

Why "CARE"
**– "Interactions With,
Understanding of,
Regulatory/Legislative Bodies"**

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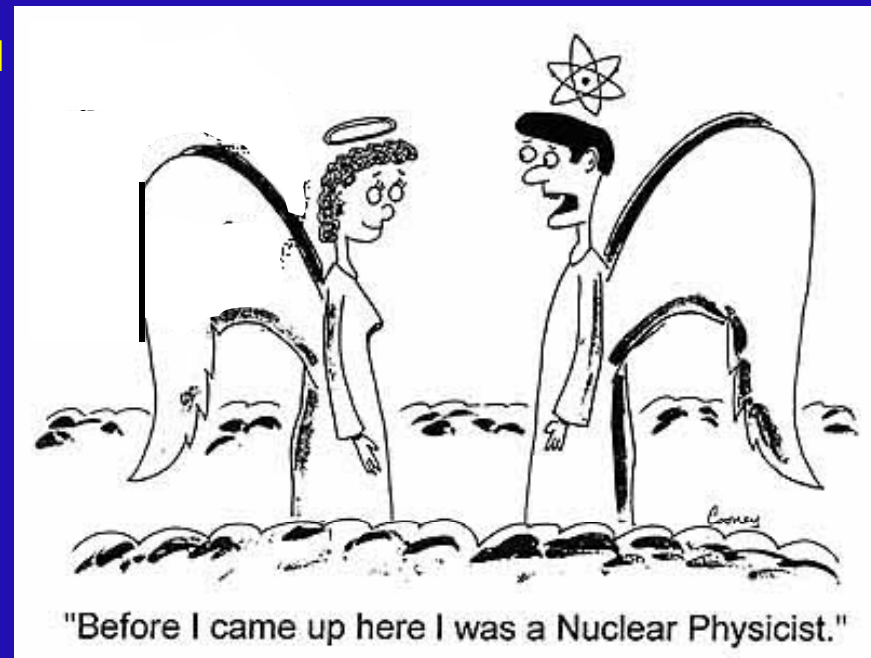
Great Lakes RAMPS
November 18, 2008

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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
- **Member Advisory Board School of Health Sciences – Purdue University**



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Topics to be Discussed

- Legislative and Regulatory Processes
 - **Role Advisory Committees**
 - **Role of the States**
- Example Legislation
- Example Regulations
- Media Influences

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Why Should You Care

- Regulations and/or Legislation can greatly impact your day-to-day practice
 - Dictate what you must do.
 - Dictate what you can bill and how much.
 - Frustrate you when professional judgment and regulation conflict!!

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Sample Legislation Critical to Medical Physicists

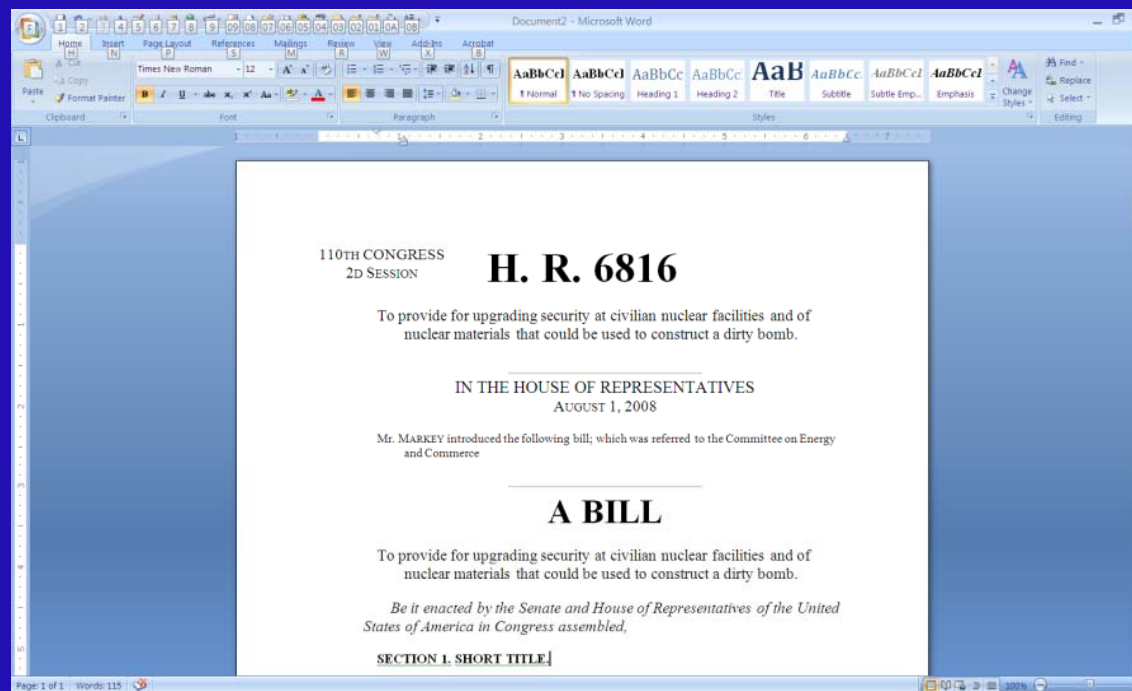
- H.R. 583 and S. 1042 – The Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) Bill
 - 149 Co-sponsors for H.R. 583, 26 for S. 1042
 - 4th Congress - Identical bills
- H.R. 6816 - Nuclear Facility and Material Security Act of 2008
 - Introduced August 2008, No co-sponsors
 - No Senate bill

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A Bill

To provide for upgrading security at civilian nuclear facilities and of nuclear materials that could be used to construct a dirty bomb.



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A Bill

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.

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.

110TH CONGRESS
1ST SESSION

S. 1042

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

<http://thomas.loc.gov/cgi-in/query/z?c110:S.1042>

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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

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Brief Legislative History

- **106th Congress:** First CARE bill was introduced late in 2000 by Rep. Rick Lazio (R-NY). The bill died when Congress adjourned.
- **107th Congress:** A “new” CARE bill was introduced in the House on March 13, 2001 by Rep. Heather Wilson (R-NM); the bill died when Congress adjourned.
- **108th Congress - 2004**
 - House bill had 112 cosponsors -73 Democrats, 39 Republicans
 - New Senate bill had 18 co-sponsors - 15 Democrats, 2 Republicans, 1 Independent
 - Bill died.



