Congressional Research Service

MEMORANDUM August 16, 2012

To: Senate Homeland Security and Governmental Affairs Committee
Attention:

From: Jonathan Medalia, Specialist in Nuclear Weapons Policy, 202-707-7632, jmedalia@crs.loc.gov

Subject: **Analysis of Nuclear Regulatory Commission Final Rule, Physical Protection of Byproduct Material, 10 CFR 37**

This memorandum responds to your request of April 12 for an analysis of 10 CFR 37, a forthcoming rule promulgated by the Nuclear Regulatory Commission (NRC), "Physical Protection of Byproduct Material." "Byproduct material" includes specified types radioactive material other than uranium or plutonium; **Appendix A** provides the full definition of the term. 10 CFR 37 regulates byproduct material of the types and quantities in "category 2" or greater, as described below; such material could be used to make a "dirty bomb" or other types of radiological dispersal devices.

In order to analyze the rule, I conducted detailed telephone interviews with 14 professionals in the radiation industry. They include radiation safety officers at large universities, industrial radiographers, Agreement State officials, manufacturers and distributors of radioactive sources, a representative of the Nuclear Energy Institute, and a transporter of radioactive material. I took notes of each interview, worked with the interviewee to make sure that the notes reflect his or her views correctly, and compiled the notes as **Appendix B** to this memo. Most interviewees have given permission to attribute these notes; a few have requested anonymity. **Appendix B** contains these notes, including notes without identifying information from interviewees who wish to remain anonymous. As a result, this memo may be distributed without limitation.

These notes—views of front-line radiation professionals—constitute the database for analyzing 10 CFR 37. They display the widespread effects of this new rule, and the widely divergent views that these professionals hold of virtually every part of this rule. At the same time, one interviewee commented, "Part 37 is a sweeping, high-impact rule that affects the entire industry"; based on their responses, most if not all interviewees would agree.

In preparing this memo, I asked NRC to review the memo in draft form to provide comments, ensure accuracy, and provide the agency's views. This memo incorporates NRC's comments as appropriate.

As we discussed, you gave me permission to convert this document into a CRS report that will be available to all Members of Congress and their staffs. I plan to do so.

Please contact me if I can be of further assistance.

Technical Background

While there had been concerns about the vulnerability of the United States to "weapons of mass destruction," or more precisely Chemical, Biological, Radiological, and Nuclear (CBRN) weapons, for many years prior to September 11, 2001, the events of that day elevated concern about CBRN attacks, especially those that might be mounted by "non-state actors" such as terrorists.

One concern is that a terrorist group might acquire and set off a radiological dispersal device, or RDD. An RDD has the potential to contaminate several square miles (more or less, depending on many factors) with radioactive material. The radioactive material in the device would probably result in few prompt fatalities, though it could cause additional long-term cancer fatalities. Its main potential impact, however, would be rendering key sections of a city or critical infrastructure (e.g., Wall Street, Pennsylvania Avenue, the Port of Los Angeles-Long Beach) off-limits for years, thereby causing immense societal and economic disruption, forcing many people to relocate, and requiring cleanup that could cost many billions of dollars. A "dirty bomb," in which radioactive material is dispersed using explosives, is one type of RDD, but many other means of dispersal are possible, such as dropping material from an upper story of a tall building on a windy day.

Every element has at least one radionuclide, or radioactive form of its atom, and many elements have a dozen or more, but only a few are of concern for an RDD. Radionuclides with half-lives of a few days or less decay quickly, resulting in little long-term dislocation and modest cleanup costs. Radionuclides with half-lives of tens of thousands of years emit so little radiation per unit mass that a huge quantity, perhaps tons, would be required to emit the amount of radiation, per unit time, of a few grams of some other materials. Different types of radiation pose different threats. Most radionuclides are rare or nonexistent in commerce. The International Atomic Energy Agency (IAEA) screened radionuclides and found 16 of particular concern.[1] **Table 1** shows these 16 radionuclides (or combinations of radionuclides). In 2004, the IAEA produced a Code of Conduct on the Safety and Security of Radioactive Sources that was intended to "serve as guidance to States for—*inter alia*—the development and harmonization of policies, laws and regulations on the safety and security of radioactive sources."[2] It applies to specified quantities of the 16 radionuclides. According to the IAEA,

> Category 1 sources, if not safely managed or securely protected would be likely to cause permanent injury to a person who handled them, or were otherwise in contact with them, for more than a few minutes. It would probably be fatal to be close to this amount of unshielded material for a period of a few minutes to an hour. … Category 2 sources, if not safely managed or securely protected, could cause permanent injury to a person who handled them, or were otherwise in contact with them, for a short time (minutes to hours). It could possibly be fatal to be close to this amount of unshielded radioactive material for a period of hours to days.[3]

A category 1 source of a radionuclide has 100 times as much material as a category 2 source, which has 10 times as much material as a category 3 source. Most category 2 quantities of the 16 radionuclides

[1] International Atomic Energy Agency, *Code of Conduct on the Safety and Security of Radioactive Sources*, January 2004, http://www-pub.iaea.org/MTCD/publications/PDF/code-2004_web.pdf. As of July 2012, 113 states, including the United States, had made political commitments to follow the Code of Conduct. International Atomic Energy Agency, "List of States that have a made a political commitment with regard to the Code of Conduct on the Safety and Security of Radioactive Sources and the Supplementary Guidance on the Import and Export of Radioactive Sources," updated July 10, 2012, http://www.iaea.org/Publications/Documents/Treaties/codeconduct_status.pdf.

[2] International Atomic Energy Agency, *Code of Conduct* …, p. 2.

[3] Ibid., p. 15.

weigh a few grams or less. Note that these categories are defined in terms of harm to an individual; nonetheless, they have become the international standard for defining harmful quantities of harmful materials meriting protection against possible terrorist use. 10 CFR 37 applies to the IAEA's category 1 and 2 quantities of the 16 specified radionuclides.[4]

Table 1. Radionuclides and Quantities of Concern Regulated by NRC

Quantities Correspond to Category 2 Sources in IAEA Code of Conduct

Radionuclide	Quantity of Concern, in Units of …			Threshold (Ci) to contaminate 1 square km assuming perfect dispersion
	terabecquerels (TBq)	curies (Ci)	grams (g)	
Americium-241	0.6	16	4.73	78
Americium-241/beryllium	0.6	16	~4.73	~78
Californium-252	0.2	5.4	0.01	49
Curium-244	0.5	14	0.17	130
Cobalt-60	0.3	8.1	0.007	11
Cesium-137	1	27	0.31	42
Gadolinium-153	10	270	0.08	390
Iridium-192	0.8	22	0.002	100
Promethium-147	400	11,000	11.66	410,000*
Plutonium-238	0.6	16	0.95	220
Plutonium-239/beryllium	0.6	16	16.22*	220*
Radium-226	0.4	11	10.93	13
Selenium-75	2	54	0.004	150
Strontium-90 (yttrium-90)	10	270	1.98	200
Thulium-170	200	5400	0.033*	2000
Ytterbium-169	3	81	0.003	600

Source: The list of radionuclides and the TBq column are from "Table 1: Radionuclides of Concern," in U.S. Nuclear Regulatory Commission, "Order Imposing Increased Controls (Effective Immediately)," EA-05-090, November 14, 2005, http://www.nrc.gov/security/byproduct/table1.pdf. (1 Bq = 1 radioactive disintegration of an atom per second; 1 Ci = 3.7 x 10^{10} disintegrations per second; 1 TBq = 27.027 Ci) NRC extracted the list and TBq column from International Atomic Energy Agency, "Code of Conduct on the Safety and Security of Radioactive Sources," Table 1, "Activities Corresponding to Thresholds of Categories," p. 16. Specific activity, used here to calculate grams, is from U.S. Department of Energy. Office of Environmental Management. "Table B.1. Characteristics of Important Radionuclides," http://www.orau.org/ptp/

[4] NNSA commissioned Sandia National Laboratories to perform a screen similar to that done by the IAEA. Sandia started with all nuclides, eliminated those that were nonradioactive, low in threat potential, rare in commerce, etc., and arrived at essentially the same list of radionuclides as the IAEA's Code of Conduct Further, "The Category 1 and 2 quantities of [the 16] radioactive sources listed in the Code of Conduct are considered the most risk significant and have been the focus of [U.S.] Federal and State efforts to place tighter controls for security." Radiation Source Protection and Security Task Force, *The 2010 Radiation Source Protection and Security Task Force Report,* p. 7, http://www.nrc.gov/security/byproduct/2010-task-force-report.pdf. The task force also *"reevaluated the list of risk-significant radioactive sources and the associated threshold quantities* warranting enhanced security and protection to assess their adequacy in light of the evolving threat environment" and "concluded that no changes should be made to the list of existing 16 radionuclides and associated established threshold quantities, but 7 additional radionuclides may be considered for enhanced control in some limited situations." Ibid., p. i; original emphasis.

PTP%20Library/library/DOE/Misc/Table%20B_1_%20Characteristics%20of%20Important%20Radionuclides.htm. CRS calculated columns for Ci and g. Data for column, "Threshold (Ci) to contaminate 1 square km," are from Sandia National Laboratories, *Radioactive Material Downselection and Source Prioritization Methodology: A Sandia National Laboratories Study in Support of the Global Threat Reduction Initiative,* May 8, 2009, p. 40, "Threshold Quantities Comparison." This document is Official Use Only; these figures are unclassified when not associated with a specific weapon. William Rhodes of Sandia National Laboratories provided data for cells marked with an asterisk.

Notes: "Radionuclides of concern" are those for which, in the specified "quantities of concern," NRC requires enhanced security, such as access control, personnel security, and record-keeping. These quantities are Category 2 sources in the IAEA Code of Conduct. The threshold for Category 1 sources is 100 times that for Category 2 sources; the threshold for Category 3 sources is one tenth that for Category 2 sources. A quantity of concern is a very small amount. One ounce is 28.35 grams; many quantities of concern are less than 1 gram.

