Chapter 9

An *Aperçu* of Codes, Directives, Guidances, Notices, and Regulations in Brachytherapy

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**Brachytherapy Regulatory Overview (What’s New Since 1994 Summer School?)**

Is the regulatory climate hot (for more regulations) or cold (quiescent)?

Regulations are like taxes: Everyone thinks they should be reduced! However, it rarely occurs. And, like taxes, when the “Code” is revised, taxes or regulations that appear to have been eliminated in one section often appear in other sections, often at higher rates! Occasionally, a lonely voice cries out for reform, but usually the cry goes unanswered. Mossman proposes that regulatory effectiveness and efficiency would be improved by three changes: (1) adoption of a dose-based rather than the current risk-based system;
(2) adoption of the International System of Units; and (3) establishing a single, independent office to coordinate nuclear regulations established by U.S. federal agencies and departments (Mossman 2003). However, the pace of regulatory change is glacial—usually advancing, not retracting! So, let us review the significant changes in the past 10 years in brachytherapy and the corresponding changes in regulations. The significant changes were: (1) Increased use of the World Wide Web Internet to disseminate regulations; (2) changes in types of brachytherapy procedures; (3) concerns about byproduct material security (or lack thereof) in medical facilities; (4) the adoption of new federal codes, and (5) implementation of these codes by Agreement States. The opinions expressed are exclusively those of the author, based on 30 years of experience working directly, and concurrently, with regulators under both an NRC license (Edward Hines VA Hospital) and Agreement State (Illinois) license (Loyola University Chicago Medical Center).

There is no excuse not to know the regulations: They are on the web!

A comprehensive overview (Deye 1988), now dated, still serves as an excellent tutorial for those unfamiliar with organizations, such as the International Atomic Energy Agency (IAEA), International Commission on Radiological Protection (ICRP), and International Commission on Radiation Units and Measurements (ICRU), and codes and regulations. Table 1 presents useful, current web addresses for international organizations that often make recommendations that become the basis of subsequent federal regulations made by federal agencies.

The National Council on Radiation Protection and Measurements (NCRP) makes, via statements and publications, recommendations on matters of radiation usage and, subsequently, safety issues. Through the Environmental Protection Agency (EPA), the federal agencies, Departments of Energy (DOE) and Transportation (DOT), Food and Drug Administration (FDA), currently coordinate their regulatory efforts. The U.S. Nuclear Regulatory Commission (NRC) is the lead agency for promulgating regulations related to brachytherapy sources and their use. Their regulations apply in 17 non-Agreement states and in federal facilities directly holding federal licenses. Agreement States, currently 33 in number, agree, under certain terms, to apply those regulations adopted by the NRC. The Conference of Radiation Control Program Directors (CRCPD) coordinates regulatory issues among its member states and proposes model state license and regulatory language. Their web site has electronic links to all state regulatory agencies. The Radiation Safety Officers Toolbox, via Idaho State University (http://www.physics.isu.edu/radinf/rsotoolbox.htm), provides direct links to the Code of Federal Regulations (CFR) discussed later in this chapter. Other organizations, such as the American Association of Physicists in Medicine (AAPM), Health Physics Society (HPS), Society of Nuclear Medicine (SNM), often issue position statements regarding proposed regulations. Higson (2001) offers a useful international view of the regulation of medical devices for public health and safety. Benedetto (1995) reviews how regulations arise in the United States.

What’s hot and what’s not in brachytherapy procedures?

Brachytherapy prospers in the United States. Interstitial prostate implants with \(^{125}\text{I}\) and \(^{103}\text{Pd}\) seeds are popular and show no signs of decaying! Remote high dose rate (HDR) afterloading procedures are increasing; mobile units serve multiple hospitals in heavily populated urban areas. Traditional single-session procedures (gynecology treatments with manually loaded \(^{137}\text{Cs}\) sources, interstitial sarcoma implants, etc.) are being replaced with multiple fractional HDR twice-a-day treatment regimens. Our original (7/88) HDR program at Hines VA Hospital was a Gamma Med IIIi located in a \(^{60}\text{Co}\) teletherapy vault. Treating lung, esophagus, and the vagina, we performed about 49 procedures yearly. Since relocating (8/03) the program to a new facility at Loyola with a dedicated HDR vault, and opening a full gynecologic service and interstitial sarcoma and head and neck implant service, we perform 200+ cases yearly. Treatment of a new site (breast) with MammoSite® applicator additionally increased the total number of annual procedures.
Regulatory hurdles to treating with pulsed dose rate (PDR) remote afterloading devices have been lowered. Intravascular brachytherapy (IVB), popular for a short time, unfortunately exhibited a reasonably short half-life and was rapidly abandoned at many facilities.

