28, 2017

Certified Mail No. 7015 3010 0000 7901 6192

ML17004A263 (pkg.) **ML17053A925(Letter)**

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Richard Struckmeyer	Debra Miller	Tomas Herrera	Lymari Sepulveda
DATE	02/22/2017	02/22/2017	02/23/2017	02/27/2017
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB		
NAME	Hipólito J. González	Richard Struckmeyer		
DATE	02/27/2017	02/28/2017		

OFFICIAL RECORD COPY

North Pass, Ltd. DBA Hi-Viz Shooting Systems Amendment Request dated December 27, 2016
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the North Pass, Ltd., DBA Hi-Viz Shooting Systems amendment request dated December 27, 2016, and determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your Sealed Source and Device amendment application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

The information related to review of your exempt-distribution license amendment application is required by 10 CFR 32.22, 32.23, and 32.24, and is described in the relevant guidance document NUREG-1556, Volume 8, titled "Program-Specific Guidance about Exempt Distribution Licenses."

A. Information Required for Review of Sealed Source and Device Amendment Application

General

1. Please include non-proprietary versions of the technical drawings in Attachment B that can be used in your Registration Certificate.

Description of the Product/Construction

2. The amendment request appears to indicate that North Pass, Ltd., DBA Hi-Viz Shooting Systems (North Pass) is requesting to add two different rear sights, the N3L-R01 and the N3S-R01. However, the amendment request also includes a statement that "There are 8 different front sight mounting styles and 1 different rear sight mounting style." The table in Attachment A of your amendment only refers to the model N3L-R01. Please clarify if North Pass is seeking to register the N3S-R01, and if it is, please include the dimensions and information provided in Attachment A.

3. Please clarify the statement in your amendment request, "and the dovetail mounting are the same as existing models." The drawings provided in the amendment request identify different types of mountain styles for the gun sights. Please identify the methods of how the gun sights will be attached to the firearms in the N3L and N3S Series.

4. Please state which of the tritium sources listed in your Registration Certificate you will use for the N3L and N3S Series of gun sights. Also, please state the number of sources per gun sight and the maximum activity per source.

5. Please identify the materials of construction for both the N3L and N3S Series of gun sights, and discuss any potential for corrosion between unlike materials. The materials of construction should also include the type of material used for the gun sights.

6. Please describe the differences and similarities between the N3L and N3S Series of sights.

7. Please confirm that the dimensions stated in the table in Attachment A are all in inches.

8. Please confirm that the activities listed in the table in Attachment A are in millicuries, not in GBq.

9. Please identify the adhesives used in the assembly processes for the N3L and N3S series of sights.

10. Please address the maximum radiation levels per 10 CFR 32.22(a)(2)(vi) and the maximum dose commitments per 10 CFR 32.22(a)(2)(xiii) and (xiv).

Labeling

11. Please confirm that there have been no changes to the labeling, as stated in NR-1382-D-101-E.

Conditions of Use

12. Please provide the estimated working life of the gun sights.

13. Please provide the maximum allowable temperature, vibration, and shock to which the gun sights may be subjected.

Prototype Testing

14. Please provide the model numbers and dimensions of the devices used for prototype testing. In addition to providing the dimensions for the prototypes that were tested, please provide the rationale used for selecting the dimensions that were tested.

15. Provide the Pass and Fail criteria for all the prototype tests conducted for the N3L Series and gun sights.

16. We note that only the N3L series were subjected to the prototype tests. The N3S series gun sights appear to be similar in design, however the N3S Series uses two “Lite Pipes” instead of one used in the N3L Series. Please explain the rationale of not testing the N3S Series.

17. Volume 8 of NUREG-1556 states that at least five gunsights (of each model) are to be subjected to each of the test and the same gunsights are to be used for each test. We noted that only one front and rear model gun sight from the N3L Series were subjected to the Mechanical Shock test. Please explain the rationale for only testing one front and rear model gun sight from the Series.

