Revised Regulations for Medical Use of Byproduct Material

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Outline

- Overview of Regulatory Environment
- Goals/history of 10 CFR 35 revision process
- 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

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. medicine
  - Large state-to-state variability in regulatory rigor

Varieties of NRC Regulation

- Rules per se: Title 10 Code of Federal Regulations
  - 10 CFR Part 20: Exposure control standards and limits
  - 10 CFR Part 35: Specific regulations on Medical Use
- Licensing process:
  - Regulatory/Licensing Guides: rule interpretations
- Bulletin Process: impose rules without review if public safety threatened (Bulletin 93-01)
- Corrective actions imposed on licensees following rule violations/incidents

Medical Policy Statement

- NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.
- NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
- NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician’s directions

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

- Jun 97: Commission SRM starts process off
- 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
- Aug 00: Revised Medical Policy Statement published in Fed Register
- Oct 00: Commission approves complete 10CFR 35 package
- Mar 01: Final rule Submitted to OMB
- ??? 01: Final rule published in Federal Register
- ???+6 mo.: Effective compliance date including 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, stereotactic
- 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:
  - Detailed requirements reduced: follow 10 CFR 20.1101
  - Implement program commensurate with operation scope sufficient to ensure compliance...
  - Use procedures/controls to keep exposures ALARA
  - AND management must: review amendments; AU/AMP appointments; ministerial program changes; make written RSO job description
  - Rad Safety Comm: only if 2 or more modalities/devices used
- RSO training and experience:
  - (a) Certification by recognized Board that includes
  - OR (b) 200 hr didactic, 1 yr experience under RSO + preceptor's statement
  - OR (c) AU, AMP, or ANP with proper range of experience...

Procedure Requiring Written Directive

- No QMP requirement. But 35.41 requires
  - verification of patient identity
  - Each administration is in accord with written directive
  - Checking manual and computer-generated dose calculations
  - Verifying that computer-generated treatment plans are correctly transferred to device console

Authorized Medical Physicist (AMP) T&E Requirements: 35.51

- (a) Certified by recognized Board whose certification process includes requirements (b)
- OR (b) MS degree + 1 yr training in Rad Onc
  - 1 yr experience under AMP at an institution including the following activities:
    - Perform remote afterloader/teletherapy/Co-60 Stereotactic full calibrations
    - Establish/review spot checks for above
    - Be available/physically present during RAL/gamma stereotactic treatments
    - Sr-90 eye plaque decay corrections
    - Leak testing brachytherapy sources & performing surveys
    - Preceptor's statement documenting above
- 35.57 may grandfather teletherapy physicists currently listed on agreement/NRC license as full AMPS

AMP T&E Consequences

- ABR and ABMP do not require teletherapy, HDR and/or gamma stereotactic
  - Unlikely that physics boards will be recognized
  - Not obvious that rule language allows for "partial," e.g., HDR only, AMP
  - Boards will no longer be "default" pathway to AMP status
  - Establish compliance with "alternative pathway" requirements
    - Via license amendment for specific scope licensee
    - By management review for broadscope licensees
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

New Patient Release Rule: 10 CFR 35.75
(effective 29 May 1997)

- Old rule: may release radioactive patient when
  - Permanent Implants: Exposure rate < 5 mR/h at 1 m
  - Radiopharmaceutical Patient
    - Exposure rate < 5 mR/h at 1 m or Activity < 30 mCi
- New rule: may release a radioactive patient if the total effective dose equivalent (TEDE) to any other exposed individual is not likely to exceed 5 mSv (500 mR)
  - If TEDE > 1 mSv ⇒ written instructions to patient
  - If breastfeeding ⇒ infant’s TEDE > 1 mSv
    - Provide guidance to do/stop breastfeeding
    - Explain consequences of ignoring guidance
    - Retain justification if you use: occupancy factor < 0.25, retained rather than administered mCi, biological rather than physical half-life or tissue shielding

Written Directives

- Unsealed therapeutic or I-131 > 30 μCi:
  - Radioactive drug, route, and administered activity (or range thereof)
- Sealed sources
  - Gamma stereotactic: at each distinct site: dose, site and no. of target settings
  - Teletherapy: site, total dose, dose/Fx, N.o. Fx
  - HDR: radionuclide, site, total dose, dose/Fx, N.o. Fx
  - Current 10 CFR 35 specifies only total dose

