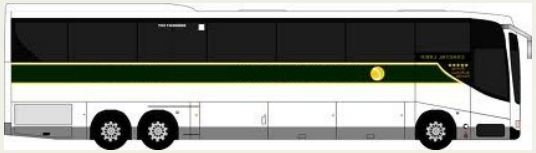
How Far Have We Traveled in 12 Months? Or is there progress in regulatory/legislative developments?

Legislation – Progress or Bus Wreck?

CARE Bill – H.R. 2104 and the 112th Congress

- CARE stands for: *Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2011*
- Introduced June 2011 by Representative Ed Whitfield (R-KY) as H.R. 2104
- Following the introduction of the bill, it was immediately referred to the House Energy and Commerce Committee and House Committee on Ways and Means for review.
- Does not include exemption for MIPPA* Advanced Imaging Modalities
  - Diagnostic magnetic resonance imaging,
  - Computed tomography, and
  - Nuclear medicine-including positron emission tomography
- Amends title XVIII (Medicare) of the Social Security Act to allow Medicare payment for medical imaging and radiation therapy services, only if the examination or procedure is planned or performed by an individual who meets this Act's requirements.



*MIPPA= Medicare Improvements for Patients and Providers Act of 2008

Purpose

- Amends the Public Health Service Act to require personnel who perform or plan the technical component of either medical imaging examinations or radiation therapy procedures for medical purposes to possess, effective January 1, 2014:

  (1) certification in each medical imaging or radiation therapy modality and service they plan or perform from a certification organization designated by the Secretary of Health and Human Services (HHS); or

  (2) **state licensure or certification where such services and modalities are within the scope of practice as defined by the state for such profession** and **where the requirements for licensure, certification, or registration meet or exceed the standards established by the Secretary**.

  – Exempts physicians, nurse practitioners, and physician assistants from the requirements of this Act.

Purpose (continued)

- Directs the Secretary to:

  (1) establish minimum standards for personnel who perform, plan, evaluate, or verify patient dose for medical imaging examinations or radiation therapy procedures;

  (2) establish a program for designating certification organizations after consideration of specified criteria;

  (3) provide a process for the certification of individuals whose training or experience are determined to be equal to, or in excess of, those of a graduate of an accredited educational program; and

  (4) publish a list of approved accrediting bodies for such certification organizations.

- Authorizes the Secretary to develop alternative standards for rural or health professional shortage areas as appropriate to ensure access to quality medical imaging.

79 Co-Sponsors as of March 18, 2012
25 Republicans, 54 Democrats

- **California**
  - Rep Matsui, Doris [D-CA-5] - 9/15/2011
  - Rep Garamendi, John [D-CA-10] - 3/1/2012
  - Rep Speier, Jackie [D-CA-12] - 3/1/2012
  - Rep Lofgren, Zoe [D-CA-16] - 9/15/2011
  - Rep Berman, Howard [D-CA-28] - 3/1/2012
  - Rep Waters, Maxine [D-CA-35] - 2/16/2012
  - Rep Richardson, Laura [D-CA-37] - 6/2/2011
  - Rep Napolitano, Grace [D-CA-38] – 6/25/2011
- **Colorado**
  - Rep DeGette, Diana [D-CO-1] - 2/16/2012
  - District of Columbia
  - Rep Norton, Eleanor Holmes [D-DC] - 10/5/2011
- **Georgia**
  - Rep Barrow, John [D-GA-12] - 6/2/2011
  - Rep Scott, David [D-GA-13] - 11/4/2011
- **Illinois**
  - Rep Rush, Bobby L. [D-IL-1] - 6/2/2011
  - Rep Lipinski, Daniel [D-IL-3] - 12/20/2011
  - Rep Gutierrez, Luis [D-IL-4] - 3/8/2012
  - Rep Shimkus, John [R-IL-19] - 10/12/2011
- **Indiana**
  - Rep Burton, Dan [R-IN-5] - 6/16/2011
  - Rep Carson, Andre [D-IN-7] – 6/3/2011
  -
- **Iowa**
  - Rep Braley, Bruce [D-IA-1] - 12/8/2011
  - Rep Loebsack, Dave [D-IA-2] – 8/2/2011
  - Rep Boswell, Leonard L. [D-IA-3] - 6/2/2011
- **Kentucky**
  - Rep Whitfield, Ed [R-KY-1] – 6/2/2011 (sponsor)
  - Rep Guthrie, Brett [R-KY-2] - 6/2/2011
  - Rep Rogers, Harold [R-KY-5] - 6/16/2011
- **Maryland**
  - Rep Bartlett, Roscoe [R-MD-6] - 3/1/2012

