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

July 31, 2015

Triple, Inc. DBA Nixon
ATTN: Joe King
701 South Coast Highway
Encinitas, CA 92024

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING TRIPLE, INC. EXEMPT DISTRIBUTION LICENSE APPLICATION AND SEALDED SOURCE AND DEVICE REGISTRATION CERTIFICATE APPICATION

Dear Mr. King:

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Triple, Inc. application dated May 6, 2015, for a new exempt distribution license (Agencywide Documents Access and Management System (ADAMS) accession no. ML15135A407) and a new sealed source and device registration certificate (ADAMS accession no. ML15135A406). The staff has determined that additional information is needed. In order to continue with our review, please address the issues listed in the enclosure.

Any correspondence regarding your application should reference the control number specified below. Please submit the requested information within 30 days of the date of this letter. If we have not received complete information within 30 days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete 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 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/NRC/ADAMS/index.html (the Public Electronic Reading Room).

If you have any questions regarding the Sealed Source and Device Registration you can contact Tomas Herrera at (301) 415-7138 or by email at Tomas.Herrera@nrc.gov. For questions related to the exempt distribution license, please contact me at (301) 415-6004 or email at Hector.Rodriguez-Luccioni@nrc.gov.

Sincerely,

/RA/

Hector Rodriguez-Luccioni, Ph.D.
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-38834
Mail Control No. 586788

If you have any questions regarding the Sealed Source and Device Registration you can contact Tomas Herrera at (301) 415-7138 or by email at Tomas.Herrera@nrc.gov. For questions related to the exempt distribution license, please contact me at (301) 415-6004 or email at Hector.Rodriguez-Luccioni@nrc.gov.

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Materials Safety Licensing Branch
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Docket No. 030-38834
Mail Control No. 586788

ML15203A565 (RAI) - Certified Mail Tracking Number: 7014 0510 0000 4426 4912

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Hector Rodriguez-Luccioni	Shirley Xu	Maria Arribas-Colon	Tomas Herrera
DATE	07/ 22 /2015	07/29/2015	07/29/2015	07/29/2015
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB		
NAME	Hipolito Gonzalez	Hector Rodriguez-Luccioni		
DATE	07/30/2015	07/31/2015		

OFFICIAL RECORD COPY

Joe King
Triple, Inc. DBA Nixon
030-38834

A. REQUEST FOR ADDITIONAL INFORMATION REGARDING EXEMPT DISTRIBUTION LICENSE AND SEALED SOURCE AND DEVICE REGISTRAITON (SSD) CERTIFICATE

1. In your exempt distribution license application, on page 4, you stated that the maximum activity per watch is 80.1 mCi under "Description of radioactive sources" and 81.43 mCi under "Estimated quantity of radioactive material to be distributed on an annual basis." In a table that you provided on page 6, you stated that the maximum activity per watch is 81.61 mCi. The dose calculation in Attachment K states that the total activity per watch is 100 mCi. In your SSD application you stated that the H-3 maximum activity for the Model Night Ranger watch is 81.1 mCi. However, the testing report in Attachment F indicated that the prototypes contained 81.43 mCi of H-3. Please clarify the quantity of byproduct material in each Model Night Ranger, and include the tolerances. Please provide a detailed table (similar to Table 1, located Attachment F, Page 3 of SSD application) with the source tube specifics to be included in the Registration Certificate.

2. In your exempt distribution license application, on page 7, you stated that each watch will be labeled as "T181," industry standard meaning "Tritium, 81 mCi." The watch diagrams included in Attachments G and I, show the watch labeled as "T81." Attachment H, "Prototype Testing," has diagrams showing that the watch is labeled as "T100."

   a. Please clarify the proposed method of labeling or marking each unit.

   b. Please clarify which industry standard you are following for the labeling.

   c. Please clarify if you will be distributing Night Ranger "T81" and Night Ranger "T100."

   d. Provide the dimension for the labeling mark.

3. In Attachment H of the exempt distribution license application and in Attachment F of the SSD application, you provided the prototype testing for the Night Ranger watches. In Figure 1, on page 3 of 45 of the report the watch is labeled as "T100" instead of the "T81" that was requested in the application. Please describe the differences between watches marked "T100" and "T81".

B. REQUEST FOR ADDITIONAL INFORMATION REGARDING EXEMPT DISTRIBUTION LICENSE

This information is required by 10 CFR 32.22, “Self-luminous products containing tritium, krypton or prometrhium-147: Requirements for license to manufacture, process, produce, or initially transfer,” and described in the relevant guidance document NUREG-1556 Volume 8 titled “Program-Specific Guidance about Exempt Distribution Licenses.”