Brief Legislative History

- 109th Congress:
- Bills in both Houses of Congress – however language is not identical
- Passed unanimously in Senate however, no time left in Session to pass the House.
- Bill died!!!!!!

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CARE Act Current Status

- **110th Congress**
 - **House introduced H.R. 583 – Rep. Doyle [PA-14]**
 - **150 co-sponsors (including sponsor)***
 - **97 Democrats**
 - **53 Republicans**
 - **Senate introduced S. 1042 – Sen. Enzi [WY]**
 - **26 co-sponsors (including sponsor)***
 - **8 Democrats**
 - **17 Republicans**
 - **2 Independents**
 - **Both Bills are identical!**
 - **Will probably die unless a miracle happens this week during the “Lame Duck Session”!**

(*As of October 2, 2008)

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MIPPA

- Medicare Improvements for Patients and Providers Act of 2008 (Section 1834 of the Social Security Act, (e) (2) (A) Factors for Designation of Accreditation Organizations)
 - signed into law in July 2008
 - Requires practice accreditation for the “advanced imaging” modalities which includes CT, MR, and Nuclear Medicine.
 - Does not include x-ray, fluoroscopy, sonography, or anything in radiation oncology.



MIPPA [2]

- **MIPPA facts:**
 - Only addressed the big ticket imaging items
 - They only impact 17% of Medicare diagnostic imaging expenditures
 - Only accredits the facility, not the personnel performing the imaging
 - The accrediting body can place requirements on the operators of imaging equipment but these requirements can be very minimal such as completing a manufactures operators course
 - Requires Centers for Medicare and Medicaid Services (CMS) to recognize accrediting bodies

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AAPM November 17th Letter to CMS

- **Stated:**
- **It is essential that factors determined by CMS pursuant to subsection (vi) require that the Accreditation Organizations include performance metrics related to image quality and (for ionizing radiation) dose measurement.**
- **Including measurement of image quality parameters for both clinical and phantom images as well as comparison of the resulting site-specific data to commonly accepted benchmarks.**

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AAPM November 17th Letter to CMS (2)

- **AAPM Stated:**
 - In the criteria established for designation of an Accreditation Organization the standards for equipment performance should include both measurement and evaluation requirements for radiation dose and image quality by a Qualified Medical Physicist (QMP)
 - AAPM recommends that CMS ensure QMPs are recognized and required to support accreditation programs mandated under the new Medicare legislation for advanced diagnostic imaging. Accreditation criteria should require that a QMP supervise the process that determines image quality and patient dose / exposure. It is imperative that any accreditation criteria reflect the role of Medical Physicists in facility and program accreditation.

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MIPPA and CARE Legislation

- Alliance is unanimous in their continued and strong support of the principles advocated in the CARE legislation – priority is to have new legislation introduced early in 111th Congress.
- Need to identify the appropriate targeted sponsors of the respective bills after the committee chairs and membership have been formulated.
- Need to educate Congress on the difference between MIPPA and the intent of the CARE legislation.

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What Now?

- Medical Physicists need to get aggressive in supporting the CARE Legislation
 - Active campaign to promote new legislation
 - Support and quickly respond to legislative alerts from the AAPM and ACMP
 - Talk with your Congressional Representative when they are home during breaks
 - Discuss the need to enact CARE legislation
 - Emphasize importance of medical physics in ensuring patient care
 - Explain the difference between MIPPA and CARE legislation
 - Ask them to be co-sponsor on the new legislation

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Regulatory Process

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Regulatory Interactions

- **Key Agencies**
 - **Nuclear Regulatory Commission (NRC)**
 - **Food and Drug Administration (FDA)**
 - Center for Radiological Devices and Health
 - Center for Drugs
 - **Health and Human Services**
 - National Institutes of Health
 - National Cancer Institute
 - National Institute for Biomedical Imaging and Bioengineering
 - **Centers for Medicare and Medicaid Services (CMS)**
 - **Department of Homeland Security (DHS)**
 - **Department of Transportation (DOT)**
 - **Conference of Radiation Control Program Directors (CRCPD)**

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The Nuclear Regulatory Commission (NRC)

- Created by the Energy Reorganization Act of 1974, recent amendment Energy Policy Act of 2005
- Exercises authority through licensing, regulations, and enforcement
- Scope of authority includes commercial nuclear power plants; medical, academic, and industrial use; transport, storage, and disposal of radioactive material
- May relinquish authority over radioactive materials to Agreement states

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NRC Organizational Framework

- Five member Commission
- Executive Director of Operations
- Office of Federal and State Materials and Environmental Management Programs
- Office of the General Counsel
- Advisory Committee on Medical Uses of Isotopes (ACMUI)
- Agreement States

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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>

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Purpose of the ACMUI

- **Advises** NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy.
- **Evaluates** certain non-routine uses of radioactive material; provides technical assistance in licensing, inspection, and enforcement cases; and brings key issues to the attention of the Commission for appropriate action.
- Membership includes health care professionals from various disciplines who comment on changes to NRC regulations and guidance.

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ACMUI Membership

- Chairman: Leon S. Malmud, M.D., Health Care Administrator
Vice Chairman: **Richard J. Vetter, Ph.D., Radiation Safety Officer***
- Members:
Douglas F. Eggli, M.D., Nuclear Medicine Physician
Darrell R. Fisher, Ph.D., Patient's Rights Advocate
Debbie B. Gilley, Agreement State Representative
Ralph P. Lieto, Medical Physicist, Nuclear Medicine*
Steven R. Mattmuller, Nuclear Pharmacist
Subir Nag, M.D., Radiation Oncologist*
Steven Mattmuller, Nuclear Pharmacist
Orhan H. Suleiman, Ph.D., Food and Drug Administration Representative
Bruce R. Thomadsen, Ph.D., Medical Physicist, Radiation Therapy
William A. Van Decker, M.D., Nuclear Cardiologist
James S. Welsh, M.D., Radiation Oncologist
- ***Terms are up in 2009.**

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CRCPD

- Mission is to “promote consistency” in addressing and resolving radiation protection issues. Began with the agreement state initiatives in 1959.
- 1968 - CRCPD established as a nonprofit, non-governmental organizations dedicated to radiation protection. Established a forum for states to discuss and talk about state initiatives and to share resources.
- Is the only association that addresses all radiation protection issues. Responsible for developing suggested state regulations.

