Exempt Device Distribution Discussion


VIKEN
DETECTION

11/16/2022

Pb200e CONVERSION PROCEDURE AND PRICING

Before shipping your Pb200 to be converted to a Pb200e, **please take a reading on the 1.0 standard and leave the reading on the unit.**

Ship the unit to Viken Detection at 21 North Ave Burlington, MA 01803. Include a valid wipe test certificate and the log in password inside the case.

Viken Detection Conversion Process

- Viken Detection will turn the unit on and verify that the reading that was taken is within factory specifications and is operating properly. We will notify you if there is an issue.
- Viken Detection will relabel the unit with the appropriate labels.
- A final wipe test will be performed.
- Viken will ship the unit back once wipe test results are received, with the wipe test results.
- There is no charge to convert your system to a Pb200e if the system is in for a Technical Service@vikendetection.com to convert it. **This is not done automatically, only upon request.**

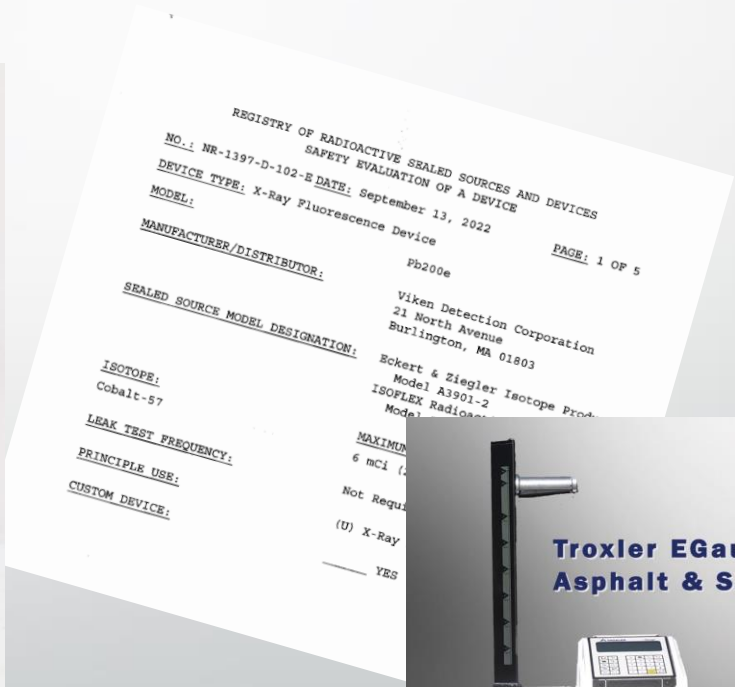
Pricing

The cost for this service is $150.00 per unit. This includes relabeling, wipe test and return shipment. The unit will be returned by FedEx 2-day shipment.

***There are no discounts for this service, there is no shipment upgrade available, and loaners are not available for this service, as it is a two day turnaround in most cases.

THE COST FOR THIS SERVICE MUST BE PREPAID.

21 North Avenue Burlington, MA 01803 / 8774675526 / vikendetection


REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE

NO.: NR-1397-D-102-E DATE: September 13, 2022

DEVICE TYPE: X-Ray Fluorescence Device PAGE: 1 OF 5

MODEL: Pb200e

MANUFACTURER/DISTRIBUTOR: Viken Detection Corporation
21 North Avenue
Burlington, MA 01803

SEALED SOURCE MODEL DESIGNATION: Eckert & Ziegler Isotope Prod
Model A3901-2
ISOFLEX Radiogr
Model

ISOTOPE:
Cobalt-57

MAXIMU
6 mCi (

LEAK TEST FREQUENCY:

PRINCIPLE USE:
Not Requ

CUSTOM DEVICE:
(U) X-Ray

YES

What criteria is used to determine if the device will be used by members of the public and is it “enforceable” if the devices are exempt?

§ 32.30 Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

(c)(2) The device is unlikely to be routinely used by members of the general public in a non-occupational environment

This authorization seems to conflict with logic of aggregation of exempt quantities of material?

30.18 (e) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in § 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

Is there any accountability of these devices?

Could the States be notified of these devices in their jurisdiction, or at the least, when one of these devices are approved?

How is the quantity of units likely to accumulate in the same disposal site determined?

32.31 Certain industrial devices containing byproduct material: Safety criteria

(2) It is unlikely that the external radiation dose in any one year, or the committed dose resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from disposal of the quantities of units likely to accumulate in the same disposal site will exceed 10 µSv (1 mrem).

If your State registers and regulates X-ray tube XRF devices, what are your plans to handle questions regarding exempt XRF devices that do not have any regulatory requirements in the States any longer?

Applicability

- 10 CFR 32.30 is applicable to industrial devices containing byproduct material for use under 10 CFR 30.22 or equivalent Agreement State regulations.
  - 8 devices currently licensed
- The use of the term, “industrial devices,” is intended to preclude the distribution of products that may be routinely used in residences. Although an exemption from licensing is not limited to any certain category of user, the products to be approved for use under this exemption should be intended for marketing to such end users as commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies.
- For the exemption to apply, it is required that the device is unlikely to be routinely used by members of the general public in a nonoccupational environment.
- The license application and registration certificate reviewers should consider whether a product could potentially be marketed to consumers for home use even if the applicant indicates that it is intended for occupational use.

Device Safety Assessment

- To demonstrate that a product meets the applicable safety criteria, a dose assessment must be developed that essentially accounts for the product throughout its entire life cycle after being transferred from the specifically licensed manufacturer and/or distributor including its ultimate disposal.
- To adequately assess the potential doses that could result from transferring a product for use under a class exemption, it must be possible to anticipate how the product will ultimately be used and the likely conditions of use.
  - This must include routine conditions, as well as likely and unlikely accident and misuse scenarios.
  - NUREG–1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials,” provides a wide range of dose assessment scenarios that applicants can adapt to fit the specific aspects of the device.

Possible Enhancements to the National Materials Program

- NRC can communicate on new exempt devices that are regulated under 10 CFR 32.30
- Provide documentation on dose assessment in SS&DR

Guidance Documents

- NUREG-1556, Volume 3, “Application for Sealed Source and Device Evaluation and Registration”
- NUREG-1556, Volume 8, “Program-Specific Guidance About Exempt Distribution Licenses”
- NUREG–1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials”

Thank you!

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