"Threshold to contaminate 1 square km" shows the amount of material, in curies, to contaminate that area to a level that a person in that area for a year would receive a dose of 2 rem in the first year after an attack, the EPA/FEMA protective action guide for relocation. (The column for curies is presented to two significant figures.) NRC explained the rationale for the area chosen, 1 square km: "Given all the uncertainties, it was a criterion used that might represent significant economic losses, primarily from decontamination and disposal from cleanup efforts. The thresholds being used for significant [radiological exposure devices] and RDDs are the IAEA Code of Conduct Category 2 values." (Comments prepared by NRC, November 30, 2010.) The figures in this column assume perfectly even dispersion of material over the total area. They are a useful metric for comparing the ability of different radionuclides to contaminate, but perfect dispersion would not occur in the real world. Further, the masses of material needed to produce this level of contamination would be somewhat higher than shown because materials used in commerce would not be pure.

For 14 of the 16 isotopes, the quantity of concern (in curies) in the center column is less than the amount of material (in curies) needed to contaminate 1 square km in the rightmost column. One of the two isotopes for which this is not the case, thulium-170, is very rare in commerce, and for the other, strontium-90, the difference between the two quantities is not great. Thus, protecting quantities of concern generally suffices to protect quantities that could be used to create a "significant" RDD.

The Code of Conduct uses TBq as the benchmark to define quantities of concern; CRS converted TBq to Ci. Entry for grams is obtained by dividing TBq by specific activity (expressed in TBq/gram). Entries in right two columns for strontium-90 (yttrium-90) are for strontium-90.

*Rhodes notes that the figure for promethium-147 is so large because that isotope is "essentially a weak pure beta emitter." That is, curies measure the number of disintegrations per second, not energy emitted per disintegration. Since each disintegration of promethium-147 produces very little energy, and in a form of particles that travel only a short distance, it takes a large amount to contaminate 1 square km to the level that would produce the specified dose.

This table is from CRS Report 41890, *"Dirty Bombs:" Technical Background, Attack Prevention and Response, Issues for Congress,* June 24, 2011, by Jonathan Medalia.

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Cesium-137 is radioactive; cesium-137 chloride is of particular concern as a potential threat:

> Because of its dispersibility, solubility, penetrating radiation, source activity, and presence across the United States in facilities such as hospitals, blood banks, and universities, many of which are located in large population centers, radioactive cesium chloride is a greater concern than other Category 1 and 2 sources for some attack scenarios. This concern is exacerbated by the lack of an avenue for permanent disposal of high-activity cesium radiation sources, which can result in disused cesium sources sitting in licensees' storage facilities. As such, these sources pose unique risks.[5]

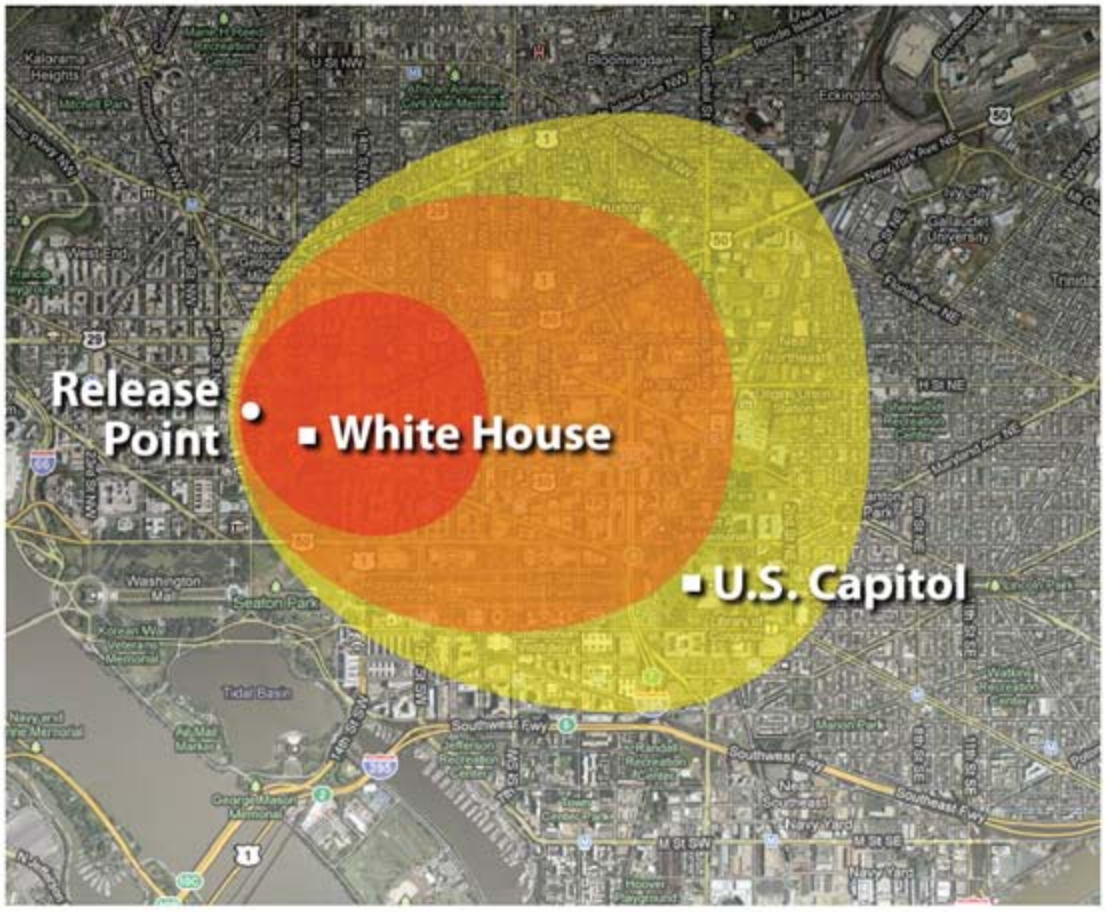
Figure 1 shows the area that an RDD attack using 1,000 curies (about 50 grams) of cesium-137 chloride could contaminate under the specified conditions. That amount fits into a vial 2-1/4 inches high by 1 inch

[5] National Research Council. Division on Earth and Life Studies. Nuclear and Radiation Studies Board. Committee on Radiation Source Use and Replacement, Radiation Source Use and Replacement, Abbreviated Version, Washington, DC, 2008, p. 78, http://www.nap.edu/catalog.php?record_id=11976.

in diameter. For comparison, 2,700 curies of cesium-137 is a category 1 quantity and 27 curies is a category 2 quantity.[6]

Figure 1. A Possible Radiological Dispersal Device (RDD) Attack on Washington, DC

Using 1,000 Curies of Cesium-137 Chloride



Effects and Actions

	Area km²	Area mi	Equivalent Dose (rem)	Exceeds relocation PAG for which year:	Population	All Cancers	Fatal Cancers
	2.10	0.81	>2.00	First year only	38,000	233	159
	7.60	2.93	>0.500	Any subsequent year	94,700	278	189
	13.2	5.10	>5.00	50 years (cumulative)	125,000	461	314

Areas and counts are cumulative. RDD detonated at 38.9 N, 77.0 W. PAG: Protective Action Guide

Source: William Rhodes III, Senior Manager, International Security Systems Group, Sandia National Laboratories, September 2010; analysis by Heather Pennington; graphics by Mona Aragon.

[6] Cesium-137 contributes essentially all the radioactivity of cesium-137 chloride; only a tiny fraction of one percent of chlorine atoms are radioactive. Lawrence Berkeley National Laboratory, Isotope Project, "Exploring the Table of Isotopes: Isotopes of Chlorine," http://ie.lbl.gov/education/parent/Cl_iso.htm.

Note (provided by William Rhodes): This map, based on an atmospheric dispersion model, shows where individuals are projected to have an increased risk of developing cancers due to radiation exposure over a year or more. The RDD in this scenario uses 1,000 curies of cesium-137 chloride (about 50 grams). The model assumes that all material used is dispersed, but that it is not dispersed evenly over the area. Wind is assumed to be from west to east at 7 mph. The model includes exposure from radioactive material both deposited on the surface and resuspended into the air and inhaled. EPA and FEMA have developed Protective Action Guides (PAGs) to indicate when long-term relocation of individuals should be considered. PAGs are primarily based on an assessment of the risk of developing cancer over an exposed individual's lifetime. They assume, conservatively, that individuals are unsheltered and remain in the area during the entire period described for each contour. Contours show where individuals, if not relocated per the PAG, are projected to receive at least a specified dose in a specified time, as follows: inner contour (red), dose in first year post-attack, >2.00 rem; middle contour (orange), dose in second year post-attack, >0.500 rem; and outer contour (yellow), cumulative dose in the first 50 years post-attack. >5.00 rem. The cigar-shaped plumes often seen in models of atmospheric dispersion occur for gases or very fine particles, which would be the case for chemical warfare agents or fallout from a nuclear weapon but not in the case depicted. Whether such plumes would occur for an RDD depends on such factors as wind speed, type of explosive, and particle size.

(Provided by CRS): This note compares lifetime incidence of, and deaths from, cancer to those resulting from the attack modeled in this Figure. For the United States, the lifetime risk of being diagnosed with cancer is 43.61 percent, and the lifetime risk of dying from cancer is 21.15 percent. (U.S. National Institutes of Health. National Cancer Institute. Surveillance Epidemiology and End Results (SEER). "SEER Cancer Statistics Review 1975-2007," Tables 1.14 and 1.17, http://seer.cancer.gov/csr/1975_2007/results_merged/topic_lifetime_risk.pdf) For the 125,000 people in the affected area, the estimated lifetime incidence of cancer would thus be approximately 54,513 people, and the estimated lifetime deaths from cancer, 26,438. The attack would increase the lifetime incidence of cancer by 461 people, and lifetime deaths from cancer by 314. The Figure assumes no relocation, sheltering, or decontamination. All these actions would occur in the real world, significantly reducing cancer incidence and deaths caused by the attack.

This figure is from CRS Report 41890, *"Dirty Bombs:" Technical Background, Attack Prevention and Response, Issues for Congress,* June 24, 2011, by Jonathan Medalia.