H.R. 2104 Co-Sponsors Continued

- **Massachusetts**
  - Rep Olver, John W. [D-MA-1] - 6/15/2011
  - Rep McGovern, Jim [D-MA-3] - 3/1/2012
  - Rep Tsongas, Niki [D-MA-5] - 2/16/2012
  - Rep Capuano, Michael [D-MA-8] - 9/8/2011
  - Rep Lynch, Stephen [D-MA-9] - 12/1/2011
- **Michigan**
  - Rep Benishek, Dan [R-MI-1] - 11/1/2011
  - Rep Kildee, Dale E. [D-MI-5] - 6/2/2011
  - Rep Rogers, Mike [R-MI-8] - 6/14/2011
- **Minnesota**
  - Rep Walz, Tim [D-MN-1] - 9/8/2011
  - Rep McCollum, Betty [D-MN-4] – 7/20/2011
- **Mississippi**
  - Rep Harper, Gregg [R-MS-3] - 6/2/2011
- **New Jersey**
  - Rep Lance, Leonard [R-NJ-7] - 6/2/2011
- **New Mexico**
  - Rep Heinrich, Martin [D-NM-1] - 6/2/2011
  - Rep Lujan, Ben [D-NM-3] – 7/6/2011
- **New York**
  - Rep Rangel, Charles [D-NY-15] - 3/1/2012
  - Rep Hinchey, Maurice [D-NY-22] - 9/8/2011
- **North Carolina**
  - Rep Butterfield, G.K. [D-NC-1] - 11/15/2011
  - Rep Jones, Walter B., Jr. [R-NC-3] - 6/2/2011
  - Rep Price, David [D-NC-4] – 8/2/2011
  - Rep Coble, Howard [R-NC-6] - 6/22/2011
  - Rep McIntyre, Mike [D-NC-7] - 6/2/2011
  - Rep Myrick, Sue Wilkins [R-NC-9] - 6/2/2011
  - Rep Miller, Brad [D-NC-13] - 9/15/2011
- **Ohio**
  - Rep Johnson, Bill [R-OH-6] - 9/24/2011
  - Rep Kaptur, Marcy [D-OH-9] – 7/12/2011
  - Rep Fudge, Marcia [D-OH-11] - 6/14/2011
  - Rep Tiberi, Pat [R-OH-12] – 7/12/2011
  - Rep Stivers, Steve [R-OH-15] – 7/20/2011
  - Rep Ryan, Tim [D-OH-17] – 7/20/2011
  - Rep Gibbs, Bob [R-OH-18] – 7/12/2011

H.R. 2104 Co-Sponsors continued

- **Oregon**
  - Rep Blumenauer, Earl [D-OR-3] - 3/1/2012
  - Rep DeFazio, Peter [D-OR-4] - 12/1/2011
- **Pennsylvania**
  - Rep Brady, Robert [D-PA-1] - 11/4/2011
  - Rep Altmire, Jason [D-PA-4] - 9/13/2011
  - Rep Gerlach, Jim [R-PA-6] - 6/15/2011
  - Rep Schwartz, Allyson [D-PA-13] - 6/14/2011
- **Tennessee**
  - Rep Duncan, John J., Jr. [R-TN-2] - 6/2/2011
  - Rep Blackburn, Marsha [R-TN-7] - 9/8/2011
  - Rep Cohen, Steve [D-TN-9] - 6/2/2011
- **Texas**
  - Rep Hall, Ralph M. [R-TX-4] - 6/2/2011
  - Rep Thornberry [R-TX-13] - 12/1/2011
  - Rep Neugebauer, Randy [R-TX-19] – 7/12/2011
  - Rep Johnson, Eddie Bernice [D-TX-30] - 6/2/2011
- **Vermont**
  - Rep Welch, Peter [D-VT-AL] - 6/22/2011
- **Virginia**
  - Rep Wittman, Rob [R-VA-1] - 6/23/2011
  - Rep Moran, James [D-VA-8] - 6/13/2011
  - Rep Connolly, Gerald E. "Gerry" [D-VA-11]-6/2/2011
- **Washington**
  - Rep Dicks, Norm [D-WA-6] - 9/8/2011
  - Rep Reichert, Dave [R-WA-8] - 6/14/2011
  - Rep Smith, Adam [D-WA-9] - 10/5/2011
- **West Virginia**
  - Rep McKinley, David [R-WV-1] - 3/1/2012
  - Rep Rahall, Nick [D-WV-3] - 6/14/2011
- **Wisconsin**
  - Rep Baldwin, Tammy [D-WI-2] - 6/16/2011
  - Rep Kind, Ron [D-WI-3] - 6/2/2011
  - Rep Moore, Gwen [D-WI-4] - 7/6/2011

Regulatory Update – Progress or Bus Wreck?

