

**Design**  
**(Construction Description,  
Labeling, Conditions of Use)**

# Purpose

- ❖ Verify that the design is:
  - clearly documented
  - adequate for conditions of use
  - comparable to the unit that was prototype tested
- ❖ Verify adequate labeling of the product

# Documentation

- ❖ Description and Summary of the Construction
  - overall drawing/schematic/picture
  - written description of containment and shielding, and purpose and how it works
- ❖ Specific, Detailed Information
  - engineering drawings (revision numbers and dates)
  - product data/specification sheets
  - detailed written descriptions/explanations
  - drawings are preferred but text is acceptable

# What Level of Detail is Required?

- ❖ Dependent on the Product and Reviewer's Discretion
- ❖ Overall Details for Safety Related Components, e.g.:
  - outer housing
  - secondary shielding
  - c-frames
  - environmental control systems
- ❖ Complete Details for Safety Critical Components, e.g.:
  - primary containment
  - primary shielding
  - safety features
  - regulatory requirements

# What are Details?

- ❖ Materials of construction:
  - raw materials
  - machined components
  - manufactured components
  - dimensions/tolerances
  - assembly methods (e.g., welds, bolts, screws), including size, materials, and spacing
  - manufacturing/production processes
- ❖ Specification Ranges
- ❖ Function/Operation
- ❖ Safety Features (e.g., return springs, interlocks)
- ❖ On/Off Mechanisms and Indicators

# What are Details? (cont.)

- ❖ Source Containment and Shielding
- ❖ Installation/Mounting
- ❖ Fixed/Mobile/Portable
- ❖ Accessibility of the Radiation Beam During Use
  - air gaps that could allow any part of a human body to enter the radiation beam
  - barriers/guards
  - location of installation
- ❖ Source/Shielding Movement (e.g., Shutters, Movable Source)
- ❖ Tamper Resistant Construction/Hardware

# Importance of the Information

- ❖ To Have a Complete Understanding to Allow for Adequate Evaluation of the Design
- ❖ Regulatory Tie-Downs
- ❖ Commitment to Manufacture Correctly
- ❖ Documentation of the Approved Design
- ❖ Working Life Provides an Indication of when Servicing or Re-evaluation of a Product Integrity May Be Necessary
- ❖ A Chain Is as Strong as its Weakest Link

# Adequate for Conditions of Use

- ❖ Normal Use and Likely Accident Conditions.
- ❖ Includes Receipt, Use, Handling, Storage, Decommissioning, and Transportation (Extremes Experienced During Accident Conditions During Transportation Need Not Be Considered)
- ❖ At a Minimum, Must Consider:
  - corrosion
  - vibration
  - impact
  - puncture
  - bending
  - compressive loads
  - fire/explosion
  - flooding
  - air quality
  - excessive high or low temperatures
  - thermal cycling
  - cycling of the on/off mechanism



# Adequate for Conditions of Use (cont.)

- ❖ Product:
  - Will perform its intended uses after being subjected to likely, normal use conditions for the applicant's estimated working life of the product.
  
  - This does not necessarily mean the product will perform its intended uses after being subjected to an accident or unlikely use conditions.
  
- ❖ Under all conditions, the product should still ensure the byproduct material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. (rule of thumb is < 20% increase in radiation levels)

## Adequate for Conditions of Use (cont.)

- ❖ Use of dissimilar materials may cause failure (e.g., welds) or corrosion (e.g., corrosion is likely when you have direct contact between aluminum and steel, or depleted uranium and steel).
- ❖ Materials may cause corrosive environments without direct contact (e.g., Teflon can break down when subjected to radiation and cause a corrosive environment for certain metals).
- ❖ Materials (e.g., adhesives, lubricants, and gaskets) may be detrimentally affected by exposure to radiation or expected conditions of use.

## Adequate for Conditions of Use (cont.)

- ❖ Assembly methods may have detrimental effects on the product during its fabrication (e.g., heat from welding a holder directly to the sealed source; securing the sealed source by tightening a screw or bolt against the wall of the sealed source).
- ❖ The fixed shielding will not move nor easily become dislodged from the device. For example, what happens to it after a drop or fire?
- ❖ Source mounting will not allow for unintentional movement during use nor dislodging of the source.
- ❖ Source is secured from unauthorized access.

## Adequate for Conditions of Use (cont.)

- ❖ Spacing between moving parts - should be adequate to ensure binding will not occur (e.g., from bending, temperature changes causing expansion or contraction, introduction of foreign materials). Need to consider tolerances.
- ❖ The device can be locked in the closed condition (source fully shielded) and cannot be locked in the open condition, if applicable.
- ❖ At least one “positive” position indicator that clearly identifies whether the source shielding is in the open or closed position. Color - red for open/green for closed.