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Regulatory Background

The Atomic Energy Act of 1947 created the Atomic Energy Commission, which was responsible for military and civilian uses of atomic energy. That act has been replaced by the Atomic Energy Act of 1954, as amended. The Energy Reorganization Act of 1974 "assign[ed] to one agency, now the Department of Energy, the responsibility for the development and production of nuclear weapons, promotion of nuclear power, and other energy-related work, and assign[ed] to the NRC [Nuclear Regulatory Commission] the regulatory work, which does not include regulation of defense nuclear facilities."[7] Pursuant to these laws, NRC is responsible for regulating the use and protection of special nuclear material—which for practical purposes consists of uranium enriched in isotope 235 (highly enriched uranium, or HEU, and low-enriched uranium, or LEU) and plutonium—in civilian uses, but does not regulate nuclear weapons or special nuclear material for weapons use. NRC also regulates fuel in nuclear reactors, which is typically low-enriched uranium, and "byproduct material," which includes many types of radioactive material other than plutonium or enriched uranium.[8] Byproduct material is widely used in medicine, industry, and research. NRC issues licenses permitting facilities (such as nuclear power plants or hospitals) or other organizations (such as industrial radiography companies that use mobile radioactive sources in the field) to possess specified quantities of radioactive material. A

[7] U.S. Nuclear Regulatory Commission. "Governing Legislation," section on Energy Reorganization Act of 1974, http://www.nrc.gov/about-nrc/governing-laws.html#era-1974. This website provides summaries and full text of legislation relating to NRC.

[8] For legislation governing NRC, see U.S. Nuclear Regulatory Commission, "Governing Legislation," http://www.nrc.gov/about-nrc/governing-laws.html#era-1974.

license is not needed to possess minute quantities of radioactive material, such as are found in home smoke detectors.

Agreement States are a central component of the nation's regulatory framework. Pursuant to the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), NRC is responsible, with respect to radioactive material, for maintaining the health and safety of the public and the common defense and security. Section 274(b) of the Act permits NRC to relinquish its authority to regulate certain types of radioactive material possessed or used within their borders to states that have entered into agreements with NRC for this purpose. There are 37 of these "Agreement States."[9] NRC can relinquish its regulating authority in the area of public health and safety; however, pursuant to Section 274(m) of the act, NRC cannot relinquish its regulatory authority in matters concerning the common defense and security to Agreement States. Each Agreement State regulates radioactive materials within its boundaries, which can include most medical, academic, and industrial uses of byproduct material. Agreement States do not regulate commercial nuclear power plants, research and test reactors, and facilities that are part of the fuel cycle chain.

In the wake of the 9/11 attacks, NRC issued orders to its licensees to enhance the security of radioactive materials. The NRC website has a full listing of its security orders.[10] These orders included:

- Licensees of panoramic and underwater irradiators having more than 10,000 curies of material (68 FR 35458, June 13, 2003).[11] [12] NRC, under its common defense and security authority, issued this order to NRC and Agreement State licensees.
- Manufacturers and distributors of radioactive material (69 FR 5375, February 4, 2004). NRC, under its common defense and security authority, issued this order to NRC and Agreement State licensees.
- Licensees transporting radioactive materials in quantities of concern (69 FR 44407, August 2, 2005), with category 1 as the threshold for a quantity of concern. NRC, under its common defense and security authority, issued this order to NRC and Agreement State licensees.
- Increased Controls (IC) order for licensees authorized to possess 16 types of radioactive material above specified "quantities of concern," which are the same as category 1 or category 2 sources in the IAEA Code of Conduct. (70 FR 72128, December 1, 2005). [13] In this case, NRC acted because "the Commission has determined that certain additional controls are required to be implemented by Licensees to supplement existing regulatory

[9] For a map of Agreement States and contact information for all states, see U.S. Nuclear Regulatory Commission, "NRC:FSME – State Regulations and Legislation," http://nrc-stp.ornl.gov/rulemaking.html.

[10] U.S. Nuclear Regulatory Commission. "Security Orders." http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/index.html#6.

[11] For information on these irradiators, see U.S. Nuclear Regulatory Commission. "Fact Sheet on Commercial Irradiators," April 2009, http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/commercial-irradiators.html.

[12] U.S. Nuclear Regulatory Commission, "In the Matter of All Panoramic and Underwater Irradiators Authorized to Possess Greater than 370 Terabecquerels (10,000 Curies) of Byproduct Material in the Form of Sealed Sources; Order Imposing Compensatory Measures (Effective Immediately)," 68 *Federal Register* 35458-35462, June 13, 2003. NRC redacted specific requirements except for those on handling information.

[13] U.S. Nuclear Regulatory Commission. "Order Imposing Increased Controls (Effective Immediately)," EA 05-090 in the matter of licensees authorized to possess radioactive material quantities of concern, November 14, 2005, http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/2005/ml053130218.pdf. This order was subsequently issued in 70 *Federal Register* 72128-72132, December 1, 2005.

requirements" in order to enhance the security of certain quantities of certain radioactive sources.[14] The order required licensees to: (1) allow only "trustworthy and reliable" personnel to have unescorted access to category 1 and 2 material; (2) have a program to monitor and immediately respond to unauthorized access; (3) follow certain procedures in shipping category 2 material; (4) obtain from NRC an order to implement certain additional security measures in order to ship category 1 material; (5) protect mobile or portable radioactive sources; (6) retain documentation; and (7) protect information describing protection of radioactive material from unauthorized disclosure. NRC issued the IC order to its licensees under its public health and safety authority. The Agreement States issued legally binding requirements, identical to the IC order, to their licensees.

- Fingerprinting orders: The Energy Policy Act of 2005 (P.L. 109-58, August 8, 2005), Section 652, amended Section 149 of the Atomic Energy Act to require fingerprinting and an FBI criminal history records check of any individual permitted unescorted access to certain radioactive materials. NRC determined that individuals with unescorted access to category 1 or 2 material required fingerprinting and a records check, and issued orders requiring these measures to irradiator licensees and manufacturer and distributor licensees (71 FR 63046, October 27, 2006), licensees making shipments of category 1 material (71 FR 62302, October 24, 2006), and to all other licensees with category 1 or 2 quantities of material (72 FR 70901, December 13, 2007). NRC issued the fingerprinting orders to its licensees under its public health and safety authority. The Agreement States issued legally binding requirements, identical to the fingerprinting orders, to their licensees.
- "Order for Issuing Trustworthiness and Reliability Requirements for Service Providers that are not Manufacturers or Distributors [M&D] [75 FR 160, January 4, 2010]: In the December 2007 Fingerprinting Order, Paragraph IC 1.c of the IC requirements was superseded by the requirement that 'Service provider licensee employees shall be escorted unless determined to be trustworthy and reliable by an NRC-required background investigation.' However, NRC did not require background investigations for non-M&D service provider licensees. Consequently, only service representatives of certain M&D licensees may be granted unescorted access to the radionuclides of concern at an IC licensee facility, even though non-M&D service provider licensees provide similar services and have the same degree of knowledge of the devices they service as M&D licensees. To maintain appropriate access control to the radionuclides of concern, and to allow M&D licensees and non-M&D service provider licensees to have the same level of access at customers' facilities, NRC can impose trustworthiness and reliability (T&R) requirements for unescorted access to radionuclides of concern, as set forth in this Order, per licensee's request. These T&R requirements are equivalent to the requirements for M&D licensees who perform services requiring unescorted access to the radionuclides of concern. The Order was issued to NRC and Agreement State licensees by the NRC under its common defense and security authority."[15]

In the *Federal Register* of June 15, 2010, NRC solicited comments for a proposed rule, "Physical Protection of Byproduct Material," that would incorporate and modify previous security orders as 10 CFR 37.[16] The proposed rule would deal with "the security requirements for use of category 1 and category 2

[14] Ibid., p. 72129.

[15] The Nuclear Regulatory Commission provided this paragraph, August 7, 2012.

[16] U.S. Nuclear Regulatory Commission. "Physical Protection of Byproduct Material; Proposed Rule," 75 *Federal Register* (continued...)

quantities of radioactive material."[17] It is intended to supersede the security orders. According to NRC, "The NRC will rescind the security orders once the requirements [of the rule] become effective."[18] On December 8, 2011, R.W. Borchardt, Executive Director for Operations, NRC, sent a memo to the NRC Commissioners asking their approval to publish the new rule in the *Federal Register.* The Commission approved the rule on March 16, 2012. After clearing NRC final review, the rule will be sent to the Office of Management and Budget (OMB). As an independent agency, NRC is not required to submit its rules to OMB for approval. However, OMB reviews rules pursuant to the Congressional Review Act to determine whether or not a rule is a major rule (5 USC 804); this has already been done, and OMB determined that 10 CFR 37 is a major rule. In addition, OMB will review this rule for its information collection requirements. OMB could disapprove of the rule on this latter basis, but cannot modify the rule. NRC anticipates that the rule will be published in the *Federal Register* in late 2012.[19] For states regulated by NRC, the rule becomes effective one year after it is published in the *Federal Register.* For Agreement States, the rule takes effect two years later. Once NRC and the Agreement States implement the rule, NRC and, when appropriate, Agreement States will rescind the various orders it replaces.

There are several 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, and a waiting period before the rule takes effect. An order intended to address an urgent situation will not necessarily have any feedback from stakeholders, while a rule, such as 10 CFR 37, entails extensive feedback, often with hearings, working groups, and lengthy correspondence. Orders apply only to current applicable licensees; having it apply to future licensees requires notifying them individually that the rule applies to them. In contrast, a rule applies to all applicable licensees. An order and a rule both have the effect of law.

NRC wanted to replace its orders with a rule for various reasons:

> The orders issued by the NRC could stay in place indefinitely. However, the regulations would not reflect current Commission policy or requirements. Imposing long-term requirements through orders has not traditionally been the agency's preferred method of regulation. Orders, unlike rules, do not apply prospectively to applicants for new licenses. The NRC would have to periodically issue new orders to cover new and amended licenses. In order to make the requirements generally applicable to all present and future licensees, the security-related requirements need to be placed in the regulations. In addition, notice and comment rulemaking allows for public participation and is an open and transparent process.[20]

In addition, NRC's policy is to publish an implementation guidance document in the *Federal Register* when, or shortly after, it issues a rule. Such documents provide details (often in the form of questions and answers) on how licensees are to implement a rule. The guidance, unlike a rule, is not mandatory, and licensees may find other ways to implement a rule, but guidance shows what NRC finds acceptable. NRC

(...continued)

33902-33947, June 15, 2010.