Health Policy/Economics Update

AAPM Reimbursement Resources

- AAPM Website under 2012 Health Policy Update
  - Summary of Medicare regulations
  - Payment and impacts to radiation oncology and medical physics codes
  - AAPM comment letters
  - Frequently asked coding questions

  http://aapm.org/government_affairs/CMS/default.asp

- 2012 Medicare final rule webinars are recorded and available on the website, under meetings, webinars, webinar archives

  http://www.aapm.org/meetings/default.asp

2012 Updates to Medicare Physician Fee Schedule (Applies to Physician & Freestanding Centers)

- 2012 Conversion Factor = $34.0376
  - Congress passed legislation to avert the 27.4% reduction to the conversion factor through December 31, 2012
- January 4, 2012 Correction Notice
  - Minor 0.1 RVU reductions to CPT codes 77402, 77615, 77776 and 77787
- See AAPM website for revised and final 2012 RVUs and payments – Must be an AAPM members to access this information
  - http://aapm.org/government_affairs/CMS/2012HealthPolicyUpdate.asp

- RVU = Relative Value Units

2012 Updates to Hospital Outpatient Prospective Payment System (HOPPS) –
Applies to Hospital Outpatient Setting

- January 4, 2012 Correction Notice
  - In reviewing the claims data used to establish the APC median costs for the 2012 HOPPS final rule, CMS discovered that the trim of unpaid lines was not applied correctly.
  - Results in minor increases or decreases to all radiation oncology procedure APCs and slight decreases to all brachytherapy source APCs.
- See AAPM website for revised and final 2012 HOPPS payments – Must be an AAPM member to access this data
  - http://aapm.org/government_affairs/CMS/2012HealthPolicyUpdate.asp

- APC = Ambulatory Payment Classification Groups
- CMS = Centers for Medicare & Medicaid Services

Health Policy Contacts

- Jim Goodwin, Chair of Professional Economics
  - Email: James.Goodwin@vtmednet.org
- Wendy Smith Fuss, AAPM Staff Consultant
  - Email: wendy@healthpolicysolutions.net

NRC Safety Culture Policy Statement

DEFINITION OF NUCLEAR SAFETY CULTURE

Nuclear safety culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.

TRAITS OF A POSITIVE NUCLEAR SAFETY CULTURE

Experience has shown that certain personal and organizational traits are present in a positive safety culture. The following are traits of a positive safety culture:

- **Leadership Safety Values and Actions**—Leaders demonstrate a commitment to safety in their decisions and behaviors.
- **Problem Identification and Resolution**—Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.
- **Personal Accountability**—All individuals take personal responsibility for safety.
- **Work Processes**—The process of planning and controlling work activities is implemented so that safety is maintained.
- **Continuous Learning**—Opportunities to learn about ways to ensure safety are sought out and implemented.
- **Environment for Raising Concerns**—A safety-conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.
- **Effective Safety Communication**—Communications maintain a focus on safety.
- **Respectful Work Environment**—Trust and respect permeate the organization.
- **Questioning Attitude**—Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

There may be additional traits not included here that are also important in a positive safety culture. These traits were not developed for inspection purposes.

NRC MISSION

The mission of the NRC is to license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials in order to protect public health and safety, promote the common defense and security, and protect the environment.

Photo Courtesy EPE

NUREG/BR-0500
June 2011

TO GET MORE INFORMATION

www.nrc.gov
www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

SAFETY CULTURE
Policy Statement

Photo Courtesy Nordion

CHAIRMAN'S MESSAGE

"The importance of a positive Safety Culture has been demonstrated by a number of significant events in the United States and throughout the world. The NRC's Policy Statement, supported by a wide range of stakeholders–from nuclear power plant operators to public interest groups–further emphasizes the tremendous importance of both safety and security in the nuclear industry."