Do you know where your sources are? **Who else knows?**

A new international and national concern is the security of byproduct sources in medical facilities. Most medical licensees have small (multiple millicurie) quantities of long-lived byproduct materials (\(^{137}\)Cs, \(^{60}\)Co, etc.), ideal components for a dispersal “dirty bomb.” The IAEA has developed an action plan to combat nuclear terrorism (Health Physics News and Notices 2002, 2003). These international efforts likely will lead to new national and state regulations requiring greater security for radioactive sources.

You still haven’t read the “new” (4-24-02) USNRC 10 CFR 20, 32, and 35 regulations?

Shame on you! You will not be spared! This limited presentation (NB: think of it as “Regulations Lite”) reviews the cogent details of regulations that did not change as well as those that did.
I’m an agreement state licensee! Why should I be concerned about changes in federal codes?

Agreement States have certain periods (5 years or more) within which state regulations must become compliant, at certain levels of compliance, with NRC regulations. A licensee may be in “regulatory transition,” a dangerous period of change! For example, at this time (2005) Illinois is enforcing state regulations based on NRC regulations in force prior to the 2002 regulatory changes, as they prepare new state regulations compliant with the recent changes in federal codes. Other states are in similar regulatory transitions.

**Brachytherapy Regulatory Overview (What’s Unchanged Since 1994 Summer School?)**

10 CFR 19 (Notices, Instructions, and Reports to Workers; Inspections)

This long-standing regulation (USNRC 1981), with 14 sections, issued 12/18/1981, un-revised, remains in force. Table 2 lists seven important sections with brief comments about their content. Staying compliant with “instructions” to a constantly changing workforce is a regulatory challenge!

10 CFR 20 (Standards for Protection Against Radiation)

These standards, consisting of 69 sections, are (with one exception discussed later) mostly unchanged from the 5/21/1991 release (USNRC 1991). Tables 3A and 3B list 10 key headings with brief comments about their content. Note that security of radioactive materials (RAM) is addressed in §20.1801.

**Regulatory Review: What’s Changed in 10 CFR 20 (Standards…Radiation)?**

10 CFR 20.1002/Scope; –.1003/Definitions, and –.1301/Dose Limits for Individual Members of the Public (USNRC 2002)

20.1002/Scope now states that “…limits in this part do not apply…to exposures from individuals administered RAM and released under §35.75…”

20.1003/Definitions adds “Occupational dose does not include…dose…from individuals administered RAM and released under §35.75…” “Public dose does not include…dose…from individuals administered RAM and released under §35.75…”

20.1301/ Dose Limits for Individual Members of the Public now adds to the exclusion of dose from RAM in sanitary sewers, the following: “…does not exceed 0.1 rem (1 mSv) in a year exclusive of the dose contributions from background radiation, from any medical administration to the individual, from individuals administered RAM and released under §35.75, from voluntary participation in medical research programs….” Also, added: “…a licensee may permit visitors to an individual…to receive a radiation dose greater than 0.1 rem (1 mSv) if (1) the radiation dose…does not exceed 0.5 rem (5 mSv) and (2) the authorized user has determined before the visit that it is appropriate.”
Table 2. 10 CFR 19 (*Notices, Instructions, & Reports to Workers; Inspections*) (Partial Contents)

