Writing The Certificate

The Certificate

Basic Presumption:

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

The Certificate

Purpose – summarize information

- "Any manufacturer or initial distributor of a sealed source or device containing a sealed source…may submit a request to NRC for evaluation of radiation safety information about its product and for its registration" (10 CFR 32.210(a)); and

- "The request for review of a sealed source or a device containing a sealed source must include sufficient information about…to provide reasonable assurance that the radiation safety properties are adequate to protect health and minimize danger to life and property" (10 CFR 32.210(c))

The Certificate
Sealed Sources and Devices Registry

- The Nuclear Regulatory Commission (NRC) maintains a registry of radiation safety information on all, NRC and State certified, sources and devices containing byproduct materials.

- Thus, a vendor needs to provide detailed information about its sealed source or device only to a single agency, and the results of the radiation safety evaluation will be available for use in granting licensing approval to users of a source or device throughout the United States.

The Certificate
Information Provided

Registrant application must provide information about:

- Design
- Manufacture
- Prototype Testing
- Quality control program
- Labeling
- Proposed uses
- Leak tests

The Certificate
Information Provided

(continued from previous slide)

- Installation;
- Service and maintenance;
- Operating and safety instructions;
- On-off mechanism, testing and indicators; and
- Potential hazards

The Certificate Stakeholders

Who is the target audience?

- Manufacturer and Distributors
- Licensing Reviewers
- Inspectors
- Other Agencies (FDA, DOT, AECB, DOE, IAEA)
- General public (?)
  - Information may be requested by the General Public under the U.S. Freedom of Information Act Request
  - Registry is currently password protected – Agreement State staff can receive access
  - Have your supervisor request access from:
    Mr. Ujagar Bhachu at 301-415-7894 or by email at ujagar.bhachu@nrc.gov

The Certificate

Use different formats based on:

- Exempt vs non-exempt
- Use under general or specific license
- Medical vs non-medical
- Source vs device

Writing the Registration Certificate

Header:

- Include the title of the document, the registration number, date of issue, page numbering, and the sealed source or device type. If the certificate is an amendment or correction, this needs to be indicated in the title.

- The issue date is the date the certificate has received both reviewer and a concurrence signature.

Header:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ITS ENTIRETY

NO: OH-0522-D-0102-B Date: **Sept 1, 2009** Page: 1 of 18

DEVICE TYPE: Density, Level & Weight Gauge

Writing the Registration Certificate

First Page Information:

- The first page of a certificate includes the name and complete address of the manufacturer and the distributor, the model number, the identification of the sealed source used in the device, isotopes, maximum activity, leak test frequency, principal use, and if the product is designed for custom use.

- If registered for custom use, the name and the address of the custom user are added.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
AMENDED IN ITS ENTIRETY

NO: OH-0522-D-0102-B Date: **Sept 1, 2009**

DEVICE TYPE: Density, Level & Weight Gauge

MODEL: SH-x series, SH-Fx series

MANUFACTURER/
DISTRIBUTOR:

Ohmart/VEGA
4241 Allendorf
Cincinnati, OH 45209

SEALED SOURCE
MODEL DESIGNATION:

Ohmart source model numbers
A-2100, A-2102, A-2104, A-57878, A-58804
A-58755, A-60324, A-61234, A-63613

ISOTOPE:	MAXIMUM ACTIVITY:
Cobalt-60	148 GBq (4 Ci)
Cesium-137	740 GBq (20 Ci)

LEAK TEST FREQUENCY: 36 months

PRINCIPLE USE: (D) Gamma Gauge

CUSTOM DEVICE: _____ Yes ___XX__ No

Writing the Registration Certificate

Description:

- This section provides a narrative about the construction of the product (not manufacturing instructions), safety features, i.e., shutter, shielding and safety indicators. The description includes materials of construction and fabrication techniques for critical safety components of the product.

- Overall dimensions of the sealed source and the device are also added.

