

G. Degree of access to human beings during normal use

COMMENTS: _____

H. Total quantity of BPM expected to be distributed annually

COMMENTS: _____

I. Expected useful life of product

COMMENTS: _____

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

COMMENTS: _____

1. Manufacturer or initial transferor of product

COMMENTS: _____

2. BPM in product

COMMENTS: _____

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

COMMENTS: _____

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: _____

M. Estimated external radiation doses and dose commitments

COMMENTS: _____

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

COMMENTS: _____

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

COMMENTS: _____

P. Any additional studies and tests

COMMENTS: _____

Not Applicable
11/12/10
[Signature]

Appendix Q

§32.26 Certification of Application/License Review and Reviewer Check List

NOTE: All references to pages, Attachments are to the application package submitted to the NRC by Teledyne letter GLN/113 dated 6 May 2010

Amendment No.: _____

License No.: _____

Docket No.: _____

Licensee Name: Teledyne API

Address: 9480 Carroll Park Drive, San Diego, CA 92121-5201

Mail Control No.: 22800

Expiration Date: _____

Program Code: _____

Reference No.: _____

Action Type:

New License

New License/Licensee

Sheet 1 of 4

Renewal _____
 Product Transfer Report _____
 Amendment _____

I certify that I have reviewed the licensee's request dated _____, as supplemented by any letters referenced in the license and in accordance with guidance provided by the Office of Nuclear Material Safety and Safeguards, appropriate Standard Review Plans and regulations, and the attached checklist.

 Reviewer _____ Date _____

 Reviewer _____ Date _____

 Person Signing the License _____ Date _____

GENERAL COMMENTS: _____

Mail Control No.: _____

§32.26: GAS AND AEROSOL DETECTORS (§30.20)

To manufacture, process, or produce gas and aerosol detectors containing BPM, and designed to protect from fire

A. Applicant must satisfy §30.33 (except in Agreement States)

COMMENTS: California possession license 7790-37 [Provided by Teledyne letter 614113 of 6 May 2010] provides evidence of satisfaction to §30.33

B. Submit the following information:

COMMENTS: _____

1. Description of product and intended use

COMMENTS: This is provided on page E-2 and Attachment D page 7 of the application package

2. Type and quantity of BPM per unit

COMMENTS: This is provided on page E-2 of the application package

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

COMMENTS: Provided by pages D-2 through D-5 of the application package.

4. Solubility in water and body fluids of the forms in §32.26(a)(2)(ii)

COMMENTS: As stated on page E-4, ingestion or inhalation of the active material is unlikely; the solubility of the active material (BaCO₃) is 2.4×10^{-2} g/L @ 20°C.

5. Details and design as related to containment and shielding and other safety features under normal and severe conditions of handling, storage, use, and disposal

COMMENTS: Attachments B, D, I, J, K, L and M provide details of the design as well as the testing results.

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

COMMENTS: This is provided by Attachment I and summarized by pages D-2 and D-6.

7. Degree of access to human beings during normal use

Sheet 2 of 4

COMMENTS: This is provided by pages 5, D-3 through D-5 and I-7.

8. Total quantity of BPM expected to be distributed annually

COMMENTS: This information was requested by the NRC letter of 22 Feb 2010 (Sepulveda to Hunt) and answered by Teledyne letter GLH113 of 6 May 2010. A maximum of 100 units are expected to be distributed annually.

9. Expected useful life of product

COMMENTS: This is described by pages D-7 through D-9.

10. Proposed method of labeling or marking (§32.29(b))

COMMENTS: This is described on pages 4 and D-7 and modified at NRC request per Teledyne letter GLH119 dated 22 October 2010

11. Procedures for prototype testing (containment, shielding and other safety features)

COMMENTS: This is provided by Attachments A, D, I, J, K, L and M.

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

COMMENTS: This is provided by Attachment I

13. Estimated external radiation doses and dose commitments

COMMENTS: This is also provided by Attachment I.

14. A determination that the criteria referred to in §§32.27 and 32.28 will be met

COMMENTS: This is also provided by Attachment I

15. Quality Control procedures followed in fabrication of production lots of product and Quality Control standards the product must meet

COMMENTS: This is provided by Attachments C and E [specifically pages E-2, E-3 and E-7]

16. Any additional studies and tests

COMMENTS: This is provided by Attachments A, I, J, K, L and M.

§32.29(b): LABELS

A. Each detector must contain a durable, legible, readily visible label or marking on external surface of detector containing:

COMMENTS: This is provided by pages E-4 through E-6 and amended at NRC request by Teledyne letter GLH119.

1. "CONTAINS RADIOACTIVE MATERIAL"

COMMENTS: Provided by page E-6

2. Name and quantity of activity of BPM

COMMENTS: Also provided by page E-6

3. Identification of the person licensed to transfer the product

COMMENTS: Also provided by page E-6

B. Label or marking is located where it will be readily visible when the detector is removed from its mounting

COMMENTS: Also provided by page E-6

C. The external surface of the point-of-sale package has a legible, readily visible label or marking containing _____

COMMENTS: Also provided by page E-6

- 1. Name and quantity of activity of BPM _____
- 2. Identification of the person licensed to transfer the product _____
- 3. The following or similar statement: _____

THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS

COMMENTS: [As above]

4. Each detector and point-of-sale package is provided with any other information as may be required by the Commission _____

COMMENTS: Provided by pages E-4 through E-6 and as amended by Teledyne letter GLH119 as requested by NRC.

5. Applicant must maintain records and product transfer reports _____

COMMENTS: This is provided by page E-7

Appendix R Materials License - Letterhead Format

The following page shows an example of a Materials License in Letterhead Format.

MATERIALS LICENSE
[Licensee Name]
[Street Address/P.O. Box]
[City, State, Zip Code]

License No. X-XXXXX-XXE

Docket No. 030-XXXXX

Amendment No. XX

In accordance with application/letter dated _____, NRC License No. X-XXXXX-XXE is hereby issued/renewed in its entirety to read as follows:

Pursuant to the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended (Public Law 93-438); 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; Section 32.XX, 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; application dated _____; and letters dated _____; and _____; a license is hereby issued to (Licensee's Name) to distribute (product such as calibration sources) containing (list radionuclides) in individual quantities not to exceed the amounts specified in Section 30.71, Schedule B, 10 CFR Part 30 (may list specific activities), to persons exempt from licensing pursuant to Section 30.18, 10 CFR Part 30, or equivalent provisions of the regulations of any Agreement State.

This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and other applicable rules, regulations, and orders of the U.S. Nuclear Regulatory Commission, now or hereafter in effect, and to the following conditions:

- 1. This license does not authorize possession or use of licensed material.
- 2. The licensee is authorized to distribute only from its facility located at (locations or points-of-distribution).
- 3. The licensee shall submit periodic material transfer reports as specified in Section 32.XX, 10 CFR Part 32.

This license shall expire on [Expiration date].

DATE: _____ FOR THE U.S. NUCLEAR REGULATORY COMMISSION
BY: _____
[License Reviewer]

Applicable to 11/12/10

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