



CAMP CO
WWW.CAMP CO.COM

4625 W. Jefferson Blvd. Los Angeles, CA 90016
Tel.#(323)766-2555 Fax#(323)766-2424

February 16, 2017

Pamela J. Henderson
Deputy Director
Division of Material Safety, State, Tribal and Rulemaking Programs Office of Nuclear Material
Safety and Safeguards
US Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852

RE: Reply to Letter Dated January 23, 2017

Dear Ms. Henderson:

Below is our reply to your letter dated January 23, 2017. For your convenience we have listed your comments from your December 20, 2016 along with our response.

- 1. The President of Campco will submit an article via social media (e.g, Facebook, Twitter) to consumers of tritium watches.**
 - a. Within 6 months, the President of Campco will submit a draft of the article to NRC for review and approval.**
 - b. The article will summarize the existence of NRC and Agreement State requirements for watches containing tritium, emphasize the importance of compliance with NRC and Agreement State requirements, and raise awareness of a potential consumer safety hazard for non-compliant watches.**

To CampCo Facebook and Twitter Accounts:

Dear Friends:

The manufacture and distribution of tritium watches for sale in the United States is regulated by the U.S. Nuclear Regulatory Commission. Watch distributors selling watches containing less than 25 millicuries of tritium are required to have a US NRC Exempt Distribution License. Watch distributors selling watches containing greater than 25 millicuries of tritium are also required to have a device registration in addition to an exempt distribution license.

A US importer of foreign made watches must first import them through a licensed domestic US facility before they can be distributed in the US (no drop shipping).

The distribution of tritium watches is licensed under NRC regulation 10 CFR 32.22. In summary, some basic requirements for tritium watches are that the applicant provide a description of:

- The product and its intended use
- The type and quantity of radioactive material (tritium) in each unit
- The chemical and physical form of tritium in the product and changes in chemical and physical form that may occur during the useful life of the product
- The solubility in water and body fluids of the forms of tritium
- The details of construction and design of the product as related to containment and shielding of the tritium, and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product
- 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
- The degree of access of the user to the tritium during normal handling and use
- The total quantity of tritium expected to be distributed in the product annually
- The expected useful life of the product
- 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
- The 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
- The 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
- The estimated external radiation doses and dose commitments relevant to the safety criteria in regulation 10 CFR 32.23 (potential product use doses) and the basis for such estimates
- A determination that the probabilities with respect to the doses referred to in § 32.23(d) (accidental doses) meet the criteria of that paragraph
- 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
- Any additional information, including experimental studies and tests, required by the NRC

Both the manufacturer and distributor of the watches, whether foreign or domestic, are required to have a written Quality Assurance Program (QA). The QA program of the manufacturer is required to meet NRC guidelines, which are similar to the ISO 9001 Certification Program (though ISO 9001 registration is not a specific requirement). Watches must also be manufactured according to industry standards, as specified by license conditions or other commitments made in the license application. It is the responsibility of the US distributor to audit the QA program of the manufacturer in order to demonstrate that they are carrying out the commitments made in their written QA program.

In addition to NRC licensing, a radioactive materials possession license is issued by the state they are operating in (if it is an Agreement State), or by the NRC if a non-Agreement State. The possession license dictates how the radiation safety program will be run for storage, handling, and distribution of the watches.

It is important to comply with NRC and Agreement States requirements as to not do so can result in violations, civil penalties (fines), or potential radiation dose through accident conditions.

CampCo maintains licenses with the US NRC and the California Department of Public Health, Radiological Health Branch.

- 2. The President of Campco will send written notification to watch manufacturers and assemblers in China, and other international locations as identified by Campco.**
 - a. Within 6 months, the President of Campco will submit a draft of the notification to NRC for review and approval, and will submit to NRC a list of proposed recipients.**

Proposed recipients:

Bonding Company, Ltd.

Betaglo Technologies (H.K.), Limited

Betalight B.V.

Mb microtec/Tracer Watches

NTP Radioisotopes SOC Ltd.

Smith and Wesson

Smolsys Ltd.

Dear Friends:

The manufacture and distribution of tritium watches for sale in the United States is regulated by the U.S. Nuclear Regulatory Commission. Watch distributors selling watches containing less than 25 millicuries of tritium are required to have a US NRC Exempt Distribution License. Watch distributors selling watches containing greater than 25 millicuries of tritium are also required to have a device registration in addition to an exempt distribution license.

A US importer of foreign made watches must first import them through a licensed domestic US facility before they can be distributed in the US (no drop shipping).

The distribution of tritium watches is licensed under NRC regulation 10 CFR 32.22. In summary, some basic requirements for tritium watches are that the applicant provide a description of:

- The product and its intended use
- The type and quantity of radioactive material (tritium) in each unit
- The chemical and physical form of tritium in the product and changes in chemical and physical form that may occur during the useful life of the product
- The solubility in water and body fluids of the forms of tritium
- The details of construction and design of the product as related to containment and shielding of the tritium, and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product
- 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
- The degree of access of the user to the tritium during normal handling and use
- The total quantity of tritium expected to be distributed in the product annually
- The expected useful life of the product
- 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

- The 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
- The 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
- The estimated external radiation doses and dose commitments relevant to the safety criteria in regulation 10 CFR 32.23 (potential product use doses) and the basis for such estimates
- A determination that the probabilities with respect to the doses referred to in § 32.23(d) (accidental doses) meet the criteria of that paragraph
- 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
- Any additional information, including experimental studies and tests, required by the NRC

Both the manufacturer and distributor of the watches, whether foreign or domestic, are required to have a written Quality Assurance Program (QA). The QA program of the manufacturer is required to meet NRC guidelines, which are similar to the ISO 9001 Certification Program (though ISO 9001 registration is not a specific requirement). Watches should also be manufactured according to industry standards. It is the responsibility of the US distributor to audit the QA program of the manufacturer in order to demonstrate that they are carrying out the commitments made in their written QA program.