[17] Ibid., p. 33904.

[18] U.S. Nuclear Regulatory Commission, "Final Rule: Physical Protection of Byproduct Material (RIN 3150-AI12)," memorandum for the Commissioners from R.W. Borchardt, Executive Director for Operations, SECY-11-0170, December 8, 2011, p. 7, http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0170scy.pdf.

[19] Personal communication, Nuclear Regulatory Commission staff, April 11 and June 14, 2012.

[20] U.S. Nuclear Regulatory Commission. "Regulatory Analysis for Final Rule: Physical Protection of Byproduct Material …," December 2011, p. 1, http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0170scy.pdf, pdf page 480.

issued draft guidance in June 2010 for 10 CFR 37;[21] however, there have been many changes to the rule since then, so there will be many changes to the guidance document as well.

The rule makes many changes as compared to the orders. NRC provides details in a 69-page table comparing the rule and orders.[22] Changes include a requirement for "the reviewing official to be subject to the full background investigation, including fingerprinting"; a requirement that individuals already deemed T&R must complete certain security training; a new requirement for a personal history disclosure; a new requirement for licensees to "develop, implement, and maintain written procedures for implementing the access authorization program"; a requirement for the licensee "to the extent possible, [to] obtain independent information to corroborate that provided by the individual (e.g., seek references not supplied by the individual)" in adjudicating T&R decisions; a requirement for licensees to reinvestigate every 10 years individuals deemed T&R; a requirement for each licensee to "review the access program content and implementation" at least once a year; and many more.

10 CFR 37: Summary and Comments

10 CFR 37 is found on pages 318-370 of the NRC document, "Physical Protection of Byproduct Material."[23] The rule is divided into six subparts (with a seventh, Subpart E, reserved) and an appendix. This section of the memo comments on selected sections of Subpart A, General Provisions; comments on each section of Subparts B (Background Investigations and Access Control Program), C (Physical Protection Requirements During Use), and D (Physical Protection in Transit); and summarizes Subparts F (Records) and G (Enforcement) and the Appendix (Category 1 and Category 2 Radioactive Materials). As noted earlier, comments are based on interviews with 14 radiation professionals. What is most striking about these interviews collectively is the extent to which there is a diversity of views on almost every issue raised, and the extent to which the rule impacts so many facets of the radioactive-materials industry in so many ways.

Subpart A: General Provisions

§ 37.1, Purpose: The purpose of the rule is to "provide the requirements for the physical protection program for any licensee" possessing certain quantities of certain radioactive material in order to "provide reasonable assurance of the security" of this material. While an RDD attack using less than a category 1 source of material could impose costs of billions of dollars in lost productivity and remediation, the requirements seek to provide only "reasonable assurance of the security" of such material. Issues are whether this standard is high enough and, conversely, what would be the cost vs. benefit of imposing a higher standard.

[21] U.S. Nuclear Regulatory Commission. *Implementation Guidance for 10 CFR Part 37, Physical Protection of Byproduct Material, Category 1 and Category 2 Quantities of Radioactive Material,* June 2010, draft for comments, http://www.aapm.org/government_affairs/documents/Part37DraftGuidanceJune2010.pdf.

[22] U.S. Nuclear Regulatory Commission, 10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73, RIN 3150-AI12, [NRC-2008-0120], December 8, 2011, Enclosure 2, pp. 13-81 (pdf pages 404-472), http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0170scy.pdf.

Physical Protection of Byproduct Material

[23] U.S. Nuclear Regulatory Commission. "Physical Protection of Byproduct Material," (10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73), December 2011, http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0170scy.pdf.

§37.5, Definitions: Two definitions are of particular interest. (1) The rule provides a complex technical definition of "byproduct material," which is what the rule protects. In brief, the term refers to various categories of radioactive material.

(2) NRC states that "trustworthiness and reliability," or T&R, "are characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security." Note that the T&R definition is subjective, and requires the person or persons making the T&R adjudication to decide if an individual is "considered" "dependable in judgment, character, and performance," and if unescorted access to certain radioactive material by that person "does not constitute an unreasonable risk to the public health and safety or security." Since it is up to each licensee to formulate its own criteria for adjudicating T&R, that approach inevitably results in non-uniform criteria, so that an individual might be granted T&R status by one licensee and not by another.

An issue is whether it is reasonable to expect persons without extensive training in deciding whether or not someone is a security risk, such as radiation safety officers or human resources (HR) personnel, to make such determinations, and if such persons can do so reliably. Opinion on the part of radiation professionals varied widely on this point. An RSO at a large university said, "the idea that any university could determine if someone is a terrorist is silly. Universities are not set up for that." An RSO at another large university described a process in which an outside personnel security firm, for $125, runs background checks on individuals seeking T&R status. The firm gives its findings to university HR personnel, who say that they have no question about their ability to review T&R candidates because that is part of their job. The RSO then makes the final adjudication. An Agreement State director felt that licensees are best positioned to adjudicate T&R because they know their employees well, "so they can evaluate their character more easily and accurately than someone in [his state's capital] or Washington." He emphasized that the ability of small licensees to judge T&R is critical because a single misjudgment could cause major problems for the company, if not result in its end. Yet another university RSO felt, "having a federal agency make T&R adjudications would eliminate bias, as the adjudicators would not know the individuals being submitted for T&R." Most interviewees had an opinion one way or another on T&R, as discussed later.

§37.13, Information collection requirements: OMB [Office of Management and Budget] approval: The rule imposes many such requirements: "(b) The approved information collection requirements contained in this part appear in §§ 37.11, 37.21, 37.23, 37.25, 37.27, 37.29, 37.31, 37.33, 37.43, 37.45, 37.49, 37.51, 37.55, 37.57, 37.71, 37.75, 37.77, 37.79, and 37.81." Some radiation professionals stated that 10 CFR 37 placed a much more extensive burden of information collection on them than did the IC order; some felt otherwise.

An RSO at a large university:

> Regarding the security plan that the new rule requires (§37.43), we didn't write the plan under the orders because anything we documented would have to be protected, and it's very difficult to impose document security on a university campus. A concern is that writing a detailed security plan creates a vulnerability: if a terrorist gained access to it, the plan could outline the strengths and potentially weaknesses." And, "10 CFR 37 is very administratively driven. There are a great many administrative requirements, such as for record-keeping, written security plans, and a requirement for annual reviews of these plans. Some of these are excessive, but we agree with other parts of 10 CFR 37.

An RSO at another large university:

> NRC doesn't typically regulate by orders to licensees but decided to do so after re-evaluating the threat environment in the wake of 9/11, I feel the orders were the best that NRC could do at the time. However, I find 10 CFR 37 too burdensome. The rule is one size fits all, which causes a lot of problems. For example, radioactive sources in medical therapy units may be hard to steal, but have the same security requirements under the rule as self-shielded irradiators, which may be easier to break into. …
>
> Because of the difficulties of complying with the rule, I am urging researchers and users at my organizations to plan to switch to x-ray based irradiators rather than current ones that use radioactive materials. Since x-ray-based irradiators do not use radioactive material, they do not fall under the IC orders or 10 CFR 37. A blood bank I oversee plans to move to a new facility. It will replace one cobalt-60 irradiator with two x-ray irradiators; two are needed because of operational reliability issues that do not arise with radioactive material irradiators.

An Agreement State regulatory official:

> I think that we are all working under what Past Commissioner McGaffigan stated was the mandate from the Commission regarding security: 'To provide reasonable assurance of adequate protection, not absolute assurance of perfect protection.' Under that premise, it is my belief that the burden or costs of implementing the previous orders or Part 37 are not too great.

Subpart B: Background Investigations and Access Authorization Program

§37.21, Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material: Requires licensees with a certain amount of radioactive material to "establish, implement, and maintain its access authorization program." The objective of this program is to ensure that individuals with unescorted access to category 1 or 2 quantities of radioactive material and "reviewing officials" (personnel who make T&R adjudications) are T&R. There is a catch. Section 37.21(c)(3) states, "Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material." Further, reviewing officials must be T&R. However, the Energy Policy Act of 2005 amended §149 of the Atomic Energy Act of 1954 to direct NRC to require that each individual who is permitted unescorted access to radioactive material as determined by NRC, or who is given access to "safeguards information," i.e., information such as on security plans for protecting radioactive material, be fingerprinted, with the fingerprints submitted to the Attorney General (in effect, the FBI) for a criminal history record check. Often, however, T&R adjudications are done by human resources personnel, who do not need unescorted access to radioactive material or access to safeguards information to do their job. Yet since the law requires fingerprinting and a criminal history record check only of individuals requiring such access, some organizations have wound up giving HR staff unescorted access in order to enable them to be fingerprinted. One university solved this dilemma by granting HR staff unescorted access but not giving them the requisite key card that would give them physical access! One individual expressed a need for NRC to seek to have the law changed to avoid this dilemma. Another university RSO saw an imbalance between T&R and physical security:

> In general, I believe that limited funds should be spent more to augment physical security, especially internally to the devices, and less on T&R. Indeed, by spending more on physical security, there is less concern about T&R. If devices are made harder to penetrate, or if there are more alarms, it would be harder for anyone to steal radioactive material.

NRC staff elaborated on the link between fingerprinting and unescorted access:

> Section 652 of the Energy Policy Act of 2005 (EPAct) amended Section 149 of the Atomic Energy Act of 1954, as amended (AEA). The AEA requires the NRC to fingerprint any individual permitted unescorted access to (1) a utilization facility; (2) radioactive material or property regulated by the Commission that the Commission has determined to be of such significance to the public health and safety or common defense and security as to warrant fingerprinting and background checks; or (3) is permitted access to safeguards information as defined in Section 147 of the Atomic Energy Act of 1954, as amended. *The NRC does not have authority to fingerprint any other individuals.*
>
> The NRC has determined that it needs to have confidence in the integrity of the reviewing official because that official approves individuals for unescorted access category 1 and category 2 quantities of radioactive materials. Accordingly, the NRC requires that the individual be fingerprinted and undergo a background investigation and be determined to be trustworthy and reliable. However, as noted above, pursuant to Section 149 of the AEA, the NRC may only fingerprint those individuals who are permitted unescorted access to a utilization facility, certain radioactive materials or property regulated by the Commission, or safeguards information. This is why an individual designated by the licensee to serve as a reviewing official must be permitted unescorted access to category 1 and category 2 quantities of radioactive materials or to safeguards information.
>
> The reviewing official is one of the layers for defense-in-depth of the security program. If the reviewing official is not fingerprinted, a gap could be created in the security program that could potentially be exploited. The reviewing official could have a criminal history or terrorist ties and allow other individuals with a criminal history or terrorist ties to have unescorted access to radioactive material in quantities of concern.[24]

§37.23, Access authorization program requirements: (1) States that "reviewing officials" are the only individuals who may make T&R determinations, and requires the licensee to "provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee." Not stated is how the licensee is to make this determination, and what assurance there is that licensee personnel making this determination are qualified to do so.