Gregory B. Jaczko

Chairman, U.S. Nuclear Regulatory Commission

SAFETY CULTURE POLICY STATEMENT

Photo Courtesy Entergy Nuclear

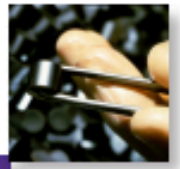
In March 2011, the U.S. Nuclear Regulatory Commission (NRC or the Commission) approved the Safety Culture Policy Statement. The Policy Statement was developed over a three-year period during which the agency engaged in extensive outreach with a broad range of stakeholders.

This Policy Statement provides the NRC's expectation that individuals and organizations performing regulated activities establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. Because safety and security are the primary pillars of the NRC's regulatory mission, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of the Safety Culture Policy Statement.

The policy statement applies to all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval subject to NRC authority. In addition, the Commission encourages the Agreement States (States that assume regulatory authority over their own use of certain nuclear materials), their licensees, and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture within their regulated communities.

BACKGROUND

The 1986 nuclear accident at the Chernobyl nuclear power plant in the Ukraine revealed the importance of safety culture and the impact that weaknesses in safety culture can have on safety. Since then, the importance of a positive safety culture has been further demonstrated by a number of significant events in the United States and the international community. Assessments of these events revealed that safety culture weaknesses were an underlying cause or increased the severity of problems.

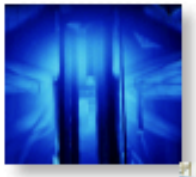


The NRC addressed the importance of safety culture in two previously issued policy statements. The 1989 "Policy Statement on the Conduct of Nuclear Power Plant Operations" applies to all individuals engaged in activities that affect the safety of nuclear power plants and provides the NRC's expectations for utility management and licensed operators in the conduct of operations. The 1996 "Freedom of Employees in the Nuclear Industry To Raise Safety Concerns Without Fear of Retaliation" policy statement applies to the regulated activities of all NRC licensees and their contractors and subcontractors. It provides the expectation that licensees and other employers subject to NRC authority establish and maintain work environments in which employees feel free to raise safety concerns without fear of retaliation.

Following the September 11, 2001 terrorist attacks, the Commission issued orders enhancing security at nuclear facilities. During the early years of implementation of these enhancements, several violations of the enhanced requirements occurred because of failures to cultivate a positive safety culture in the licensee's security program.

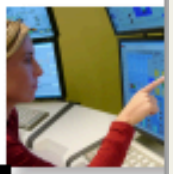
While discernable progress has been made by the nuclear community to strengthen nuclear safety culture since the Chernobyl accident, the NRC seeks to further emphasize the critical importance of safety culture by the issuance of this Policy Statement.

IMPORTANCE FOR REGULATED ENTITIES



Industry experience has shown the value of establishing and maintaining a positive safety culture. The NRC believes that through our continued outreach activities this value will become apparent. It is important to remember that individuals and organizations performing regulated activities bear the primary responsibility for safety and security. The NRC can monitor and trend the performance of individuals and organizations to determine compliance with requirements and commitments. Additionally, this information may serve as an indicator of possible problem areas in an organization's safety culture. However, the NRC does not monitor or trend the traits in the Policy Statement. The Policy Statement is not a regulation; therefore, it is the organization's responsibility, as part of its safety culture program, to consider how to apply this Policy Statement to its regulated activities.

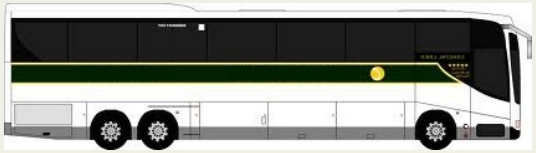
MOVING FORWARD



As the Safety Culture Policy Statement enters the next phase, outreach, cooperation and interaction with and between external stakeholders will become even more important to the success of the policy statement. During this phase, the NRC staff will continue to engage stakeholders in dialogue regarding the importance of a positive safety culture in their specific activities and will also seek out feedback on the ability of stakeholders to use the policy statement in those activities, as well as to determine whether there are areas in the policy statement where changes may be appropriate.

