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

September 21, 2015

Triple, Inc. DBA Nixon
ATTN: Joe King
Global Quality Senior Manager
Radiation Safety Officer
701 South Coast Highway
Encinitas, CA 92024

SUBJECT: SECOND 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. letter dated August 17, 2015, Agencywide Documents Access and Management System (ADAMS) accession no. ML15135A407, which responds to our first request for additional information dated July 31, 2015 (ADAMS accession no. ML15203A565). 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 Maria Arribas-Colon at (301) 415-6026 or by email at Maria.Arribas-Colon@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 Maria Arribas-Colon at (301) 415-6026 or by email at Maria.Arribas-Colon@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,

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Office of Nuclear Material Safety
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Docket No. 030-38834
Mail Control No. 586788

SSD Case 15-33

ML15253A597 **Certified Mail Tracking Number: 7014 0510 0000 4426 4868**

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	09/10/2015	09/17/2015	09/17/2015	09/18/2015
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB		
NAME	Hipolito Gonzalez	Hector Rodriguez-Luccioni		
DATE	09/18/2015	09/18/2015		

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Joe King
Triple, Inc. DBA Nixon
030-38834

A. 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. In our letter dated July 31, 2015, we requested a review of the calculations and values for the intake for workers (residents) on Table 5 of Attachment K, "Dose Calculations," of your application dated May 6, 2015. In your letter dated August 17, 2015, you provided Table 5, Rev.1, "Calculated internal doses to workers (residents) due to inhalation," with new revised values. The values for Warehouse-1 and Warehouse-2 on Table 5, Rev. 1, does not match the values calculated on Table 4 of Attachment K of your application dated May 6, 2015. Please review the values and calculations, and provide a table with the corrected values.

2. In our letter dated July 31, 2015, we requested the basis for stating that the possibility of receiving 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) is low. In your letter dated August 17, 2015, you stated "The requirement of 10 CFR 32.23 is that "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 10 CFR 32.24. Therefore, it is highly unlikely that a person would receive a dose in excess of 500 mrem." Your response is not sufficient, please provide the basis and your analysis for stating that the probability of a failure of your product causing a dose in excess of 500 mrem is low.

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

1. In your response to NRC Question 8, letter dated August 17, 2015, you provided a revised version of the procedure titled "INSPECTION OF WATCHES UPON RECEIPT," we noted that in the original submission dated May 8, 2015, the title of "QA Director Approval" was changed with the title of "Chief Operating Officer." In the version submitted in your August 17, 2015, letter the title was reverted back to "QA Director Approval" and did not have the approval signatures. Please confirm that the title of the officer that approved the procedure. If the procedure was approved by the "Chief Operating Officer," please submit a revised signed version that correctly reflects Nixon's approval process.