Performing the Review

Radioactive Materials Radiation Program

- Radiation safety programs for the use of radioactive material as a sealed source or device are structured on the presumption that the radioactive material will not breach its containment and contaminate the environment or unnecessarily expose individuals to radiation.

- This presumption depends largely upon the adequacy of the containment properties of the sealed sources or devices in withstanding the stresses imposed by the environment in which they are possessed and used.

Radioactive Materials Radiation Program

- Title 10 of the Code of Federal Regulations (CFR), Section 30.32(g), require an applicant for a specific license to use a sealed source or device to identify the sealed source or device as registered with NRC in accordance with 10 CFR 32.210 or to provide the information contained in 10 CFR 32.210.

Radioactive Material

- Energy Policy Act (EPAct) 2005 expanded definition of byproduct material to include discrete sources of Ra-226 and accelerator produced material (NARM) subject to NRC regulations and control

Transition of Regulatory Control

- Deadline of August 8, 2009
- Includes exempt distribution in all states
- Includes exempt SS&D registrations of Ra-226 and NARM in all states
- Includes SS&D registrations of Ra-226 and NARM materials in states other than Agreement States retaining an SS&D program

Purpose of The Review

- 10 CFR 32.210 provides for the registration of a product and provides a means for having a single safety evaluation of the product performed.
- This process allows applicants and license reviewers to reference the evaluation when licensing the product for use or distribution without having to perform a complete evaluation of the product for each licensing action.
- The NRC-HQ issues a unique 10 -11 character registration number for each certificate and maintains a registry of radiation safety information on sealed sources and devices authorized by the NRC and Agreement States.

The Review Process

- Three phases of the review process:
  - Prepare to review
  - Review
  - Write the review a registration certificate

Typical Licensee Requests

- A licensee may submit a license application to manufacture and/or distribute products to be used by specific licensees, by general licensees (or both), by an exempt or a custom user.
- A licensee may request registration of new, amendment to a current existing certificate, corrections, inactivation or re-activation of sealed sources (S), devices (D) and associated equipment (A)

Prepare to Review (Cont.)

Generally review the application to determine:

- The type of source or device involved, and the type of licensing action requested
- Determine if a registration certificate is required
- Identify the appropriate applicable sections of 10 CFR Parts 2, 19, 20, 21, 30, 31, 32, 34, 35, 36, 39, 40, 51, 70, 71,100, 150, regulatory guides, NUREGS, industrial national and international standards

Prepare to Review

- The application has
  - Assumptions and approximations are reasonable;
  - Adequate, complete, accurate information for a review; and
  - Is signed by a senior level manager who has the responsibility for overseeing regulatory activities.
- Note deficiencies, discrepancies, distortions and if possible complete the check list as the general review proceeds.

Prepare to Review (cont.)

For NRC, no certificate is required for:

- Calibration/reference sources used by specific licensees, not exceeding the greater of 100 uCi, or 10 times the 10 CFR 30.71 quantity for beta and/or gamma, or 10 uCi for alpha but must be listed on license
- R&D or Broad Scope, but must be licensed to the unsealed material (for sources), or the unshielded source (for devices)
- Custom, if not exceeding 200 mCi RAM or 20 Ci tritium, and licensee can handle the material in unsealed form

Prepare to Review (cont.)

Regulatory agency responsible for the review:

Agreement State

- Non-Fed entity in A/S
- Non-Fed entity in A/S at Fed-controlled site NOT subject to exclusive Fed jurisdiction

NRC

- All exempt products
- Non-Fed entity in A/S at Fed-controlled site subject to exclusive federal jurisdiction
- All Federal entities
- Non-Fed entities not in an A/S

Prepare to Review (cont.)

Medical Products

- If the application is for a medical product (new or amendment), the applicant needs to notify the FDA.
- For NRC, policy states that the registration certificate can not be issued until the applicant has submitted to the NRC a copy of a pre-marketing approval (510k) issued by FDA.
- For FDA info:

  Food and Drug Administration
  Office of Compliance
  HFZ-300
  2098 Gaither Rd.
  Rockville, MD 20850
  (301) 594-4692

Prepare to Review (cont.)

- For a full review obtain and read the tools you need:
  - Standard review plan
  - Applicable NRC and other agency regulations
  - Standing orders and other official documents
  - Regulatory guides
  - Testing standards
  - Checklists
  - Performance and historical incident data
  - NMED reports

Prepare to Review (cont.)

- Use other references as necessary (for example, if the application involves something that you are not familiar with - type of device, material, application):
  - Engineering texts
  - Product specification literature

Review

- Read the application in its entirety (gross review) and make general notes to yourself of areas that are good, unacceptable or that need more research.
- Go back and read the application again, in detail. Revise notes and formulate specific questions.
- Use the check list to ensure that all areas of the review are addressed.

Review (cont.)

- Major areas of a review:
  - Design
  - Operation/Instructions to Users
  - External radiation levels
  - Quality assurance/quality control
  - Prototype testing

Review (cont.)

- Design review:
  - Dimensions/tolerances
  - Materials
  - Fasteners
  - Manufacturing processes
  - Function
  - Safety features
  - On/off mechanism and indicators
  - Labeling – durable, visible
  - Appropriateness of assumptions, approx. and calculations

Review (cont.)

- Operation/Instructions to users, review,
  - Normal operation,
  - Installation/removal/reinstallation,
  - Leak and on/off testing,
  - Source exchange,
  - Servicing,
  - Conditions and limitations of use, and
  - Maintenance

Review (cont.)

- External radiation levels review
  - Dose rates reasonable for type of use, amount of radionuclide, and shielding
  - Measured with maximal loading for each radionuclide, and radionuclide combination for each device
  - Measured for all model series if shielding or activity levels differ in model series
  - Annual doses within limits specified for device type
  - Determine if special handling requirements are needed in user instructions

Review (cont.)

- Quality assurance/quality control review
  - Uses standard operating procedures and check lists as appropriate
  - Ensure that sources and devices manufactured and/or distributed meet the approved specifications
  - Verify anticipated dose rates
  - Verify operation of safety features
  - Verify lack of contamination
  - Verify labeling is appropriate

Review (cont.)

- Prototype testing review
  - Testing may be done without source loading for many performance tests
  - Tests of dose rates may be done with less than maximal loading and scaled provided that the test source is a meaningful percentage of maximal activity
  - Tests of moving parts should exceed the maximum number of operational life cycles expected
  - Test conditions should exceed normal conditions of use and adverse environments
  - May refer to substantially similar source/device design and use conditions

Review (cont.)

- If additional information is necessary in order to address all issue, you may need to send the applicant a deficiency letter, then evaluate their response. Sometimes this step may need to be repeated in order to obtain all necessary information.
- If the information is not clear, ASK.
- It is the applicant's responsibility to provide clear and sufficient information to demonstrate that the product safe and meets all the regulatory requirements.

Review (cont.)

- Don't be afraid to ask informational questions of the distributor or any other party. (Draw on outside sources if necessary.)

Foreign Vendors

- The distributor must be located in the US.
- If the applicant is located in a foreign country, then they must either:
  (1) go through a US distributor, or
  (2) establish their own US distribution point, including getting any necessary licenses.
- Required to establish an address to which necessary correspondence and paperwork can be served (US does not have jurisdiction outside US territories).

Write Registration Certificate

- The registration certificate is:
  - A summary of the information submitted in the application.
  - A statement that the source or device has been reviewed and approved.

Write Registration Certificate (cont.)

- Follow the standard format.
- Use the Registration Certificate Check for Completeness checklist to ensure that all necessary information is present and in correct format.
- Templates of registration certificates are also a good way