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How Regulations Are Introduced

- **Agency initiated**
 - **Advanced Notice of Proposed Rulemaking**
 - **Proposed Rule**
 - **Final Rule**
- **Petition for Rulemaking**
 - **Initiated by member of public**
 - **Must include all elements of rulemaking package equal to those initiated by an agency**

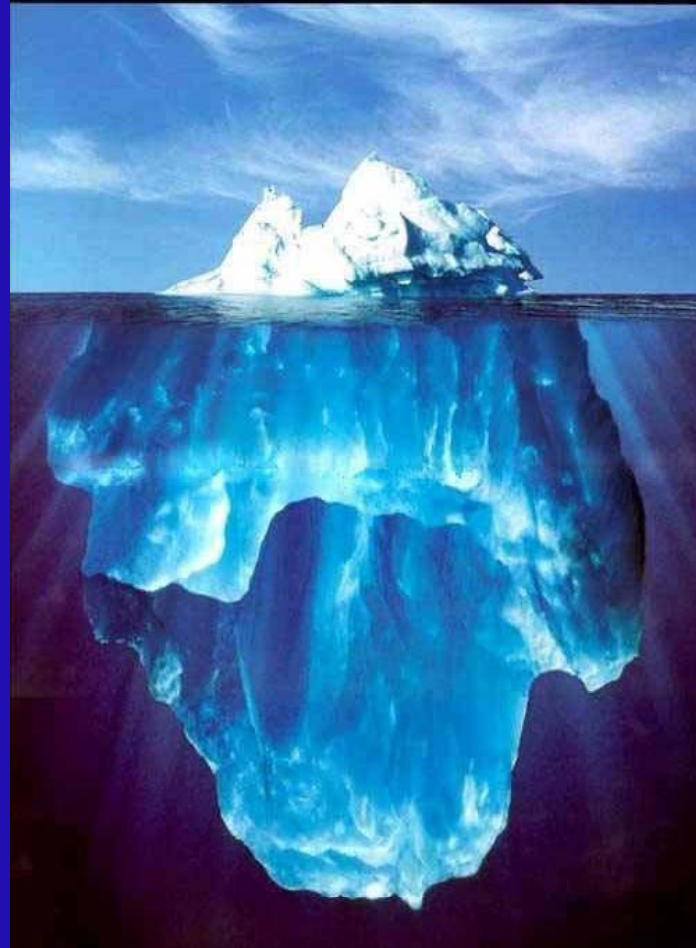
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Developing Regulations

Rule language

Implementation
and Interpretation



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Example Regulation

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10 CFR Part 35: T&E Requirements

- T&E Rulemaking published in the Federal Register December 9, 2003 (comment period closed February 23, 2004).
- 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. Not all Agreement States have adopted T&E yet.

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T&E Requirements

- **Compatibility B for Agreement States**
- **Process established to recognize certifying boards (e.g., American Board of Health Physics and the American Board of Radiology)**
- **Preceptor Statement required in addition to board certification.**
- **Grandfathering provisions**

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Regulation Promulgated

- New regulation is in effect
- As a therapy physicist you were not listed on a license as of the effective date
- What do you have to do now?

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Regulation Promulgated

- New regulation is in effect
- As a medical physicist you want to be a Radiation Safety Officer (RSO) however you were not listed on a license as an RSO as of the effective date.
- What do you have to do now?

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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**



Status of Board Recognition

- Certifying Boards **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>



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 you were not listed on a license as of the effective date.



Summary of Board Status – as of September 2008

*Board is verifying the qualifications of diplomates who have obtained their certification prior to the recognition date.

<u>Specialty Board:</u>	<u>Status:</u>	<u>Recog. Date:</u>
Board of Pharmaceutical Specialties	35.55	March 6, 1996
American Board of Nuclear Medicine	35.190, 35.290, 35.390	October 20, 2005*
Certification Board of Nuclear Cardiology	35.290	October 29, 2000 October 2006
American Board of Health Physics	35.50	Jan. 1, 2005
American Board of Science in Nuclear Medicine Nuclear Medicine Physics and Instrumentation Radiation Protection	35.50 35.50	June, 2006 June, 2006
American Board of Radiology (Radiation Oncology) American Board of Radiology (Diagnostic Radiology) American Board of Radiology (Radiologic Physics) Medical Nuclear Physics Diagnostic Radiologic Physics Therapeutic Radiologic Physics	35.390, 35.490, 35.690 35.290, 35.392 35.50 35.50 35.51	June, 2007 June, 2006* June, 2007* June, 2007* June, 2007*
American Osteopathic Board of Radiology (Rad. Onc.) American Osteopathic Board of Radiology (Diag.Rad.)	35.390, 35.490, 35.690 35.290, 35.392	May 1, 2007 July 1, 2000
American Osteopathic Board of Nuclear Medicine	35.290	May 18, 2006
American Board of Medical Physics	Awaiting input from board	
Certification Board of Nuclear Endocrinology	Awaiting input from board	
Canadian College of Physicists in Medicine	Awaiting input from board	

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)

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Preceptor Attestation Issues

- The need for a preceptor statement at all for the board certification pathway
- The need for the preceptor statement to address the individual's level of competency
- Compliance and enforcement



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

Preceptor “Attestation”

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

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ATTESTATION

To what is preceptor attesting?

- “Individual has completed the structured educational program”
- Competent to function independently
[Federal Register, 4/24/2002, p. 20293]

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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

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WHO CAN PRECEPTOR an AMP Applicant?

