

# Radiation Safety Regulatory Training, NRC Requirements

Campco

May 19, 2017



# Regulation

- The use and distribution of tritium watches is licensed under NRC regulations:
  - 10 CFR 32.14
  - 10 CFR 30.15
  - 10 CFR 32.22

# Required Authorizations

- In order to distribute tritium watches, up to three authorizations are required:
- A device registration, unless you are below the activity limit listed in 10 CFR 30.15(a) (**understood to be 100mCi of activity**)
- A US NRC exempt distribution license
- A possession license incident to exempt distribution. Issued by An Agreement State, or the NRC if you are in an NRC state

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

## Continuation of tritium watch distribution requirements:

- 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

## Continuation of tritium watch distribution requirements:

- 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 , 10 CFR 32.25(a)
- Any additional information, including experimental studies and tests, required by the NRC

# License amendments

- You must keep your US NRC exempt distribution license current, in regards to:
  - The company name
  - Mailing Address and location of use
  - Manufacturers and Model numbers of products to be distributed
  - Manufacturers and models of sources used in products
  - Any other changes in the terms and conditions of your license

# License amendments

- License amendment must be send in writing to the NRC. In the past the NRC required duplicate hard copies, but they now seem open to only having single copies
- You may supplement hard copy reports with an emailed copy. Mr. Tomas Herrera has accepted emailed reports before at [Tomas.Herrera@nrc.gov](mailto:Tomas.Herrera@nrc.gov)
- Although they are required to be sent to the NRC's official mailing address in Washington DC, regulators have asked clients in the past to send correspondence directly to NRC in Rockville, MD



# License Conditions

- 10. Each lot of timepieces, hands and dials received, containing tritium for distribution pursuant to 10 CFR 30.15, must be accompanied by a certificate which attests to the following:
  - A. Timepieces, hands, and dials have been manufacturer in accordance with the International Atomic Energy Agency, International Standards Organization, OECD Nuclear Energy Agency, American National Standards Institute, or equivalent industry standard, and
  - B The amount of tritium on the timepieces does not exceed the maximum permissible amounts in 10 CFR 30.15(a)

# License Conditions

- 11 You must maintain a possession license
- 12 Distribution may only occur from 4625 West Jefferson Blvd. (no drop shipping directly from a foreign manufacturer to the end user)
- 13 omitted on the license
- 14 file annual reports as per 10 CFR 32.16

# License Renewal

- NRC licenses expire every 10 years
- 60 days prior to expiration you should receive a letter informing you that your license will expire
- You must submit a renewal application at least 30 days in advance of expiration

# Timely Renewal Letter

- After you have submitted your renewal application, you will receive a timely renewal letter which allows you to continue to operate after the expiration of your license

# Annual Transfer Reports

- Required under 10 CFR 32.16
- Every year you must submit the annual exempt distribution report
- Reports are due by January 31 for the previous calendar year
- See NRC REGULATORY ISSUE SUMMARY 2014-10 REQUIREMENTS FOR EXEMPT DISTRIBUTION LICENSEE ANNUAL TRANSFER REPORTS

Licensees transferring products under 10 CFR 32.14 must include the following information in their annual transfer reports:

- identification of the licensee, including the license number of the licensee;
- indication that the products are transferred for use under 10 CFR 30.15, giving the specific paragraph designation (for example, 10 CFR 30.15(a)(8) for electron tubes), or equivalent Agreement State regulation(s);
- • a description and/or identification of the type of each product, including the model number if applicable

# Annual reports continued

- the total quantity of each radionuclide contained in each type of product/model; (and the total activity distributed)
- the number of units of each type of product transferred, by model number (if applicable), during the reporting period.

## Who to send Reports to:

- Send the report to the “Document Control Desk, not to a specific individual
- Must send a hard copy. You may supplement hard copy reports with an emailed copy. Mr. Tomas Herrera has accepted emailed reports before at [Tomas.Herrera@nrc.gov](mailto:Tomas.Herrera@nrc.gov)
- Although they are required to be sent to the NRC’s official mailing address in Washington DC, regulators have asked clients in the past to send correspondence directly to NRC in Rockville, MD



# NRC Form 3

- Post NRC Form 3 “Notice to Employees”

# Recordkeeping

- For activities related to your NRC exempt distribution license, most records follow either a 3 year or 5 year retention period. To be conservative, retain records for at least 5 years.

# Guidance Documents

- US NRC NUREG 1556, Vol. 3 Revision 2, Applications for Sealed Source and Device Evaluation and Registration
- US NRC NUREG 1556, Vol.8, Program-Specific Guidance About Exempt Distribution Licenses
- NRC REGULATORY ISSUE SUMMARY 2014-10 REQUIREMENTS FOR EXEMPT DISTRIBUTION LICENSEE ANNUAL TRANSFER REPORTS