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Licensing Guidance for Medical Use Under the Revised 10 CFR Part 35

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Overview

- Purpose:
  - Preparation of applications for medical use using NRC Form 313
  - Evaluation guidance for NRC's license reviewers
  - Informational content

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Overview

- Revisions to Vol. 9
  - Stakeholder comments
  - Agreement State input
  - NRC regional and HQ staff

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Overview

- Model Procedures
  - Multiple perspectives on inclusion of model procedures
  - Clear deliniation between procedures requiring regulatory review and informational only

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Overview

- Supercedes
  - RG 10.8, “Guide for the Preparation of Applications for Medical Use Programs”
  - RG 8.23, Radiation Surveys at Medical Institutions
  - RG 8.33, QMP
  - Several Policy and Guidance Directives

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Overview

- Guidance only
- Does not impose any conditions beyond those required in 10 CFR
- Not a substitute for NRC regulations

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Overview

- Also Covers
  - Part 20 - related to radiation safety
  - Part 30 - related to licensing
- Does Not Cover
  - Broad Scope Licenses
  - Part 21, Reporting of Defects
  - Manufacturing, distribution, and service of sources

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Organization

- Overview
- Management Responsibility
- How to File and Where to File
- **Section 8 Contents of Application**

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Organization

- Appendices
  - Forms and Samples
  - Model Procedures (examples only)
  - Record keeping and Reporting Requirements
  - References

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Organization

- Text box
  - Beginning of each Section and Items in Section 8
  - Type of use and applicability check box
- Table 1.1
  - Indicate Form 313 sections applicable to each type of use

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Section 8 - Contents of Application

- Division of information
  - Items requiring response on Form 313
  - Program-related guidance- no response required on Form 313

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Section 8 - Contents of Application

- Items containing technical information
  - **Regulations** - applicable to item
  - **Criteria** - to judge adequacy of response
  - **Discussion** - additional info
  - **Response from Applicant** - suggested response or no response required

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Form 313 Items Needing Response

- **Item 5 - Radioactive Material**
  - 35.100 & 35.200 use
    - ANY Chemical/Physical Form
    - Maximum Amount = As Needed
  - 35.300 use
    - ANY Chemical/Physical Form
    - Specify Maximum Amount

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Form 313 Items Needing Response

- **Item 5 continued:**
- 35.400, 35.500, 35.600, 35.1000 Use
  - Specify radionuclide
  - Chemical/Physical Form = sealed source identified by manufacturer and model number
  - Specify maximum activity
- Also include Depleted Uranium used for shielding in maximum kg amounts

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Form 313 Items Needing Response

- **Item 6 - Purpose(s) for Which Licensed Material Will Be Used**
  - Reference applicable section of Part 35 and description of modality
  - Include manufacturer's name and model number of device, if applicable

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Form 313 Items Needing Response

- **Item 7 - Individuals Responsible for Radiation Safety Program and Their T&E**
  - Identify applicable RSO, AU, AMP, ANP
- Provide
  - Previous License No. OR
  - Copy of Specialty Board Certification OR
  - Description of T&E AND Written preceptor statement

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Form 313 Items Needing Response

- **Item 9 - Facility Diagram**

Provide

- 35.100 and 35.200
  - Room numbers for areas of use and preparation
  - Adjacent areas and rooms (including above and below)
- 35.300 and 35.400
  - Rooms and adjacent areas as above
  - Location where sources are stored
  - Description of rooms where patients are housed under 35.75
  - Description of shielding, if used

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Form 313 Items Needing Response

- **Item 9 - Facility Diagram continued**

Provide

- 35.500
  - Room numbers of use
- 35.600
  - Room numbers for areas of use and preparation
  - Adjacent areas and rooms (including above and below)
  - Location where sources are stored
  - Description of rooms where patients are housed under 35.75
  - Description and calculations of shielding

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Form 313 Items Needing Response

- **Item 9 continued**
- Radiation Monitoring Equipment
  - Commit to calibration of radiation monitoring instruments by a qualified person OR to develop, maintain, and implement calibration procedures
- Dose Calibrator and Other Equipment Used to Measure Dosages (if applicable)
  - Commit to calibrate equipment in accordance with nationally recognized standards or manufacturer's instructions

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Form 313 Items Needing Response

- **Item 9 continued**

- Dosimetry Equipment and Use
  - Provide procedures required by 35.642, 35.643, 35.645 (if applicable)

- Other Equipment and Facilities
  - Provide description of safety systems for therapy units

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Form 313 Items Needing Response

- **Item 10** - Radiation Protection Program
  - *Occupational Dose
  - *Area Surveys
  - *Safe Use of Unsealed Licensed Material
  - *Spill Procedures
  - *Minimization of Contamination
  - *Safety Procedures and Instructions EXCEPT 35.600

*** commit to develop, implement, maintain procedures**

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Form 313 Items Needing Response

- **Item 10 continued**
- Provide for 35.600
  - Safety procedures required by 35.610
    AND
  - Qualifications for employee servicing therapy units, if applicable

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No Response Needed for Form 313

- 17 program-areas with no response required
- Program -related guidance only
- Examples:
  - Opening packages
  - Procedures for administrations when a written directive is required
  - Release of patients
  - Mobile medical service
  - Audit program

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Summary

- Covered
  - Purpose of Vol. 9
  - Organizational Structure
  - Some details in Section 8
    - Written statements of commitment
    - Items to provide
- Any questions?