NRC Safety Culture Policy Statement

- **Definition:**
  - Nuclear safety culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.
- **NRC Safety Culture Website**
  - http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html



10 CFR Part 37

Physical Protection of Byproduct Material

Final Rule

- Create new 10 CFR Part 37 for physical protection of byproduct material
  - Category 1 and Category 2
  - Irradiated fuel (<100 grams)

- Conforming changes to Parts 20, 30, 32, 33, 34, 35, 36, 39, 51, 71, and 73

Overview/Background

- Proposed rulemaking and guidance document issued by U.S. Nuclear Regulatory Commission (NRC) (June/July 2010)
- Objective:
  - Provide reasonable assurance of preventing the theft or diversion of Category 1 and Category 2 quantities of radioactive material for malevolent use
- Proposed rule addresses security of byproduct material
- Industry requested and received extension to comment period – comments were due January 15, 2011

Overview

- Major Provisions:
  - Access Authorization (Subpart B)
  - Security During Use (Subpart C)
  - Transportation Security (Subpart D)

- NRC Public Meetings:
  - In both meetings industry and Agreement States unanimously commented that proposed rule contained many onerous requirements with no benefit. **All agreed that existing order requirements were working satisfactorily and were effective**.

Industry Concerns

- Personnel Security Background Verification Process:
  - Reviewing Official (RO) roles and responsibilities
- Relationship with Local Law Enforcement Agency (LLEA):
  - Ineffective/fractured relationship between licensee and LLEA officials
- Pre-planning and Coordination:
  - Adds significant resource burden to continually follow-up on source deliveries for an Manufacturer & Distributor licensee due to large quantity of shipments and receipts
  - License Verification System (LVS)

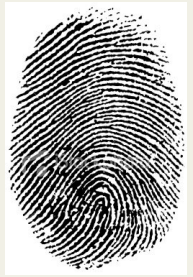
Significant Points of the Part 37 Draft Final Rule to Commissioners for Approval

- One year implementation period
- Agreement states must implement in 3 years
- Still a one size fits all approach
- Only applicable if have aggregated quantity not if license authorizes possession

General Provisions

- Exemptions
  - NRC-licensed activities exempt from Subparts B and C if covered by a Part 73 *Physical Protection of Plants and Materials* security plan
  - Radioactive waste exempt from Subparts B, C, and D
    - Unless contains discrete sources, ion-exchange resins, or activated material < 2,000 kg

Background checks



- Elements
  - Fingerprinting and criminal history record check
  - Verification of true identity
  - Work and education history evaluation
  - Character and reputation determination
  - Independent information

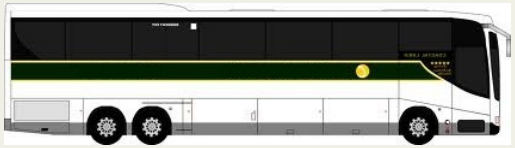
- **No credit check** required as part of background check
  - NRC received numerous negative comments

- Licensee can transfer the background check information to another licensee when the employee authorizes this.

- Initial check go back 7 years and recheck every 10 years

Reviewing Official

- The Reviewing official must have an FBI background check and must have unescorted access to Cat 1 or 2 security zones or access to SGI.
  - HR personnel impact



- Licensee can designate the Reviewing official, must submit to NRC under oath – T&R, NRC does not need to approve.

Shipping and Receiving

- The no later than arrival time needs to be agreed between shipper and receiver. Receiver must notify shipper of receipt.
- If source is not received by the agreed no later than arrival time, must immediately investigate.
- If the source is determined to be missing or lost must notify NRC within 4 hours.
- If still missing after 24 hours (allows time to trace through carrier system) must immediately notify NRC.
- If there is a safety concern, do not have to disable the vehicle.

License Verification

- Must verify Category 2 source transfers through the NRC Licensing verification system, or if this system is not in place, must contact the regulatory authority that issued the receiver's license to verify.

- If you can't get hold of regulator, you can accept certification from receiving licensee but you must get approval from regulator by close of next business day. This verification must be documented.

Local Law Enforcement Agency (LLEA)

- Coordinate a response plan with LLEA, if LLEA still refuses attempts at coordination after 60 days of initial attempt must notify NRC within 3 days. Need annual meeting with LLEA to review response plan.
- No notification of LLEA required for temporary job site.
- No notification by LLEA of a degradation in response.

Impact

- Substantial administrative burden
  - Additional systems and procedures need to be developed
  - Increase in the documentation requirements
  - Training
  - Audits

Implementation

- Costs
  - Total $400-500 million
  - Average cost to implement – $23,000
  - Annual cost – $21,000
- Implementation Guidance document will be available within 30 days of final rule

Part 37 - Timeline

- Final rule currently with the Commission
  - SECY-11-0170 (ADAMS ML112920070)
- Effective date one year from publication

NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

Office of Public Affairs Telephone: 301/415-8200
Washington, D.C. 20555-0001
E-mail: opa.resource@nrc.gov Site: www.nrc.gov
Blog: http://public-blog.nrc-gateway.gov

No. 12-027 March 16, 2012

NRC AMENDS REGULATIONS ON SECURITY OF RADIOACTIVE MATERIALS

The Nuclear Regulatory Commission is amending its regulations to codify and expand upon recent security measures the agency has imposed for certain sensitive radioactive materials.