(2) Requires licensees to "develop, implement, and maintain written procedures for implementing the access authorization program." Each licensee is to develop its own procedures, which inevitably means that the procedures will differ from one licensee to another. Several interviewees expressed concern about this point. For example, if an individual moves from one organization to another, the first organization can transfer to the second the information on the individual's background investigation but cannot transfer its adjudication of the individual as T&R. Several interviewees stated that NRC has not developed a uniform set of standards or guidelines for adjudicating someone as T&R, and found this to be quite frustrating. A representative of the Nuclear Energy Institute said, "NRC does not want to adjudicate T&R even for difficult cases, and it has not even put out criteria that would disqualify someone as T&R even though that would be helpful. At a minimum, NRC needs to provide clear guidance on T&R to its licensees." An official at a company that manufactures and distributes radioactive sources echoed similar sentiments, and noted that the T&R requirement imposes real burdens, such as requiring the company to actively seek out references for T&R applicants who were not listed in the applicant's paperwork. This official stated, "NRC did not even provide guidelines on what factors should lead to rejecting someone as T&R."

A statement by an Agreement State regulator may help resolve the discrepancy between those saying that T&R adjudications are best done by employers but that NRC has not provided adequate guidelines for such adjudications: "The licensees begged NRC to provide T&R criteria. They asked over and over

[24] Information provided by Nuclear Regulatory Commission staff, email, June 28, 2012. Emphasis added.

again, including for examples, but NRC wouldn't do it, though it's not clear as to why. At this point, however, licensees have so much experience in adjudicating T&R that there would not be much value added if NRC provided criteria."

§37.25, Background investigations: This section sets 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. Regarding the latter point, "reference checks under this subpart must be limited to whether the individual has been and continues to be trustworthy and reliable," yet it is unclear whether the references are able to judge whether the applicant is T&R. An issue is whether an applicant undergoing a background investigation would give as references individuals who would not vouch for him or her; accordingly, §37.25(a)(6) states, "The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (*e.g.*, seek references not supplied by the individual)." Yet one interviewee said it was very difficult to find references not listed by the applicant. A draft of the rule had a requirement for a credit check, but many stakeholders opposed that provision on grounds that a person's credit history—especially in the current economy—has no bearing on whether he is T&R. For example, a person could have lost her job, or gone bankrupt because of medical bills; such events would not indicate lack of T&R. NRC dropped that provision from the final rule.

§37.27, Requirements for criminal history records checks …: This section requires licensees seeking to grant unescorted access to category 1 or 2 quantities of radioactive material to individuals to fingerprint the individuals and transmit the fingerprints to NRC. NRC will then transmit the fingerprints to the FBI, which will conduct a criminal history records check. The FBI then transmits the criminal history records check to NRC, which in turn transmits it to the licensee. The licensee uses this information as part of the required background investigation to determine whether or not to grant unescorted access to the individual. Radiation professionals felt that this procedure is cumbersome; they should be able to send fingerprints directly to the FBI, and receive information directly from the FBI. Two interviewees complained that they wanted to collect fingerprints electronically rather than by using fingerprint cards, but said that they could not do so because of the rule. While §37.27(c)(1) specifically permits use of an electronic fingerprint scan, a university RSO said

> my institutions can only use NRC fingerprint cards, at a cost of $26 per FBI background check request (if more than two cards are needed by FBI, up to an additional $52 may be required). When establishing the required fingerprinting program, I investigated use of a vendor to provide electronic fingerprinting service similar to that used by the state's Department of Elementary & Secondary Education. I ultimately learned that the NRC would only accept electronic fingerprints if sent directly from the licensee, and not a vendor (equipment like this is cost prohibitive for materials licensees). I have had several hundred people go through FBI fingerprint background checks, which is quite burdensome. Why pay NRC to be the middleman instead of going directly to the FBI? Why can't one central federal agency make these kinds of T&R adjudications?

NRC provided the following comment:

> 42 USC 2169 prescribes this process:
>
> > (2) All fingerprints obtained by an individual or entity as required in paragraph (1) shall be submitted to the Attorney General of the United States through the Commission for identification and a criminal history records check.
> >
> > (3) The costs of an identification or records check under paragraph (2) shall be paid by the individual or entity required to conduct the fingerprinting under paragraph (1)(A).

> (4) Notwithstanding any other provision of law–
>
> (A) the Attorney General may provide any result of an identification or records check under paragraph (2) to the Commission; and
>
> (B) the Commission, in accordance with regulations prescribed under this section, may provide the results to the individual or entity required to conduct the fingerprinting under paragraph (1)(A).

The law also permits electronic fingerprinting as follows:

> d. The Commission may require a person or individual to conduct fingerprinting under subsection a.(1) by authorizing or requiring the use of any alternative biometric method for identification that has been approved by–
>
> (1) the Attorney General; and
>
> (2) the Commission, by regulation.

However the Department of Justice has determined that criminal history record information cannot be provided to any party other than the NRC, the licensee, or the individual that is the subject of the record. That is why the use of a third party contractor is an issue.[25]

§37.29, Relief from fingerprinting, identification, and criminal history records checks …: This section provides that individuals in 13 categories do not need to undergo these checks in order to have unescorted access. Categories include Members of Congress; employees of NRC, of the executive branch, and of Members and committees of Congress who have undergone fingerprinting for a prior U.S. Government criminal history records check; federal, state, and local law enforcement personnel; state governors or their representatives; and others.

§37.31, Protection of information: This section requires licensees to protect personal information obtained through background investigations. It requires licensees to "establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure." It also permits personal information to be provided to another licensee under certain conditions. While none of the interviewees expressed concern about protecting personal information, quite a few expressed concern about requirements throughout 10 CFR 37 for creating and protecting written procedures. This issue is dealt with in more detail below, but this section is an example of what many interviewees saw as an administrative burden. Some interviewees also felt that it should be possible to transfer a T&R adjudication in addition to personal information. One said, "It also seems arbitrary that an employee moving to another company can have his or her background investigation data transferred to the new employer, but not the first company's adjudication of the person as T&R."

§37.33, Access authorization program review: Requires each licensee to "be responsible for the continuing effectiveness of the access authorization program. … The review program shall evaluate all program performance objectives and requirements." An issue is whether each licensee has the ability to review its own program, and whether it can do so objectively. This section also requires licensees to document results of the reviews and any recommendations. Further, "Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of

[25] Information provided by Nuclear Regulatory Commission, August 7, 2012.

the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken." This is another instance of an administrative burden imposed by the rule.

Subpart C: Physical Protection Requirements During Use

§37.41, Security program: "Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material." Specific requirements are detailed, and commented on, in following sections.

§37.43, General security program requirements: This section requires licensees to have a security plan, implementing procedures, training, and methods to protect information. The security plan shall be written and specific to each licensee's facilities and operations. The plan shall describe measures, and identify resources, for implementation. It shall be "reviewed and approved by the individual with overall responsibility for the security program." This individual shall also approve, in writing, the implementing procedures. In an effort to ensure that this individual and others have the training and expertise necessary to determine the adequacy of the security program, this section requires "each licensee [to] conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively." Training must, at a minimum, include instruction in the licensee's security program, the responsibility to report to licensee conditions that may violate NRC requirements, the responsibility of the licensee to report promptly to local law enforcement actual or potential threats to category 1 or 2 material, and how to respond to security alarms. Finally, this section requires licensees to protect security-related information, such as the security plan and implementing procedures, and requires "written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan and implementing procedures."

Interviewees offered many comments on these requirements. An RSO at a university stated,

> 10 CFR 37 is very administratively driven. There are a great many administrative requirements, such as for record-keeping, written security plans, and a requirement for annual reviews of these plans. Some of these are excessive, but we agree with other parts of 10 CFR 37, such as the need to verify that systems work." … An NRC manager said NRC thinks that the new rule will not be much of a burden to licensees because they have already implemented many of the requirements in 10 CFR 37. I strongly disagree. The rule is one size fits all: security plans, training, procedures, new concepts (like security zones). There were orders, and we implemented them. After we had been inspected a few times, we were able to understand how to comply with the orders. Now with the new rule, we will have to set the rule as the new baseline. We will be reinspected against the new standards. It will take significantly more time. There are 37 Agreement States plus NRC, so there will be 38 interpretations of what the rule means. We will have to start all over again. A big problem will be the paperwork.

Regarding the requirement for a written security plan and written implementing procedures, the RSO continued,

> we didn't write the plan under the orders because anything we documented would have to be protected, and it's very difficult to impose document security on a university campus. A concern is that writing a detailed security plan creates a vulnerability: if a terrorist gained access to it, the plan could outline the strengths and potentially weaknesses. It is easier for NRC to inspect a written plan than to sit down and discuss (orally) what the plan is. This puts the burden on the licensee.

An RSO at another university said,

> there is a new requirement to train people every year on security. This is a large time commitment for individuals with unescorted or need-to-know access and for me as compared to the orders. For example, staff can have refresher courses in health and safety online, but security training cannot be done online because of the security nature of the material. Since the institutions for which I am the RSO have several hundred people currently granted unescorted access to category 1 and 2 material, several training sessions must be done so as to cover all the people needing training every year.