Writing the Registration Certificate

Description: (cont)

Subtopics

- General Construction
- Prior registration
- Prior sources no longer used
- Size/dimensions/weight
- On/off indicators and mechanism
- Materials of construction
- Method of securing source in device
- Mode of operation
- Installation
- Safety features
- Source description
- Source storage
- Source access security
- Modifications
- FDA 510(k) reference
- Corrosion Prevention
- Transportation

Writing the Registration Certificate

Labeling:

- This section describes how the labeling requirements are fulfilled. It lists the information that can be found on the label, and how and where the labeling is attached to the product.
- Any exemptions from labeling requirements or omission of information typically included in the label will be noted.

Writing the Registration Certificate

Diagrams:

- This section lists the diagrams, drawings, sketches, or pictures of the product that are included in the certificate.
- A person using the certificate, such as an inspector or license reviewers, should be able to identify a device given the diagrams and description from the certificate.
- Keep diagrams “clean”

Diagrams:

Traditionally Diagrams are listed as :

Attachment 1 to ##

DIAGRAMS:

Attachment 1 - Model SH-1A and SH-F1A
Attachment 2 - Model SH-1B and SH-F1B
Attachment 3 - Model SH-2 and SH-F2
Attachment 4 - Model SH-F2S
Attachment 5 - Model SH-F3A
Attachment **6** - Model SH-3 and SH-F3
Attachment **7** - Model SH-F4
Attachment **8** - Model SH-F4-2
Attachment **9** - Model SH-F4-3
Attachment **10** - Revised shutter retaining plate assembly
Attachment **11** - General License Label text

Writing the Registration Certificate

Conditions of Normal Use:

- This section lists the environmental conditions the product is designed to withstand.
- The normal intended uses of the products and any limitations that define the uses are included in this section.
- The working life may also be included.

Writing the Registration Certificate

Prototype Testing:

- This section describes tests performed on prototypes to demonstrate it will maintain its integrity.
- If alternative methods are provided then this section will provide the details of operational history or analysis and the basis for determining the design adequacy.

Writing the Registration Certificate

External Radiation Levels:

- State the maximum radiation levels from the product when loaded with the maximum activity of each nuclide or a combination of nuclide. If applicable, the isodistance radiation profiles, for distances for 5 cm, 30 cm, 100 cm, are listed for a shutter open and shut.

- Manufacturer may provide calculated results for maximum radiation instead of measured results.

Writing the Registration Certificate

Quality Assurance Control:

- This section contains a summary of the QA or QC procedures that will be followed to ensure that product meets all applicable specifications.
- If QC procedures or a QA Program meets a national or industrial standard or regulation, it is specified in this section.

Writing the Registration Certificate

Limitations and Other Considerations of Use:

- This section establishes the limiting conditions imposed on the sealed sources or device (e.g. mechanical, environmental, radiological safety).
- This section may contain significant reviewers' notes.
- This section needs to clearly indicate the services that may be performed by a licensed user of the products.

Reviewers Note:

REVIEWER NOTE: Device Failure Issues

Commonly reported device failures associated with this device series includes stuck shutters, shutter handles breaking off, and broken screws. A review of these failures indicate common root cause issues are associated with: operating the devices outside the normal conditions of use; failure to seek appropriate device service when shutters start becoming difficult to operate; shutter binding due to environmental contaminant intrusion into the shutter; and, forcing operation of shutter instead of seeking corrective action. The most commonly involved series is the SH-F2 which is the model typically installed in harsh environmental conditions.

Writing the Registration Certificate

Safety Analysis Summary:

- This section summarizes the conclusions of the evaluation performed by the reviewer and states that the product is acceptable for licensing.
- May also list additional features that the device, surroundings, environment, or accessories may contribute to the integrity or the safety of the product.

Writing the Registration Certificate

References:

- This section lists the documents that were submitted in support of the application.
- These references include applications, letters, faxes, electronic mail messages, and enclosures to such documents.

Writing the Registration Certificate

Issuing Agency:

- This section identifies the issuing agency, the date of issue and typed name and signature of the two people who reviewed the certificate.
- All certificates include two signatures as a part of quality control measures.

