

## 21<sup>ST</sup> CENTURY TECHNOLOGIES SAFETY EVALUATION REPORT

### BACKGROUND

In a letter and application dated July 19, 2004, 21<sup>st</sup> Century Technologies requested an amendment to exempt distribution license no. 27-23914-01E, to add the distribution of luminous thumbstuds. 21<sup>st</sup> Century indicated that the luminous thumbstuds would be for use on knife blades. Additional information was provided in letters dated September 27, 2004 and September 29, 2004, and a conference call with U.S. Nuclear Regulatory Commission (NRC) staff on September 29, 2004. The thumbstud would consist of a screw containing 30 mCi tritium "dot" sources on each end of the screw, for a total of 60 mCi per screw. The thumbstud would be assembled, tested, and marketed in the same manner as currently approved gun and bow sights. Once the thumbstuds are manufactured, they would then be transferred as an exempt product to a third party who would mount them onto the knife blades. The third party would then market the knives to consumers. The intent of use for the knives with the tritium thumbstuds installed would be for firefighters, police officers, military, and other similar type personnel to use as a safety device. It would provide these personnel a method of locating the knife in dark or smoke filled areas, especially if dropped or knocked out of their hand. 21<sup>st</sup> Century requested authorization solely for distribution of the tritium thumbstuds alone.

### REGULATORY REQUIREMENTS

21<sup>st</sup> Century's license, mentioned above, currently authorizes the distribution of gun and bow sights containing tritium, in accordance with Title 10 of the Code of Federal Regulations (10 CFR) Section 32.22, to persons exempt from the licensing requirements, pursuant to 10 CFR 30.19. 10 CFR 30.19 exempts, from the requirements of a license, any person who receives, possesses, uses, transfers, owns, or acquires self-luminous products containing tritium, krypton-85, or promethium-147, which have been manufactured or initially transferred in accordance with 10 CFR 32.22. 10 CFR 32.23 provides the safety criteria that the design of the self-luminous products must meet. However, according to 10 CFR 30.19(c), the exemption does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments. Additionally, under 10 CFR 32.22(b), the Commission may deny an application if the end use of the product cannot be reasonably foreseen. The provisions under 10 CFR 30.19 and 32.22 would also govern 21<sup>st</sup> Century's request for the tritium thumbstuds. These regulations are consistent with the Consumer Products Policy Statement issued on March 16, 1965, by the Atomic Energy Commission, now the NRC.

The 1965 Consumer Products Policy Statement discusses the criteria to be used for the evaluation of products containing radioactive material that would be used by the general public (consumer products). Under this policy, the applicant must show that the product is unlikely to cause individuals in the population to receive more than a small fraction of the individual dose limits recommended by such groups as the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the Federal Radiation Council (FRC), and that the probability of individual doses approaching any of the specified limits is negligibly small. Otherwise, a careful weighing of several factors are required, including the potential exposures and doses to individuals and the general population during handling, use, and disposal of the product, as well as the benefit that

will accrue to or be denied the public because of the approval or disapproval of the product. Additionally, products subject to mishandling, especially by children, must be found to combine an unusual degree of utility and safety. A copy of this policy statement is attached.

## SAFETY EVALUATION

### 1.0 Introduction

The NRC staff has conducted an evaluation of 21<sup>st</sup> Century's request for the distribution of tritium thumbstuds, using the guidance in NUREG-1556, Vol. 8. During an evaluation of a request for products intended to be distributed in accordance with a license issued under 10 CFR 32.22, the following areas are usually reviewed:

- a) Description of product and intended use
- b) Type and quantity of BPM (byproduct material) per unit
- c) Chemical and physical form of BPM and changes that may occur during the useful life of the product
- d) Solubility in water and body fluids of the forms in 32.22(a)(2)(ii)
- e) Details of construction and design as related to containment and shielding and other safety features under normal and severe conditions of handling, storage, use, and disposal
- f) Maximum external radiation levels at 5 and 25 cm from external surface of product and the method of measurement
- g) Degree of access to human beings during normal use
- h) Total quantity of BPM expected to be distributed annually
- i) Expected useful life of product
- j) Proposed method of labeling or marking each unit with manufacturer or initial transferor of product, and BPM in product
- k) Procedures for prototype testing (containment, shielding and other safety features) in both normal and severe conditions
- l) Results of prototype testing including any change in form, extent of release to environment, increase in radiation levels and changes in safety features
- m) Estimated external radiation doses and dose commitments
- n) A determination that the criteria of 32.23(d) will be met
- o) Quality Control procedures followed in fabrication of production lots of product and Quality Control standards product must meet
- p) Any additional studies and tests
- q) Sealed source and device resulting in issuance of a registration certificate

### 2.0 Description of Product and Intended Use

Based on information provided by 21<sup>st</sup> Century in the application, subsequent letters, and conference call, the NRC staff reviewed the first area under a) above, the description of the product and its intended use. Specifically, the staff evaluated whether the use of the product was frivolous in accordance with 10 CFR 30.19(c), and the end-use potential of the product in accordance with 10 CFR 32.22(b).

