Why "CARE" or The Good, The Bad, The Ugly – A Regulatory Update

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Midwest Chapter
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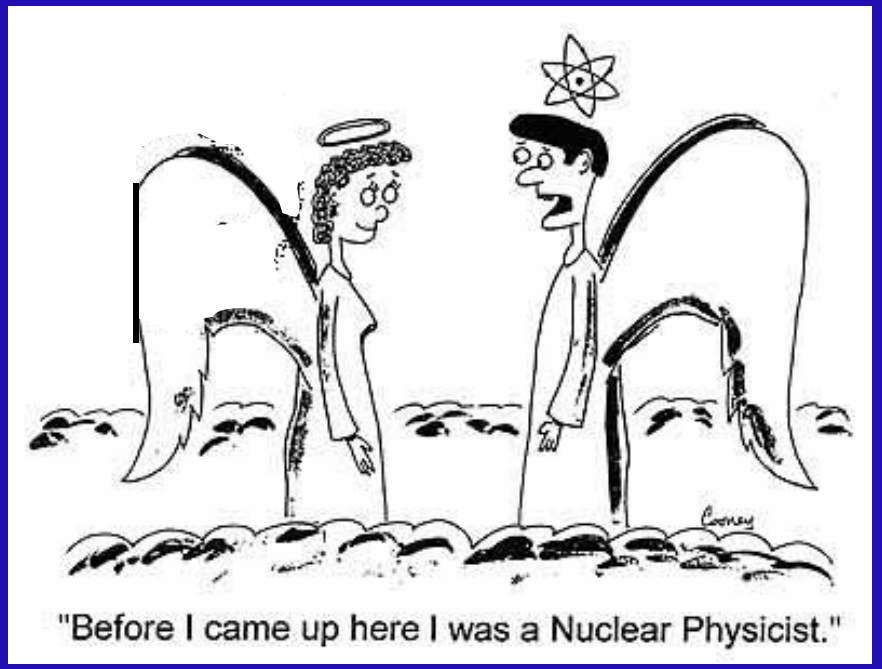
Career Experience

- Regulatory
  - Nuclear Regulatory Commission
  - Department of Energy
- Consulting
  - Science Applications International Corporation, Inc.
  - Lamb Associates, Inc.
  - Advanced Technology and Laboratories, Inc.
  - The Environmental Company, Inc.
- Association/Non-Profit
  - Nuclear Energy Institute
  - National Council on Radiation Protections and Measurements
  - American College of Radiology
  - AAPM



Topics to be Discussed

- CARE Act
- NRC Part 35 Training and Experience
- Status of Board Recognition
- Energy Policy Act of 2005
- National Source Tracking System Database
- National Academy of Sciences report on Cs Irradiators

CARE Bill

- **CARE stands for:**
  - **The Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) Bill**

CARE Act

- **Medical imaging examinations and procedures, as well as radiation therapy treatments for patients covered under these programs, and would need to be performed by personnel meeting the federal standards in order to be eligible for reimbursement.**

CARE Act

- **Excludes physicians, physician assistants and nurse practioners**
- **Does not mandate licensure but does not preclude licensure**
- **Requires Secretary of HHS to work with expert advisers to develop standards (e.g., regulations)**

Who is the Alliance for Quality Medical Imaging and Radiation Therapy, referred to as "The Alliance"?

ASRT & the Alliance

- In July 1998, the ASRT and the SNM Technologists Section (SNMTs) recognized the importance of collaborating with other organizations and they founded the Alliance for Quality medical Imaging and Radiation Therapy

Members of the Alliance

- American Association of Medical Assistants
- American Association of Medical Dosimetrists
- American Association of Physicists in Medicine
- American College of Medical Physics
- American Registry of Radiologic Technologists
- American Society of Radiologic Technologists
- Association of Educators in Imaging and Radiologic Sciences
- Association of Vascular and Interventional Radiographers
- Cardiovascular Credentialing International
- Joint Review Committee on Education in Cardiovascular Technology
- Joint Review Committee on Education in Diagnostic Medical Sonography
- Joint Review Committee on Education in Radiologic Technology
- Joint Review Committee on Education Programs in Nuclear Medicine Technology
- Nuclear Medicine Technology Certification Board
- Section for Magnetic Resonance Technologists of International Society of Magnetic Resonance in Medicine
- Society of Nuclear Medicine-Technologist Section
- Society for Radiation Oncology Administrators
- Society for Vascular Ultrasound
- Society of Diagnostic Medical Sonography
- Society of Invasive Cardiovascular Professionals

Members of the Alliance

- **Consulting Organizations:**
- American College of Radiology
- American Healthcare Radiology Administrators
- American Society for Therapeutic Radiation and Oncology
- Conference of Radiation Control Program Directors

- **Other Supporters**
- American Cancer Society
- American Heart Association Council on Cardiovascular Radiology
- American Organization of Nurse Executives
- American Osteopathic College of Radiology
- Cancer Research Foundation of America
- Help Disabled War Veterans/Help Hospitalized Veterans
- International Society of Radiographers and Radiological Technologists
- National Coalition of Cancer Survivorship
- Medical Imaging Consultants, Inc.
- Philips Medical Systems, Inc.

ACMP, AAPM & the Alliance

- Initially, the ACMP and AAPM were just financial contributors to the Alliance
- After the second House bill had almost finished being drafted, ACMP then AAPM requested that medical physics be added to the bill
  - ACMP liaison to the Alliance – Herb Mower
  - AAPM liaisons to the Alliance – Jerry White, David Keys, and Jeff Masten

Why Join the Alliance?