- Only an individual listed on an NRC or an Agreement State license as an AMP for the modality being sought e.g., an individual who is listed on a license as an AMP for gamma knife may sign a preceptor statement for someone who wants to use a gamma knife. Cannot sign for someone to do HDR unless they also are listed on a license for HDR.
- Attests applicant meets T&E requirements & achieved level of competency to function independently

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WHO CAN PRECEPTOR a RSO Applicant?

- Only someone listed on a NRC or Agreement State license as an RSO.
- Attests applicant meets T&E requirements & **achieved level of radiation safety knowledge to function independently**



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).

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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.

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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:

- | | |
|--|---|
| <input type="checkbox"/> 35.400 Ophthalmic use of strontium-90 | <input type="checkbox"/> 35.600 Teletherapy unit(s) |
| <input type="checkbox"/> 35.600 Remote afterloader unit(s) | <input type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s) |

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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 and RSOs
- Documentation of T&E
 - Straightforward if conducts or directs T&E
 - Overly prescriptive documentation

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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



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]

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ISSUES/CONCERNS

- Attesting competency
 - NRC refuses to change BUT Statement of Consideration 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?

The Competency Problem

- Competency is difficult to quantitatively define
- Competency cannot be taught
- Competency cannot be reliably measured
- Competency cannot be guaranteed
 - How long does a competency attestation last?
- Competency has a legal liability risk.
 - Preceptors are reluctant to accept this risk.

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ACMUI Recommendation*

- The Commission should remove the attestation statement requirements for board certified individuals.
- The attestation statement should be rewritten for individuals seeking authorization under the alternative pathway
 - It should not include the word “competency” but should instead read “has met the training and experience requirements.”

*Presented to the Commission April 29, 2008

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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?



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.



Need to Petition for Rulemaking

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Grandfathering of Existing Board Certified Individuals (1)

- 10 CFR § 35.57 grandfathers certain individuals from the training and experience requirements
- **AAPM Petition for Rulemaking** submitted under 10 CFR § 2.802, September 10, 2006
- NRC evaluation process consisted of a Working Group and a Petition Review Board

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Grandfathering (2)

- **AAPM petition requested two revisions to the existing rule**
 - Recognize all medical physicists certified by either the American Board of Radiology or the American Board of Medical Physics on or before October 24, 2005
 - 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 an RSO

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NRC Issues Decision on AAPM Petition

- Issued decision in the May 14, 2008 Federal Register (73FR27773).
- AAPM is pleased that the Nuclear Regulatory Commission recognized the validity of the AAPM position.
- The FR notice instructs NRC staff “to attempt to form a Technical Basis for future rulemaking.”

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Letter to Chairman Klein 9/22/08

- **AAPM stated that:**
 - the development of a “technical basis” will unnecessarily consume significant amounts of time, as well as NRC staff and industry resources, to address a fairly straightforward issue.
 - Furthermore, it is unclear what type of technical basis will be viewed as sufficient, and what methodology would be used to gather such data.



Letter to Chairman Klein (September 22, 2008)

- **AAPM stated that:**
 - **the certifying boards have no knowledge regarding the number of individuals currently listed on a license and certainly not for what modality.**
 - **anyone who is certified has the potential to be listed on a license.**

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Letter to Chairman Klein

- This impact pattern is now well established and recognized by the professional community, the ACMUI, the Working Group and the Petition Review committee. Indeed, this was a central thesis in the PRM, and was affirmed by the Commission in granting the petition. The sole group who has failed to recognize this impact is the NRC Medical Staff.



Letter to Chairman Klein

- **AAPM recommended that:**
 - **an adequate methodology would be to ask the Boards to provide an estimate of the number of diplomates holding current certifications issued prior to October of 2005 and then have the NRC recognize that each of them in practice may be called upon to serve as an AMP, AU, ANP or RSO.**
 - **All diplomates are at risk for unnecessary impediments to being named on a license now and for the duration of their careers.**

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NRC Plans for Rulemaking to Address AAPM Petition

- **NRC October 2008 Letter to Boards asked:**
 - “As a service to their diplomates, to provide NRC with the number and percentage of its currently active diplomates that are not grandfathered under 10 CFR 35.57, by virtue of being named on a license or permit, and that are now or who may in the future be seeking appropriate authorization (as RSO, ANP, AMP or AU) on an NRC or an Agreement State license. Information obtained will be used to determine if there is technical basis to support rulemaking including cost and resource requirements.”

