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 time table
- 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
- 1995: IOM/NAS Report "Radiation Medicine: A Need for Regulatory Reform"
- 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
SRM-COMSECY-96-067

- **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)**

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**

June 99

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:
  - $|D_{Rx} - D_{Px}| > 5$ R EDE or 50 R organ/skin **AND**
    - Total $|D_{Rx} - D_{Px}| > 20\%$ or one fraction $|D_{Rx} - D_{Px}| > 50\%$
  - $D_{Rx} > 5$ R EDE or 50 R organ/skin **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., β 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**