<table>
<thead>
<tr>
<th>Section</th>
<th>Major contents of section</th>
</tr>
</thead>
<tbody>
<tr>
<td>.3/Definitions</td>
<td>Workers, licenses, restricted areas defined.</td>
</tr>
<tr>
<td>.11/Postings notices to workers</td>
<td>a) Post regulations, (i) license &amp; its conditions; (ii) operating procedures; (iii) violations; b) Documents, forms must be conspicuous.</td>
</tr>
</tbody>
</table>
| .12/Instructions to workers | Inform about:  
  a) storage, use RAM;  
  b) health protection problems;  
  c) procedures to reduce exposures;  
  d) regulations;  
  e) report conditions, violations;  
  f) response to warnings;  
  g) their exposures. |
| .13/Notification & reports to individuals | a) Written exposure reports; b) annual exposure reports per workers request; c) other provisions not stated here. |
| .14/Presence of licensee’s & workers representatives during inspections; | a) Licensee to allow inspections; b) inspectors may meet workers; c) representatives may accompany inspectors during inspections; d) other provisions not stated here. |
| .15/Consultations with workers during inspections | a)Inspectors may consult privately with workers; b) workers may consult privately with inspectors. |
| .16/Requests by workers for inspections | Workers may request, without retribution, inspections. |

**Regulatory Review: What’s Changed in 10 CFR 32 (*Specific…Material*)?**

The “new” (4-24-2002) 10 CFR 32 (*Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material*) changes are only notational bookkeeping, changing the paragraphs numbers and sections in Part 32 to correspond with the corresponding sections of the new 10 CFR 35.

**Regulatory Review: What’s “New” in 126 Sections of 10 CFR 35 (*Medical Use…Material*)?**

With 126 sections, we focus only on those of direct interest or applicability to brachytherapy.

Tables 4A through 4E summarize, using some shorthand notations, the major contents of the important sections. The bulk of regulatory changes relative to brachytherapy occur in these sections.
A new term, “Authorized Medical Physicist (AMP)”, and the training thereof, is defined, as well as types [LDR (low dose rate), PDR, HDR] of remote afterloading units (RAU), including medium dose rate (MDR). Mobile services and medical events are new additions. Roles of management, the radiation safety officer (RSO), and authorized users (AU) supervision of individuals are explained. Dose prescriptions, or written directives (WD) details and procedures are enumerated.

Table 4B notes source inventories are now at 6-month intervals. Section 35.75 explains new release criteria for patients (NB: See Glasgow (2002b) for a discussion relative to 192Ir seed patients) (USNRC 1997). Some requirements for mobile medical services are in this section, as well as rules for decay-in-storage of RAM.
Some Components of 10 CFR 35 (F) Applicable to Manual Brachytherapy (Table 4C)

One major change is a requirement to decay output or source activities in 1% intervals. Another section adopts AAPM good practices, per various protocols, for quality assurance of therapy planning systems, as a regulation! (NB: To present and future task group members: Be careful what you write lest it become a required regulation!)

Some Components of 10 CFR 35 (H) for Photon-emitting Remote Afterloaders (Tables 4D,E)

In the nine sections, the most significant change is the requirements for MDR and PDR units. Physicians other than AUs, trained in MDR and PDR operation, emergency procedures, and source removal, may work under the supervision of an AU [NB: I will denote them as “substitute authorized users (SAU)”]. For the initial treatment, the AMP and AU or SAU must be present; during subsequent (continuation) treatments, the AMP, AU, or SAU must be immediately available. (NB: In the medical world, that’s by pager!) These requirements are less onerous than the prior requirements of the AU always being present during all treatments. These changes may (or may not!) allow PDR to develop in the United States. Another section adopts AAPM good practices, per various protocols, for quality assurance of RAU therapy planning systems, as a regulation!

Table 3B. Unchanged Components of 10 CFR 20 (Standards...Protection...Radiation)

<table>
<thead>
<tr>
<th>Section</th>
<th>Major contents of section</th>
</tr>
</thead>
<tbody>
<tr>
<td>.1901/Caution Signs</td>
<td>Radiation symbol (trefoil) color schema (magenta, purple, black) on yellow &amp; design defined.</td>
</tr>
</tbody>
</table>
| .1904/Labeling Containers Radioactive Materials | a) Containers of RAM must be marked either “CAUTION” or “DANGER”, RADIOACTIVE MATERIAL;  
  |                                | b) Label must identify quantity, date, radiation levels, kind of material;  
  |                                | c) Remove/deface labels on empty containers.                                                |
| .1906/Receiving/Opening Packages | a) Package receipt & monitoring procedures;  
  |                                | b) Carrier notified if wipe test or radiation levels exceed limits;  
  |                                | c) Package opening procedures;  
  |                                | d) Other provisions not stated here.                                                        |
| .1501/Surveys and Monitoring   | a) Make necessary surveys;  
  |                                | b) Equipment used for surveys calibrated;  
  |                                | c) Excluding direct/indirect pocket dosimeters, NVLAP accreditation for badge processor.   |
| .2001/Waste Disposal           | a) By transfer to authorized recipient;  
  |                                | b) By decay in storage;  
  |                                | c) By effluent release within limits;  
  |                                | d) Others provisions not stated here.                                                       |

