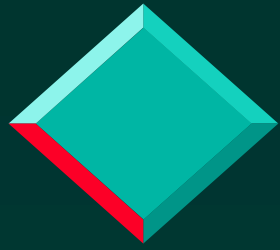


***Revised Regulations for Medical Use of
Byproduct Material***

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

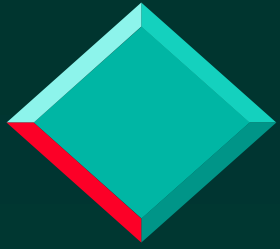
Jeffrey F. Williamson, Ph.D.

**Radiation Oncology Center
Washington University
St. Louis, Missouri**



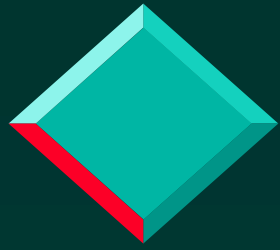
Current Regulatory Framework

- ❖ **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**



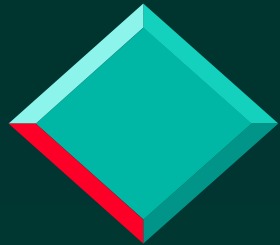
Why Regulatory Change?

- ❖ **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**



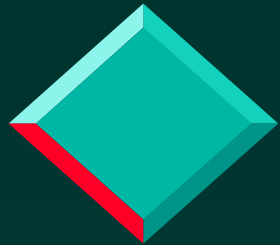
Commission-Level Direction

- ❖ **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”**



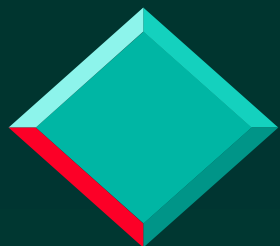
NRC Commissioner's Instructions ***SRM-COMSECY-96-067***

- ❖ **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”**



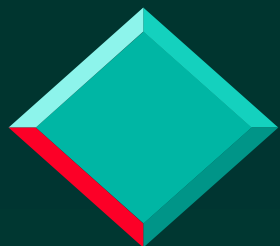
“Fast track” 10 CFR 35 Timetable

- ❖ **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



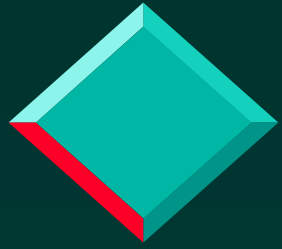
Part 35 Outline: Subparts

- ❖ **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)**



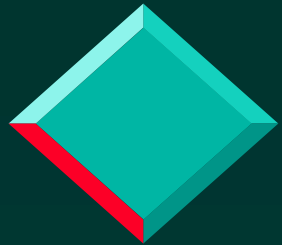
Radiation Safety Program Structure

- ❖ **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



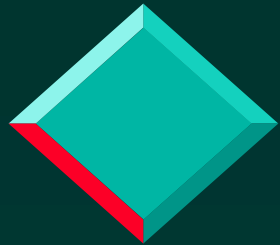
Authorized Medical Physicist (AMP)

- ❖ **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**



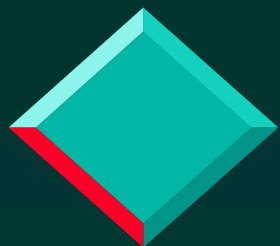
Unsealed byproduct materials

- ❖ **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**



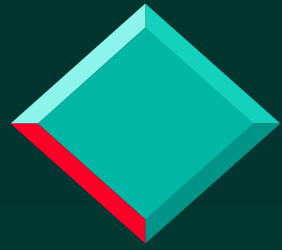
Written Directives

- ❖ **Unsealed therapeutic or I-131 > 30 μ Ci:**
 - 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**



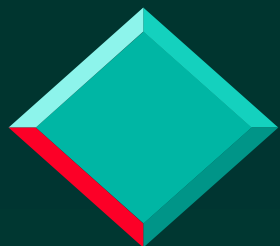
35.300: Radioactive Drugs Written Directive Req'd

- ❖ **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**



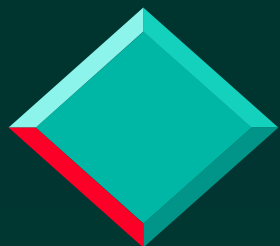
35.400: Manual Brachytherapy

- ❖ **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



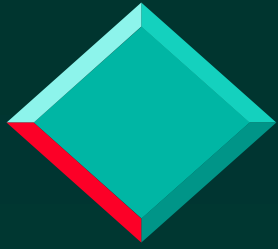
35.400 QA Requirements

- ❖ **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



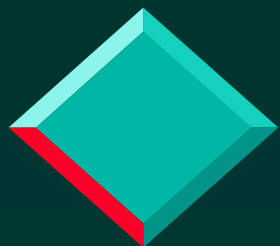
35.600 Photon-emitting Medical Devices

- ❖ **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**



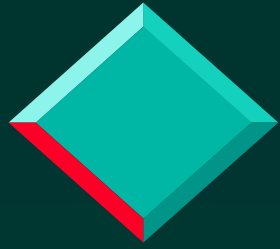
35.600: RAL Attendance

- ❖ **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**



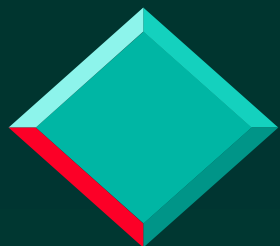
35.600 RAL QA Protocols

❖ 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**



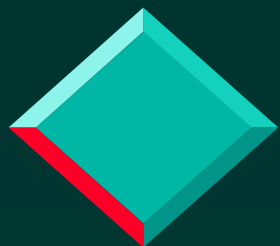
35.600 Teletherapy Protocols

❖ Full (annual) calibration

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

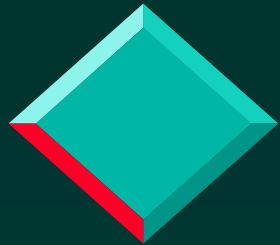
❖ Spot checks

- 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

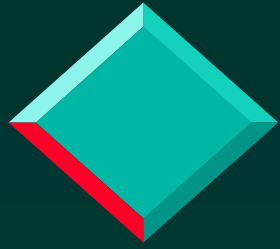
- ❖ **Full (annual) calibration**
 - Output check; timer constancy, linearity & end effect
 - Isocenter coincidence; trunion centricity & safety systems/interlocks
- ❖ **Spot checks**
 - Typical output measurement; timer constancy, linearity & end effect
 - Table retraction with power failure; helmet microswitches; stereotactic frame accuracy
 - Interlocks and ancillary safety devices



Medical Event Reports

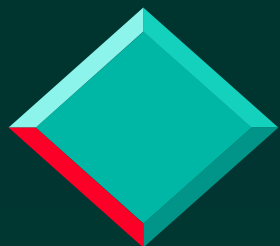
Subpart M: 35.3045

- ❖ **ME = any event, excluding patient intervention, in which administration results in one of following:**
 - **$|D_{Rx} - D_{Px}| > 5 \text{ R EDE or } 50 \text{ R organ/skin AND}$**
 - ◆ **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 = 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**