

APPENDIX P

GENERAL COMMENTS: _____

Mail Control No.: _____

§32.22: SELF-LUMINOUS PRODUCTS (§30.19)

Completed sealed source and device evaluation resulting in issuance of
Registration certificate No. NR-XXX-X-XXX-E _____

COMMENTS: NR-418-D-101-E, this ~~is~~ certificate
is being amended to ~~increase~~ increase the limit of H-3 for the bow sights

To manufacture, process, produce, or initially transfer self-luminous
products containing H-3, Kr-85, or Pm-147, the applicant must satisfy §30.33(except
in agreement States) and provide the following information: _____

COMMENTS: Yes - [21-19874-01], ^{Docket} 030-19451

A. Description of product and intended use _____

COMMENTS: Yes - Bow sight, ~~previously~~ previously approved on SS+D sheet

B. Type and quantity of BPM per unit _____

COMMENTS: Yes - H-3, 250 mci per source

C. Chemical and physical form of BPM and changes that may occur during
the useful life of the product _____

COMMENTS: No

D. Solubility in water and body fluids of the forms in §32.22(a)(2)(ii)

COMMENTS: OK - approved in prior ~~an~~ application/amendment

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

COMMENTS: OK \Rightarrow the Bow sight ~~is~~ was previously approved in the device registration certificate

F. Maximum external radiation levels at 5 and 25cm from external surface of product and the method of measurement

COMMENTS: OK

G. Degree of access to human beings during normal use

COMMENTS: OK \Rightarrow the H-3 source is enclosed in the gun sight

H. Total quantity of BPM expected to be distributed annually

COMMENTS: 500,000 mCi of BPM

I. Expected useful life of product

COMMENTS: 15 yrs

J. Proposed method of labeling or marking each unit with:

COMMENTS: OK - laser etched Trijicon and 3H

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1. Manufacturer or initial transferor of product _____

COMMENTS: Trijicon

2. BPM in product _____

COMMENTS: Not listed on the ~~page~~ ^{product} ⇒ Not enough
space

K. Procedures for prototype testing (containment, shielding and other safety features) in both normal and severe conditions _____

COMMENTS: OK ⇒ * 1 deviation from Vol. 8 Appendix O
the evaluation test was not performed until after all
testing was complete

L. Results of prototype testing including any change in form, extent of release to environment, increase in radiation levels and changes in safety features _____

COMMENTS: Need clarification - the evaluation test
seems to have been conducted several weeks after the
rest of the tests were completed OK

M. Estimated external radiation doses and dose commitments _____

COMMENTS: OK - No ~~an~~ dose is expected

N. A determination that the criteria of §32.23(d) will be met _____

COMMENTS: OK - reasonable

O. Quality Control procedures followed in fabrication of production lots of product and Quality Control standards product must meet _____

COMMENTS: OK - will follow same QA program
that was previously approved

P. Any additional studies and tests

COMMENTS: N/A