NVLAP: National Voluntary Laboratory Accreditation Program
Table 4A. Components of 10 CFR 35 (A, B) Applicable to All Forms of Brachytherapy

<table>
<thead>
<tr>
<th>Section</th>
<th>Major contents of section</th>
</tr>
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</table>
| .2/Definitions | a) Authorized medical physicist defined;  
| | b) LDR, MDR, HDR, PDR defined;  
| | c) Mobile medical service defined;  
| | d) Medical event (no more misadministrations!) explained;  
| | e) Manual prescribed dose (total sources strength & time, or dose per WD) given;  
| | f) Remote prescribed dose (total dose & dose per fraction per WD) given.  
| .24/Authority Radiation Protection Program | a) Defines a stronger management role;  
| | b) Defines & strengths RSO role.  
| .27/Supervision | Explains role of authorized user (AU) & supervised individuals with respect to process & procedures with RAM.  
| .40/Written Directives (WD) | a) Written directives required or oral directives with 48 h for written;  
| | b) HDR: radionuclide; site, fx dose, # fxs, total dose;  
| | c) Others; before tmt: radionuclide; site, dose; before finish: # sources, total source strength & time (or total dose); revisions allowed during treatment.  
| .41/Procedures…written directives | a) ID patient;  
| | b) Administration per WD;  
| | c) Check manual, computer dose calculations;  
| | d) confirm console data.  
| .51/Training authorized medical physicist | a) Board certifications;  
| | b) Degrees + 1 y training + 1 y experience;  
| | c) Preceptor’s written statement regarding training.  

Requirements for dosimetry systems (DS), full calibrations (FC), and spot-checks (SC) are described, including those for mobile services.
### Table 4B. Some Components of 10 CFR 35 (C) Applicable to All Forms of Brachytherapy

<table>
<thead>
<tr>
<th>Section</th>
<th>Major components of section</th>
</tr>
</thead>
</table>
| .67/Requirements for possession | a) Leak tests (<5 nCi) before 1st use, 6 mos.;  
b) Exempt $^{192}$Ir seeds in ribbons & unused sources;  
c) 6-months inventory. |
| .75/Release…patients containing…RAM | a) OK if others TEDE < 5 mSv/y;  
b) Instruction if others TEDE > 1 mSv/y. |
| .80/Mobile medical services | a) Facility agreement letters;  
b) On-site, before use survey meter checks;  
c) Post-treatment surveys;  
d) Possession licenses required for all sites. |
| .92/Decay in storage | a) $T_{1/2} < 120$ d; decay to background level;  
b) Remove labels; keep records. |

### Table 4C. Some Components of 10 CFR 35 (F) Applicable to Manual Brachytherapy

<table>
<thead>
<tr>
<th>Section</th>
<th>Major contents of section</th>
</tr>
</thead>
</table>
| .404/Surveys after… implant & removal | a) After implant; source accountability;  
b) After source removal; keep records. |
| .406/Source accountability | a)…at all times…in storage & use; record. |
| .410/Safety instructions | a) Initially, annually…to caregivers;  
b) Size, type, handling, shielding, visitor. |
| .415/Safety precautions | a) No room sharing with regular patients;  
b) Post room (RAM) & visitor limits;  
c) Emergency equipment for source retrieval from or in patient. |
| .432/Source calibrations (post 10/24/04) | a) Determine output or activity;  
b) Positioning in applicators per “protocols”;  
c) Decay outputs/activities at 1% intervals; keep records. |
| .433/Decay $^{90}$Sr sources | Only AMP shall calculate decayed activity & keep records. |
| .457/Therapy-related computer systems | a) Acceptance testing per “protocols”;  
b) Source input parameters; c) accuracy of dose/time at points; isodose & graphics plots;  
d) localization image accuracy. |
**Table 4D.** Some Components of 10 CFR 35 (H) for Photon...Remote Afterloaders

