Revised Regulations for Medical Use of Byproduct Material

Review of U.S. NRC’s revised 10 CFR Part 35

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Current Regulatory Framework

❖ U.S. Nuclear Regulatory Commission
  - Byproduct materials only (10% of Radiation Medicine)
  - Medical Use program: < 3% NRC resources
  - Directly regulates 21 non-agreement states
  - Major influence on agreement states/NARM programs

❖ FDA: approves and regulates drug/device testing and manufacture

❖ States regulate NARM - 90% of rad med
  - Large state-to-state variability in regulatory rigor
Outline

❖ Political background and history of 10 CFR 35
   revision process
❖ Revision process and timetable
❖ 10 CFR 35 content and important changes
   - Modified T&E requirements
   - Authorized medical physicist created
   - Reduced requirements for Diagnostic
   - QA regs for HDR, PDR and Stereo based on AAPM TG reports
   - New modalities (35.1000) addable by amendment
   - Revised medical event definition
Why Regulatory Change?

- **1992**: Indiana PA incident, Plain Dealer
  “Radiation Kills” series, & Congressional hearings
- **1993-97**: NRC Strategic Assessment and Rebaselining Initiative
- **Constant criticism**: NRC is cost ineffective, overly intrusive and adversarial, and unjustified by risk to patients
Commission-Level Direction

- **Radical regulatory reform rejected**
  - Uniform regulation regardless of radiation source
  - Leaving Rad Medicine regulation to the states or health-oriented Federal agency
  - Rad medicine patient risk < other medical specialties
  - Patient safety/QA regulation unnecessary

- **Revised Medical Policy Statement: NRC will regulate patient safety to assure correct delivery of physician’s prescription**

- **Relying on voluntary standards ⇔ “relying on fox to guard the henhouse”**
NRC Commissioner’s Instructions

Focus Part 35 on highest risk modalities & low risk modality oversight
- Risk-informed: Risk dictates regulatory intensity
- Performance-based: set performance goals and let licensee develop compliance strategy

Timely incorporation of new modalities

Capture safety issues and precursor events

Revised QMP to focus on essential safeguards

Use industry guidance whenever possible

Change “misadministration” to “medical event”
“Fast track” 10 CFR 35 Timetable

- **May 97 to May 98**: Public meetings and "strawman rule" on Internet
- **Aug-Dec 98**: Draft rule published and open for public comment
- **July 99**: Revised draft Rule approved by Commission
- **Dec 99**: Commission approves complete 10CFR 35 package
- **Mar 00**: Final rule published in Federal Register
- **Oct 00**: Effective compliance date
- **Apr 02**: Compliance date for New T&E
Part 35 Outline: Subparts

- **A - C: (35.1 - 35.92)** General info, administrative & technical requirements
- **D: (35.100/200)** Unsealed byproduct material: written directive not required
- **E: (35.300)** Unsealed byproduct material: written directive required
- **F: (35.400)** Manual brachytherapy
- **H: (35.600)** Remote afterloaders, teletherapy, stereo
- **K: (35.1000)** Other medical uses of byproduct material
- **L: Record keeping requirements**
- **M: Reports (ME, Embryo/fetus dose, leaking source)**

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Radiation Safety Program

Structure

❖ Program definition:
- No detailed program requirements: essential management functions listed beyond 20.1101
- RSC: only if 2 or more modalities or devices in use.

❖ RSO training and experience:
- Certification by Board recognized by Commission OR
- 200 hr didactic, 1 yr experience + preceptor’s statement
- OR AU, AMP, or ANP with proper range of experience

❖ No QMP, but 35.41 requires verification of
- Patient identity, RTP calc’s, administration in accord with treatment plan, data transfer to device console
**Authorized Medical Physicist (AMP)**

- **Certification by NRC-recognized Board**
- **OR** MS degree, 1 yr training, 1 yr experience & preceptor's statement
  - experience must include RAL, HDR, teletherapy, etc.
    as applicable

- **AMP Tasks**
  - Perform RAL/teletherapy full calibration
  - Establish/review spot checks
  - Be available/physically present during RAL/teletherapy treatments
Unsealed byproduct materials

- Old part 35: all photon-emitting and non-unit α- or β-emitting doses require dose calibrator check

