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Date: 20 December 2010

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SUBJECT: RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR NEW LICENSE,
MAIL CONTROL NO. 022793

Hello,
This letter supplies the additional information requested.

A sealed source and device registration application is currently under reference:
NR1323D101E. A license, **L04096**, to possess and distribute the Specter OS from the
ELCAN - Richardson, Texas facility to customers throughout the United States is approved
from Texas Department of State Health Services.

We appreciate your continued help with Raytheon ELCAN's application and look forward to
complete resolution of the outstanding issues. Please let me know if you have any questions
or comments.

Regards,



Michael Hopkins
Manager, Contracts Administration

Response to Request for Additional Information
ELCAN Optical Technologies Specter Sighting System OS

(1) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product;

Source: glass encased tritium vial

Tritium vial mounting: Adhesive RTV630 and shrink wrap around metal dowel pin and fluorescent fiber with optical cement (Norland 61)

Device: Anodized aluminum exterior housing with bonded optics and purged with nitrogen gas

Tritium (^3H) is the sole radionuclide used in this device as tritium gas in sealed glass tubes. Each source consists of a quantity sealed glass tubes, each containing 0.148 mCi (5.476 GBq) of tritium for a total of 0.296 mCi per device.

Due to the decay characteristics of tritium (weak energy beta), there is no measurable exposure rate emanating from the sealed source.

Following beta particle emission, some of the kinetic energy of the beta particles is converted into X-rays. These X-rays are called "Bremsstrahlung," or braking radiation. Unlike the beta particles which give rise to it, Bremsstrahlung radiation may form an external hazard due to the penetrating ability of X-rays.

Bremsstrahlung energies cannot exceed the maximum energy of the beta particles which produce them. The maximum energy tritium beta particle is only 18 keV; therefore, no X-rays can exceed 18 keV. These low energy X-rays are easily attenuated in any shielding material, even several inches of air. No Bremsstrahlung radiation will be capable of penetrating through the metal components surrounding the sealed tritium source utilized in the sight assembly. As a result, there is no potential for user exposure to photons emanating from the tritium source.

The Specter Sighting System OS incorporates an aluminum housing that holds all of the lenses, a prism, and reticule in fixed alignment. Each lens is designed with reasonably thick edges for added strength and the lens mounts are retained with an adhesive that remains slightly flexible to allow for the thermal expansion of components. The sights are also designed to withstand the typical levels of shock and vibration to which they might be subject. "O-rings" are located around the outer objective and eyepiece lenses and the assembled optical housing is waterproof.

The housing itself is cast from extremely durable, high-grade aluminum. The surface finish is anodized to provide a scratch resistant membrane surrounding the housing or alternatively may be covered with an optional rubber cover. A sketch of the OS that shows the location of the tritium source within the sight housing is provided.

Each Specter Sighting System OS incorporates a mount that clamps the sight securely to the weapon's hardened steel rail. The weapon is not manufactured nor supplied by ELCAN-Midland or ELCAN-Richardson.

Even in an accident scenario, such as fire and explosion associated with handling, storage, and use of a device, it would be impossible for an individual exposed to the tritium to receive a dose commitment in excess of the 15 rem whole body limit included in 10 CFR 32.24 Table Column IV.

The only entry point near the tritium point is the portal is used for gaining access for installation of tritium vials before unit is permanently sealed.

The portal cover is pinned & potted in place with Flamemaster CS3201. A custom bolt that is then bonded with Loctite 271 retains the cover. The bolt head is then covered with CS3201 to eliminate any possible tampering.

The only access point to the sight is the purging screw. It is used during scheduled maintenance and only accessible with tools in a recessed opening. The screw is removed and old nitrogen gas is replaced.

(2) Total quantity of byproduct material expected to be distributed in the product annually;

As this is not yet a valid product, Raytheon ELCAN only has potential market forecasts. The guidance is a minimum of 0, a forecasted maximum 20,000 units, and an estimated average of 10,000 sights.

(3) The expected useful life of the product;

The working life is 10 years.

(4) Any additional information, including experimental studies and tests to facilitate a determination of the safety of the product.

The portfolio of Sights products is branded under the Specter name. The acronyms depict the model of sight as: OS#X: Optical Sight for daylight operations that is magnified by the amount indicated by the number before the times symbol. The models are OS 3.4X, OS 4X, OS 6X, OS DR 1-4X, OS DR 1.5-6X, and OS DR 1-6X where DR stands for Dual Role for short and long range use. These models have all used the similar eyepiece subassembly materials, methods and quality assurance. Unique part numbers are utilized to control configuration the exact reticle patterns, labeling, color and accessories but all models utilize the core ideas of anodized aluminum housing with bonded glass optics.

Specter sights by ELCAN have been developed and tested since 1986, in close cooperation with North American, European and allied forces. Hundreds of thousands are now deployed with allied armies around the world. Specter sights by ELCAN have been battle-proven to perform flawlessly under the harshest battlefield conditions.

A sample of the military procurement of Specter Sights is:

OS 3.4X – Canada, Netherlands, Denmark, Australia, United States (M145 LED)

OS 4X – United Kingdom (LED)

OS 6X – Netherlands, United States 6X M145 LED)

OS DR 1-4X – Canada, United States (Special Forces SU-230/PVS LED)

OS DR 1.5-6X – United States (LED)

OS DR 1-6X – In development for United States (LED)

“LED” is the reticle illumination method of Light Emitting Diode with a 3 Volt battery.

Additional information may be obtained at: <http://www.elcan.com> in the Sighting Systems section.

All of the models above utilize eyepiece subassemblies similar to that shown in the tritium vial mounting drawing except certain users have preferred LED illumination instead of a beta light. Other users, specifically the US Marines and Army have requested this application for to ELCAN better support the United States services (i.e. FedBizOpps notice Date: 2006-08-11 Solicitation # W15QKN-06-R-1411 to have an illuminated reticle visible without the use of batteries as the sole source of illumination.

ELCAN's is funding the design and manufacture of this variant of our Commercial-of-the-Shelf sighting products. ELCAN utilized our own Quality Engineering personnel to manage the prototype manufacture and testing. The appropriate facilities and test methods were used at ELCAN Midland plant, Colt Canada and the firing range.

Attached as Adobe Acrobat (.pdf) file is the ELCAN Optical Technologies authored test report that is based on the NUREG-SR1556 Vol. 8, Appendix O Consolidated Guidance about Material Licenses: Program Specific Guidance about Exempt Distribution Licenses.

In regard to the reference to ISO9001:2008 Quality Standards. Attached as Adobe Acrobat (.pdf) file is the certificate.