<table>
<thead>
<tr>
<th>Section</th>
<th>Major components of section</th>
</tr>
</thead>
<tbody>
<tr>
<td>.604/Surveys of patients</td>
<td>Before releasing patient...survey patient &amp; RAU to confirm...returned to safe.</td>
</tr>
</tbody>
</table>
| .605/Installation,…,repair                   | a) Certain source work, i.e., install, adjust, etc., by licensed person;  
                                        | b) For LDR RAU, licensed person or AMP can do certain source work; record. |
| .610/Safety procedures                       | a) Secure unattended RAU;                                       |
|                                              | b) Only approved individuals present in room;                   |
|                                              | c) No dual operations;                                          |
|                                              | d) Written procedures for abnormal situations; posted copies; initial/annual instructions with drills; records. |
| .615/Safety precautions                      | a) Control access with interlock;                               |
|                                              | b) Area monitors;                                               |
|                                              | c) CCTV/audio for all except LDR RAU;                          |
|                                              | d) For MPD/PDR an AMP & AU or operator-emergency response MD present at initiation & immediately available during treatments; |
|                                              | e) For HDR an AU and AMP physically present at initiation, but, during continuation, AMP & AU or operator- emergency response MD; |
|                                              | f) Emergency equipment for unshielded source or source in patient. |
| .657/Therapy-related computer system         | a) Acceptance testing per “protocols”;                          |
|                                              | b) Source input parameters;                                    |
|                                              | c) Accuracy of dose/time at points; isodose & graphics plots;  |
|                                              | d) Localization image accuracy;                                 |
|                                              | e) Electronic transfer to RAU accuracy.                         |
### Table 4E. Some Components of 10 CFR 35 (H) for Photon…Remote Afterloaders

<table>
<thead>
<tr>
<th>Section</th>
<th>Major contents of section</th>
</tr>
</thead>
</table>
| .630/Dosimetry system (DS) equipment | a) Except for LDR RAUs, NIST/ADCL calibrated DS;  
  b) 2 y & after service; or,  
  c) 4 y, if intercompared with calibrated DS within 18 to 30 mo. & < 2% change. |
| .633/Full calibrations (FC) of RAUs | a) Before 1st use; at source exchanges &/or repairs to exposure assembly;  
  b) For $T_{1/2} > 75$ d, excluding LDR RAUs, quarterly;  
  c) LDR RAUs yearly;  
  d) FC: 5% output/1 mm positions, source retraction, timer accuracy/linearity;  
  e) Tube lengths & functions;  
  f) Quarterly autoradiographs of LDR RAU sources;  
  g) Decay outputs/activities at 1% intervals;  
  h) FC & decay by AMP; keep records; for LDR RAU can use manufacturer’s data for FC. |
| .643/Periodic spot-checks (SC) of RAUs | a) For LDR RAUs, before 1st treatment; for other RAUs 1st use daily;  
  b) Per WP by AMP;  
  c) AMP review by 15 d;  
  d) SC includes: interlocks, status lights, audio & CCTV, emergency equipment, source position monitors, timer, clocks, decayed source activity. |
| .647/Additional requirements…mobile RAUs | a) Survey meter checks;  
  b) Source inventory;  
  c) All .643 checks;  
  d) Interlocks, status lights, radiation monitors, source positioning, before 1st use, simulated treatment at each address. |

ADCL: Accredited Dosimetry Calibration Laboratory  
NIST: National Institute of Standards and Technology
Table 5. Some Components of 10 CFR 35 (L) (Record Retentions)