- Medical physicists are Allied Health Professionals not “providers”
- ACR will not initiate such a licensure effort for its small physics contingency
- The ability of RTs to safely deliver radiation is certainly dependent upon the physicists doing their job well
- Numbers, dollars, and significant other resources are needed to get a Federal bill passed

ASRT

- **ASRT has numbers and it has dollars**
  - **RTs are the largest group of allied health professionals in the country**
  - **More than 300 million radiologic procedures are performed every year in the US and 7 out of 10 Americans undergo some type of medical imaging exam or radiation therapy treatments annually.**

ASRT National Legislative History

- 1965 -Started working on standards-setting federal legislation
- 1981 Consumer-Patient Radiation health and Safety Act
  - Non-enforceable with no penalties for non-compliance
- 1985 HHS Standards
  - ASRT initiated legal action for promulgation

Current Legislation

- **Consumer-Patient Radiation Health and Safety Act of 1981:**
  - **Discretionary for each state (meaning no hard hammer if the states did not adopt or comply)**
  - **As a result:**
    - **only 38 states voluntarily license, regulate or register radiographers**
    - **32 states license radiation therapists**
    - **26 states license nuclear medicine technologists**
    - **4 states license medical physicists – T X, NY, FL and HI**
  - **8 States allow personnel to perform medical imaging without obtaining any education or credentials (e.g., requiring only a few hours of coursework or a couple of weeks on-the-job training.**
    - **AL, AK, GA, ID, MO, NC, OK, SD and DC**

Brief Legislative History

- **In 2000, it was first introduced late in the 106th Congressional year by Rep. Rick Lazio (R-NY). The bill died when Congress adjourned.**

Brief Legislative History

- Introduced in the House on March 13, 2001 by Rep. Heather Wilson (R-NM) 107th Congressional year
- Medical physics joined late in the wording of the bill (March 2001)
- Bill died when Congress adjourned

Brief Legislative History

- **Jump ahead to 2004**
  - **House bill had 112 cosponsors (73D / 39R) and**
  - **New Senate bill had 18 co-sponsors (15D / 2R /1I)**
- **Bill died when Congress adjourned**

D = Democrat, R = Republican, I = Independent

CARE Act Current Status

- 110th Congress
  - House introduced H.R. 583 – Rep. Doyle [PA-14]
    - 143 co-sponsors
  - Senate introduced S. 1042 – Sen. Enzi [WY]
    - 25 co-sponsors
  - Both Bills are identical!

  - As of April 17, 2008

110TH CONGRESS
1ST SESSION

H. R. 583

To amend the Public Health Service Act to make the provision of technical services for medical imaging examinations and radiation therapy treatments safer, more accurate, and less costly.

http://thomas.loc.gov/cgi- bin/query/z?c110:H.R.583

110TH CONGRESS
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H.R. 583 - 143 Co-Sponsors as of April 18, 2008

- **Illinois**
  - Rep Emanuel, Rahm [IL-5]
  - Rep Gutierrez, Luis V. [IL-4]
  - Rep Jackson, Jesse L., Jr. [IL-2]
  - Rep LaHood, Ray [IL-18]
  - Rep Schakowsky, Janice D. [IL-9]
  - Rep Shimkus, John [IL-19]
  - Rep Weller, Jerry [IL-11]
  - Rep Bean, Melissa L. [IL-8]
  - Rep Davis, Danny K. [IL-7]
  - Rep Biggert, Judy [IL-13]
- **Wisconsin**
  - Rep Ryan, Paul [WI-1-R]
  - Rep Baldwin, Tammy [WI-2-D]
  - Rep Kind, Ron [WI-3-D]
- **Indiana**
  - Rep Burton, Dan [IN-5]
  - Rep Souder, Mark E. [IN-3]
  - Rep Hill, Baron P. [IN-9]

S. 1042 Co-Sponsors as of April 18, 2008 (25)

- Sen Barrasso, John [WY]
- Sen Bennett, Robert F. UT]
- Sen Biden, Joseph R., Jr. [DE]
- Sen Bingaman, Jeff [NM]
- Sen Bunning, Jim [K Y]
- Sen Burr, Richard [NC]
- Sen Chambliss, Saxby [GA]
- Sen Cochran, Thad [MS]
- Sen Coleman, Norm [MN]
- Sen Conrad, Kent [ND]
- Sen Craig, Larry E. [ID]
- Sen Dodd, Christopher J. [CT]
- Sen Domenici, Pete V. [NM]
- Sen Dorgan, Byron L. [ND]
- Hagel, Chuck [NE]
- Sen Hatch, Orin D. [UT]
- Sen Isakson, Johnny [GA]
- Sen Johnson, Tim [SD]
- Sen Kennedy, Edward M. [MA]
- Sen Kerry, John F. [MA]
- Sen Klobuchar, Amy [MN]
- Sen Lieberman, Joseph I. [CT]
- Sen Lott, Trent [MS]
- Sen Sanders, Bernard [VT]
- Sen Wicker, Rogers [MS]

After the bill has passed

- No later than “x” months after the date of enactment of the CARE act, the Secretary shall promulgate regulations to ensure that all programs under the authority of the Secretary that involve the performance of or payment for medical imaging or radiation therapy, are performed in accordance with the standards established under this section.

CARE ACT General Purpose

"(1) IN GENERAL.—The Secretary, in consultation with recognized experts in the technical provision of medical imaging and radiation therapy services, shall establish standards to ensure the safety and accuracy of medical imaging studies and radiation therapy treatments. Such standards shall pertain to the personnel who perform, plan, evaluate, or verify patient dose for medical imaging studies and radiation therapy procedures and not to the equipment used.

HHS Regulations to Implement the Care Legislation

- The Alliance for Quality Medical Imaging and Radiation Therapy has been working to develop revised regulations that will be submitted to the Department of Health & Human Services (HHS) after the CARE bill is enacted.

- The current regulations (42 CFR, 6 Part 75) were published by HHS in 1985 after the Consumer-Patient Radiation Health & Safety after the Act was passed by Congress in 1981.

HHS Regulations to Implement the Care Legislation

- **The HHS Secretary can accept the Alliance recommendations at least as a starting point *or* start from scratch**

- **In either case, the Alliance will be actively working with the Secretary to draft the final regulations**

HHS Regulations to Implement the Care Legislation

- The 1985 regulations address only radiography, dental radiography, radiation therapy and nuclear medicine and do not reflect many of the current practice standards of medical imaging and radiation therapy disciplines.

- The medical physics provisions will require board certification and are consistent with the Scope of Practice approved by AAPM and ACMP.

What Now?

- **Medical Physicists need to get aggressive in supporting the Care Bills**
  - **Active campaign to promote both bills**
  - **Support and quickly respond to legislative alerts from the AAPM**
  - **Talk with your Congressional Representative when they are home during breaks**
    - **Ask that they become a Co-sponsor**
    - **If they are, thank them and ask that they urge the leadership to move the bills forward for a vote**
    - **Emphasize importance of medical physics**

Current Status

- S. 1042 was voted out of committee by the Senate Health, Education, Labor, and Pensions (HELP) committee.
- S. 1042 must be voted out of Senate Finance.
- H.R. 583 needs a push to move it out of committee and towards a House vote.