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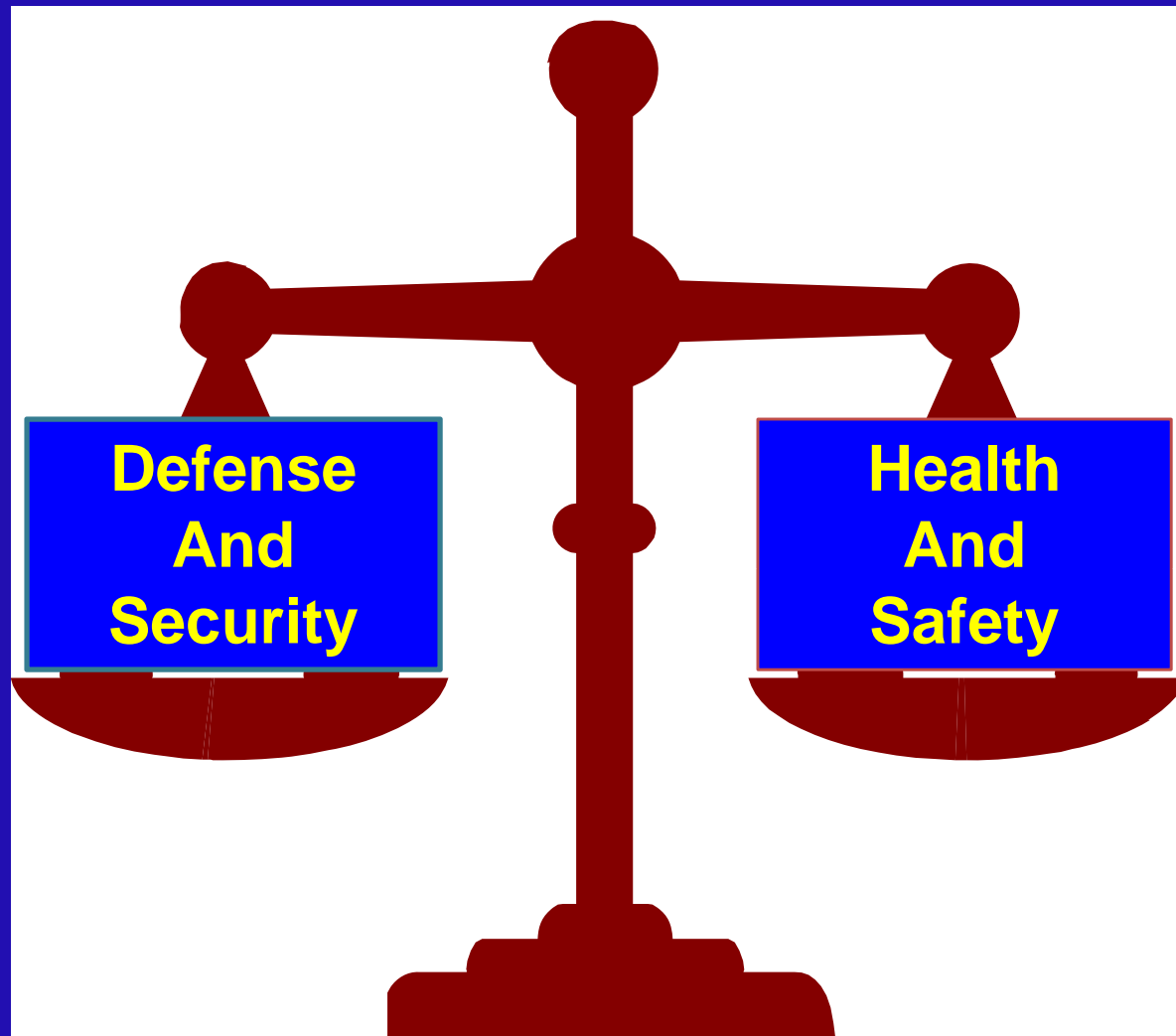


The “New” NRC for Materials

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Defense & Security or Health & Safety?



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Government Accountability Office (GAO) Investigation

- Applied for and Obtained NRC License
- Altered NRC License
- Contacted Suppliers to Sell Materials
- Parallel Attempt to Obtain Agreement State License Aborted When Notified of Site Visit



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>

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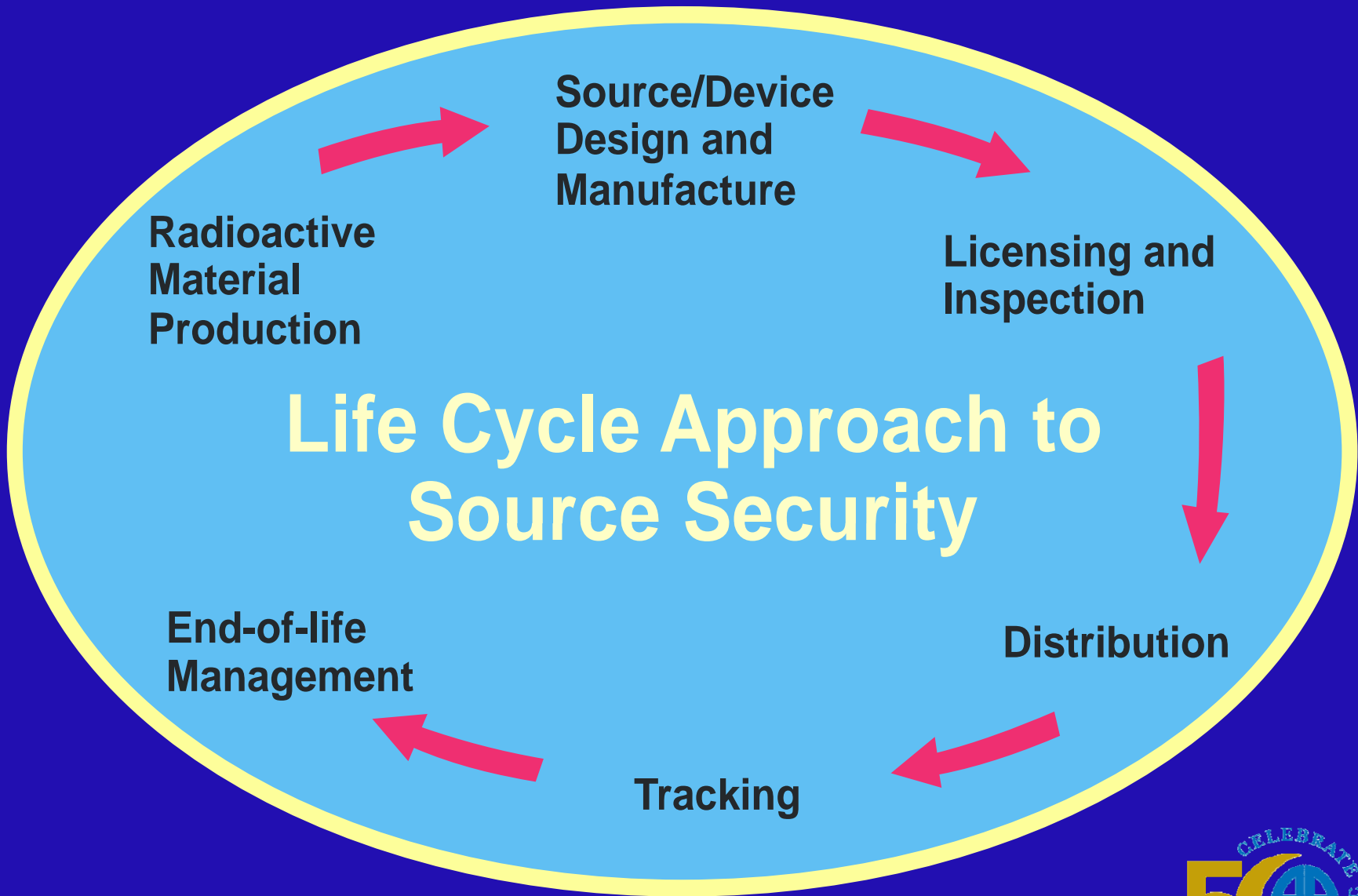