1. As required by 10 CFR 32.22(a)(2)(iii), please provide 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.

2. In your application you sated that tritium in gaseous form has a low radiotoxicity. As required by 10 CFR 32.22(a)(2)(iv), please provide the solubility in water and body fluids of tritium gas.

3. As required by 10 CFR 32.22(a)(2)(vi), please provide 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.

4. As required by 10 CFR 32.22(a)(2)(ix), please provide the expected useful life of the product.

5. On page 8 of Attachment K, “Dose Calculations,” you stated that Nixon is licensed for 300 Ci of H-3, which converts to 3,000 watches. Your first accident scenario is a fire in a warehouse with 1,200 watches. Please explain the basis for using 1,200 watches instead of 3,000 watches.

6. Table 5 on page 13 of Attachment K, “Dose Calculations,” you provided the values for the intake for workers (residents). The values on this table does not match the values calculated on page 12 (Table 4). Please review the calculations and provide the tables with the correct values.

7. On page 17 of Attachment K, “Dose Calculations,” you provided the ingestion doses for firefighters for different accident scenarios. After reviewing the calculations it was noted that the ingestion doses calculations and the inhalation doses calculations on page 14 are exactly the same. Please explain and provide the basis for stating that the inhalation and ingestions doses are the same for each accident scenario.

8. In Attachment K, “Dose Calculations,” you stated that the probability is low for a person to 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 32.24 (i.e. 500 mrem). Your Total Effective Dose Equivalent (TEDE) calculations on page 18 show accident situations where a person will receive a dose higher than 500 mrem. Please explain the basis for stating that the possibility of receiving this higher doses are low.

C. REQUEST FOR ADDITIONAL INFORMATION REGARDING SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

In order to continue with our review, please address the issues listed below. This information is required by 10 CFR 32.210 and described in the relevant guidance document NUREG-1556 Volume 3 titled "Applications for Sealed Source and Device Evaluation and Registration."

General

1. In your application, you referred to the watch model as "Night Ranger", however there were other references within the application as "Part Number A93600", "T81", and "T100." Please state the exact model number that should be listed in the Registration Certificate.

Description/Construction

2. Please confirm how many tritium tubes will be used in the Night Ranger watches and confirm the location of the tubes.

3. Please provide the source assembly details that includes how the sources will be mounted/attached and secured in the watch.

4. Please provide details of the watch tamper-resistance features.

5. Please discuss the corrosion compatibility between the materials used in the construction of the Model Night Ranger watch.

Conditions of Use

6. Provide the estimated working life for the Model Night Ranger watch.

Quality Assurance

7. In your application, you provided Bonding Company Limited (located in China) QA/QC Program. Please note that you must provide Triple, Inc. DBA Nixon (U.S. Distributor) QA/QC Program. Triple, Inc. DBA Nixon must ensure that the product is manufactured and distributed in accordance with the representations made in your application, and the statements contained in the registration certificate for the product. At a minimum, your QA/QC program needs to ensure that: (a) the materials of construction and the final assembly meet the design specifications; (b) the final product is leak tested; (c) a final radiation profile is performed; (d) a test that verifies the product operates as intended, including all safety functions, is performed; and (e) a visual and mechanical inspection of components that are considered critical to safety or are expected to be susceptible to failure under extreme or unusual conditions must be performed.

   In addition, because you are affiliated with a foreign manufacturer, then it is your responsibility to assess Bonding Company Limited (located in China) QA/QC program performance in accordance with your established procedures, accepted standards, or guides. Triple, Inc. DBA Nixon must have an established program for assessing Bonding

Company Limited QA/QC program at a frequency necessary to assure quality assurance is met. Triple, Inc. DBA Nixon also must maintain records of such audits for future regulatory review.

Copies of all records must be maintained in the U.S. as specified by the provisions of 10 CFR 110.53(b). With every lot of the product, the foreign manufacturer must forward, to the U.S. distributor, (a) the leak test results and (b) copies of documents certifying that the QA/QC commitments made in the application have been met. The records must be reviewed and approved by the U.S. distributor before the release of the lot. Other QA/QC records must be forwarded to the U.S. location on a periodic basis and must be available upon request in a reasonable time.

8. In Attachment I, you provided the Inspection Procedure for the watches upon receipt from the manufacturer. The procedure had hand written corrections and do not seem to be a final copy. NRC cannot accept drafts, please provide a final copy of the Inspection Procedure.