



AAPM ANNUAL MEETING
INDIANAPOLIS INDIANA AUGUST 2013

***Challenges of
Increased Controls of Radioactive Materials***

Bringing Orders & Rules into Practice



Bette W. Blankenship M.S., D.A.B.R.
Medical Physicist
Sharp Memorial Hospital
7901 Frost Street
San Diego CA. 92123

A NEW RULE TO PROTECT RADIOACTIVE MATERIALS



10CFR37:

The Rule Objective:

***To provide reasonable
assurance of preventing the
theft or diversion of category 1
and category 2 quantities of
radioactive material***



ORDERS AND RULES

Differences between an Order and a Rule

- An Order can be effective immediately.
- The Rulemaking process may take years, as it involves issuing a preliminary draft, soliciting comments, in some cases obtaining approval from the Office of Management and Budget (OMB), and a waiting period before the Rule takes effect. An Order that addresses an urgent situation, may have little or no feedback from stakeholders, while a Rule, such as 10CFR37, entails extensive feedback, often with hearings, working groups, and lengthy correspondence.
- Orders apply only to current licensees; having an Order apply to future licensees requires notifying them individually that the Order applies to them. In contrast, a Rule applies to current and future licensees. **An Order and a Rule both have the effect of law.**

THE ORDERS



“In the wake of the 9/11 attacks, the NRC issued Orders to its licensees to enhance the security of radioactive materials. These Orders went, among others, to licensees of large irradiators, manufacturers and distributors of radioactive material, and certain transporters of radioactive material. An “Increased Controls” (IC) Order went to other licensees authorized to possess specified quantities of certain radioactive material.”

THE RULE



“The Rule will have broad impacts across the country and across most if not all aspects of industries that use radioactive material, including hospital and blood bank irradiators, industrial radiography equipment, massive facilities for irradiating certain foods and medical supplies, laboratory equipment for research into radiation and its effects, state regulators, and manufacturers, distributors, and transporters of radioactive sources. “

IMPLEMENTING THE RULE



***“The NRC approved the Rule in March 2012 and sent it to the OMB for its review in July. The NRC anticipates that the rule will be published in the Federal Register in early 2013. For states regulated by the NRC, the rule will become effective one year after it is published in the Federal Register.*”**

For Agreement States, the Rule will take effect two years later. Once the NRC and Agreement States implement the Rule, the NRC and, when appropriate, Agreement States will rescind the various Orders the Rule replaces.”

IMPLEMENTING THE RULE



The Rule implements changes to the original Orders such as:

- Requiring individuals already deemed trustworthy and reliable (T&R) to complete certain security training***
- Requiring a personal history disclosure***
- Requiring each licensee to “review the access program content and implementation” at least once a year.***

The NRC provides details in a 69-page table that compares the Rule and Orders.