- New Part 35
  - Vendor’s activity measurement, if licensed under 32.72, suffices for photon-, α- and β-emitting unit doses or non-unit doses prepared volumetrically
  - Dose calibrator possession and activity measurements required only if 32.72-licensed vendor calibration not used or available
  - Adherence to “Nationally recognized protocols replaces Prescriptive dose calibrator QA rules
Other Technical Requirements

- **Surveys:**
  - Daily exposure rate surveys required only where doses needing written directives are prepared/admin. except where radioactive patients confined
  - Weekly removable contamination tests deleted

- **DIS:** half life increased from 65 to 120 days and 10 half-life holding rule deleted.

- **Inventory:** now semi-annual

- **Patient release (35.75) requirements unchanged**

- **Endpoints covered by 10 CFR 20, e.g., ALARA, are deleted**
Written Directives

❖ Unsealed therapeutic or I-131 > 30 μCi:
  - radioactive drug, route, and activity

❖ Sealed sources
  - Gamma stereotactic: at each distinct site: dose, site and target settings/site
  - Teletherapy: site, total dose, dose/Fx, No. Fx
  - HDR: radionuclide, site, total dose, dose/Fx, No. Fx
  - Other brachy (incl. PDR, and LDR RAL)
    ❖ Prior to implant: radionuclide, site, dose
    ❖ After implant: radionuclide, site, no. sources, total source strength and treatment time (or total dose)
35.100 Uptake, Dilution and excretion

35.200 Imaging and Localization

❖ No written directive required
❖ Only first Tc-99m elute need be tested for Mo-99 concentration
❖ Dose calibrator assay of unit photon-emitter doses eliminated
❖ 35.200 Training and experience
  - Recognized Board certification OR
  - 700 hr training (didactic + work experience + administrations) and preceptor’s statement (reduced from 1200 hr)
  - Consistent with fraction of radiology residency spent on nuclear medicine imaging
35.300: Radioactive Drugs

Written Directive Req’d

- **Simplified Safety precautions:**
  - Sharing room with other radioactive patients allowed
  - Thyroid burden assays, wipe tests, and room surveys deleted: performance-based implementation of Part 20 limits expected

- **Training and experience: General**
  - Board certification OR
  - 700 hr and 3 cases each of: I-131 < 33 mCi, I-131 > 33 mCi, < 150 keV parenteral, other parenteral administration

- **I-131 treatment of hyperthyroidism and thyroid cancer:** 80 hr didactic + 3 cases T&E retained
35.400: Manual Brachytherapy

- Sources and medical uses allowed: specific list of radionuclides/uses deleted
  - Any source/device as approved by Sealed Source & Device registry or FDA-approved IDE
- Technical requirements
  - Surveys for lost sources upon loading and removal
  - Source inventory req’d, but detailed rules deleted
  - Initial and annual training to caregivers
  - Posting, emergency procedures for dislodged sources
- AU: Board certification OR
  - 700 h didactic + experience, 3 yr ACGME-approved Rad Onc residency & preceptor statement
35.400 QA Requirements

❖ Source calibration: prior to first use
   - source positioning accuracy determined
   - Source strength measured by licensee or vendor
     ◆ according to nationally recognized protocols
     ◆ using system or source with NIST-traceable calibration < 2 yr old

❖ RTP acceptance testing per national protocols
   - Dose algorithm parameters & accuracy of
     ◆ dose/treatment time calculation
     ◆ Isodose/graphic display
     ◆ Source position reconstruction
     ◆ Electronic transfer of device programming parameters
35.600 Photon-emitting Medical Devices

- Replaces 35.600 for Co-60 and Licensing Guide
  FC 86-4 for afterloaders

- General provisions
  - AU T&E: same as 35.400
  - Written emergency procedures & annual training therein
  - Room security, interlocks, posting, area monitors, permitting only AU, AMP, & RSO in room during Rx
  - Visual and aural monitoring except for LDR RAL
  - Limit treatments to those permitting source recovery in event of retraction failure
35.600: RAL Attendance

- **LDR/PDR/MDR afterloaders**
  - AU and AMP (or other trained physician) present at Rx initiation
  - AMP on-call during Rx and an individual (nurse, physician, etc.) trained in emergency applicator removal