<table>
<thead>
<tr>
<th>Record Retention Requirement</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of license</td>
<td>.2024/RPP (b) RSO authority.</td>
</tr>
<tr>
<td>Duration of program (device)</td>
<td>.2610/Safety procedures for device.</td>
</tr>
<tr>
<td>Five years</td>
<td>.2041/Procedures for WP;</td>
</tr>
<tr>
<td></td>
<td>.2026/RPP changes.</td>
</tr>
<tr>
<td>Three years</td>
<td>.2040/WDs;</td>
</tr>
<tr>
<td></td>
<td>.2061/Meter calibrations;</td>
</tr>
<tr>
<td></td>
<td>.2067/Leak tests &amp; inventories;</td>
</tr>
<tr>
<td></td>
<td>.2070/Surveys;</td>
</tr>
<tr>
<td></td>
<td>.2075/Patient release;</td>
</tr>
<tr>
<td></td>
<td>.2080/Mobile services;</td>
</tr>
<tr>
<td></td>
<td>.2092/Decay in storage;</td>
</tr>
<tr>
<td></td>
<td>.2310/Safety instructions;</td>
</tr>
<tr>
<td></td>
<td>.2404/Implants &amp; source removals;</td>
</tr>
<tr>
<td></td>
<td>.2406/Source accountability;</td>
</tr>
<tr>
<td></td>
<td>.2432/Source calibrations;</td>
</tr>
<tr>
<td></td>
<td>.2433/Sr-90 decays;</td>
</tr>
<tr>
<td></td>
<td>.2605/RAU installation, repairs;</td>
</tr>
<tr>
<td></td>
<td>.2632/Full calibrations;</td>
</tr>
<tr>
<td></td>
<td>.2643/Spot checks;</td>
</tr>
<tr>
<td></td>
<td>.2647/Additional mobile records.</td>
</tr>
</tbody>
</table>

Some Components of 10 CFR 35 (L) (*Record Retentions*) (Table 5)

Table 5 summarizes the duration (for license, for program, and for 5 and 3 years) requirements for the retention of records.

Some Components of 10 CFR 35 (M) (*Reports...Medical Events...Sources*) (Table 6)

Misadministration is no more! We now have medical events (ME)! Very careful reading is required for this section, as the ME depends, in some cases, on the *difference* (presumably lower or higher) in delivered dose and prescribed dose (PD), and in other cases, in *exceeding* the PD. Moreover, the definitions are not in medical physics terms of absorbed dose in gray (Gy); rather, they are in health physics terms of effective dose equivalent (EDE), and shallow dose equivalent (SDE), in sievert (Sv). Recall that in partial organ irradiation in health physics, organ or tissue weighting factors apply in calculating EDE. As a brachytherapy ME will likely involve adjacent organs, some judgment may be required in deciding on the correct EDE in an ME.

Table 6 summarizes the reporting of medical events; reporting requirements are similar to pre-2002 regulations.
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### Table 6. Some Components of 10 CFR 35 (M) (Reports…Medical Events…Sources)

<table>
<thead>
<tr>
<th>Section</th>
<th>Major contents of section</th>
</tr>
</thead>
<tbody>
<tr>
<td>.3045/Report/notification medical event (excluding patient intervention) (1)</td>
<td>Dose differs from PD more than 0.05 Sv EDE, 0.5 Sv organ/tissue &amp; SDE skin, and, TD, and, TD delivered differs from PD by +20% or falls outside PD range; or single fraction delivered dose differs from single fraction PD +50%.</td>
</tr>
<tr>
<td>.3045/Report/notification medical event (excluding patient intervention) (2)</td>
<td>Dose exceeds 0.05 Sv EDE, 0.5 Sv organ/tissue &amp; SDE skin, and, TD from wrong: a) byproduct material; b) administration route; c) person; d) treatment mode; e) leaking source.</td>
</tr>
<tr>
<td>.3045/Report/notification medical event (excluding patient intervention) (3)</td>
<td>Excluding migrating permanent implant seeds, dose to skin/organ/tissue other than treatment site that exceeds 0.5 Sv organ/tissue and +50% dose expected from WD.</td>
</tr>
<tr>
<td>.3045/Report/notification medical event (excluding patient intervention) (3) (b)</td>
<td>Report any patient interventions producing permanent/physiological damage.</td>
</tr>
<tr>
<td>.3045/Report/notification medical event (excluding patient intervention) (3) (c, d)</td>
<td>Notify NRC next calendar day after ME with written report in 15 days; notify referring MD &amp; patient unless referring MD chooses not to for medical reasons; details of reports omitted here.</td>
</tr>
<tr>
<td>.3067/Report leaking source.</td>
<td>Report &gt;5 nCi removal contamination within 5 days.</td>
</tr>
</tbody>
</table>

EDE: effective dose equivalent  
SDE: superficial dose equivalent  
PD: prescribed dose  
TD: total dose

### Bulletins, Directives, Guidances, Information Notices, Newsletters, and Regulatory Summaries, for Brachytherapy

The USNRC issues to licensees bulletins, directives, guidances, information notices, newsletters, and regulatory summaries as new issues not covered in regulations arise and must be addressed. In some cases, these documents endure for many years, and may actually be incorporated by Agreement States into their regulatory statutes.