In a final rule to be published soon in the *Federal Register*, the NRC adds a new Part 37 to its regulations in Title 10 of the U.S. Code of Federal Regulations (10 CFR), and makes conforming changes to other parts of NRC regulations regarding radioactive materials.

The new regulation, which takes effect one year after publication, establishes security requirements for the most risk-significant radioactive materials (those in Category 1 and Category 2 of the International Atomic Energy Agency's rankings of radiation sources), as well as for shipments of small amounts of irradiated reactor fuel.

Next Installment or Stay Tuned!

March 14, 2012 – NY Times Article

March 14, 2012

Hospitals With Radioactive Materials Expose Weakness in Antiterror Rules

By MATTHEW L. WALD

WASHINGTON — Ten years into a campaign to make radioactive materials harder for terrorists to steal, Congressional auditors have found one hospital where cesium was kept in a padlocked room but the combination to the lock was written on the door frame and another where radioactive material was in a room with unsecured windows that looked out on a loading dock.

In testimony prepared for delivery on Wednesday to a Senate Homeland Security subcommittee, an official from the Government Accountability Office plans to say that people with responsibility for security told the auditors that they were trained as physicists or radiation health technicians and were being told to enforce regulations "that they did not believe they were fully qualified to interpret."

SECURITY MANAGEMENT
SECURITY'S WEB CONNECTION

Published on *Security Management* (http://www.securitymanagement.com)

Hospitals a Weak Link in Nuclear Nonproliferation

By Carlton Purvis
Created *03/15/2012 - 15:50*

Hospitals are a weak link when it comes to securing radioactive material in the United States even after audits by the Nuclear Regulatory Commission and state inspectors, according to a Government Accountability Office (GAO) report released on Wednesday.

Around 1,500 hospitals in the United States contain high-activity radiation sources. Of the 25 visited by the GAO, many had "a number of potential security weaknesses."

At one hospital, a machine with radioactive material was kept on a wheeled pallet in a room with no cameras located next to a loading dock. Another facility, described as, "a hospital in a major U.S. city," kept a blood irradiator (a machine that uses radiation applied to blood to treat certain conditions) in a room with a combination lock, but the combination to the lock was kept on the door. At a university facility, a radiation safety officer said that its systems could only hold 500 records at a time of who had access to radiation sources, but more than that had unrestricted access.

Radioactive material cobalt-60, cesium-137, and strontium-90 are usually sealed in metal when used in medical or industrial machinery. The concern is unsecured radioactive material and machinery that when combined with conventional explosives could make a dirty bomb capable of breaking that seal and contaminating a large area.

The report points to a 1987 incident in Brazil involving medical devices that contained cesium as an example of the outcome of a dirty bomb attack. After radiation therapy equipment was left at an abandoned medical facility, two men dismantled it for parts, presumably to sell, and unsealed the cesium. The "glowing powder" made its way around the city until doctors discovered it was radioactive.

Nuclear Nonproliferation – Further Action Needed By U.S. Agencies To Secure Vulnerable Nuclear And Radiological Materials

- GAO Report – GAO-12-512T, Issued March 14, 2012
- Basis for the report –
  - President Obama announced in 2009 an international initiative to secure all vulnerable nuclear material worldwide within 4 years.
  - Leaders from 47 countries endorsed this effort at the 2010 Nuclear Security Summit
  - Next Nuclear Security Summit is March 2012 – it will review their current effort and set new goals for nuclear security

GAO Report

- Discusses:
  - the U.S. strategy to secure all vulnerable nuclear material within 4 years,
  - U.S. agencies' ability to track and evaluate the security of U.S. nuclear materials transferred to foreign countries,
  - challenges coordinating federal nuclear nonproliferation efforts, and
  - preliminary observations regarding GAO's ongoing work on federal efforts to secure radiological sources in U.S. hospitals and medical facilities.