## Adequate for Conditions of Use (cont.)

- ❖ Safety interlocks, barriers, or guards prevent access to the radiation beam and prevent exposures in excess of those specified in the regulations (the inclusion of barriers or guards should be included as reviewer notes to alert license reviewers). Can be accounted for in the review of generally licensed devices.
- ❖ Pneumatic or hydraulic systems have appropriate filtration, relief valves, and operating pressures.
- ❖ Fail-safe designs - loss of power or a failure in the system would cause the shutter to return to, or remain in, the fully shielded position.

## Adequate for Conditions of Use (cont.)

- ❖ Use of tamper-resistant hardware or assembly methods (e.g., generally licensed and exempt devices).
- ❖ Device is hermetically sealed from foreign materials or moisture.
- ❖ Sealed sources contain appropriate internal void spacing to ensure accurate leak testing results.
- ❖ Void spaces, in both sources and devices, should allow for any thermal expansion of the materials.

## Adequate for Conditions of Use (cont.)

- ❖ Review the intended design/logic of electronic circuits. Typically, we do not review schematics.
- ❖ Review of design/logic of safety related features of computer software - automatic source returns. Typically, we do not review code and are not concerned with intended operation of the software.

# Comparison to Prototype Testing

❖ All Product Designs must Meet One of the Following:

- product design is identical to unit that was prototype tested
- an engineering analysis was performed
- operational history of the product including subjecting of the product to extreme(s) of the dimensional/construction range
- comparison to a similar or equivalent model previously reviewed and registered, including partial testing of changes/modifications/differences



# Testing Requirements & Procedures

- ❖ Are There Any Conditions That Have Not Been Accounted for?
- ❖ Any Additional Areas of Concern?
- ❖ Is the Product Used Outside the Normal Expected Uses?
- ❖ Is There a Probability of Extreme Accident Conditions?
- ❖ Something That You Just Don't Like?

# Design

## ❖ Regulations

§ 30.15

§ 30.19(a)&(c)  
and § 32.22(a)

§ 30.20(a)  
and § 32.26

§ 31.5(a)  
and § 32.51(a)(2)

§ 32.53(c)&(d)

§ 32.61(c)&(e)

§ 32.74(a)(2)

§ 34.20 & 34.23

§ 36.21(a)(2)(3)&(4)

§ 39.41(a)(1)&(2)

## Applicability

Exemption for certain items

(i.e. timepieces containing  $^3\text{H}$  or  $^{147}\text{Pm}$ )

10 CFR 30.19 exemption ( $^3\text{H}$ ,  $^{85}\text{Kr}$ ,  
 $^{147}\text{Pm}$ )

10 CFR 30.20 exemption (gas &  
aerosol dets.)

10 CFR 31.5 general license (meas. &  
gauging)

10 CFR 31.7 general license (aircraft -  
luminous)

10 CFR 31.10 general license ( $^{90}\text{Sr}$   
ice detection)

Medical

Radiography

Irradiators

Well logging

# Labeling

- ❖ Applicants should provide a sample of labels.
- ❖ Information on Labels:
  - devices - model number, serial number, isotope, activity, distributor's name, date of assay, trefoil symbol, and the words "CAUTION/DANGER - RADIOACTIVE MATERIAL"
  - sources - as much as possible, but is left to the discretion of review based on information from the applicant (reference notes in Vol. 3)
  - may contain additional information
  - labeling must not misinterpret, misrepresent, or lead the user into violating any applicable regulations (e.g. GL vs. SL labeling)

# Labeling (cont.)

- ❖ Labeling must be legible
- ❖ Construction - durable, will remain on the product, and will remain legible under normal use conditions through the working life of the product
  - sealed sources: engraved or laser etched
  - devices: metal label, with the information engraved or etched into the label
  - other materials may be acceptable (e.g., mylar).
- ❖ Attachment
  - prefer screws, rivets, metal tethers, embossed, engraved
  - other methods may be acceptable (e.g., adhesives).

# Labeling (cont.)

## ❖ Location

- visible to the users
- attached to the component that contains the radioactive material
- not attached to the detector housing, barrier, guard, or C-frame
- can have additional labeling

# Labeling (cont.)

## ❖ Regulations

### Regulations

§ 32.25(b)

§ 32.29(b)

§ 32.51(a)(3)

§ 32.54

§ 32.61(d)

§ 32.74(a)(2)&(3)

§ 34.20

§ 39.31(a)

### Applicability

10 CFR 30.19 exemption

10 CFR 30.20 exemption

10 CFR 31.5 general license

10 CFR 31.7 general license

10 CFR 31.10 general license

Medical

Radiography

Well Logging