Your professional future

It’s up to YOU!

10 CFR Part 35

NRC Web Addresses

- **NRC Medical Uses Toolkit:**
  - **http://www.nrc.gov/materials/miau/med-use-toolkit.html**
- **NRC Part 35 Regulation:**
  - **http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/**
- **NUREG 1556, Volume 9, Revision 1;**
  - **http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/#abstract**
- **Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35**
  - **http://www.nrc.gov/materials/miau/miau-reg-initiatives/spec-board-cert.html**

10 CFR Part 35: History

- Over seven years were spent in developing the regulations – almost 10 years on training and experience (T&E) requirements.
- One of the first attempts to have parallel rulemaking process.
- Agreement states and stakeholders participated in the rule development process.

T&E Requirements

- T&E Rulemaking published in the Federal Register December 9, 2003 (comment period closed February 23, 2004). AAPM filed extensive comments in collaboration with ACR and ASTRO.
- T&E Rule published March 30, 2005, effective date for Non-agreement States was April 29, 2005.
- Subpart J (old Part 35 T&E) was extended until October 25, 2005. No longer in effect in Non-agreement States.
- Agreement States must adopt the T&E rule by April 29, 2008. Three 3 years after effective date in non-agreement states.

T&E Requirements

- Compatibility B for Agreement States
- Process established to recognize certifying boards such as American Board of Radiology and American Board of Medical Physics.
- Preceptor Statement required in addition to board certification.
- Grandfathering provisions

Part 35 Sections to be Addressed

- Subpart A--General Information
  - 35.2 Definitions
- Subpart B--General Administrative Requirements
  - 35.24 Authority and responsibilities for the radiation protection program.
  - 35.51 Training for Authorized Medical Physicist
  - 35.57 Grandfather Provision
  - 35.59 Recentness of Training

35.2 Definition of Authorized Medical Physicist (AMP)

Authorized medical physicist **means an individual who–**

- **(1) Meets the requirements in §§ 35.51(a) and 35.59; or**
- **(2) Is identified as an authorized medical physicist or teletherapy physicist on—**
  - **(i) A specific medical use license issued by the Commission or Agreement State;**
  - **(ii) A medical use permit issued by a Commission master material licensee;**
  - **(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or**
  - **(iv) A permit issued by a Commission master material license broad scope medical use permittee.**

35.2 Definition of Preceptor

- **Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.**

Pathways to be listed on a License

- Three pathways
  - Specialty Board certification
  - Evaluation of an individual's training and experience – the "alternate pathway"
  - Identification of an individual's approval on an existing license

§ 35.51 Training for AMP – the Board Pathway

- (a) Is certified by a specialty board . . . and who meets the requirements in paragraphs (b)(2) and (c) of this section
- (b)(2) Preceptor requirement
- (c) New Modality Training Requirement

§ 35.51 Training for AMP – the Preceptor Statement

- **(b)(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.**

§ 35.51 Training for AMP – the Preceptor Statement (continued)

- The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

§ 35.51 Training AMP – Vendor Training Requirement for New Modalities

- **(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.**

§ 35.51 AMP – Board Recognition

- (a) Is certified by a specialty board . . . and who meets the requirements in paragraphs (b)(2) and (c) of this section. . . . To have its certification process recognized, a specialty board shall require all candidates for certification to:
  - (1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

§ 35.51 AMP – Board Recognition (continued)

- **(2) Have 2 years of full-time practical training and/or supervised experience in medical physics –**
  - **(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or**
  - **(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in §§ 35.490 or 35.690; [and]**

§ 35.51 AMP – Board Recognition (continued)

- **(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or**

§ 35.51 Training for AMP – the Alternate Pathway

- (b)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and

§ 35.51 Training for AMP – the Alternate Pathway (continued)

must include:

- **(i) Performing sealed source leak tests and inventories;**
- **(ii) Performing decay corrections;**
- **(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and**
- **(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and**

- **(b)(2) Preceptor Requirement, and**
- **(c) New Modality Training**

Status of Board Recognition

- Certifying Boards (e.g., ABR and ABMP) **have requested recognized status.**
- Recognized boards are posted on NRC's website:

  http://www.nrc.gov/materials/miau/miau-reg-initiatives/spec-board-cert.html

Boards Currently Recognized, as of April 18, 2008

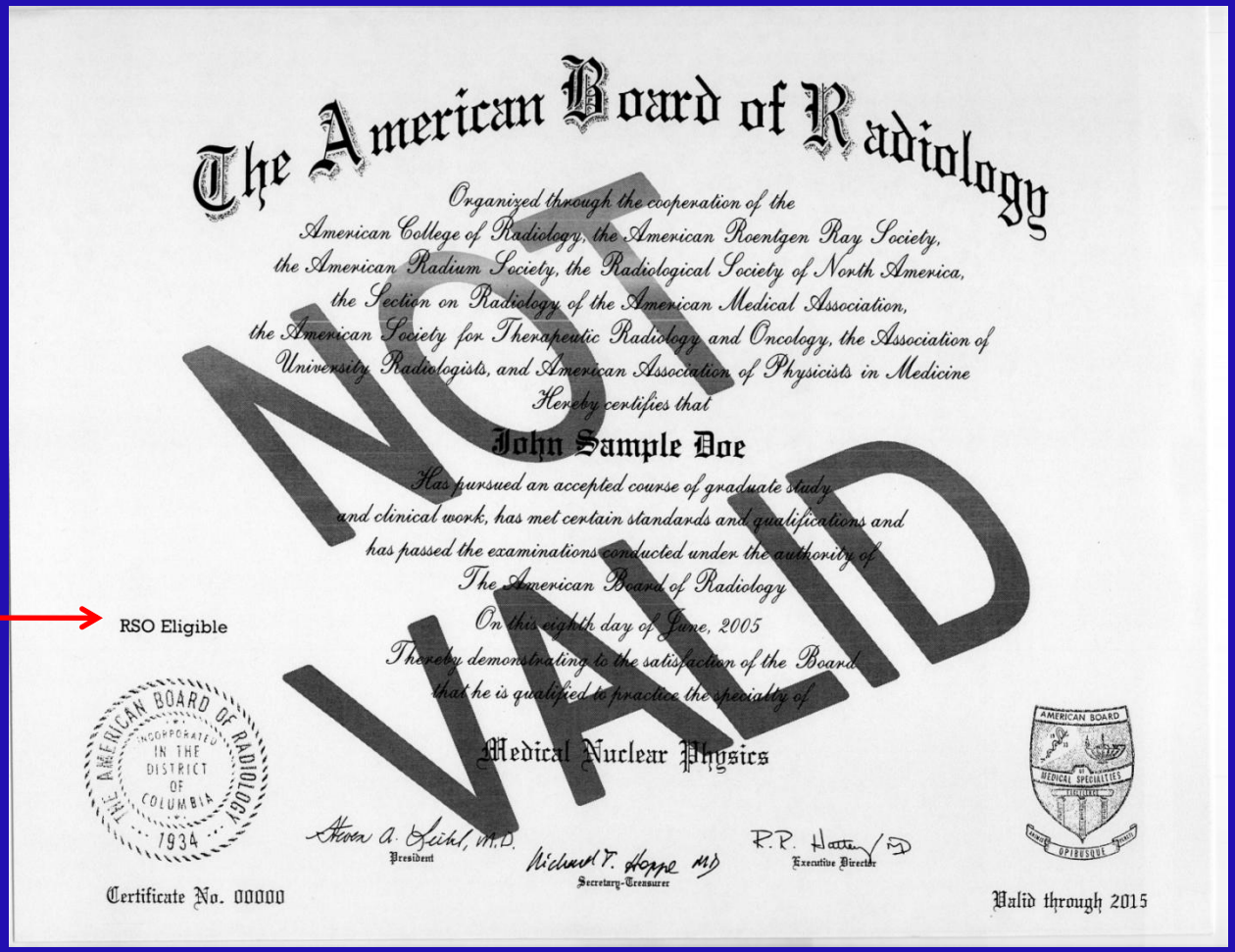
- **§35.50 Training for Radiation Safety Officer.**