Writing the Registration Certificate

Attachments:

- This section contains diagrams, sketches or pictures of the product. The attachments also may contain designations of specific models and their characteristics, such as dimensions and sealed sources activities, if a series of devices is registered.

- The header for this section is similar to the main body of the certificate except it does not contain the sealed source or device type.

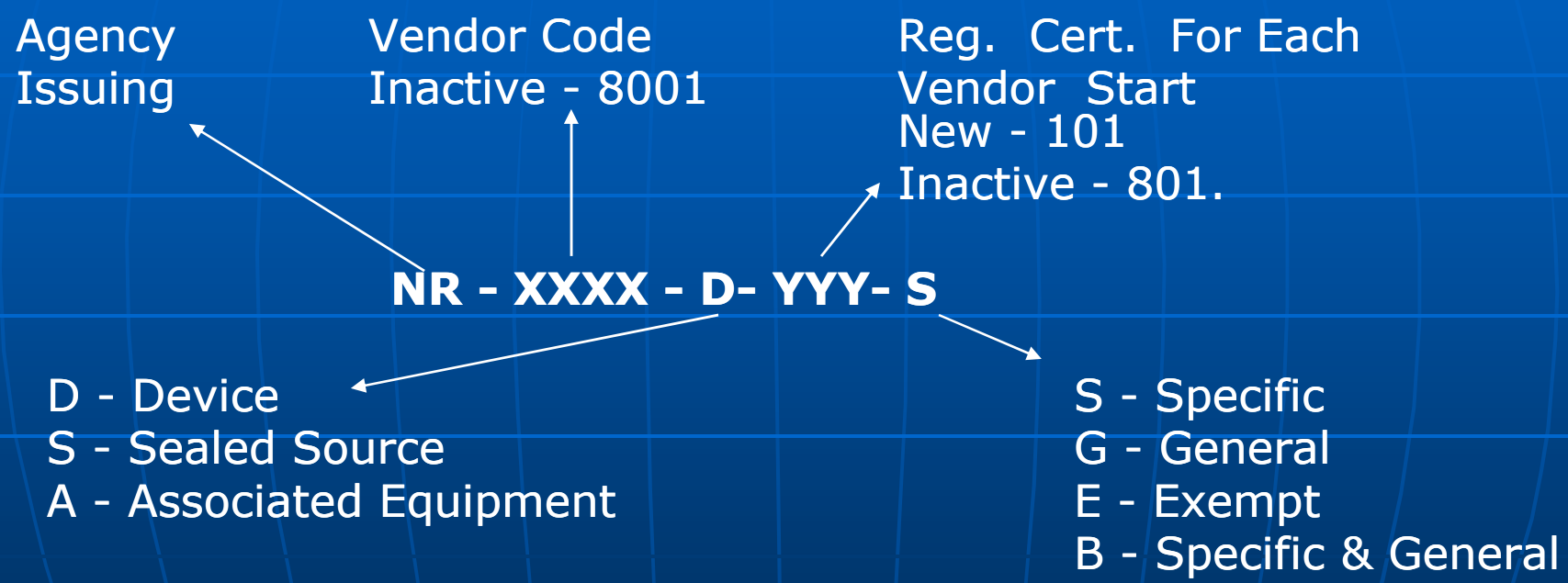
Writing the Registration Certificate

Dimensions and Use of Dual Units:

- All measurements should be stated in the units employed by the registration certificate holder, followed by the appropriate USA or International System of Units conversion in parentheses.