GAO Approach

- Visited 25 hospitals and medical facilities in 7 states (CA, MD, NY, PA,TN, TX, VA) and the District of Columbia

- Interviewed regulatory officials from:
  - Al, AK, CA, CO, FL, KY, MD, MA, MS, NM, NY, NC, PA, RI, TN, TX, VA, WA, and WI

"NRC's Security Requirements Do NOT Prescribe Specific Measures for Protecting Radiological Sources at Hospitals and Medical Facilities"

- NRC Issued Security Orders in 2005
- Orders provide a general framework for what constitutes adequate security practice and do not prescribe the specific steps a licensee must take to secure their sources.
- According to NRC, the intent of the increased controls is not to provide absolute security from theft or unauthorized access but to develop a combination of people, procedures and equipment that will delay and detect an intruder, and initiate a response to the intrusion.

Approaches to Implementation

- Widely variable
- At some locations, the controls resulted in significant security upgrades such as:
  - the addition of surveillance cameras,
  - upgrades to locks on doors, and
  - alarms.
- Other facilities had minimal security.
- Law enforcement personnel indicated that the NRC controls have an inherent weakness: the controls do not specify what the facility is protecting against and are not linked to a design basis threat.

Potential Security Weaknesses Observed Example 1

- Scenario:
  - At a hospital in one state, two cesium-137 research irradiators using approximately 2,000 curies and 6,000 curies, respectively, are housed in the basement of a building that is open to the public.
  - The hallway leading to the irradiator room has a camera, but it is pointed away from the room.
  - The door to the room is opened by a swipe card lock, and there are no cameras or other security measures inside the room.

Potential Security Weaknesses Observed Example 1

- Observation:
  - One of the irradiators was sitting on a wheeled pallet. When we asked the radiation safety officer (RSO) if he had considered removing the wheels, he said no.
  - This response was given even though the irradiator room is located in close proximity to an external loading dock, and the cameras along the corridor to the loading dock are displayed on a single monitor.

Potential Security Weaknesses Observed Example 1

- Status:
  - This facility had passed its most recent NRC security inspection because access to the room where the irradiators were located was restricted through use of a swipe card.
  - However, it could be vulnerable because of the limited security we observed and the potential mobility of the device.

Potential Security Weaknesses Observed Example 2

- Scenario:
  - At a hospital in a major U.S. city, we observed that the interior door to the hospital blood bank, which had a cesium-137 blood irradiator of approximately 1,500 curies, had the combination to the lock written on the door frame. The door is in a busy hallway with heavy traffic, and the security administrator for the hospital said that he often walks around erasing door combinations that are written next to the locks.
- Observation:
  - According to NRC, a single lock is not necessarily a security weakness, however, they noted that writing combinations on the door is a weakness.

Potential Security Weaknesses Observed Example 3

- The RSO at a university hospital in another state told us that he did not know the exact number of individuals with unescorted access to the hospital's radiological sources, although he said that there were at least 500 people—the current data system does not allow for entering records of individuals beyond 500. In the past, he said, the hospital had as many as 800 people with unescorted access to sources.

- In contrast, at a major medical research facility at a military installation we visited, access was limited to 4 safety and security personnel.

Credentials of Personnel Responsible for Implementation

- Backgrounds in radiological safety and facilities management
- Limited security experience
- None of these officials has been trained in how to implement the controls.

Observations – Licensee Personnel Credentials

- At another hospital we visited, the RSO said that when the controls were instituted in 2005, his new responsibilities included ensuring the security of a cobalt-60 gamma knife of approximately 2,600 curies and a cesium-137 blood irradiator of about 2,400 curies.

- He told us that he was not comfortable with his security role because his training was as a health physicist.

Observation – Licensee Personnel Credentials

- One facility manager who oversees the security for an approximately 1,700 curie cesium-137 blood irradiator at a blood bank told us that he has a background in construction, not security. He said that it would have been helpful if NRC's controls were more specific so that he would be in a better position to determine what security measures were necessary to adequately protect the device.

Training for Regulatory Inspectors

- NRC Stated:
  - NRC and Agreement State inspectors receive training in security inspections.
  - Only qualified inspectors can conduct security inspections.
  - Qualification includes training and inspection accompaniments with qualified inspectors.

Observation – NRC Comments

- Even after receiving the training, an NRC inspector said that security inspections were particularly difficult for her because she is trained as a physicist. She said that the controls were confusing, and she did not understand the nuances of security.

Observation – Agreement State Comments

- An Agreement State inspector from another state we visited also told us that he was not qualified to do security inspections. However, he said that he was doing the best he could to interpret the controls and help the licensees implement the requirements.

