

ACCEPTANCE REVIEW FOR SEALED SOURCE AND DEVICE REGISTRATIONS

The Radiologic Health Branch (RHB) is requesting that licensees use guidance document NUREG 1556 Volume 3, Rev.1 (April 2004) to complete their new application or amendment requests. Requests must be submitted to RHB both electronically and in hard copy. Electronic copies must be submitted in Microsoft Word.

For a more timely review, RHB is requesting that licensees use Appendix C of NUREG 1556 Volume 3, Rev. 1 (April 2004) as a model to format their submittals. RHB will use the criteria listed below to ascertain whether or not your submittals are adequate to commence the technical review. If any of the criteria is missing, the submittal will be returned in its entirety.

- Designation of model number, sealed source or device type, and principal use code.
- Designation of manufacturer, distributor, or U.S. representative for foreign vendors.
- Designation of suppliers.
- Certification and signature of a management representative.
- Specification of proprietary information, adequacy of affidavit.
- Registration of medical devices (i.e., Food and Drug Administration Form 510k); commercial distribution or custom user.
- Radionuclides used in the product.
- Leak test frequency.
- Conditions of use:
 - likely environments;
 - use, handling, storage, and transportation;
 - extreme conditions (corrosion, vibration, impact, compressive loads, explosion, flooding,
 - poor air quality, excessive low or high temperatures, thermal cycling), operational cycling;
 - estimated working life.

- Design features, construction of the product:
 - description of the operation;
 - design and construction data;
 - integrity in accident and unlikely use conditions.
- Labeling:
 - text;
 - construction;
 - location.
- Prototype testing (one or combination of):
 - test results;
 - engineering analysis;
 - operational history;
 - comparison to similar or equivalent products.
- Radiation profiles.
- Quality control and quality assurance.
- Installation, servicing, and instructions to users.