# Brachytherapy Ramifications of Revised 10 CFR Part 35

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## Revised 10 CFR 35

- effective NRC States 10/24/2002
- Agreement States 10/24/2005
- Risk-informed
- Recognizes voluntary consensus standards
- NRC Guidance - NUREG 1556, vol.9
- Permits source research applications if obtain FDA-approved IDE



## Terminology Removed

- Dose calibrator
- Teletherapy Physicist
- Misadministration
- Recordable event
- Quality Management Program (QMP)

## General Info - Definitions

- Authorized Medical Physicist (AMP)
- Brachytherapy
- Brachytherapy source
- HDR: >12 Gy/hr
- MDR
- LDR: ≤ 2 Gy/hr

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## General Info - Definitions

- Manual Brachytherapy
- Management
- Patient intervention
- Preceptor
- Pulsed dose-rate remote afterloader
- Written Directive

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## General Info

License Amendments (§13)

- AMP
- RSO
- Changes in possession limit, form, or radionuclide
- Changes in areas of use, except §100 or §200 uses
- Revision to safety procedures or spot checks for teletherapy, remote afterloaders, gamma knife

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## Administrative Requirements
### Subpart B

- Management approves in writing:
  - » license changes
  - » AU, AMP, ANP
  - » Protection program changes
  - » appoints RSO
  - » authority/duties of RSO
- Temporary RSOs ≤ 60 d; notify NRC

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## Administrative Requirements

- RSC required if ≥2 types of use or devices requiring written directive
  - » membership listed but not frequency, agenda, quorum, etc.
- Can change program that comply with regs (§26)
  - » if Mgmt/RSO review & approval
  - » instruct affected individuals
  - » document changes

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## Administrative Requirements

- Supervision (§27)
  - » Licensee must instruct on rad protection & written directive procedures, regs, license
  - » supervised worker obligated to follow
- Written Directive Procedures (§41)
  - » "Assurance Program" to provide "high confidence"
    - verify patient's identity before
    - each administration follows directive
    - check manual & computer calcs
    - verify computer generated calcs correctly transfer into device consoles

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## Administrative Requirements

- Written Directive (§40)
  - » signed & dated by AU before, unless medical emergency
  - » HDR: radionuclide, Tx site, dose per fraction, # fractions, total dose
  - » Other brachytx - before: radionuclide, Tx site, total dose
  - » Other brachytx - after: radionuclide, Tx site, # of sources, total source strength, total dose (or time)

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## Technical Requirements
### Subpart C

- Dose calibrator checks (§60)
  - » manufacturer specs or consensus standards
- Calibration of Survey Instruments (§61)
- Sealed/Brachytherapy Source (§67)
- Patient release (§75)
- Mobile?
- Decay-in-Storage Waste (§92)

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## Manual Brachytherapy
### §400 or Subpart F

- Surveys must be done:
  - » after implantation
  - » after removal of temp implants
- "Accountability at all times in storage & use"

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## Manual Brachytherapy
### §400 or Subpart F

- For patient who cannot be released (§35.75):
  - » safety instruction to all caregivers initially & annually (§410):
    - source description
    - safe handling & shielding
    - patient & visitor control
    - emergency response
    - commensurate with duties

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## Manual Brachytherapy
### §400 or Subpart F

- For patient who cannot be released (§35.75):
  - » Safety Precautions (§415):
    - Can quarter patient with only another brachytx patient
    - Visibly post room with "RAM" sign
    - Visiting times on door or chart
    - Emergency equipment near room
  - » Emergency notification = RSO, or designee, & an AU

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## Manual Brachytherapy
### §400 or Subpart F

- Calibration (§432) must:
  - » Before first medical use
    - includes pre-existing sources if not done
  - » determine source output/activity with calibrated dosimetry system (§630)
  - » Use protocol from nationally recognized body (e.g. AAPM TG40)
- Decay correct output/activity "consistent with 1% physical decay"

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## Manual Brachytherapy

- Calibration can be from:
  - » manufacturer's assay if done per national protocol; or
  - » AAPM-accredited lab; or
  - » Licensee's own measurements
- Batch sampling if ≥ 10% of sources

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## Manual Brachytherapy

- Sr-90 (eye treatment)
  - » numerous misadministrations
  - » requires an AMP for decay-correction (§433)
  - » added AU training requirements for ophthalmic use (§491)
  - » AU training does not have to be at medical institution

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## Remote Afterloaders (RA)
### §600 or Subpart H

- Applies to photon-emitting devices only
- Allows medical research uses outside of SSDR if obtain FDA-approved IDE
- Codified license conditions:
  - » Record patient survey post treatment (§604)
  - » Safety Procedures (§610)
  - » Safety Precautions (§615)
- Based on AAPM TG Report Nos. 40, 56, 59

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## RA Safety Procedures (§610)

- Secure console/key/device/room
- Only approved persons in room during Tx
- Prevent dual device operation in same room
- *Develop/implement/maintain emergency procedures*
  - » Copy at console
  - » Post location & emergency contacts
  - » Instruction initially & annual; drills

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## RA Safety Precautions (§615)

- Door interlocks
- Use radiation meters for entrance
- Viewing & intercom systems (not LDR)
- Treatment must allow removal of decoupled/jammed source
- AU & AMP presence during treatment:
  - » MDR/PDR initial: AMP & AU/supervised
  - » MDR/PDR continue: AMP & AU/supervised
  - » HDR initial: AMP & AU
  - » HDR continue: AMP & AU/supervised