21<sup>st</sup> Century described the intended use of the tritium thumbstuds as a safety device mounted on knives that would be distributed to firefighters, police officers, the military, and other similar type personnel. The thumbstud would consist of a screw with tritium sources mounted on each

side of the screw. To aid in the evaluation of the tritium thumbstuds, the staff considered the evaluations of other products containing tritium that have been previously requested for distribution to persons exempt from the regulatory requirements. The discussion below under sections 2.1 and 2.2, presents the basis for the approval, or disapproval, of these products as it relates to the tritium thumbstuds. As with 21<sup>st</sup> Century's request, these products were not specifically addressed in the regulations as products that may be approved for exempt distribution. Products specifically mentioned in the regulations that may be approved are identified in 10 CFR 30.15.

## 2.1 Products Previously Approved

Flashlights, which contain tritium light sources installed on their lens cap, were approved in accordance with the provisions of 10 CFR 32.22, for use by persons exempt from the licensing requirements under 10 CFR 30.19. The flashlights appeared to have a low radiological risk based on a comparison done to the dose assessment in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials", for wrist watches that are similar in activity and potential use. Besides their use by consumers, such as in-home, automobile, and outdoor sporting, the applicant pointed out that the flashlights would serve an important safety function, to military, law enforcement, and other similar organizations. The flashlights also had similar construction to timepieces and other already approved devices. However, the intent of the flashlight was for it to be initially distributed as a finished product with the tritium sources already installed. The NRC performed a safety evaluation on the finished product as a whole, and determined that it contained an unusual degree of utility and safety for a product that was subject to mishandling.

Gun and bow sights containing tritium were also approved in accordance with the provisions of 10 CFR 32.22. The gun sights serve a useful purpose for military, law enforcement, and security organizations. Both gun and bow sights enhance sighting in poor lighting conditions. However, small gunsights were required to be mounted on the gun prior to initial distribution, to address labeling concerns. Additionally, the gun and bow sights were designed and evaluated for use on weapons only. Modification of the designs may be required to use the sights in other unintended products, therefore making the product's end-use reasonably foreseen.

## 2.2 Products Previously Disapproved

Personal markers were originally authorized by NRC under a license for distribution to persons exempt from regulatory requirements. This license is currently terminated. The NRC staff does not plan to license this product again. The design of the product simply consisted of a self-luminous tritium source fastened to a small plastic holder. Because of this design, these markers had the potential of being used in a fashion not originally reviewed and authorized by the NRC, such as in toys or adornments, therefore not having an end-use that was reasonably foreseen.

A petition for rulemaking was disapproved by the Atomic Energy Commission, to exempt from licensing requirements self-luminous screws containing tritium. Since self-luminous screws might be used in toys, novelties, and adornments, the Commission could not determine that granting the exemption would meet the criteria for approval of products intended for use by the general public. Therefore, the Commission decided that it would not be in the public interest to grant the requested rule-making allowing this exemption. The Commission determined that the end use of the screws could not be reasonably foreseen.

A petition for rulemaking was disapproved by the Atomic Energy Commission to exempt from licensing requirements fishing lures containing tritium. The Commission determined that due to the potential radiation exposure to the general public that could result from the widespread use of the fishing lures, it would not be in the public interest to initiate the requested rulemaking that would allow this exemption.

In addition, the NRC denied an application for the distribution of home address numbers containing tritium. The NRC determined, in accordance with the 1965 Consumer Products Policy Statement, that the use of the radioactive light source for the purpose of illuminating home address numbers was questionable. The Commission determined that there was no demonstrated benefit for introducing radioactive material into home address numbers. Home address numbers could be illuminated by other means, therefore the use of tritium in home address numbers was considered frivolous.

### 2.3 Evaluation of Product

Based on the design of the tritium thumbstuds, the NRC considers that the potential exists for the thumbstuds to be used in unintended applications. Although the product is intended to be a safety device, the thumbstuds may easily be inserted into other products (such as toys, adornments, and other novelties) in place of standard screws, using standard tools available to the general public. Additionally, since 21<sup>st</sup> Century requested approval for the thumbstuds alone instead of the full thumbstud/knife configuration, the thumbstuds have the potential of being distributed to persons besides the intended firefighters, police officers, military, and other similar type personnel. The knives themselves with the thumbstuds installed, upon distribution by the third-party, are not precluded from being distributed to other consumers, therefore also have the potential of being distributed to unintended persons. If approved under an exempt distribution license, the thumbstuds may legally be distributed to any member of the public with no control or oversight as to who the thumbstuds go to after their initial distribution. This may result in misuse of the product and proliferation, thus raising the concern of exposure of the public to the radioactive material.

### CONCLUSION

Based on the NRC staff's review of the description of the product and its intended use, the NRC denies 21<sup>st</sup> Century's request to approve the distribution of luminous thumbstuds containing tritium, to persons exempt from regulatory requirements. The end-use of the product cannot be reasonably foreseen, and has the potential to be used in a frivolous manner. Therefore, there was no reason to complete the remaining portion of the review as outlined under the Safety Evaluation, Section 1.0, above.