- Other inspectors from this state told us that they were placed in the awkward situation of having to enforce regulations that they did not believe they were fully qualified to interpret.

Concerns with Agreement States

- Some Agreement States lacked sufficient staff and adequate training to ensure the security of radiological sources.
  - One Agreement State has experienced significant turnover and that inspectors did not have an adequate understanding of the controls. According to a state official, high staff turnover and the resulting lack of security experience affected the quality of their oversight. As a result, inspectors had difficulty assessing licensee compliance with the security requirements.
  - Second Agreement State – NRC found the state's newer inspectors would have benefitted from additional training on NRC's security requirements. A state inspector told NRC that he did not understand the meaning of some of the documentation he was reviewing. Another state official stated that he was authorized to inspect a radiological device before he was ready to do so. Furthermore, according to state officials, staff turnover has significantly affected the state's timely follow-up of increased controls violations.

NRC Response

- NRC indicated they will take action in future reviews of these Agreement States to remedy these problems.

- Since 2006, NRC has conducted 41 reviews that contained reports on state's performance regarding the inspection and licensing of the increased control.

- Of the 41 reviews, 4 noted problems with how the state was implementing the increased controls.

NNSA Enhanced Security Initiative

- NNSA States:
  - Approximately 1,500 hospital and medical buildings in the United States —that they have identified—that contain high-activity radiological sources.
  - Estimates that these buildings are authorized to cumulatively contain about 22 million curies of radioactive material
- Offers a voluntary program to further improves security beyond NRC and Agreement State regulatory requirements

NNSA Voluntary Program Components

- U.S. hospitals with security upgrades to the devices that contain high-activity radiological sources.
- Training for hospital personnel and local police departments through its Alarm Response Training program at the Y-12 National Security Complex in Oak Ridge, Tennessee.
  - Training is designed to teach facility personnel and local law enforcement officials how to protect themselves and their communities when responding to alarms indicating the possible theft or sabotage of nuclear or radioactive materials.
- NNSA funds the cost of the security upgrades and training.
- However, the licensee is responsible for maintaining the security systems once the 3-to-5-year warranty period established by NNSA expires.
- NNSA officials told us that they estimated the average cost of maintaining the upgrades at each hospital was typically less than $10,000 per year.

Cost of NNSA Initiative – as of December 2011

- Estimated $96 million to secure radiological sources at 302 U.S. hospitals and medical facilities.
- The program plans to complete voluntary security upgrades at all 1,503 hospital and medical buildings it has identified as high-risk by 2025, at a projected cost of $608 million.
- Estimated average cost to upgrade a medical building has been $317,800.

Examples of NNSA Actions

- Remote monitoring systems,
- Surveillance cameras,
- Hardened doors,
- Iris scanners,
- Motion detectors, and
- Tamper-proof alarms.

Criteria for Determining Eligibility

- Ranks facilities to be upgraded based on the relative risk of the radiological sources and expected risk reduction resulting from the planned GTRI activity.

- The criteria NNSA uses include the following:
  - the attractiveness for theft or diversion of nuclear and radiological materials;
  - existing site security conditions; threat environment; and
  - location to a potential target, such as a large population center.

Why Hospitals Don't Participate

- Comments indicated the GTRI program is limited because it is a voluntary program and because of the potential financial burden placed on hospitals and medical facilities to maintain the upgrades beyond the 3- to 5-year warranty period.

- An RSO of one facility said that the security the hospital has in place is adequate. Furthermore, the hospital is under serious budget pressure that makes it difficult to justify spending more money on protecting the sources. Therefore they have declined to participate.

NNSA Upgrades for Smaller Sources e.g., Brachytherapy

- These devices contain between 10 and 15 curies of iridium-192. The curie level is not considered high enough to be subject to NRC's security controls, but NNSA officials told us that the devices' portability makes them a potential target for theft.

GAO Observations

- One GTRI-upgraded facility where the security of the brachytherapy device had not been upgraded.
  - No security cameras monitoring the area, and in particular, there were no cameras in the room where the device was located.
  - Access to the room was controlled by a wooden door with a padlock, and
  - A hospital official retrieve the key to the padlock from an unlocked desk immediately outside the door.
  - Upon entering the room, we observed that the device was not secured to the floor, as required by the hospital's own security protocol.

So What Does All This Mean?

- Not clear at this point
- GAO is continuing with additional audits
- There has been discussion in Congress that increased controls should be expanded to include all sources.
- No decision yet.
- Will continue monitoring.

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