Restrictions on RAM Clinical Indications

- No list of radionuclides and allowed indications
- Radioactive drugs:
  - prepared by 32.72 vendor or ANP/AU
  - OR for use in IND protocol approved by FDA
- Sealed source or device:
  - As approved by Sealed Source & Device Registry (SSDR)
  - OR supplied by 32.74 vendor for research in accord with FDA IDE
- Broadscope licensees are exempt, but must perform own SSDR-like review

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

Two Compartment Model

- Activity delivered
- extra-thyroidal pool
- Thyroid
- Physical decay
- Physical decay
- Urine, feces, sweat

- Thyroid Tissue Uptake: 0% - 7%
  - Effective half life = Physical half life = 8.04 d
- Extra-thyroidal uptake: 70 - 100%
  - Effective half life = 0.5 d
- Can release patients with burdens as high as 300 mCi (11 GBq)
Written Directive: Other Brachytherapy

- Manual & RAL LDR, PDR
- Prior to implant: radionuclide, site, dose
- After implant: radionuclide, site, no. sources, total source strength and treatment time (or total dose)
- “dose” can be mg-hrs for manual, LDR/PDR RAL but for HDR.

35.300: Radioactive Drugs

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
- (a) certified by recognized Board which includes (b)
  - OR (b) 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

35.400: Manual Brachytherapy

Technical requirements and safety precautions
- Surveys for lost sources upon loading and removal
- Source inventory req’d, but less detailed rules
- Initial and annual training to caregivers
- Posting, emergency procedures for dislodged sources
- Not quarter patient in same room with non-brachy pat.
- AU T & E certified by a Board including the following
  - OR 200 h didactic + 500 h experience (incl surveys, inventories, preparing sources) , 3 yr ACGME-approved Rad Onc residency & preceptor statement

35.400 QA Requirements

Source calibration: prior to first use
- Verify source positioning accuracy in applicator
- 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/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 (incl. reviewing calibration checks, emergency procedures for each type of device + preceptor’s statement)
- Emergency procedures & annual training thereof
- 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: AU Training & Experience

- (a) certified by recognized Board which includes
  - OR (b) has completed structured education program including
    - 200 h didactic in Physics and Radiobiology
    - 500 h experience including reviewing calibrations, preparing Tx plans, preventing ME's, selecting doses
    - AGCM approved 3-year residency in Rad. Onc.
  - Preceptor's statement: can function independently as AU of each device for which AU status requested

- What if training program lacks stereo, Co-60 or stereo?

35.600 RAL QA

- Full calibration and daily spot checks replace daily and monthly checks
  - **LDR**:
    - full calibration annually/first use,
    - spot check prior to each treatment
    - autoradiograph for source inventory quarterly
  - **PDR/HDR/MDR**:
    - full calibration on first use/repair/source replacement or quarterly for \( T_{1/2} > 75 \) d;
  - AMP must perform full calibration and review spot checks

- More compliant with AAPM TG56, TG40 and TG59

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

Single-Stepping Source High Dose-Rate Remote Afterloading

- 10 Ci HDR Ir-192 source: \( S_p = 4.08 \times 10^6 \) Gy m² h⁻¹
- Step sequentially through applicators
  - discrete stopping points
  - dwell positions
  - treatment time/position = dwell time

35.600: Full Calibration Options for HDR RAL

- Left: calibrated re-entrant well chamber
- Right: cavity ion chamber on transverse axis
Autoradiographic verification of Positional Accuracy

Selectron LDR-6 Afterloading Facility

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 the following:
  - \(|D_{Rx} - D_{Px}| > 5 \text{ R EDE or } 50 \text{ R organ/skin AND}
  - 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 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 = patient intervention causing death or unintended permanent damage
- 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 \text{ R}
  - Administration to breast feeding patient ⇒ unplanned nursing child dose > 5 \text{ 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
  - 35.100 can impose new regulations via license condition

Major Changes

- Less prescriptive more performance-based rules
  - Detailed survey, contamination & thyroid assays; inventory; survey instrument possession; and RSC deleted or simplified
  - Replaced by general requirements 20.1101 and 20.1501
- Regulatory relief: diagnostic Nuc Med
  - Modest β T&E; β dose assay, Mo breakthrough, and survey rules
- Medical event “wrong site” rule fixed
- QA rules: in 10CFR35 more consistent with AAPM TG’s
- New sources, devices, modalities easier to add
- Board certification:
  - Marginalized for physics
  - Rad Onc: no longer covers radionuclide Tx & may not cover devices
- For more information and your own copy of Part 35 go to: http://www.nrc.gov/NRC/COMMISSION/SECYS/secy2000-0118/2000-0118scy.html