  American Board of Health Physics from January 1, 2005 to present.

  American Board of Science in Nuclear Medicine from June 2006 forward for the Nuclear Medicine Physics and Instrumentation Specialty and the Radiation Protection Specialty.

  American Board of Radiology (ABR) certification process from June 2007 forward for the Radiologic Physics - Medical Nuclear Physics and the Radiologic Physics - Diagnostic Radiologic Physics specialties for diplomates who have been issued certificates before and after that date with the words "RSO Eligible" appearing above the ABR seal."

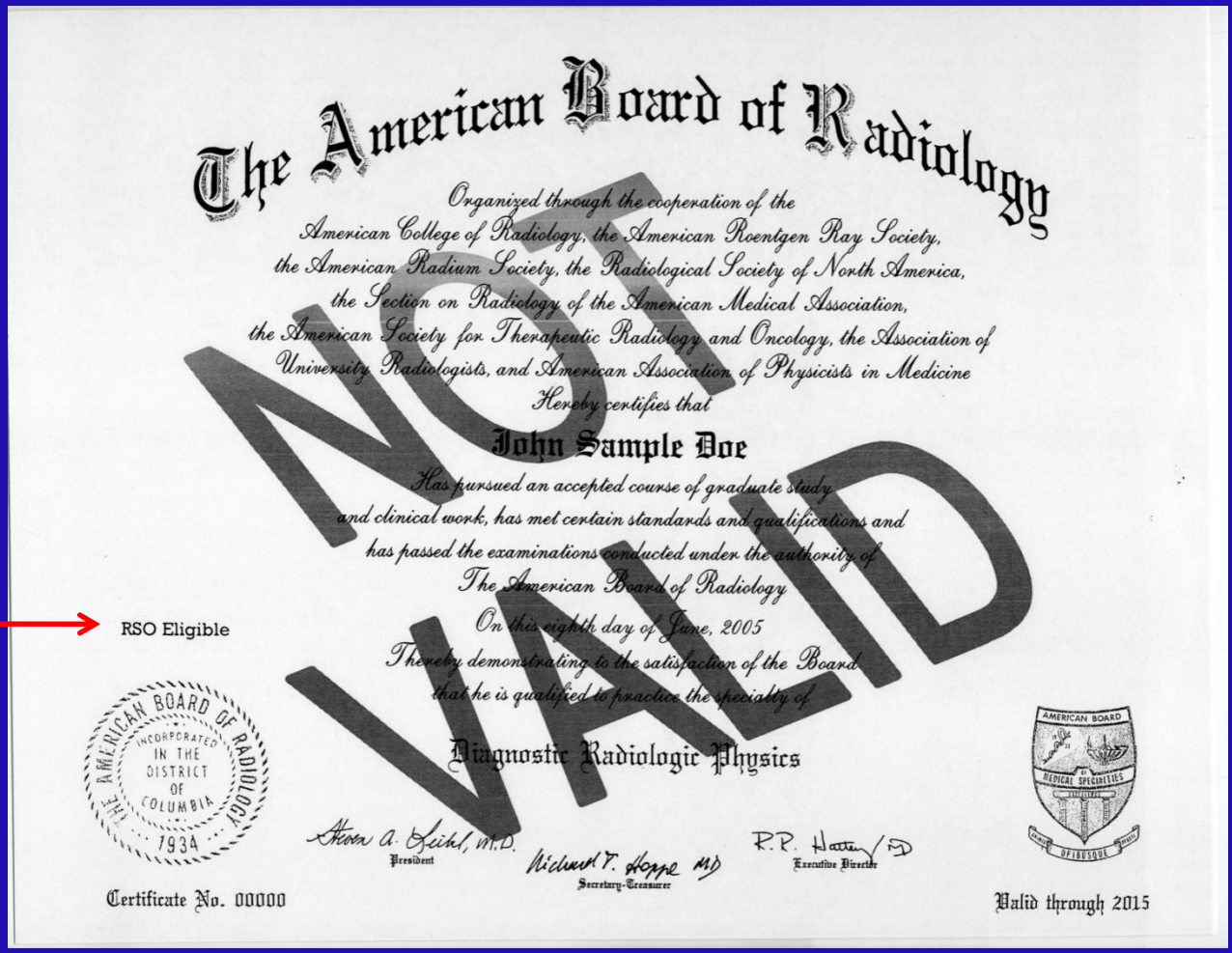
ABR Certificate
Medical Nuclear Physics



Honoring the past Celebrating the present Preparing for the future

CELEBRATE 50 YEARS

ABR Certificate
Diagnostic Radiologic Physics



Honoring the past Celebrating the present Preparing for the future

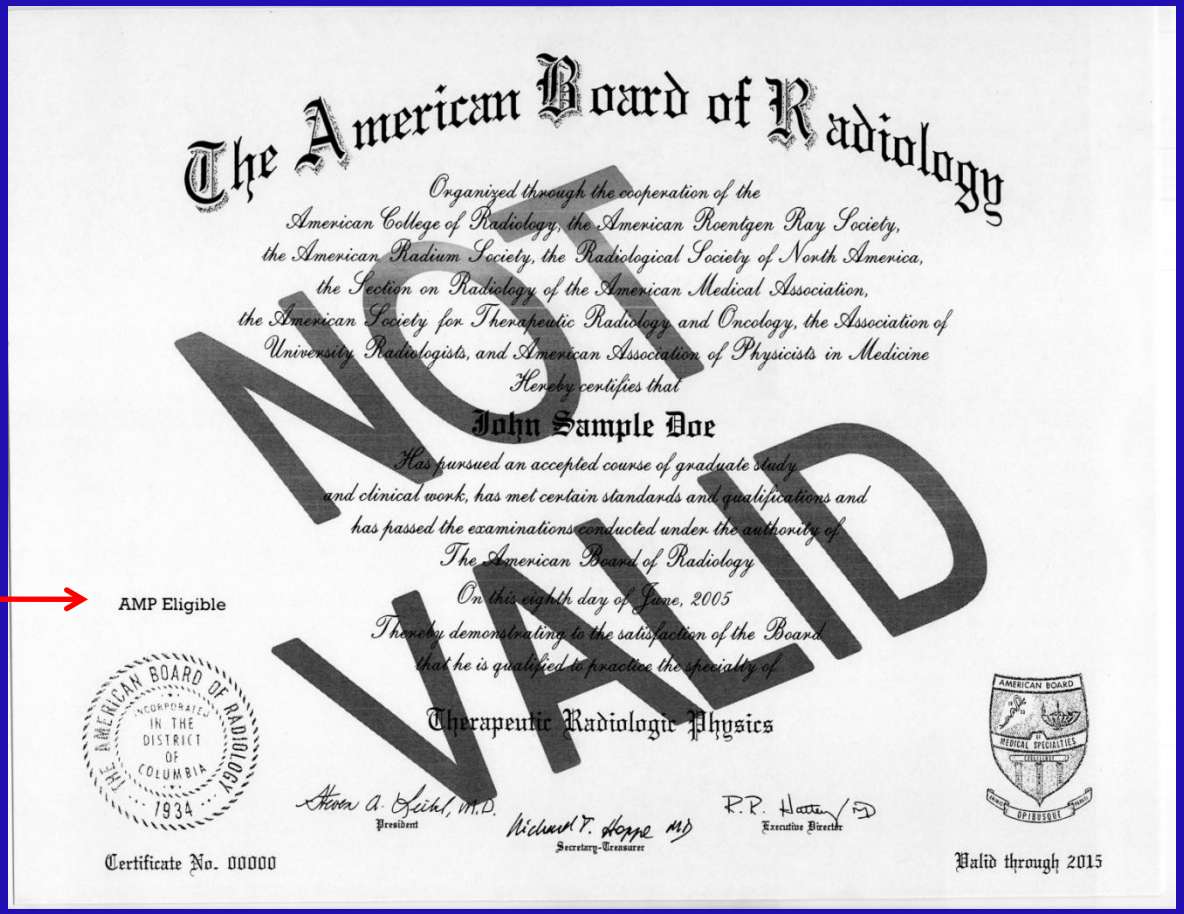
CELEBRATE 50 YEARS

Boards Currently Recognized, as of April 18, 2008 (continued)

- Training for an authorized medical physicist American Board of Radiology (ABR) certification process from June, 2007 forward for the Radiologic Physics - Therapeutic Radiologic Physics specialty for diplomates who have been issued certificates before and after that date with the words "AMP Eligible" appearing above the ABR seal.**“

- **Diplomates from June 2007 forward certified under 10 CFR 35.51 for the Therapeutic Radiologic Physics subspecialty of the ABR-Radiologic Physics specialty also satisfy the certification portion of the regulatory requirements in 10 CFR 35.50(c)(1) for Radiation Safety Officer authorization.

ABR Certificate
Therapeutic Radiologic Physics



Honoring the past Celebrating the present Preparing for the future

CELEBRATE 50 YEARS

Issues with Effective Dates for Board Recognition

- Anyone certified prior to the effective date listed for recognition of the board process must go through the alternate pathway if not already on a license.