Findings

- 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.**

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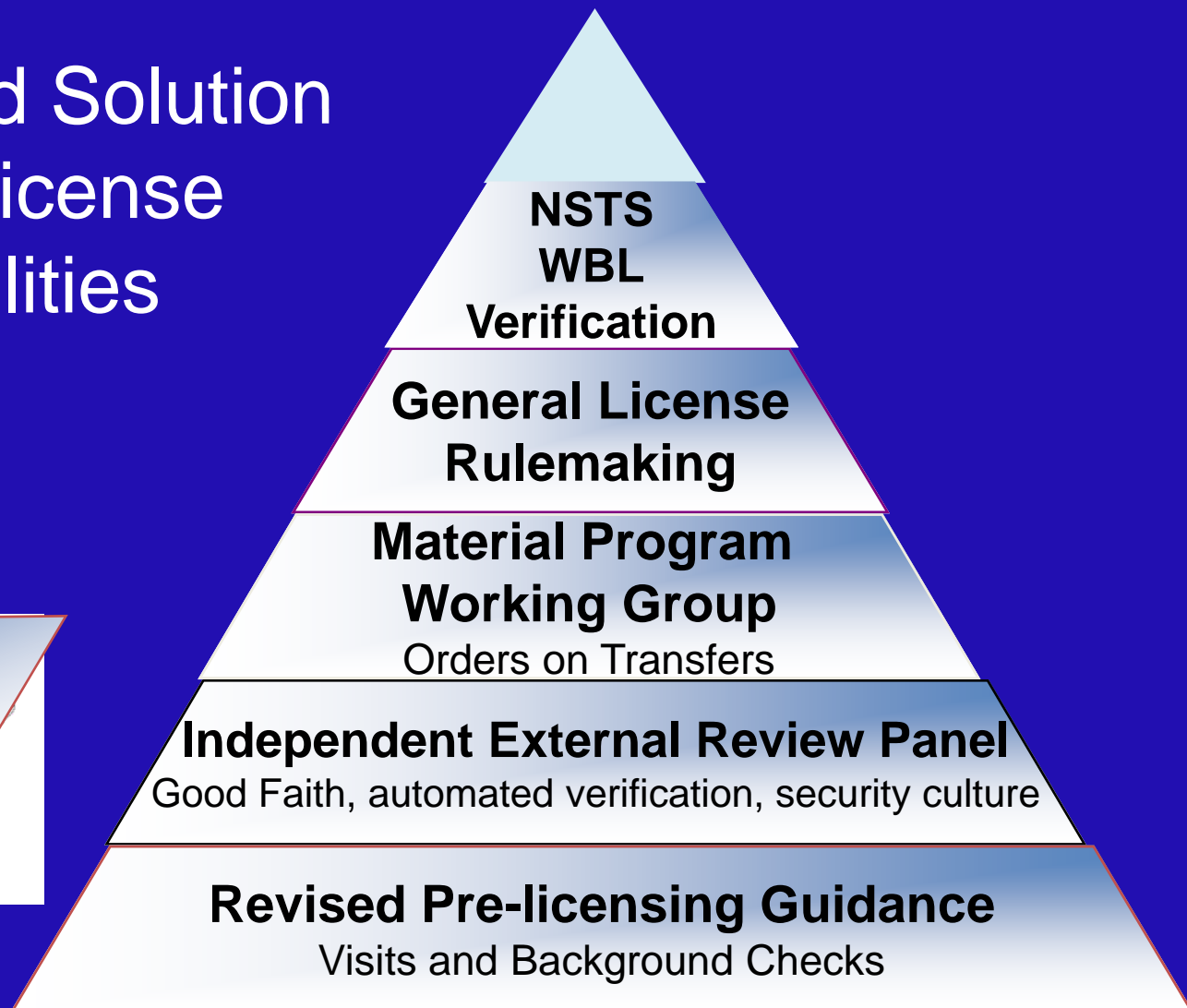




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Integrated Solution to NRC License Vulnerabilities



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The National Source Tracking System will improve control of radioactive materials.



National Source Tracking System Overview

- Tracks transactions of Category 1 and 2 sealed sources that could be used in a radiological dispersal device
- Spans entire life-cycle from manufacturing or import through transfer to export, decay, or burial
- Category 3 and 1/10 of category 3 proposed rule – comments currently being analyzed
- System design and development completed; testing underway
- Plans for user training, deployment, providing user credentials



Increased Controls

- NRC Orders imposing “increased controls” – EA-05-090
- Limited to licensees who possess radioactive materials in “quantities of concern”
- Agreement State compatibility
- Unescorted access to radioactive materials of concern only for trustworthy and reliable individuals



Fingerprinting Requirements

- For increased controls licensees
- Fingerprinting and criminal history check for individuals having unescorted access to radioactive materials of concern
- Licensee evaluation of trustworthiness and reliability
- Agreement state compatibility

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NRC Public Meeting: Security and Continued Use of Cesium- 137 Chloride Sources

September 29 – 30, 2008

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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