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## Dosimetry Equipment (§610)

- Required for sources/device (not LDR)
- Required for spot-check & full calibration
- Calibrate every 2 yrs; or
- Calibrate every 4 yrs + 18-24 mos. intercomparison; AND
- NIST-traceable source/system with protocol from nationally recognized body; OR
- AAPM accredited calibration lab

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## RA Full Calibration (§633)

- Done by AMP
- Installation/source exchange/repair
- Annual for LDR
- Quarterly all others ($T_{1/2}$ > 75 days)
- Follow protocol by nationally recognized body
- 7 items listed + autoradiograph (LDR)
- Decay correct output at 1% physical decay intervals

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## RA Spot-Check (§643)

- Before first use of day & source exchange
- Follow procedures written by AMP
- AMP not required but must review in 15 days
- 8 items listed

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## Training and Experience

- Unresolved controversy
- No board certification will meet new requirements for RSO, AMP, AU, ANP
- "Old" criteria (Subpart J) effective until 10/24/04
- Recentness of training < 7 yrs (§59)

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## Training and Experience

Recent proposal:

1) Board certification pathway; or
   - » NRC approved Boards listed on website
2) Alternate pathway [fcn. hrs. training, # cases, yrs. of experience]; and
3) Modality specific training; and
4) Signed preceptor statement

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## Emerging Technologies §1000 or Subpart K

- IVBT Devices
- I-125 Gliasite
  - » Liquid brachytx source & device
- Y-90 Theraspheres/SIRSpheres
  - » Microsphere brachytx device

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## IVBT Devices
### Common Conditions

- Condition of use limited to Intravascular Brachytx
- Procedures conducted under supervision of AU
  - » AU to consult with intervent. cardiologist & AMP
  - » Physical presence of AU or AMP
- Training and experience for AUs as set forth in:
  - » 10 CFR 35.690, 35.940
- Vendor training for AU, AMP, and intervent. cardiologist
- AMP to independently measure source output
  - » 11 vendor calibration errors reported

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## IVBT Devices
### Common Conditions

- Written directive, prior to treatment, specifies:
  - » Treatment site
  - » Radionuclide
  - » Dose
- Written emergency procedures for:
  - » Stuck sources
    - 28 events reported
  - » Detached sources

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## Records Retention
### Subpart L

- Specifies retention time & record content
- Name vs. signature vs. initials
- Nearly all: 3 years
- Notable exceptions:
  - » 5 years
    - License amendment/renewal/application
    - Rad protection program changes
    - Approval of AU, AMP, ANP

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## Records Retention

- Notable exceptions:
  - » Duration of license
    - Signed RSO duties/responsibilities agreement
    - Written directive assurance procedures
    - Dosimetry equipment calibrations
  - » Life of source/device
    - Sr-90 ophthalmic decay records
    - HDR safety procedures
    - HDR spot-checks

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## Records Retention

- Brachytx Source Accountability (§2406)
  - » Temporary implants
    - Removal: #, activity,time, date, name, location of use
    - Return: #, activity,time, date, name
  - » Permanent:
    - Removal: #, activity, date, name,
    - Return: #, activity, date, name
    - # & activity implanted

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## Records Retention

- Brachytx Source Calibration (§2432)
  - » AMP signature & date
  - » Name, model #, serial # of source & instruments
  - » Source output or activity
  - » Positioning accuracy in applicators

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## Reports/Notifications
### Subpart M

- Medical Event (§3045)
- Embryo/Fetus or Nursing Child (§3047)
- Leaking Source (§3067)
  - » > 5 nCi (185 Bq)

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## Medical Event

1) >5 rem EDE or 50 rem to organ/tissue/skin
   AND
   - » Total dose/dosage ≥ ±20%; or
   - » Single fraction ≥ ±50%; or
   - » Wrong patient; or
   - » Wrong mode of treatment; or
   - » Wrong radioactive drug; or
   - » Wrong route of administration for rad drug;
   - » Leaking sealed source



## Medical Event

2) Dose to tissue/organ/skin
   - Other than treatment site; and
   - > 50 rem (0.5 Sv); and
   - > ±50% expected from written directive plan
   - Excludes migrated but correctly implanted seeds
3) Patient intervention excluded, except:
   Administration or radiation causing unintended permanent functional damage to organ or system per physician



## Dose to Embryo/Fetus

- >5 rem (50 mSv) total EDE
- Unless approved by AU <u>in advance</u>

## Dose to Nursing Child

- >5 rem (50 mSv) total EDE; or
- Unintended permanent functional damage to organ or system

## Removed But Not Gone

- Relevant Items under 10 CFR Part 20
  - » ALARA Program (§20.1101)
  - » Survey procedures (§20.1501)
    - contiguous/adjacent areas of hospitalized patients
    - can do maximal representative situation
    - Storage/use areas
  - » Source security (Subpart I)

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## Recent Developments

- HIPPA
  - » Required creation of a data bank to receive/disclose certain final adverse actions against healthcare practitioners, providers, & suppliers
  - » NRC/Agreement States required to report adverse actions against healthcare licensees & their employees
  - » Reporting actions since 10/21/1996

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## References


- http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/
- http://www.nrc.gov/materials/miau/miau-reg-initiatives/by-product.html
- Nuclear Regulatory Commission, Advisory Committee on Medical Use of Isotopes (ACMUI) Meeting, May 20-21, 2003 (http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/)


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