#### Bulletins

Apparently there are no recent bulletins pertaining to brachytherapy; the last one was “Release of Patients after Brachytherapy with Remote Afterloading Devices” (USNRC 1993).

#### Directives

Directives appear in several forms. FC86-4, *Revision 1–Information Required for Licensing Remote Afterloading Devices*, a long-standing (1986) policy and guidance directive, explained the contents for NRC license applications for RAUs (USNRC 1986). While it is not currently on the NRC web site, Illinois (and, I imagine, other states) adopted it, with some changes, into their licensing process for RAUs. FC83-20, *Revision 2–Facility Interlocks and Safety Devices for High, Medium, and Pulsed Dose-Rate Afterloading Units*, is not on the NRC web site. As the title implies, this release clarified the requirements for
interlocks and safety devices (USNRC 1983). It appears that issues raised are addressed in the 2002 10 CFR 35 revisions.

Guidances

Guidances often discuss evolving technologies. For example, as intravascular brachytherapy developed, the NRC issued several guidance documents (Glasgow 2002a, USNRC 2004a). These were necessary as the “new” 10 CFR 35 applies only to photon-emitting RAUs; beta-emitting RAUs fall into the “emergent technology” category evaluated on a “case-by-case” basis.

Information Notices

Information Notices advise licenses of recent concerns usually arising from medical events reported to the NRC. A recent notice discussed failures of HDR RAUs (USNRC 2003).

Newsletters

Newsletters, notably “Nuclear Materials Safety and Safeguards” (NMSS), announce medical events and enforcement actions against those who violate regulations. A recent one reported on a hospital’s failure “…to secure…licensed material…” (USNRC 2004b).

Regulatory Summaries

Regulatory Summaries often clarify issues about the interpretation of regulations, such as the calibration measurements for brachytherapy sources (USNRC 2002b).

Recent NRC Activities—Specialty Boards and Training Requirements

The 2002 revisions in 10 CFR 35 did not address personnel training. On March 30, 2005, the NRC published the final rule (USNRC 2005) regarding specialty boards and personnel training. The rule identifies (on the NRC web-site, not in the published rule!) various approved specialty boards and describes pathways for approval of RSOs, AMPs, authorized nuclear pharmacists (ANPs), and physicians using many forms of by-product materials. This flexible rule offers multiple pathways by which individuals may achieve authorization to perform various tasks or assume authorized titles, e.g., RSO, AMP, ANP, or physician authorized user, while maintaining the integrity of the approval process. One major pathway is the educational degree → experience → specialty examination → certification path. Another major pathway is the supervised experience → preceptor statement path. Table 7 (replete with necessary acronyms) shows five ways an individual, depending on education, experience, and certification status, can achieve authorization as a RSO.

For non-physicians, the education requirements are either (a) a bachelor’s degree or graduate degree in physical science, or, engineering or biologic science with 20 college credits in physical science, or, (b) a master’s degree or doctorate in physics, medical physics, or physical science, engineering, or applied mathematics. Experience requirements vary from 1 year to 5 years depending on the authorization, and are shorter for those with higher degrees. Generally, experience must be gained under a certified medical physicist (CMP) or authorized individual, and documented. Preceptors must document the successful completion of any structured training programs and attest to the individual’s competencies and abilities to perform learned tasks independently. In some instances, structured didactic training programs include classroom and laboratory training in topical areas. For example, topical areas for an RSO include: radiation physics and instrumentation, radiation protection, mathematics pertaining to use and measurement.
of radioactivity, radiation biology, and radiation dosimetry are allowed. Table 8 shows the requirements for approval as an AMP or ANP. [NB. No single-page synopsis with two tables can adequately describe the seven pages of new federal regulations on specialty boards and training requirements; interested readers are advised to study the new regulations in their entirety to fully understand them! (USNRC 2005)]

Similar tables (not presented here) describe approval processes for physician authorized users for use of by-product materials.

