



CAMP CO
WWW.CAMP CO.COM

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

May 24, 2017

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738

RE: Reply to Letter Dated April 20, 2017

Dear Ms. Henderson:

Below is our response providing the three revised draft articles that will be submitted to social media, manufacturers, and watch industry publications as required by items 1, 2, and 3 of the Confirmatory Order for your review. The social media article will only be submitted to our Facebook accounts CampCo Inc, UZI Gear and Smith and Wesson watches. We were unaware that Twitter limits Tweet lengths to 140 characters, therefore we are unable to post the article on Twitter.

To CampCo Facebook 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, and civil penalties (fines). In addition, it is important to obtain tritium watches only from authorized dealers, and use of non-compliant watches could pose safety hazards. If not manufactured correctly, non-compliant watches could result in unintended radiation doses to consumers and the public, as well as potential radio-logical contamination.

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

- 1. 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.**

After reviewing the original proposed recipients in our letter dated February 16, 2017 we have reduced them to only the direct manufacturers and assemblers in China that CampCo sources for our tritium timepieces:

Betaglo Technologies (H.K.), Limited

Mb microtec/Tracer Watches

Herofame Industrial Limited

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, and civil penalties (fines).

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 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.

2. 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.**

We have identified the most effective publication for our industry is **Surplus Today**.

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, and civil penalties (fines).

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