- Impacts medical physicists for both RSO and AMP status.
- AMP is problematic because it did not exist in old regulations.

§ 35.57 Training for experienced RSO, teletherapy or medical physicist, and Nuclear Pharmacist – the Grandfather Provision

- (a)(1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of
- §§ 35.50, 35.51, or 35.55, respectively.

§ 35.57 the Grandfather Provision (continued)

- **(a)(2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.**

Problem with Grandfather Provision

- **Most medical physicists are not listed on an NRC or Agreement State license whether specific or broad scope.**

- **AAPM has been working with Conference of Radiation Control Program Directors (CRCPD) to develop a suggested license amendment for adding medical physicists to state licenses.**

Problem with Grandfather Provision

- **AAPM sent letter to Commissioner Jaczko on May 10, 2005**
  - **Suggested adding an amendment to the Energy Policy Act of 2005 proposed rule *that NRC rewrite the grandfathering provision (§ 35.57) to state that medical physicists certified by the ABR or the ABMP on or before October 24, 2005 are grandfathered for the modalities that they practiced as of October 24, 2005*.**

AAPM Petition for Rulemaking

- Filed September 10, 2006
- Noticed in Federal Register November 6, 2006 (71 FR 64168)
- Comment Period Closed January 16, 2007
- 166 Comments submitted – majority requested granting of Petition
- Status – NRC reviewing comments

AAPM Petition for Rulemaking

- **10 CFR § 35.57, *Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist,* be amended to recognize medical physicists certified by either the ABR or the ABMP on or before October 24, 2005 as grandfathered for the modalities that they practiced as of October 24, 2005. This change should be independent of whether or not a medical physicist was named on an NRC or an Agreement State license as of October 24, 2005.**