- **HDR afterloaders/gamma Stereotactic**
  - AU and AMP present during Rx initiation
  - During HDR Rx, AMP and physician trained in emergency applicator removal (vs. AU in FC 86-4)
  - During stereotactic Rx, AU and AMP physical presence
35.600 RAL QA

- Full calibration and daily spot checks required vs. daily/monthly in FC 86-4
  - **LDR:** full calibration annually/first use, spot check prior to each treatment and quarterly inventory autoradiograph
  - **PDR/HDR/MDR:** spot checks prior to each day of use
  - **PDR/HDR/MDR:** full calibration on first use/repair/source replacement
  - $T_{1/2} > 75$ d.: full calibration at quarterly intervals

- **AMP** must perform full calibration and review spot checks
35.600 RAL QA Protocols

❖ Full calibration
- Source output using NIST-traceable system (for LDR vendor measurements OK); timer accuracy/linearity
- Source positioning accuracy; transfer tubes and applicator lengths
- Retraction under power loss; source-safe leakage

❖ Spot checks
- Interlocks, emergency response equipment, area monitors, viewing/intercom systems
- Timer accuracy, date/time setting, source decay
- RAL status indicators
35.600 Teletherapy Protocols

- **Full (annual) calibration**
  - Output over field size/distance range; timer constancy, linearity & end effect
  - Light-Radiation field coincidence & field flatness vs. orientation; distance indicator

- **Spot checks**
  - Typical output measurement; timer constancy, linearity & end effect
  - Light-Radiation field coincidence; distance indicator
  - Interlocks and ancillary safety devices
35.600 Stereotactic Radiosurgery QA Protocols

- Full (annual) calibration
  - Output check; timer constancy, linearity & end effect
  - Isocenter coincidence; trunion centricity & safety systems/interlocks

- Spot checks
  - Typical output measurement; timer constancy, linearity & end effect
  - Table retraction with power failure; helmet microswitches; stereotactic frame accuracy
  - Interlocks and ancillary safety devices
Medical Event Reports
Subpart M: 35.3045

❖ ME = any event, excluding patient intervention, in which administration results in one of following:
- $|D_{Rx} - D_{Px}| > 5 \text{ R EDE or } 50 \text{ R organ/skin}$\text{ AND}$
  - $\text{Total } |D_{Rx} - D_{Px}| > 20\%$ or one fraction $|D_{Rx} - D_{Px}| > 50\%$
- $D_{Rx} > 5 \text{ R EDE or } 50 \text{ R organ/skin}$\text{ AND}$
  - leaking source or wrong patient, drug, route or mode
- A dose to a site other than treatment site that exceeds expected (planned) dose by 50 R AND 50%$

❖ ME = death or injury reported caused by patient intervention$

❖ ME reported to NRC, referring physician & patient
Other Subpart M Reports

- Dose to embryo/fetus/nursing child (35.3047)
  - administration to pregnant individual  unplanned
    embryo/fetus dose > 5 R
  - administration to breast feeding patient  unplanned
    nursing child dose > 5 R or permanent damage

- Written patient notification still required
  - Need only describe event its medical consequences

- Leaking source (35.3067)
35.1000 Emerging Technologies

- 35.400/35.600 covers both IDE and SSDR devices
- Approved sources/devices not in 35.100 - 35.600
  - For specific scope licensees, new modalities can be added by license amendment/application w/o Part 35 exemption or rule making
- Intravascular brachytherapy T&E/QA requirements
  - Not addressed by New 10 CFR 35
  - My opinion: cardiology techniques (e.g., $\beta$ sources and stents) may require a new Subpart while peripheral vessel HDR treatments can be covered by 35.600
  - 35.1000 can impose new regulations via license condition
Major Changes

❖ Less prescriptive more performance-based rules
  - detailed survey, contamination & thyroid assays;
    inventory; survey instrument possession; ALARA; and
    RSC deleted or simplified
  - Replaced by general requirements 20.1101 and 20.1501

❖ Regulatory relief: diagnostic Nuc Med
  - Modest T&E; dose assay, Mo breakthrough, and
    survey rules

❖ Medical event “wrong site” rule fixed

❖ QA rules moved into regulations and more
  consistent with AAPM guidelines

❖ New sources, devices, modalities easier to add