Writing the Registration Certificate

Certificate Numbering:



Medical Devices

- Identify FDA approval / 510(k) premarketing approval – most common
- Other acceptable FDA approvals: PMA, HDE, and IDE
- FDA summary provides medical use conditions and limitations
- Important section for medical use licensees, in addition to "use codes" on title page – medical rules specifically state sealed sources and devices can be used only according to SS&D registration certificate

Principle Use Codes for Medical Devices:

AA	***Manual Brachytherapy***	For use in manual brachytherapy in accordance with 10 CFR 35.400, or equivalent Agreement State regulations.
AB	***Medical Diagnosis Sources***	For use in medical diagnosis in accordance with 10 CFR 35.500, or equivalent Agreement State regulations.
AC	***Photon-emitting Remote Afterloaders***	For use in Photon-emitting Remote Afterloaders in accordance with 10 CFR 35.600, or equivalent Agreement State regulations.
AD	***Photon-emitting Teletherapy Units***	For use in photon-emitting teletherapy units in accordance with 10 CFR 35.600, or equivalent Agreement State regulations.
AE	***Gamma Stereotactic Radiosurgery Units***	For use in Gamma Stereotactic Radiosurgery Units in accordance with 10 CFR 35.600, or equivalent Agreement State regulations.
AF	***Other Medical Uses***	For other medical uses that are regulated under 10 CFR 35.1000 or equivalent Agreement State regulations, Includes intervascular brachytherapy and beta-emitting remote afterloaders.

Check for Completeness of the Certificate

- Before the certificate is complete the reviewer or issuing agency should check to ensure the accuracy and completeness of the certificate. For Agreement States this should be done prior to sending a copy of the certificate to the NRC for inclusion in the National Sealed Source and Device Registry (NSSDR)

- As an example - two checklists have been provided to you that are used by the State of Ohio to assist in ensuring that the certificate is complete (one for devices and one for sources).

Check for Completeness of the Certificate

- The 4-digit number in the certificate number must correspond to the distributor, there must be only one distributor, and the distributor must be in the U.S.
- The States must contact NRC HQ for vendor numbers for new vendors or vendors that are going inactive.

Check for Completeness of the Certificate

- Make sure that the maximum external radiation levels are listed for the product when loaded with the maximum activity of each nuclide or a combination of nuclides. Devices with both on and off positions should list levels for each position.

Check for Completeness of the Certificate

- Ensure that the Issuing Agency section contains the Issuing Agency, the date issued and the typed name and signature of the two persons who reviewed the certificate.

- The certificate must not contain any proprietary information.

Check for Completeness of the Certificate

- All registration certificates previously issued in an old format should be updated to the new format at the earliest possible amendment.

Agreement State Issued Certificates

- A copy of the registration certificate is forwarded to the Division of Materials Safety and State Agreements (MSSA) by the State.
- MSSA performs an administrative review of each certificate as a part of data entry.

Licensing of Foreign Vendors

- A foreign vendor is required to establish an address in the United States to which the necessary correspondence and papers can be served.
- Products tested to international or foreign standard must be acceptable to the USA regulatory body.

Amendments to the Certificate

- If the registrant requests an amendment to the certificate, the certificate header should include the title, (AMENDED IN ITS ENTIRETY).

- The certificate should be assigned a new issue date and the certificate should be reissued in its entirety. The reviewer should use **bold** type face to highlight the changes that have been made to the certificate.

Corrections to the Certificate

- If the change is only a correction, not requiring a safety review, then only the affected pages of the certificate need to be updated and issued.

- The reviewer should use **bold** type face to make the corrections. Each affected page should include, in the header, under the title, the words "corrected pages," an example of this format is shown below:

(Corrected pages 1, 2, & 4, July 4, 1776)

Corrections to the Certificate

- The issue date of the certificate should remain the same as the last issue date.
- If the correction requires a change to the signature page of the certificate, the certificate should be amended in its entirety.

Inactivation of the Certificate

Prior to transferring a registration certificate to an inactive status, the reviewer needs to ensure that:

- the registrant provides the number of the products sold and the number of products still in use
- a commitment that the certificate holder will no longer distribute the product
- no changes were made to the product since the initial or last amendment.

Inactivation of the Certificate

- List any continued services that will be provided to users of the product.
- Write an updated registration certificate to reflect current certification practice.
- Obtain and assign a new number to the certificate.

The Certificate
Upon Submission to NRC

- A cursory review of the certificate is conducted as a part of the data entry into the registry.