Regarding the requirement to protect information, an industrial radiographer said,

> Yet another concern I have is that 10 CFR 37 requires limiting information on security to people with a need to know, but in practice information is often widely disseminated. At the steel mill, all 200 electronics technicians know that there is a storage room where spare devices are stored. Same story in a hospital, where most of the doctors and nurses know if their hospital has a gamma knife. Limiting information can be tough to implement in practice.

An official at a manufacturing and distribution company noted a disparity in regulations protecting radioactive and other material:

> The nuclear industry is very heavily regulated, while other industries that pose significant health and safety risks are much less stringently regulated. For example, tanker trucks carrying large quantities of dangerous chemicals can go through large cities.

§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." Among other things, the licensee must notify LLEA "that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material." The licensee shall notify NRC if LLEA has not responded to the request for coordination within 60 days, or if LLEA does not plan to participate in coordination.

Many interviewees reported excellent cooperation between licensees and LLEA. An Agreement State official found that the security orders (preceding 10 CFR 37) promoted working relationships:

> before NRC issued its security orders, there was often not a good relationship, if any, between licensees and LLEA. The orders, which require licensees to contact LLEA to try to work out a response plan, have in many cases led to the establishment of relationships between licensees and LLEA.

Initially, he said,

> regulators and licensees came to the orders with limited security real world/operational experience, but believe training, knowledge gained and partnerships formed while under the orders prepare everyone well for the implementation of 10 CFR 37. The orders and the new rule are designed to motivate the integration of LLEA, by both regulators and licensees. LLEAs bring that real world security experience to the final safety culture product.

He found LLEAs receiving homeland security grants provided by the U.S. Department of Homeland Security are more sensitized to potential threats from radioactive materials, and said, "LLEA is absolutely much more aware of the need for radioactive material security post-9/11."

A second Agreement State official found cooperation improving:

> In the beginning, LLEA was not so cooperative in coordinating security plans with licensees; this was a common violation. Often, they were not interested. But as LLEA awareness of radioactive threats

> increased and as regulators tried to help licensees contact the right people in law enforcement, LLEA now "gets it" and wants to know if there is radioactive material in their jurisdictions.

A third Agreement State official noted that LLEA work closely with licensees, conduct security inspections[26] to facilities housing radioactive material, have alarms linked to police headquarters, and provide armed escort of radioactive material within the state's borders. Some police departments, including those in some large cities, send all their officers to Advanced Radiological Response Techniques training courses at the Y-12 National Security Complex in Tennessee. LLEA in states such as these would give high priority to a theft of radioactive material.

On the other hand, other interviewees reported instances of noncooperation. In one case, LLEA rebuffed repeated attempts to contact it; the interviewee found the situation "unworkable." Another said that LLEA was unaware of the issue of radioactive material security. Further, circumstances of budget and distance may conspire to render LLEA less cooperative than they might like to be. An Agreement State official noted this in his state, and pointed out that there is no mechanism to force LLEA to cooperate, let alone to the extent NRC wants:

> Local law enforcement agencies (LLEAs) are cooperative up to a limit. They want to cooperate but don't want to be pinned down to certain requirements, such as responding within [a specified time]. NRC would like the theft of a radioactive source to be high on the LLEA priority list, but that probably won't happen. Some state troopers cover several hundred miles on their routes. If an event happens at one end of their route, it's unrealistic to expect them to drop everything and rush to the other end in [a specified time]. LLEA is committed to assisting if feasible, but if there's a bank robbery or other emergency situation, should they disregard it to respond to a radiological event? They need to make a choice. As a regulator, neither the NRC nor the Agreement States have any control over LLEA. Licensees also have no control. They try to get LLEA to participate, and document their efforts to do so.

§37.47, Security zones: Licensees shall ensure that category 1 and 2 materials are within security zones established by the licensee. Security zones shall allow unescorted access to approved individuals in several ways: (1) "Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone." (2) By direct control of the security zone, or (3) by both methods.

There are potential issues with the isolation approach. First, the definition is tautological: isolation is to be achieved by use of barriers sufficient for isolation. Second, there is no requirement for the amount of control, if any, that must be present at an access control point. In particular, would it be vulnerable to an armed attack by terrorists?

An industrial radiographer said,

[26] NRC prefers to use "security visits" because "security inspections" could be "interpreted to mean that the LLEA could inspect against the orders and Part 37 requirements. Only the NRC or Agreement States can inspect against the security requirements contained in the orders and Part 37 and issue a notice of violation. Licensees can coordinate or consult with the LLEAs and in fact are required to attempt to coordinate with the LLEA. LLEAs may be able to inspect under their own authority." Information provided by Nuclear Regulatory Commission, August 14, 2012.

> 10 CFR 37 will be burdensome in terms of cost and what it requires. I am particularly concerned about security zones. Most of my clients are in industries, such as steel and petrochemicals, and use radioactive sources in the form of gauges, such as to measure thickness of steel or flow of chemicals.

He noted that a steel mill inherently has many features that would make it exceedingly difficult for terrorists to steal radioactive sources, and security devices such as alarms and cameras.

> The security features already in place should be sufficient to keep people from gaining unauthorized access to the material. It seems excessive to require the licensee to set up a security zone, which is a barrier that absolutely prevents people from getting to that area. It is even more burdensome for licensees if the security zone extends well beyond the gauge itself.

An Agreement State official said, "The rule establishes security zones, which are not in the [Increased Controls order] and are confusing to the Agreement States as to where a zone must be established. Licensees will have to learn about establishing these zones."

On the other hand, another Agreement State official is pleased that the rule is not overly prescriptive, i.e., that it does not specify in minute detail what must be done. As a result, the rule "leaves us a lot of room to work. For example, not telling me how to do security zones is fine."

§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." In contrast to much of the rest of 10 CFR 37, this section is prescriptive and detailed. Examples of methods for monitoring and detection include a monitored intrusion detection system linked to a central monitoring facility, and a monitored video surveillance system. Licensees must also be able to detect unauthorized removal of radioactive material from the security zone. For category 1 material, this can be achieved by electronic sensors linked to an alarm or direct visual surveillance. For category 2 material, it can be achieved by weekly verification through physical checks. Specified other means for monitoring and detection may also be used. The section also requires immediate assessment of actual or attempted unauthorized entry; maintenance of communication and electronic data transmission, including an alternative communication capability; and requesting an armed response by LLEA involving theft, sabotage, or diversion of category 1 or 2 materials.

Some interviewees were unsure how many, and what types of, security features they needed to install in order to satisfy these requirements. Others consulted security professionals who designed security systems for their facilities. Many felt that NNSA's Global Threat Reduction Initiative, described below, was important in helping them set up a security system.

An industrial radiographer expressed concern about the requirement for a weekly inventory of category 2 sources:

> the rule takes us from a quarterly inventory of sources to a weekly inventory. On the surface, this is not a bad idea. For me, this is not a problem because most of my sources come back each night, and there is a benefit of source security, which is a top concern for us. But [another] company … works in all 50 states and its sources do not return to a centralized location. This provision of Part 37 is a nightmare for them, imposing a huge logistical burden.

The requirement for weekly verification of category 2 sources to ensure that the material is present is found in 10 CFR 37.49(a)(3)(ii). NRC notes that the Increased Controls order does not require a quarterly inventory of category 2 sources.[27]

An official with a company that manufactures and distributes radioactive sources expressed a similar concern:

> One example of the burden is a requirement to do a weekly check of all sealed radioactive sources. This may be workable for a company with a few dozen sources, but [our company] has thousands of sources. It would be impossible to check them all each week, and someone doing the checking would receive too much radiation exposure.

A university RSO favors the British model for deciding on the adequacy of physical protection measures:

> In discussions with colleagues from Great Britain, all hospital security plans are centrally reviewed by a police agency PRIOR to paying for the new equipment or installations. Therefore, there is agreement between groups of the necessary security before any money is spent. While not every site is the same and some flexibility is required, it would be really nice to know if the systems being paid for will be deemed adequate before they are installed.

§37.51, Maintenance and testing: 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. The RSO at a large university found this requirement problematic:

> An earlier version of Part 37 required quarterly testing of alarms, or as recommended by the manufacturer. Quarterly was too frequent because of the number of alarms and the amount of documentation. Some items can break or be knocked out of alignment if tested, such as magnetic door position switches. And some plastic access controls can be damaged during disassembly to test the internal tamper alarm. These really do not have any method for breakage so they don't really need to be tested. Furthermore, testing can be complicated, as it sends alarms to police, distracting them from their work. Section 37.51 of the final rule calls for testing in accordance with the manufacturer's recommendation, and if no recommendation then at least every 12 months. One manufacturer states: "This security system requires very little maintenance, however, test the system weekly to ensure it is working properly" The company then goes on to offer to sell the testing service to the customer. … Thus, the change in the final rule is not an improvement. In some circumstances it requires much more frequent testing than the Draft Part 37 required.

The RSO suggested an alternate wording: "The equipment relied on to meet the security requirements of this part must be inspected and tested for operability and performance at a least annually."

§37.53, Requirements for mobile devices: Licensees with mobile devices containing category 1 or 2 quantities of radioactive material must "have two independent physical controls that form tangible barriers to secure the material from unauthorized removal." None of the interviewees expressed concern about this provision. Security of mobile sources has not been a problem. An industrial radiographer said,

> Up until 2011, no one had stolen a source, though people occasionally stole trucks that incidentally had small radioactive sources on them. Last year, a radiography camera was stolen in Texas and was never recovered. However, since its radioactive material was iridium-192, with a half-life of 74 days, over 99 percent of that radionuclide will have decayed in about two years. That source, 33 curies of

[27] Information provided by Nuclear Regulatory Commission, August 7, 2012.

> Iridium 192, would be approximately 2 curies now, so this clearly was not a theft for terrorist purposes.

§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. An RSO at a large university commented,

> 10 CFR 37 is very administratively driven. There are a great many administrative requirements, such as for record-keeping, written security plans, and a requirement for annual reviews of these plans. Some of these are excessive, but we agree with other parts of 10 CFR 37, such as the need to verify that systems work.

An RSO at another large university found the burden worth the effort:

> At first glance, 10 CFR 37 appeared to impose additional burdens compared to the Increased Controls Order. For example, it required security system reviews each quarter and a performance review every year. Despite the burden, … the university police department mandated these periodic security system reviews two years ago. The university police has experts in security, security systems and a capable police force, so their judgment on security matters is well-respected in the local law enforcement authority (LLEA) community. The security reviews have proven to be of great value.