Table 7. Some Components of 10 CFR 35 (J) Requirements for Radiation Safety Officers

<table>
<thead>
<tr>
<th>Person</th>
<th>Degree or Certification</th>
<th>Experience</th>
<th>Certification Examination</th>
<th>Classroom Laboratory Training</th>
<th>Preceptor Statement</th>
<th>Special Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Radiation Safety Officer</td>
<td>B or GD in PS; or, E or BS with 20 cc in PS;</td>
<td>and 5 or more yrs in HP including 3 yrs in AHP</td>
<td>and Passes Exam</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Or, (2) Radiation Safety Officer</td>
<td>M or PhD in P, MP, or PS, E, AM</td>
<td>and 2 yrs full-time training in MP under supervision by CMP, or, in CNM, by physician AU</td>
<td>and Passes Exam</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>or, (3) Radiation Safety Officer</td>
<td></td>
<td>1 yr full-time RS under supervision by RSO</td>
<td>and 200 h in topical areas</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>or, (4) Radiation Safety Officer</td>
<td>CMP</td>
<td>and applicable experience</td>
<td>and has written attestation by preceptor</td>
<td>and training in RS, regulatory issues, &amp; emergency procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>or, (5) Radiation Safety Officer</td>
<td>AU, AMP, or ANP on license</td>
<td>and applicable experience</td>
<td>and has written attestation by preceptor</td>
<td>and training in RS, regulatory issues, &amp; emergency procedures</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ANP = Authorized Nuclear Pharmacist  
AMP = Authorized Medical Physicist  
B = Bachelor’s Degree  
BS = Biological Science  
CC = College Credits  
E = Engineering  
GD = Graduate Degree  
M = Master’s Degree  
PhD = Doctoral Degree  
AHP = Applied Health Physics  
PS = Physical Science  
CMP = Certified Medical Physicist  
RS = Radiation Safety  
AU = Authorized User  
CNM = Clinical Nuclear Medicine  
MP = Medical Physicist or Physics  
RSO = Radiation Safety Officer  
AMP = Authorized Medical Physicist  
HP = Health Physics
Table 8. Some Components of 10 CFR 35(J) Requirements for AMPs and ANPs

<table>
<thead>
<tr>
<th>Person</th>
<th>Degree or Certification</th>
<th>Experience</th>
<th>Certification Examination</th>
<th>Classroom Laboratory Training</th>
<th>Preceptor Statement</th>
<th>Special Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Authorized Medical Physicist</td>
<td>M or PhD in P, MP, or PS, E, AM</td>
<td>and 2 yrs under supervision by CMP</td>
<td>and Passes Exam</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>or, (2) Authorized Medical Physicist</td>
<td>M or PhD in P, MP, or PS, E, AM</td>
<td>and 2 yrs in CRF under supervision by AU eligible physician</td>
<td>and Passes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>or, (3) Authorized Medical Physicist</td>
<td>M or PhD in P, MP, or PS, E, AM</td>
<td>and 1 yr full-time training in MP and 1 yr full-time experience by AMP eligible MP</td>
<td>and has written attestation of “competency &amp; independency” by MP preceptor</td>
<td>and training in device operation, clinical use, and treatment planning systems</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) Authorized Nuclear Pharmacist</td>
<td>Pharmacy; or, passed FPGECE exam</td>
<td>4000 h in nuclear pharmacy</td>
<td>and Passes Exam</td>
<td></td>
<td></td>
<td>Current, active license</td>
</tr>
<tr>
<td>or, (2) Authorized Nuclear Pharmacist</td>
<td></td>
<td>700 h in structured program with 200 h in topical areas</td>
<td>and has written attestation of “competency &amp; independency” by preceptor ANP</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ANP = Authorized Nuclear Pharmacist  
CMP = Certified Medical Physicist  
RS = Radiation Safety  
CRF = Clinical Radiation Facility  
P = Physics  
AM = Applied Mathematics  
PhD = Doctoral Degree  
FPGEC = Foreign Pharmacy Grad Exam Committee

Conclusions

Understanding codes, regulations, and license conditions has to be the least exciting part of a medical physicist’s job! The federal codes are the basis for state codes, but state codes are not identical to federal codes, even in Agreement States. There is no joy being involved in a medical event or discovering a license
violation during an inspection! Compliance with myriad regulations and license conditions is a challenge. However, by knowing the codes and regulations, one can write a better license with which it is easier for one to comply! To be forewarned is to be forearmed! May you always be in compliance with your federal or state license!

References