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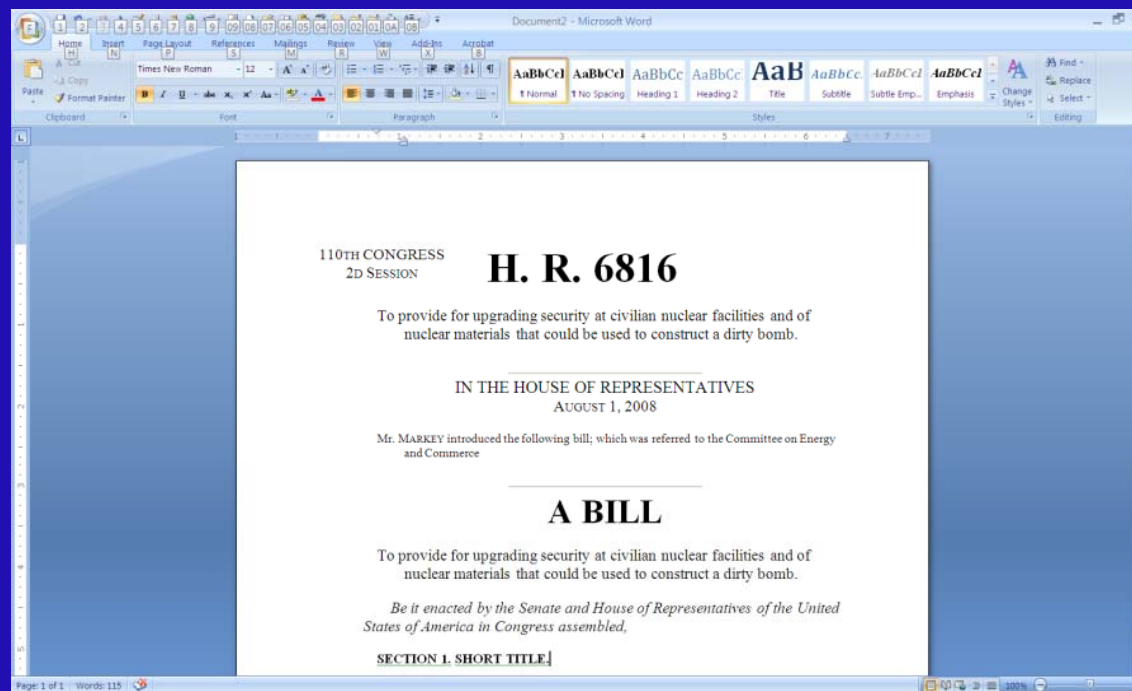
Implementation Steps

- 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.**



A Bill

To provide for upgrading security at civilian nuclear facilities and of nuclear materials that could be used to construct a dirty bomb.



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Results of the AAPM Survey on the Use of CsCl Irradiators

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AAPM CsCI Survey Results [1]

- Of the 363 respondents:
 - 297 had irradiators
 - 84.6% of those used Cs-137 as the source
 - 9.3% used conventional x-ray units
 - 6% used medical linear accelerators (linacs).
 - The Cs units represented the major vendors.
 - Only 10% were purchased within the last two years
 - 7% plan on replacing the units within the next 5 years

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AAPM CsCI Survey Results [2]

- 25% cesium units had some malfunction but most were repaired in less than 7 days.
- Of the x-ray units, 35% had malfunctions, with 44% being repaired within 7 days.



AAPM CsCI Survey Results [3]

- **Cesium units**
 - **Only 40% used for blood irradiation, with about 25% material irradiations, 25% animal irradiations and 10 % other.**
- **X-ray units:**
 - **~50% used for blood irradiation**
 - **19% were for material irradiation**
 - **32% for animals.**
- **Medical Linacs**
 - **40% used predominantly for blood irradiation**
 - **11% for animals.**

Snapshot of American Blood Center (ABC) Member Irradiators

- 10 Do NOT irradiate in-house
- 58 irradiate >531,000 components annually
- Own 80 irradiators
- Irradiate for 1,461 facilities
- Provide backup irradiation capabilities to 188 facilities
- ABC Members provide half the US blood supply (more than 9 million donations) and 100% of Canada's blood supply
- Collections by Members vary from 10,000 to 844,000 units per year
- ABC members serve over 3,300 hospitals

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Snapshot of American Blood Center Member Irradiators

Type	Number of Devices	Average Year Purchase	Average Purchase Price	Average Operating Costs	Average Anticipated Life Span	Average Years of Life Remaining
n	80	68	47	56	68	68
Cs-137	65	1996	\$107,272	\$ 9,230	25	12
X-Ray	13	2005	\$149,747	\$20,375	10	7
Co-60	2	1993	N/A	\$ 6,500	25	10

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Conclusion [1]

- AAPM believes that:
 - any decision to remove CsCl sources from use should be based on a true cost benefit analysis,
 - that any analysis should include a risk matrix that demonstrates where radiation risk falls in relation to the risk from all other hazards.

Conclusion [2]

- It is AAPM's belief that the additional protection level added to the already safe use of CsCl irradiators by a heightened security program¹, coupled with proactive personnel engaged in the security of these devices, is an effective solution for the continuation of CsCl irradiator use as a vital component of high-end research and the practice of medicine.

¹ Which includes the recently mandated increased controls and security requirements, personnel security requirements, and the proposed enhancements to the irradiators themselves.

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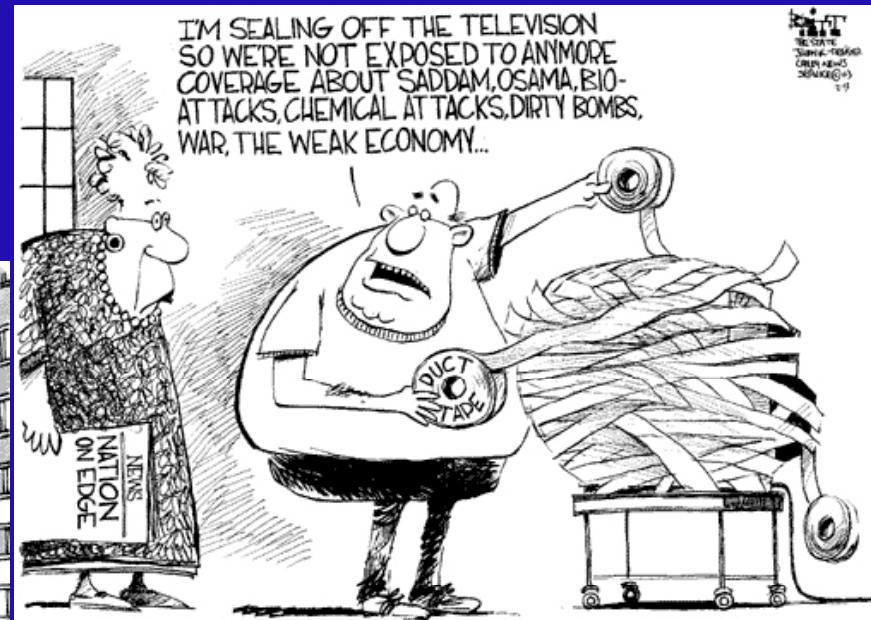


Media Influence?