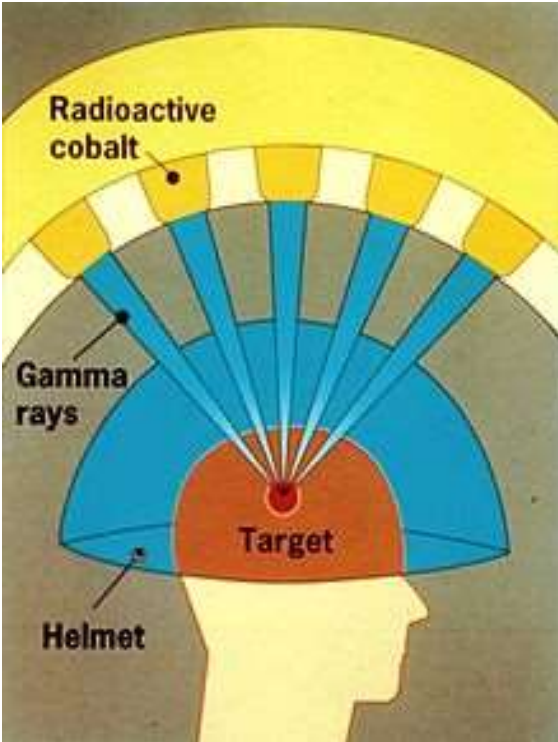
Category 1 and Category 2

Radioactive Materials

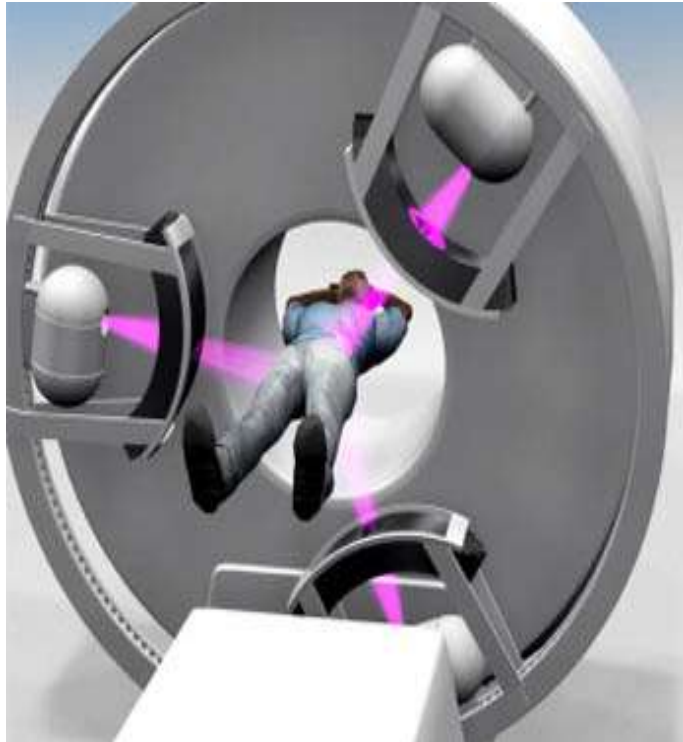


Radioactive material	Category 1 threshold		Category 2 Threshold	
	Terabecquerels (TBq)	Curies (Ci)	Terabecquerels (TBq)	Curies (Ci)
Curium-244	50	1,350	0.5	13.5
Cobalt-60	30	810	0.3	8.10
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1000	27,000	10.0	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Beryllium	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2.0	54.0
Strontium-90 (Yttrium-90)	1,000	27,000	10.0	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0
.				

Medical Devices Using Category 1 or Category 2 Sources



**Gamma-Knife
RadioSurgery**
~6000 Ci Cobalt-60



ViewRay™ System
~35,000 Ci to 45,000 Ci Cobalt-60



Gammacell® Irradiator
1000 Elite / 3000 Elan
~ 750 Ci to 3000 Ci Cs-137

WHERE TO BEGIN?



FEDERAL REGISTER

Vol. 78 Tuesday,
No. 53 March 19, 2013

Part II

Nuclear Regulatory Commission

10 CFR Parts 20, 30, 32, et al.
Physical Protection of Byproduct Material; Rule



Nuclear Regulatory Commission 10 C.F.R. 37, A New Rule to Protect Radioactive Material: Background, Summary, Views from the Field

Jonathan Medalia
Specialist in Nuclear Weapons Policy

December 14, 2012

Congressional Research Service
7-5700
www.crs.gov
R42868

CRS Report for Congress
Prepared for Members and Committees of Congress



DEVELOPING COMPLIANCE TO THE RULE:

With guidance from the Radiation Safety Committee (RSC): Develop a decision making Task-Group to Include:

The RSO

A Medical Physicist

The RSC Legal Representative

The Director of Human Resources

The Director of Each Area Using Radioactive Materials Requiring Increased Controls

The Director of Security

Establish Facility Requirements For 'Access Authorization'



Subpart B: Background Investigations & Access Authorization Program



Establishing Controlled Access to:



- All **Radioactive Materials (RAM)** regulated by Increased Control
- Information** Specific to RAM regulated by Increased Control
- Fingerprinting and background checks for all individuals granted **unescorted access** to RAM regulated by Increased Control and all information specific to RAM regulated by Increased Control

HOW ?

TASK GROUP TASKS:



§37.23: Access Authorization Program Requirements How To Adopt Requirements and Assure Staff Meet Requirements

- Identify an “Officer Of Trustworthiness and Reliability”**
- Fingerprint and Criminal History Check The Officer Of Trustworthiness and Reliability**
- Identify Personnel that will Require Unescorted Access to RAM**

§37.25, sets the minimum requirements for a background investigation, including fingerprinting and an FBI identification and criminal history records check; verification of true identity, employment history, and education; and a character and reputation determination.