AAPM Petition for Rulemaking

- **Secondly, 10 CFR § 35.57 be amended to recognize all diplomates that were certified by the named boards in Subpart J for RSO who have relevant timely work experience even if they have not been formally named as a RSO (either as an "Assistant or Associate RSO"). These diplomates need to be grandfathered as an RSO by virtue of certification providing the appropriate preceptor statement is submitted.**

RSO Status

- **RSO is problematic because only one RSO by regulation can be listed on a license.**

- **If you have acted as an RSO but not been listed on a license with that title, you will have to demonstrate qualifications via the alternate pathway even if you are board certified by ABR, ABMP or ABHP once they have been recognized.**

Preceptor Attestation, aka Preceptor Statement

- Required for both the board certification pathway and the “alternate” pathway
- From a Radiation Safety Officer, Authorized Medical Physicist, Authorized Nuclear Pharmacist, or Authorized User
- To the effect that the individual has completed the required training and has achieved a level of knowledge and competency sufficient to function independently

PRECEPTOR

Preceptor **means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer. (§35.2)**

ATTESTATION

Definition of *attest*

A. To affirm to be correct, true, or genuine by declaration, evidence, or testimony

B. [Legal] to confirm (usually in writing) that a document is genuine.

- **Presumes some verification**

ATTESTATION

To what is preceptor attesting?

- **"Individual has completed the structured educational program"**
- **Competent to function independently**

[Federal Register, 4/24/2002, p. 20293]

WHO CAN PRECEPTOR

- **AMP applicant**
  - **Signed by preceptor AMP**
  - **Attests applicant meets T&E requirements & achieved level of competency to function independently**

WHO CAN PRECEPTOR

- **RSO applicant**
  - **Signed by preceptor RSO**
  - **Attests applicant meets T&E requirements & achieved level of radiation safety knowledge to function independently**

PRECEPTOR

- Must have same credentials as applicant
- Written documentation
- Attests meets T&E requirements
  - Within past 7 yrs.
- Attests achieved level of competency (or for RSO, level of radiation safety knowledge) to function independently
- Can have multiple preceptors

NRC FORM 313A (AMP)

- **The AMP Preceptor Attestation has four sections:**
  1. **The attestation to the proposed authorized medical physicist's training.**
  2. **The attestation for the device specific training**
  3. **The attestation of the individual's competency to function independently as an authorized medical physicist for the specific devices requested by the applicant**
  4. **Requests specific information about the preceptor's authorizations to use licensed material in addition to the preceptor's signature.**

FORM AMP PRECEPTOR-1

NRC FORM 313A (AMP)
(10-2006)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section
Check one of the following:

1. Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Medical Physicist ?

10 CFR 35.51(a)(1) and (a)(2). ←

OR

2. Education, Training, and Experience

☐ I attest that _____ has satisfactorily completed the 1-year of full-time
Name of Proposed Authorized Medical Physicist

training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

FORM - AMP PRECEPTOR-2

AND

Second Section
Complete the following:

☐ I attest that _____ has training for the types of use for which authorization
Name of Proposed Authorized Medical Physicist

is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

FORM - AMP PRECEPTOR-3

AND

Third Section
Complete the following:

☐ I attest that _____ has achieved a level of competency sufficient to
Name of Proposed Authorized Medical Physicist

function independently as an Authorized Medical Physicist for the following:

☐ 35.400 Ophthalmic use of strontium-90
☐ 35.600 Teletherapy unit(s)
☐ 35.600 Remote afterloader unit(s)
☐ 35.600 Gamma stereotactic radiosurgery unit(s)

FORM - AMP PRECEPTOR-4

AND

Fourth Section

Complete the following for preceptor attestation and signature:

☐ I meet the requirements in 10 CFR 35.51, or equivalent Agreement State requirements for Authorized Medical Physicist for the following:

☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Teletherapy unit(s)

☐ 35.600 Remote afterloader unit(s) ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

Name of Preceptor	Signature	Telephone Number	Date

License/Permit Number/Facility Name

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ISSUES/CONCERNS

- **Refusal to preceptor**
  - **Perceived liability**
  - **Competitive AMPs**
- **Documentation of T&E**
  - **Straightforward if conducts or directs T&E**
  - **Overly prescriptive documentation**

ISSUES/CONCERNS

- **Burdensome to verify applicant's T&E if did not conduct or direct**
  - **Elements of trust & confidence**
  - **"Reasonable measures"**
  - **"Best of his/her professional ability & judgment"**
  - **Compounded if preceptor must also submit T&E**

[NMSS Newsletter Sept. 2006]

ISSUES/CONCERNS

- **Attesting competency**
  - **NRC refuses to change BUT SOC states," does not require attestation of clinical competency, but requires sufficient attestation to demonstrate …has knowledge to fulfill duties…"**
  - ***Why not say so in regulations and/or Form 313A?!***

ISSUES/CONCERNS

- **Documentation (Forms) fixed; do not address added/new technology e.g., add gamma knife, 35.1000 uses**

- **Significant problem with preceptor RSO because current policy of only 1 RSO per license**

CONCLUSIONS

- **Preceptor statements are not supported by the radiological organizations and ACMUI for board certified AMP, AU, or RSO.**
- **Burden & responsibility will be increased for preceptors verifying AMP or RSO.**
- **If regulations are risk-based, what is the radiation safety problem being addressed by a preceptor statement requirement, especially if board certified?**

Energy Policy Act of 2005

"Referred to as EPAct"

Regulatory Authority

- Under the Atomic Energy Act (AEA) of 1954, the federal government was given authority for regulating certain radioactive materials. This authority is vested today in the U.S. Nuclear Regulatory Commission (NRC).

- Section 274 of the AEA allows NRC to relinquish to the States regulatory authority to license and regulate byproduct materials – Agreement States

- Mechanism for transfer is an agreement signed by Governor of State and Chairman of NRC Commission

Agreement States

- Currently 35 Agreement States: all have regulations for NARM
- 15 Non-Agreement States: Most have some type of regulatory structures for NARM:
  - MO, IN, MI, WV, CT, VT, MT, ID, WY, SD, AK, HI, NJ, VA
- Letters of Intent to Become Agreement State filed by VA, NJ and MI

EPAct of 2005: Expanded Definition of Byproduct Material

- (1) Any discrete sources of radium-226….for use for a commercial, medical or research activity,
- (2) any material made radioactive by use of a particle accelerator and is produced, extracted or converted after extraction, …..for use for a commercial, medical or research activity; and,
- (3) and any discrete source of naturally occurring radioactive material (RAM) other than source material….determined would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety…

NARM Legislation

- EPAct Section 651(e) became effective upon signature of President on August 8, 2005.
- Prior to enactment of EPAct NRC did not have authority over NARM, and did not have regulations in place.
- EPAct mandated that the NRC use SSRs if possible to provide regulatory framework for NARM.
- EPAct requires NRC to consider the impact of its regulations on the availability of radioactive drugs to physicians & patients.