§37.57, Reporting of events: §37.57(a) requires licensees to immediately notify 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. There was one comment on this latter provision. An RSO at a large university had an experience in which these requirements were excessive:

> An unknown State Police Officer in uniform in his private car drove up to our reactor and requested admittance (wearing a side arm). This was very suspicious. The LLEA was notified. The LLEA sergeant responded very quickly. He knew the individual, a State Police captain. The State Police captain promised to NEVER do that again. According to §37.57 of the final rule, I must still notify the NRC within four hours.

The RSO feels that the rule should offer some flexibility as to what incidents to report. If an event occurs that initially appears suspicious but proves not to be, there should be no requirement to contact NRC. NRC comments that there is no requirement to notify NRC if, after assessing the situation, the licensee determines that there is no need to contact LLEA. The licensee only needs to contact NRC about suspicious activities if it has contacted LLEA.[28]

Subpart D: Physical Protection in Transit

Comments in this section are mainly from a shipper of radioactive materials. A key assertion he makes, not reflected in a section-by-section analysis of Subpart D, is that Subpart D should have been placed in Title 49 of the U.S. Code (transportation) rather than in Title 10 for the following reasons:

> the Agreement States will have some flexibility in how they implement the Part 37 requirements. This flexibility may result in Agreement State implementation of Part 37 Subpart D regulations in a manner that would otherwise result in preemption if the regulations were contained in Title 49. For example in the early 1990's the State of Washington attempted to establish highway routing restrictions for

[28] Information provided by Nuclear Regulatory Commission, August 15, 2012.

> radioactive materials that limited the locations that trucks hauling radioactive material could enter the State. This regulation was preempted by the DOT under the dual compliance and obstacle tests, reference 58 FR 31580. My concern is that given the pre-planning and coordination requirements contained in Part 37 Subpart D, an Agreement State could effectively restrict the routing of radioactive materials through the State. Another concern is that states may charge unreasonable fees for transporting category 1 and category 2 materials through the state, in these cases the NRC cannot challenge the fees, but the DOT could. Differences in escorting and vehicle inspections requirements could also place undue burdens on the shippers and carriers of category 1 and 2 quantities of materials. Generally speaking, when transportation requirements are set by many regulators and by federal interstate commerce rules as well, compliance with transportation regulations can become very complicated.

§37.71, Additional requirements for transfer of category 1 and category 2 quantities of radioactive material: Licensees transferring such material shall verify that the recipient's license authorizes receipt of the material. "In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. … The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day." A shipper found it generally straightforward to verify the recipient's license, and noted that, in his experience, the emergency provision did not come into play:

> §37.71(c) provides an alternative method for obtaining permission in an emergency situation, but I don't know when that would arise. We haven't had that happen. We typically plan category 1 shipments months in advance; sufficient advanced planning is associated with category 2 shipments as well.

§37.73, Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit: This section refers licensees to at least 44 provisions of 10 USC 37 and 71. Some apply to imports and exports, others apply to category 1 or category 2. A potential issue is the degree of complexity of complying with the many provisions referenced in this section. A shipper felt that it was not difficult to comply with the provisions of Subpart D because his company had to implement many of these provisions as a result of previous NRC orders, notably for radioactive material quantities of concern (RAMQC).[29] He said,

> Subpart D does not add burdens beyond the existing NRC orders. There are minor things, such as updating the transportation security plan, and developing procedures to ensure compliance with the regulation but these are administrative activities that we do not consider burdensome because the Part 37 requirements for route notifications, estimation of when a shipment is going to cross state borders, delivery time, revised delivery time if there are changes, and so on are already in the RAMQC order.

§37.75, Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive 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

[29] NRC issued an order (EA-05-006) imposing requirements on transportation of radioactive material quantities of concern (RAMQC) on July 19, 2005; the order itself was not released to the public because it contained security-sensitive information. See U.S. Nuclear Regulatory Commission. Letter from Jack R. Strosnider, Director, Office of Nuclear Material Safety and Safeguards, to Holders of Material Licenses Authorized to Possess and Transfer Items Containing Radioactive Material Quantities of Concern as listed in Attachment A to Enclosure 1, Subject: Issuance of Order for Additional Security Measures on the Transportation of Radioactive Material Quantities of Concern, December 16, 2005, http://pbadupws.nrc.gov/docs/ML0533/ML053350222.pdf.

which the shipment will pass, identify safe havens along the planned route, and document these activities. Requirements for category 2 shipments are less stringent. As noted under §37.73, the shipper did not consider these requirements burdensome because they are already in the RAMQC order. According to NRC, "A safe haven is a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the LLEA. The NRC expects safe havens to be identified and designated by the licensee."[30] However, the shipper noted that NRC "provides for safe havens, but doesn't provide a list of safe havens. It is up to us to identify safe havens."

§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. This section spells out detailed procedures for submitting advance notification, including where notification is to be made and what information the notification must contain. Again, this is standard procedure and has been in place for some years.

§37.79, Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment: This section spells out requirements for shipment by road and rail in great detail. For example, a licensee transporting category 1 quantities of material by road shall ensure that movement control centers and redundant communications are established, and that shipments are "continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center." For shipments of category 1 quantities of material by rail, the licensee shall "ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system." While shipment by truck entails a driver in close proximity to the radioactive material, that is not the case for rail shipments. In theory, this might constitute a vulnerability. In practice, however, the shipper said that this section "provides for security of transportation of category 1 and 2 radioactive material by rail, but I don't know of any instances where such material is transported by rail." The shipper also noted that §37.79 does not address shipments by air for imports or exports of radioactive material. "Part 37 applies to the domestic portion of the highway (or rail) shipment, so once we deliver the shipment to the airport we are relieved of the transportation security burden." In contrast,

> Imports and exports by sea are much more difficult because we have to coordinate the arrival or departure of our shipment with the arrival or departure of a ship. This is difficult because ships may encounter delays enroute. We planned an export to South Africa, to be carried on a ship from Baltimore. The ship was delayed for 48 hours. The port would not accept the material, so the truck, with its two drivers, had to wait at a truck stop. If we could have delivered the material to the port, we would have been in compliance with the NRC order, and the port would have been much more secure than the truck stop.

§37.81, Reporting of events: The licensee doing the shipping 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. This section provides additional details for such notifications.

[30] Nuclear Regulatory Commission, "10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73, RIN 3150-AI12, [NRC-2008-0120], Physical Protection of Byproduct Material," *Federal Register* notice, p. 52; pdf page 63 of http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0170scy.pdf. [As of the date the referenced document was issued, the rule had not been published in the *Federal Register*.] The referenced page provides a detailed description of characteristics of a safe haven.

Subpart F – Records

§37.101, Form of records: Provides that records required by 10 CFR 37 must be legible, may be stored electronically, and must be protected against tampering and loss.

§37.103, Record retention: Specifies how long records are to be retained.

Subpart G – Enforcement

§37.105, Inspections: Each licensee shall afford NRC the opportunity to inspect its records and its category 1 or 2 quantities of material.

§37.107, Violations: NRC may obtain a court order to prevent violations of the Atomic Energy Act and other laws, regulations, and orders, and may obtain a court order for payment of a civil penalty for violations of specified laws, rules, regulations, or orders.

§37.109, Criminal penalties: The Atomic Energy Act "provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate" the regulations in 10 CFR 37, excepting for nine specified sections.

Appendix A to Part 37 – Category 1 and Category 2 Radioactive Materials

This Appendix consists of a table specifying the category 1 and category 2 thresholds for 16 radioactive materials, and how to calculate if multiple sources or multiple radionuclides meet or exceed the threshold so that they are subject to the requirements of 10 CFR 37. These are the same radionuclides and thresholds as used by the International Atomic Energy Agency.[31]

Additional Comments

Discussions with radiation professionals yielded comments on several topics that are not directly a part of 10 CFR 37 but are related to it. They are discussed here because they give added insight into how radiation professionals view, and are affected by, the new rule. This section presents views—often, contending views—on each of several topics from various radiation professionals.

The Rulemaking Process

The transition from security orders to a rule: Opinions differed on whether the orders should have been left in place, or should have been codified into a rule and subsequently modified, or combined into a new rule. A university RSO said:

> NRC says it is incorporating lessons learned in the rule, and that it issued orders because it had to get them out quickly. But if the orders provide adequate security, why not codify the orders and modify them later as needed? NRC is making fundamental changes to the orders in 10 CFR 37, with additional requirements and burdens for licensees. If the Orders were adequate, why change?

[31] International Atomic Energy Agency, *Code of Conduct on the Safety and Security of Radioactive Sources*, January 2004, "Table 1: Activities Corresponding to Thresholds of Categories," p. 16, http://www-pub.iaea.org/MTCD/publications/PDF/code-2004_web.pdf.

A Nuclear Energy Institute representative said,

> NEI's view is that NRC should have codified the security orders, and then done a careful analysis of enhancements beyond the orders, including vulnerability assessments.

An industrial radiographer said,

> To comply with the new rule, plans will have to be changed, and people covered by security orders will have to be retrained to the new terms. This will impose a financial burden on licensees, but without benefit. One of my clients is pulling his hair out because of the added burden. His feeling is that his organization has a good program, it has been inspected three or four times, and everything is up to snuff. Why change it? NRC should have simply codified the orders and then changed them as necessary.

According to an Agreement State official,

> Initially, most Agreement States would have preferred to simply codify the security orders. The new rule, however, is a consensus of Agreement State and USNRC ideas learned from experience while using the orders. A rule established and enhanced from experience would seem to have a better foundation than orders issued to address an immediate security need. The new rule also combines all security rules into one regulation. It is more efficient for regulators and the regulated community.

A university RSO favored having a new rule, but finds it essentially a codification of the orders. He

> likes the fact that 10 CFR 37 combines multiple orders into one new part of 10 CFR rather than codifying the orders as they were. Having them all in one place makes it easier to follow than if a licensee had to look in multiple orders, revisions to orders, Q&A, revisions to Q&A, etc. In effect, by combining the orders and adding material, NRC codified them.