- Fingerprint and Criminal History Check for Current Employees Working in Areas Using RAM Requiring Increased Controls.**
- Consider Previous Employment History as an Indication of Reliability and Trustworthiness?**
- Require all ‘New-hires’ to Pass a Third-Party Vendor Criminal History Check (including fingerprint evaluation)**

TASK GROUP TASKS:



- Develop, implement, and maintain written procedures for implementing the access authorization program
- Initiate Required Protection of Information Related to Increased Controls





§37.29, Relief from fingerprinting, identification, and criminal history records checks?

Is your RSO or do you have staff that is a Congressional Representative?

An Employee of the NRC?





§37.33 *Access Authorization Program Review*

Self evaluation?
Outside Vendor Evaluation?



TASK GROUP TASKS:



Subpart C: Physical Protection Requirements During Use

§37.41 Security Program

Develop a Program and Establish Annual Review by the RSO and RSC

§37.43 General security program requirements

Requires a security plan, implementing procedures, training, and methods to protect information.

If the staff number granted unescorted access is large, the initial training and education and annual review requirements becomes significant!



TASK GROUP TASKS:



§37.45: LLEA [local law enforcement agency] Coordination:

Licensees “shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee’s facility, including any necessary armed response...

Establishing Local Contacts



TASK GROUP TASKS:



§37.49 *Monitoring, Detection, and Assessment*

“Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones.”





TASK GROUP TASKS:

§ 37.49 Monitoring, Detection, and Assessment

Full Visibility? The Increased Control RAM access door viewable by staff 24/7

Door to RAM viewable by manned security camera 24/7?

Motion Detectors in the room, disarm-able by staff approved for unescorted access?

Best Options for Success?



TASK GROUP TASKS:



Verification of Category 2 Sources

Weekly verification of category 2 sources to ensure that the material is present? 10 C.F.R. 37.49(a)(3)(ii).

- Weekly Log by Security Staff Viewing Camera Surveillance**
- Weekly Email to the RSO from Security Staff Viewing Camera Surveillance**





TASK GROUP TASKS:

§37.51: Maintenance and Testing of Security Systems

“Licensees shall maintain physical components of the security systems, and shall test them at the frequency the manufacturer suggests. If there is no such suggestion, the frequency shall be at least once every 12 months”

§37.55 Security Program Review

“Licensees shall ensure that the security program is reviewed, at least annually, with the results and recommendations documented, and shall take actions to correct adverse conditions.”



§37.57: Reporting of Events

“Licensees must immediately notify Local Law Enforcement Agencies [LLEA] of actual or attempted theft, sabotage, or diversion of category 1 or 2 material, and also to notify NRC within four hours of discovering such event. §37.57(b) requires licensees to assess suspicious activity of this nature, notify LLEA as appropriate, and also notify NRC within four hours of notifying LLEA”





§37.71 RAM Transfer

§37.71 Transfer of Category 1 and Category 2 Radioactive Material and §37.75: Preplanning and Coordination of Shipment

“Licensees transferring such material shall verify that the recipient’s license authorizes receipt of the material.”

“Licensees planning to transport, or to have transported, category 1 material shall conduct detailed preplanning and coordination of the shipment with the recipient, and any state through which the shipment will pass, identify safe havens along the planned route, and document these activities. Requirements for category 2 shipments are less stringent.”





37.77: Advance Notification of Shipment of Category 1 Quantities of Radioactive Material

“Licensees planning to ship category 1 material shall provide advance notification of the shipment to NRC and the governor, or the governor’s representative, of each state through which the shipment will pass”

§37.79: Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment

§37.81 Reporting of Events:



“The licensee shipping the RAM shall notify LLEA and NRC within 1 hour of determining that a shipment of category 1 material is lost or missing, and shall notify NRC within 4 hours if category 2 material is lost or missing.”



A Few Thoughts



The Orders imposed many requirements and since the Rule incorporates many of these requirements, it imposes less additional regulatory burden than would have been the case if the Orders had not been issued first.

- ***Since the Rule requires many actions regardless of facility size, it will likely impose a proportionately larger burden on small licensees.***
- ***The Rule implements a layered defense. The ability of one layer to offset weaknesses in others should improve security but can't and won't guarantee it.***

QUESTIONS



THANK YOU

