

MDS Nordion C-442 Acceptance Review 6/21/2001

this is OK for Nordion only.

1. Foreign vendor,,,No US contact provided. (Registration certificate for earlier model is also Canadian vendor)
2. No information on transportation (if this means transportation of source to irradiation facility).
need info re: temps & sensitization.
3. Operational cycling not found* *N/A*
4. Working life not found*
*Can be compared with MDS Nordion model C-188, but not explicitly given for C-442 application. *need to request*
5. (If needed) radiation profiles not given for individual body parts. *radiation profiles are for the source. doses are for people*
6. No manual or other information provided on installation, servicing, and instructions.
7. Have an approved QC/QA program. *good*

- drawings are marked proprietary - NO deviation

acceptance reviewed - OK

5.03 Elements of Applications to be Reviewed.

The reviewer should verify that the technical information in the application is adequate or subject to rejection and should document, through the use of a standardized checklist, the basis for the action. The following subject areas should be reviewed:

- ✓ (1) • 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;
- NA • 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, (2)
 - ▶ extreme conditions (corrosion, vibration, impact, compressive loads, explosion, flooding, poor air quality, excessive low or high temperatures, thermal cycling), ✓
 - ▶ operational cycling, (3)
 - ▶ estimated working life; (4)
- ✓ • 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; ✓
- ✓ • (5) radiation profiles;
- (7) quality control and quality assurance;
- (6) installation, servicing, and instructions to users.

To perform an acceptance review, the reviewer may use the list above as a guide for the subjects which should be addressed. Acceptance and rejection criteria are identical to those that are used for registration reviews in the applicable review documents.

The reviewer may use the "Application and Review Checklist," Appendix C, in "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," NUREG-1556, Volume 3, for documenting the acceptance review. It must be noted that this checklist has been designed for use in registration reviews. Therefore, when used for acceptance reviews, the reviewer should note that the checkmarks and remarks are related to an acceptance review.