Quality Assurance

18. Please confirm that there have been no changes to the commitments made in NR-1382-D-101-E regarding North Pass's quality assurance program.

B. Information Required for Review of Exempt Distribution License Amendment Application

10 CFR 32.22(a)(2) requires the applicant to submit sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the self-luminous product to demonstrate that the product will meet the safety criteria set forth in § 32.23. Your application describes models containing tritium tubes with activity levels that are higher than those approved for your original license. Therefore you should provide responses to the requirements of sections 32.22 and 32.23 of 10 CFR 32, as stated in the following paragraphs. You may reuse previously submitted information where such information is applicable to specific requirements.

1. 10 CFR 32.22(a)(2)(i) requires the applicant to submit a description of the product and its intended use or uses. Please confirm that the intended use of the product does not differ from that described in your original application for a new license.

2. 10 CFR 32.22(a)(2)(ii) requires the applicant to submit the type and quantity of byproduct material in each unit. Please confirm that the type of byproduct material does not differ from that described in your original application for a new license.

3. 10 CFR 32.22(a)(2)(iii) requires the applicant to submit the chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product. Please confirm that the chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product do not differ from that described in your original application for a new license.

4. 10 CFR 32.22(a)(2)(iv) requires the applicant to submit 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. Please confirm that the solubility in water and body fluids of the byproduct material does not differ from that described in your original application for a new license.

5. 10 CFR 32.22(a)(2)(v) requires the applicant to submit details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product. Please confirm that the construction and design of the product provides an equivalent or better degree of containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product as described in your original application for a new license.

6. 10 CFR 32.22(a)(2)(vi) requires the applicant to submit the maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement. Please provide this information based on the increased activity levels in your amendment application. Your response to this requirement may be provided in conjunction with question A.10.

7. 10 CFR 32.22(a)(2)(vii) requires the applicant to submit information about the degree of access of human beings to the product during normal handling and use. Please confirm that the degree of access of human beings to the product during normal handling and use is at least as restrictive as that described in your original application for a new license.

8. 10 CFR 32.22(a)(2)(viii) requires the applicant to submit the total quantity of byproduct material expected to be distributed in the product annually. Please provide this information based on the increased activity levels in your amendment application.

9. 10 CFR 32.22(a)(2)(ix) requires the applicant to submit information about the expected useful life of the product. You may respond to this requirement as part of your answer to question A.12, but with emphasis on the effect that the radioactive material has on the useful life.

10. 10 CFR 32.22(a)(2)(x) requires the applicant to submit the proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product. Please confirm that the labeling or marking of each unit does not differ from that described in your original application for a new license. Your response to this requirement may be provided in conjunction with question A.11.

Responses to the following two requirements (32.22(a)(2)(xi) and 32.22(a)(2)(xii)) may be made in conjunction with questions A.14 through A.17. Unless your procedures have changed, it is not necessary to resubmit them.

11. 10 CFR 32.22(a)(2)(xi) requires the applicant to submit procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product. Please confirm that the procedures for prototype testing do not differ from those described in your original application for a new license.

12. 10 CFR 32.22(a)(2)(xii) requires the applicant to submit results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features. If the prototype test results for the products described in this amendment request differ from those described in your original application for a new license, please state any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features. Otherwise, please confirm

that the prototype test results for the products described in this amendment request do not differ from those described in your original application for a new license

13. 10 CFR 32.22(a)(2)(xiii) requires the applicant to submit the estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.23 and the basis for such estimates, and 10 CFR 32.22(a)(2)(xiv) requires the applicant to submit a determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph. Please provide this information based on the increased activity levels in your amendment application.

14. 10 CFR 32.22(a)(2)(xiv) requires the applicant to submit a determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph. Please provide this information based on the increased activity levels in your amendment application.

15. 10 CFR 32.22(a)(2)(xv) requires the applicant to submit quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet. Your response to this requirement may be provided in conjunction with question A.18.