

Application for amendment for Distribution of
Radioactive Materials for Exempt Use
under 10 CFR 32.14

Bruker Detection Corporation



July 31, 2013

Original Copy

Prepared by:



§32.14: CERTAIN ITEMS (30.15)

Applicant satisfies general requirements in 10 CFR 30.33

The purpose of our request is to have additional sources be listed on our US NRC exempt distribution license, for distribution exempt sources for use with radiation detection equipment manufactured by Bruker Detection Corporation.

Bruker Detection Corporation is an existing US NRC licensee and has a license for possession incident to exempt distribution issued by the Massachusetts Department of Public Health, Radiation Control Program. Our current address is:

Bruker Detection Corporation
 40 Manning Rd.
 Billerica, MA 01821

A. Applicant submits sufficient information regarding product pertinent to evaluation of potential radiation exposure, including:

1. Chemical and physical form and maximum quantity of BPM in each product

Existing Products to be distributed:

Model	Source	Maximum Activity	Physical Form
Na-22	Na-22	0.050uCi Nominal activity is +/-20%	Sealed Source
Cs-137	Cs-137	0.015uCi Nominal activity is +/-20%	Sealed Source

Additional products to be distributed:

Model	Source	Maximum Activity	Physical Form	5 cm	30 cm	100 cm
Ba-133	Ba-133	1 uCi Nominal activity is +/-20%	Sealed Source	80.1 uR/hr	Background	Background

Ba-133	Ba-133	10 uCi Nominal activity is +/-20%	Sealed Source	800 uR/hr	22.2 uR/hr	Background
C-14	C-14	10 uCi Nominal activity is +/-20%	Sealed Source	218 mRad/hr	Background	Background
C-14	C-14	100 uCi Nominal activity is +/-20%	Sealed Source	2184 mRad/hr	Background	Background
Cd-109	Cd-109	1 uCi Nominal activity is +/-20%	Sealed Source	78.9 uR/hr	Background	Background
Cd-109	Cd-109	10 uCi Nominal activity is +/-20%	Sealed Source	789 uR/hr	21.6 uR/hr	Background
Co-57	Co-57	1 uCi Nominal activity is +/-20%	Sealed Source	20.2 uR/hr	Background	Background
Co-57	Co-57	10 uCi Nominal activity is +/-20%	Sealed Source	202 uR/hr	Background	Background
Co-57	Co-57	100 uCi Nominal activity is +/-20%	Sealed Source	2020 uR/hr	54.2 uR/hr	Background
Co-60	Co-60	1 uCi Nominal activity is +/-20%	Sealed Source	519 uR/hr	14.4 uR/hr	Background
Cs-137	Cs-137	1 uCi Nominal activity is +/-20%	Sealed Source	129 uR/hr	Background	Background
Cs-137	Cs-137	10 uCi Nominal activity is +/-20%	Sealed Source	1290 uR/hr	35.8 uR/hr	Background
Eu-152	Eu-152	1 uCi Nominal activity is +/-20%	Sealed Source	209 uR/hr	Background	Background
Fe-55	Fe-55	100 uCi Nominal activity is +/-20%	Sealed Source	155 mR/hr	4.3 mR/hr	0.388 mR/hr
Mn-54	Mn-54	1 uCi Nominal activity is +/-20%	Sealed Source	186 uR/hr	Background	Background
Mn-54	Mn-54	10 uCi Nominal activity is +/-20%	Sealed Source	1862 uR/hr	Background	Background
Na-22	Na-22	1 uCi Nominal activity is +/-20%	Sealed Source	474 uR/hr	13.2 uR/hr	Background
Na-22	Na-22	10 uCi Nominal activity is +/-20%	Sealed Source	4744 uR/hr	131 uR/hr	11.8 uR/hr
Po-210	Po-210	0.1 uCi Nominal activity is +/-20%	Sealed Source	Background	Background	Background
Sr-90	Sr-90	0.1 uCi Nominal activity is +/-20%	Sealed Source	2.18 uR/hr	Background	Background

Tl-204	Tl-204	1 uCi Nominal activity is +/-20%	Sealed Source	Background	Background	Background
Tl-204	Tl-204	10 uCi Nominal activity is +/-20%	Sealed Source	40 uR/hr	Background	Background
Zn-65	Zn-65	1 uCi Nominal activity is +/-20%	Sealed Source	123 uR/hr	Background	Background
Zn-65	Zn-65	10 uCi Nominal activity is +/-20%	Sealed Source	1237 uR/hr	Background	Background

2. Details of construction and design of product

Dimensions: 1 in. (25.4mm) disk with 1/4 in. (6.35mm) well, max. 5/16 in. (7.94mm) in height, max. 0.020 in. (0.51mm) thick. See Attachment A for a diagram of the source dimensions.

Purpose: Exempt calibration and reference sources

Working life: depends on half-life of radionuclide.

3. Method of containment or binding BMP in product

Radioactive material is sealed with epoxy in a plexiglass disk. See Attachment B for source diagram.

4. Procedures for prototype testing to demonstrate that the material will not become detached from the product or that BPM will not be released under severe conditions

The manufacturer has not provided Bruker Detection with prototype testing information.

Environmental use conditions:

Recommended use at -40°C to 82°C (-40°F to 180°F).

Temperature ratings for materials of construction:

Plexiglas: -40°C to $+93^{\circ}\text{C}$ (-40°F to 200°F)

Epoxy: 50°C to 150°C (58°F to 302°F)

Certifications:

The manufacturer certifies that sources are compliant with the terms of their QA plan.

Leak testing: not required by end user

5. Results of prototype testing

The manufacturer has not provided Bruker Detection with the results of prototype testing performed.

6. Quality control procedures to be followed in the fabrication, and the quality control standards the product will be required to meet (§32.15)

Spectrum Techniques, the manufacturer, is an NRC licensee and has a QA program compliant with the requirements listed in NRC NUREG 1556 Vol 3., Appendix G. Enclosed is a copy of Spectrum's NRC radioactive materials license as Attachment D.

Radioactive sources are calibrated by the manufacturer to verify that radionuclide and activity for sources.

Radioactive sources are batch leak tested by the manufacturer according to the criteria listed in 10 CFR 32.110.

Bruker Detection has an ISO 9001 Certified Quality Assurance Program. This program also meets the requirements of NRC NUREG 1556 Vol 3., Appendix G.

Bruker Detection commits to adding distribution of exempt sources to its existing quality control program, and will resolve any potential quality problems directly with the customer.

7. Proposed method of labeling or marking each unit, except for timepieces or hands or dials containing H-3 or PM-147 and its container with the identification of the manufacturer or initial transferor and the BPM

Bruker Detection intends to leave the original labeling provided by Spectrum Techniques on exempt radioactive sources we re-distribute.

See Attachment C for an image of the label to be used on the product.

8. Any additional information, studies, and tests regarding product safety

Spectrum Techniques has been distributing exempt sources for many years under their NRC exempt distribution license.

9. Each product will contain no more than the quantity of BPM specified for that product in §30.15

The activity level of sources to be distributed is very low, in the nanocurie range, and is well below the limits in 10 CR 30.15.

11. Information provided to user

The following documents are provided to the end user:

- Attachment E - Certificate of Compliance
- Attachment F - Certificate of Origin
- Attachment G - Product Information Sheet
- Attachment H - Certificate of Calibration

12. Distribution Volume

We do not anticipate distributing more than 100 sources per year.

13. Shipping

Sources shall be shipped with radiation detection instrumentation and will be well secured during transit.