What Is NRC Now Regulating?

- RAM produced by all accelerators that intentionally produce RAM for commercial, medical or research activities
- Will not regulate accelerators used to produce only particle beams and not intentionally to produce RAM
- In production accelerators to regulate all the RAM produced, both intentionally and incidentally produced
- EPAct does not give NRC any authority to regulate the possession or operation of particle accelerators
  - NRC will require any person subject to dose limits in 10 CFR Part 20 to continue to include radiation dose from the operation and maintenance of a particle accelerator in meeting dose limitations

Radiation Safety Officer Changes?

- **10 CFR 35.50 Training for Radiation Safety Officer**
  - **NRC considers the Radiation Safety knowledge for NARM similar to originally defined byproduct material**
  - **No changes made to T&E for any authorized person in 10 CFR Part 35**

Status of Final NARM Regulations

- The final rule which establishes requirements for the expanded definition of byproduct material was noticed in the Federal Register (72 FR 55864) on October 1, 2007.

- The final regulations became effective on November 30, 2007.

Waivers

- EPAct Section 651(e)(5) authorized the NRC Commission to issue a waiver to allow continued use of NARM under current regulations
- On August 31, 2005, the Commission issued a waiver to allow States and individuals to continue their activities involving NARM. The Commission plans to terminate the waiver in phases.
- Once the waiver is terminated, all persons that possess the new byproduct materials in NRC jurisdiction must be in compliance with NRC regulations, and will need to apply for a license amendment within 6 months, or apply for a new license within 12 months.

Final Transition Plans

- A process for orderly transition of regulatory authority with respect to the expanded definition of byproduct material as defined in paragraphs (3) and (4) of section 11e. of the Atomic Energy Act of 1954, as amended.

- Published in the Federal Register (72 FR 59157) on October 19, 2007

Phase 1 States

- On November 30, 2007, the Commission terminated the time-limited waivers of the Energy Policy Act of 2005 requirements granted by the Commission (70 FR 51581; August 31, 2005) to those Phase 1 States.

- Published in the Federal Register (72 FR 68043) on December 4, 2007.)

- Phase 1 states: Delaware, Montana, District of Columbia, Wyoming, Puerto Rico, Federal Government Agencies, U.S. Virgin Islands, Federally Recognized Indian Tribes, Indiana

Phase 2 States

- **The Commission provided advance notification that the time-limited waiver of the Energy Policy Act of 2005 requirements granted by the Commission (70 FR 51581; August 31, 2005) will be terminated for those Phase 2 States on September 30, 2008.**

- **Published in the Federal Register (73 FR 14376) on March 18, 2008.)**

- **Phase 2 States: Guam, Idaho, Missouri, South Dakota, Vermont, West Virginia, and all territories and possessions of the U.S. that were not identified as part of the first phase of waiver terminations**

Transition Plan – Agreement States

- The NRC received governor certifications from all 34 Agreement States, which document that their States have a program for licensing the new byproduct material that is adequate to protect public health and safety and that they intend to continue to regulate these materials.

- Waivers were terminated with the final rule for the 34 Agreement States at the time the rule was published.

Transition Plan - Miscellaneous

- NRC assumed authority for NARM exempt distribution licenses upon waiver termination.
- Upon waiver termination, NRC assumed authority for all Sealed Source and Device (SSD) evaluations and registrations for NARM in:
  - Agreement States without SSD authority
  - Non-Agreement States

Communication

- **Additional information on NARM related activities you may access the "NARM Toolbox" at:**

  http://nrc-stp.ornl.gov/narmtoolbox.html

Increased Controls (IC)

- Issued Jointly with Agreement States
- Require specific Actions to Enhance Control:
  - Access Controls
  - Background Checks for Unescorted Access
  - Monitor, Detect and Respond to Unauthorized Access
  - Advance Coordination with Local Law Enforcement
  - Transportation Controls
  - Protection of Sensitive Physical Protection Information
  - Nov. 14, 2005, Order EA-05-090, Published Dec. 1, 2005, 70FR72128

Examples of Common Violations

- Most violations have occurred in IC 2, IC1 and IC6
- Failure to document actions or program is a common throughout the ICs
  - IC1: Allowing unescorted access to radioactive material quantities of concern without proper trustworthiness and reliability determinations
  - IC2: Inadequate installation of equipment, dysfunctional equipment, or lack of monitoring of storage areas.
  - 1C6: Access and handling of physical protection information according to IC 6.
- Information Notice 2007-16:
  - http://nrc-stp.ornl.gov/asletters/program/sp07042.pdf

Fingerprinting Requirements

- NRC issued an order imposing **Fingerprinting and Criminal History Records Check Requirements for Unescorted Access** to Certain Radioactive Material (Effective Immediately) [73 *FR* 11159 (February 29, 2008)]

- Means Category 1 and 2 radioactive materials – gamma knife and blood irradiators at this time

- The new fingerprinting requirements supplement previous requirements issued by the Increased Controls Order (EA–05–090)

Fingerprinting Requirements

- Agreement States have until June 2008 to issue their orders
- All fingerprints will be sent to NRC for submittal to the FBI
- Cost is roughly $50/individual fingerprinted

Fingerprinting Requirements

- **Each individual who is seeking or permitted unescorted access to risk significant radioactive materials equal to or greater than the quantities listed in attachment 2.**

- **The Licensee shall review and use the information received from the Federal Bureau of Investigation (FBI) identification and criminal history records check and ensure that the provisions contained in the subject Order and this attachment are satisfied.**

Table 1 – Radionuclides of Concern

Radionuclide	Cat 2 (TBq) [1]	Cat 2 (Ci) [2]
Am-241	0.6	16
Am -241/BE	0.6	16
Cf-252	0.2	5.4
Co-60	0.3	8.1
Cm-244	0.5	14
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pu-238	0.6	16
Pu-239/BE	0.6	16
Pm-147	400	11,000
Ra-226	0.4	11
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above[3]	See footnote 4	

1. The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.
2. The primary values used for compliance with this Order are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.
3. Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.
4. f several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n, A(i,n), to the quantity of concern for radionuclide n, Q(n), listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... ≥1.