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Impact of Homeland Security and the Media



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Feds work to secure potential 'dirty bomb' source - USATODAY.com - Windows Internet Explorer

C:\Documents and Settings\lyne.AAPM\Local Settings\Temp\GW\iewer\Feds work to secure potential dirty bomb source - USATODAY..htm

File Edit View Favorites Tools Help

Feds work to secure potential 'dirty bomb'...

To help protect your security, Internet Explorer has restricted this webpage from running scripts or ActiveX controls that could access your computer. Click here for options...

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Feds work to secure potential 'dirty bomb' source

Posted | Comment | Recommend E-mail | Save | Print |

By Mimi Hall, USA TODAY

RADIOACTIVE RETROFIT

The federal government's plan to better secure dangerous radioactive material used at hospitals and in medical research labs will:

- Require retrofitting 1,300 blood irradiation machines nationwide.
- Cost up to \$3,000 per machine.
- Be done by the Homeland Security and Energy departments.

WASHINGTON — A new government program aims to make it more difficult for terrorists to steal dangerous radioactive material from the nation's hospitals and medical research labs to make "dirty bombs."

About 1,300 machines in medical facilities will be fitted with new security measures by the end of next year that will make it much harder for anyone to steal the cesium chloride inside, officials at the Homeland Security and Energy departments said. The machines use the material to irradiate blood, primarily for cancer patients.

The cesium contained in just one machine would be enough for a terrorist to make a radioactive bomb, said Vayl Oxford, head of Homeland Security's Domestic Nuclear Detection Office. The new program "takes a potential threat off the table," he said.

Although there is no immediate or credible threat, government security officials have long been concerned that terrorists will set off "dirty bombs" in the nation's cities. A dirty bomb would not kill many people, but it would wreak havoc and contaminate streets and buildings.

Concerns about hospital security took on new urgency last year when government "red teams" were able to break into irradiation machines in as little as two minutes, Oxford said. The retrofitted machines "will help keep potentially dangerous material safe and secure from theft or misuse," said Thomas D'Agostino of the Energy Department's National Nuclear Security Administration. That agency is splitting the cost — up to \$3,000 per machine — with Homeland Security.

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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**

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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**

Wise Decisions?

- A local hospital in the San Francisco area would like to get rid of some Cs-137 sources. They are nominal 15, 20, 30 mg Ra eq. Anyone who has an interest in the sources please contact: XXXXX

***From the medical physics list serve –
11/05/08**

Response (1)

- Please do not make postings such as these on this list server. They definitely have a high probability of getting the attention of Homeland Security, as ³bad guys² can tap into this, too. We do not want to broadcast to the world that there are sources up for grabs.

***From the medical physics list serve –
11/05/08**



Response (2)

- If the government does not live up to its standards, we should then avoid helping each other? Frankly, I have been looking for a post such as this, because we may be very interested in getting some of those sources. How else might I have found out about them? But, we could just toss them in a waste dump and make new ones, right? OOPS- The NRC regulates that, too, so I guess the same errors could occur.

***From the medical physics list serve – 11/06/08**

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Response (3)

- Yes, in fact I had heard of the incident with the fake company. You had already posted it before I wrote my post. My point is, so what? This list is exactly the right place to put notice of unwanted devices, even sources. Sure, in this day and age we need to be more careful, so you do a little more checking around about who wants them, but I am not one who will live in paranoia. To broaden the focus, other than being a little more aware of my surroundings I have not changed my life deliberately by one item since 9/11, because that concedes defeat. It says to the scum who believe in murder and fear that "We can affect you. We can make you do things you don't like. We can lessen the positive things in your lives." I say we live as we always did. Better to die in a free state than live in a paranoid one.

***From the medical physics list serve – 11/06/08**

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Response (4)

- I don't know about you, but I get worked up about DHS checking on my e-mail postings. Do they have a warrant to do so? No. Do I have the freedom to express my opinions? ??? Sorry if I got "worked up" about this issue.

***From the medical physics list serve – 11/07/08**



HDR Unit Security - Initial Posting

- We are going to install an HDR unit in a Linac vault with one of the heavy > sliding doors that can not be locked, and we are interested in hearing about > security or inaccessibility) solutions for the HDR unit after hours.
- From the medical physics list serve – 11/11/08



HDR Unit Security – Response (1)

- One idea that we have considered, but not implemented yet, is to construct a lockable cabinet that the HDR unit can be rolled into. That way the vault itself doesn't need to be locked.
- From the medical physics list serve – 11/11/08

HDR Unit Security – Response (2)

- Apart from adding the necessary warning signs to the vault door, here in Florida, the State would be happy with a heavy gauge cable or chain being utilized to lock the unit to the vault floor. We currently have a keypad lock on our HDR suite door but in the past we did not and the inspectors were happy with the fact that we kept the keys to the unit in a secure area and had the unit chained to the floor when not in use.

From the medical physics list serve – 11/11/08

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HDR Unit Security – Response (3)

- We have a lockable cabinet in the HDR suite for the unit. Each physicist has a key and unlocks the HDR unit before use.
- From the medical physics list serve – 11/12/08



HDR Unit Security Solutions – Response (4)

- Lockable cabinet is the easiest solution. If you call VARIAN they have a drawing for a cage design. The problem with electronic card system is that if it fails or delays entry-- then in an emergency your access will be jeopardized. We removed ours. We are installing a magnetic lock which would do the same. The simple one is the cage system/cabinet with lock.

- From the medical physics list serve – 11/12/08

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Conclusions

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The Regulatory and Political Influence

- **Need to:**
 - **teach regulations and their impact**
 - **understand the political influence on scientific fields**
 - **understand the changing times we live in and how they impact you and your career choices**
 - **understand role of professional societies**

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Conclusion

- There is a need for those who:
 - practice the science
 - apply the science, and
 - apply the science in support of regulatory development and implementation

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If anything is certain, it is that change is certain. The world we are planning for today will not exist in this form tomorrow.

Philip Crosby, *Reflections on Quality*

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Newest Federal Agency to Coordinate With



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