In addition to NRC licensing, a radioactive materials possession license is issued by the state they are operating in (if it is an Agreement State), or by the NRC if a non-Agreement State. The possession license dictates how the radiation safety program will be run for storage, handling, and distribution of the watches.

It is important to comply with NRC and Agreement States requirements as to not do so can result in violations, civil penalties (fines), or potential radiation dose through accident conditions.

CampCo maintains licenses with the US NRC and the California Department of Public Health, Radiological Health Branch.

- b. The notification will summarize the violations issued to Campco, the existence of NRC requirements for watches containing tritium, the existence of An Agreement State program, and the importance of compliance with NRC and Agreement State requirements.**

On July 27, 2015 the NRC issued a letter to CampCo detailing four apparent violations:

1. Distributing watches containing tritium (Hydrogen-3) without obtaining an amendment for CampCo's existing license, or obtaining a separate exempt distribution license for these watches, prior to transferring the watches containing byproduct material to persons exempt from use.
2. Failing to submit timely required annual reports to the NRC, as required by 10 CFR 32.16(c) (1)
3. Failing to provide required information in the annual reports, when the reports were provided upon NRC request

4. Failing to provide certificates, required by the CampCo license, with each lot distributed.

For clarification, CampCo was issued apparent violations for not informing the NRC regarding a change in the use of radioactive source suppliers prior to distribution of watches containing these sources. CampCo had previously sent the NRC notification, but it was not processed due to CampCo unfamiliarity with the licensing protocols at the NRC and who the correct contact persons were.

CampCo was informed by the NRC that the annual reports which were previously provided had not been received, and did not contain sufficient content (this is a common problem among exempt distribution licensees, so much so that the NRC put out a memo about the exact content they want to see in reports).

CampCo is now compliant in sending the required certificates with its products.

3. The President of Campco will submit an article for industry publication.

- a. **Within 1 year, the President of Campco will submit a draft of the article to NRC for review and approval, and will submit to the NRC a list of proposed recipients.**
- b. **The article will summarize the existence of NRC and Agreement State requirements for watches containing tritium and emphasize the importance of compliance with NRC and Agreement State requirements.**

Names for trade publications: Soldier of Fortune, International Watch Magazine and Gun Trade World.

Dear Friends:

The manufacture and distribution of tritium watches for sale in the United States is regulated by the U.S. Nuclear Regulatory Commission. Watch distributors selling watches containing less than 25 millicuries of tritium are required to have a US NRC Exempt Distribution License. Watch distributors selling watches containing greater than 25 millicuries of tritium are also required to have a device registration in addition to an exempt distribution license.

A US importer of foreign made watches must first import them through a licensed domestic US facility before they can be distributed in the US (no drop shipping).

The distribution of tritium watches is licensed under NRC regulation 10 CFR 32.22. In summary, some basic requirements for tritium watches are that the applicant provide a description of:

- The product and its intended use
- The type and quantity of radioactive material (tritium) in each unit
- The chemical and physical form of tritium in the product and changes in chemical and physical form that may occur during the useful life of the product
- The solubility in water and body fluids of the forms of tritium
- The details of construction and design of the product as related to containment and shielding of the tritium, and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product
- 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

- The degree of access of the user to the tritium during normal handling and use
- The total quantity of tritium expected to be distributed in the product annually
- The expected useful life of the product
- 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
- The 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
- The 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
- The estimated external radiation doses and dose commitments relevant to the safety criteria in regulation 10 CFR 32.23 (potential product use doses) and the basis for such estimates
- A determination that the probabilities with respect to the doses referred to in § 32.23(d) (accidental doses) meet the criteria of that paragraph
- 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
- Any additional information, including experimental studies and tests, required by the NRC

Both the manufacturer and distributor of the watches, whether foreign or domestic, are required to have a written Quality Assurance Program (QA). The QA program of the manufacturer is required to meet NRC guidelines, which are similar to the ISO 9001 Certification Program (though ISO 9001 registration is not a specific requirement). Watches should also be manufactured according to industry standards. It is the responsibility of the US distributor to audit the QA program of the manufacturer in order to demonstrate that they are carrying out the commitments made in their written QA program.

In addition to NRC licensing, a radioactive materials possession license is issued by the state they are operating in (if it is an Agreement State), or by the NRC if a non-Agreement State. The possession license dictates how the radiation safety program will be run for storage, handling, and distribution of the watches.

It is important to comply with NRC and Agreement States requirements as to not do so can result in violations, civil penalties (fines), or potential radiation dose through accident conditions.

CampCo maintains licenses with the US NRC and the California Department of Public Health, Radiological Health Branch.

If you have any questions please call me at 323.766.2555 or email me at motti@campco.com.

Sincerely,



Motti Slodowitz
President

P

US POSTAGE AND FEES PAID
FEB 16 2017 Mailed from ZIP 90016
PM Flat Rate Envelope
Commercial Base Price



endicla.com

071V00839956

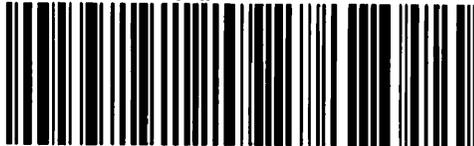
PRIORITY MAIL 2-DAY

CampeCo
4625 W Jefferson Blvd
Los Angeles, CA 90016 - 4006

C048 0006

SHIP TO: **ATTN: PAMELA J. HENDERSON
US NUCLEAR REGULATORY COMMISSION
11545 Rockville Pike
Rockville, MD 20852-2746**

USPS TRACKING #



9405 5102 0088 2311 6348 62