Footnote 5 Table 1 – previous slide

- (5) On August 31, 2005, the NRC issued a waiver, in accordance to Section 651(e) of the Energy Policy Act of 2005, for the continued use and/or regulatory authority of Naturally Occurring and Accelerator-Produced Material (NARM), which includes Ra-226. The NRC plans to terminate the waiver in phases, beginning November 30, 2007, and ending on August 7, 2009. The NRC has authority to regulate discrete sources of Ra-226, but has refrained from exercising that authority until the date of an entity's waiver termination. For entities that possess Ra-226 in quantities of concern, this Order becomes effective upon waiver termination. For information on the schedule for an entity's waiver termination, please refer to the NARM Toolbox Web site at *http://nrc-stp.ornl.gov/narmtoolbox.html.*

Fingerprinting Requirements

- No criteria was published for determining how to deal with a negative report
- Since issued via orders, no public input available
- AAPM is advocating that all orders move to rulemaking process

EPAct presents Changes and New Challenges

What is the National Source Tracking System (NSTS)?

- National system to track sealed sources
- Licensees required to report manufacture, transfer, receipt, disassembly, and disposal of sealed sources
- Licensees required to verify and reconcile inventory information annually
- Manufactures must assign a unique serial number to each nationally tracked source

APPENDIX E TO PART 20 - NATIONALLY TRACKED SOURCE THRESHOLDS

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radionuclide	Cat 1 (TBq)	Cat 1 (Ci)	Cat 2 (TBq)	Cat 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium -241/BE	60	1,600	0.6	16
Californium-252	20	540	0,2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium 238	60	1,600	0.6	16
Plutonium-239/BE	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

National Source Tracking System

- Currently includes Category 1 and 2 Sources
  – Gamma Knife, Blood Irradiators, HDR
- NRC published notice of proposed rule to include down to one-tenth Category 3 (73FR19749, April 11, 2008)
- Comments due June 25, 2008
- Currently under review

National Source Tracking System

- The isotopes that would be found in a nuclear medicine department or therapy department and their respective Category 3.5 are as follows:
  - Co-60 3GBq/0.081 Ci
  - Ir-192 8GBq/0.216 Ci
  - Cs-137 10GBq/0.270 Ci
  - Gd-153 & Sr-90 0.10TBq/2.703 Ci

- Bottom line all HDR sources!

Good Practice? Or how to get to know your local FBI or Homeland Security Agent!!!!!

We have a Cs-137 brachytherapy sealed source '3M' type sources that we no longer use and would like to find a new home for them. There are 22 sources in the current inventory ranging in activity from 9.1 to 33.7 mg-Ra-eq. There is a storage safe, 'L-Block', wheeled transport pig and sturdy wheeled steel work table in the package.

If you are interested please contact me at . . . . !!!!!

*From the medical physics list serve – 9/13/07

Good Practice? Or how to get to know your local FBI or Homeland Security Agent!!!!

- We have Cesium 137 for LDR Brachytherapy procedures that we no longer do. If anyone is interested in the Cesium please respond to this post.

  If you are interested please contact me at . . . . !!!!!

*From the medical physics list serve – 9/25/07

NRC External Review Panel to Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission's Materials Licensing Program

- **Established as a result of the GAO sting.**

- **Report issued March 18, 2008; link:**

  http://www.nrc.gov/reading-rm/doc-collections/commission/slides/2008/20080318/independent-external-review-panel-final-report.pdf

Findings

- **NRC has a clear record of success regarding health, safety, and environmental protection and has performed these functions in an excellent manner.**

- **Because of the changing environment resulting from the threat of malevolent actions, security must be upgraded as a fourth cornerstone to NRC operations.**

NAS/NRC issues report on "Radiation Source Use and Replacement"

- Study requested by the Congress to address concerns that devices containing cesium-137 and other high-risk radionuclides could be stolen for use in a terrorist attack, i.e., as a potential ingredient for a dirty bomb.

- Sponsored by Nuclear Regulatory Commission

- Link to report:
  http://www.nap.edu/catalog.php?record_id=11976

NAS Report Findings

- **Finding 3a: Because of its dispersibility, solubility, penetrating radiation, source activity, and presence across the United States in facilities such as hospitals, blood banks, and universities, many of which are located in large population centers, radioactive cesium chloride is a greater concern than other Category 1 and 2 sources for some attack scenarios. This concern is exacerbated by the lack of an avenue for permanent disposal of high-activity cesium radiation sources, which can result in disused cesium sources sitting in licensees' storage facilities. As such these sources pose unique risks.**

NAS Report Findings 2

- **Finding 3b: In view of the overall liabilities of radioactive cesium chloride, the committee judges that these sources should be replaced in the United States and, to the extent possible, elsewhere.**

- **Finding 3c: In most (and perhaps all) applications, radioactive cesium chloride can be replaced by (1) less hazardous forms of radioactive cesium, (2) radioactive cobalt, or (3) non-radionuclide alternatives. However, not all of these alternatives are commercially available now, and all are currently more expensive than radioactive cesium chloride for the users.**

- **Finding 3d: Government action is required to implement replacement of radioactive cesium chloride sources because the alternatives cost more and the liabilities or social costs of the sources currently are not borne by the end users.**

Overall Conclusion

- **“[T]he U.S. government should take steps to promote the replacement of radioactive cesium chloride radiation sources, a potential "dirty bomb" ingredient used in some medical and research equipment, with lower-risk alternatives.”**

Implementation Steps

- **The committee suggests these options as the steps for implementation.**
  - **i. Discontinue licensing of new cesium chloride irradiator sources.**
  - **ii. Put in place incentives for decommissioning existing sources.**
  - **iii. Prohibit the export of cesium chloride sources to other countries, except for purposes of disposal in an appropriately licensed facility.**

What Next?

- **Representative Markey is drafting legislation to make the NAS/NRC recommendations law.**

- **AAPM working with NRC and the Office of Science, Technology Policy, and Department of Homeland Security to determine best pathway forward for implementing the NAS/NRC's recommendations and to allow sufficient time to replace the Cs irradiators.**

Vulnerabilities

- **Are our medical facilities safe!**
- **Reallocation of assets and resources is occurring.**
- **Access to care must be maintained.**

Newest Federal Agency to Coordinate With