An Agreement State official pointed to another reason to have a rule rather than orders:

> My legal staff is of the opinion that it is easier to conduct enforcement of a rule than of an order. Specifically, the staff says, if a licensee violates a rule, the state is in a stronger position in a court case than if the licensee violates an order.

How well did NRC conduct the rulemaking process? Radiation professionals had mixed views on this point. Some found NRC to be responsive, others did not. An industrial radiographer:

> When [the Increased Controls order] was being crafted, it included a lot of provisions that wound up being jettisoned because of strong opposition. NRC included many of those items into a draft of Part 37 and, not surprisingly, they met with strong opposition. I and others testified before NRC on these points, and NRC accepted much of what we told them. But most of the industry didn't know about the draft Part 37 until very late. NRC could have sent notices to all its licensees, or to the Agreement States. I didn't see a strong NRC effort to pull in the stakeholders. … I give kudos to the NRC for listening to the users and adjusting the regulation in response to our comments. I strongly believe that input from the "experts" in the field, i.e., the end users, should have a large part in regulatory affairs as it is those in the field that see the real impact of regulations.

A Nuclear Energy Institute representative:

> The current security orders include security requirements based on vulnerability assessments. NRC says it used lessons learned from implementing the security orders, but concedes that it had not done vulnerability assessments in preparing the rule. Without the assessments, the justification for the enhancements and inclusion of some categories of licensees is unclear. … NRC issued security orders for panoramic and underwater irradiator licensees and for manufacturer and distributor licensees, and

increased controls for other licensees. Each order provided separate requirements for each type of licensee. Licensees have been operating within the security orders. NRC merged the three sets of requirements and imposed this merged set on every licensee, including nuclear power plants and licensees operating other parts of the nuclear fuel cycle. As a result, the rule is quite complicated. It would have been better if NRC had codified the orders and made revisions later in a risk-informed manner, as necessary, based on objective vulnerability assessments.

An official of the Conference of Radiation Control Program Directors:

CRCPD had serious concerns on the draft rule but the concerns have been removed. For example, NRC removed the requirement to check credit history as part of T&R; CRCPD felt that credit checks do not give good information and that other tools were sufficient.

An Agreement State official:

The state members of the rulemaking working group kept asking NRC if there was some particular threat, and if so, shouldn't they tailor the rule to the threat and the users. NRC did not provide an answer. As a result, the rule has overkill in terms of the level of security.

Another Agreement State official:

[Agreement State representatives] worked closely with NRC to develop the rule. We were co-regulators and had a good partnership with NRC. For example, we were involved in developing parts of the rule concerning fingerprinting and reviewing officials. We feel that the [Increased Controls order] and the rule provide reasonable assurance—not certainty—about the security of radioactive material. We are quite satisfied with the rule, and were able to get our input in; it was an excellent experiment in rulemaking. We feel that the rule is pretty clear.

NRC offered rebuttals to several of the foregoing comments. They are assembled here:

(1) The ICs were not revised. Stakeholder comments were used to develop the guidance document.

(2) The NRC conducted a number of outreach activities for the rule. First, the technical basis for subpart D was placed in the Federal Register for public comment. Three public meetings were held to receive comments. Second, the preliminary draft language for subparts B, C, and D were placed in the Federal Register for comment. Third, the draft final rule and guidance were placed in the Federal Register for comment. The comment period lasted for more than six months. By letter dated June 15, 2010, the NRC sent notification to every licensee that received an NRC order and everyone that commented on the preliminary rule language that the proposed rule was available for public comment (and enclosed a copy of the Federal Register notice that contained the proposed rule); the notice also provided information on the guidance document and the public meetings (2) that were planned on the guidance. The NRC also provided a copy of the letter to the Agreement States for their use and information. Many of the Agreement States provided the information to their licensees.

(3) Vulnerability assessments were performed. These assessments were used in the development of the IC requirements and 10 CFR Part 37.

(4) All Orders were essentially the same. They all contained requirements to 1) control access, conduct trustworthy and reliable determinations, 2) detect, assess, respond to unauthorized access, and 3) transportation security requirements. The performance based nature of the Orders and 10 CFR Part 37 allows licensees to tailor their security plan to their specific situation. The main difference is the Orders before the ICs had specific timelines. The timelines were and have been replaced by "immediate" and "without delay."

> (5) It was stated many times throughout the rulemaking process that the NRC does not have specific threat (organization, place, or time). It was stated that there is a general threat meaning that there is intelligence to indicate that groups are interested in using radioactive material in a terrorist attack.[32]

Characteristics of the rule

Should there be a design basis threat? NRC uses a design basis threat (DBT) to define the type of threat that a facility, such as a nuclear power plant, must be able to counter. Radiation professionals interviewed for this memo had mixed views on a DBT for radioactive materials. Some felt a DBT would have been inappropriate or unworkable; one felt the rule should have had a DBT to indicate what is required; another felt that NRC has specified the threat clearly; and one noted that having a DBT for less-than-huge quantities of radioactive material would imply that there should be a DBT for chemical tanker trucks and other potential hazards.

An industrial radiographer pointed to difficulties with a DBT:

> The regulation is right not to specify a design basis threat (DBT). I'm aware of one source that has been stolen in the past 20 years. Should I hire people with M-16s to guard each of my radioactive sources? What level of security is needed? We do want operational security, but can't bust the bank for it.

A university RSO also pointed to difficulties:

> Requiring a licensee to develop a design basis threat would not work. How would a licensee know and guard against the DBT for each different Category 1 or 2 device? Requiring armed guards at every irradiator or other source would put research and medical licensees out of business for use of these devices. Also, if information on a DBT leaked out, it could reveal to terrorists what sort of attack was being defended against, and would imply that a somewhat greater threat would succeed.

An RSO at another university felt that the rule should have had a DBT:

> there is no design basis threat or discussion of adversary capabilities provided to the licensee. Without a common security education, each site will develop their security in accordance of their understanding of the regulations AND their guess of the potential threat. This variation in security implementation combined with the variation in inspection practices will produce widely varying security levels and practices.

An Agreement State official felt that a DBT could not have been tailored to each facility's characteristics:

> I don't think there has to be a design basis threat (DBT) for each facility. When people look at a facility to see how to harden it, they are in effect doing a DBT, as they are looking for vulnerabilities specific to each room. The [city] Police Department conducts security inspections of facilities. … In my experience, when an organization needs to design a security system, RSOs consult with security professionals. This approach guards against a plausible threat that is specific to each room or facility, rather than a DBT. This is a better approach.

NRC commented, "The LLEA does not have the authority to conduct security inspections of the licensees under either the orders or the Part 37 rule."[33]

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[32] Information provided by Nuclear Regulatory Commission, August 7, 2012. Numbering is added for clarification.

[33] Information provided by Nuclear Regulatory Commission, August 7, 2012. See also footnote 26.

A university RSO maintained that NRC has clearly stated the threats that must be countered even without specifying a DBT:

> The rule does not specify a design basis threat but NRC has clearly communicated what a security program needs to do, potential scenario and the timeframes in which a police response is required. … the NRC has included security assessments into the Increased Controls Orders and the new 10 CFR 37. Even without prescribing a DBT for materials licensees, [the RSO] believes that NRC has been crystal clear in what threats must be countered … [and] does not see the need for additional guidance or a DBT.

An Agreement State official found a DBT inappropriate for most licensees, and questioned what other potential threats might require a DBT if one were set for most radioactive sources:

> A Design Basis Threat (DBT) is easy to construct for a nuclear power plant. There could be a DBT for a panoramic irradiator (with perhaps hundreds of thousands of curies) or for manufacturers and distributors of radioactive material, but it's not plausible to apply a DBT to other radioactive sources. Licensees having few employees and modest amounts of radioactive material could not handle a DBT. Terrorists could seize such sources, or mobile sources. But they could also attack tanker trucks carrying chlorine or gasoline, many of which are on the roads; should there be a DBT for them, too?

Is the rule too prescriptive, or too performance-based? A difficult issue in formulating 10 CFR 37 was striking the right balance between a performance-based vs. a prescriptive rule. The former would specify the desired result; the latter, how the result is to be achieved. A performance-based rule would specify what a program must be able to do, such as detecting attempted theft of radioactive material and summoning a prompt police response, while leaving to each licensee how to accomplish these tasks. In contrast, a prescriptive rule would specify in detail what constitutes adequate security, such as having an iris scanner for access control and a TV camera and radiation monitor with direct links to the police central alarm station. In general, radiation professionals felt that the rule strikes the right balance, and noted that a companion "implementation document," to be issued by NRC along with the final rule, will provide more details on what NRC views as constituting compliance. Closely related is the question of whether the rule is "one size fits all," i.e., does not make allowances for differing types of licensees holding vastly different quantities of radioactive material under differing security conditions. There were several criticisms of the rule on this point.

GAO, in testimony of March 2012, found the security orders to be performance-based, resulting in uneven levels of security from one facility to the next.

> NRC's security order and implementation guidance are broadly written and do not prescribe the specific steps that licensees must take to secure their sources. Rather, they provide a general framework for what constitutes adequate security practices. …It is up to the licensee to determine, for example, if security cameras are necessary or what types of locks or alarms are needed to secure doors or windows. …The ability to tailor security to a facility's needs and resources is particularly important for commercial facilities with limited resources. For example, officials from smaller medical facilities told us that implementing specific security requirements—such as cameras and other surveillance equipment—could jeopardize their continued operations because of the costs associated with this equipment. NRC officials told us that given factors such as diverse economic conditions, facility type, layout, and operations of facilities, a "one size fits all" approach is neither practical nor desirable.
>
> We found that the NRC controls have been implemented in a variety of ways in the hospitals and medical facilities we visited … At some locations, the controls resulted in significant security

> upgrades, such as the addition of surveillance cameras, upgrades to locks on doors, and alarms. In contrast, we observed minimal security in other facilities.[34]

The radiation professionals interviewed for this memo felt that the diversity in types of organizations that use radioactive materials made a prescriptive approach impossible to implement by regulation, though the implementation document will help clarify what constitutes compliance with a performance-based regulation. Some felt that the rule is one size fits all, despite what NRC told GAO, and that that was bad policy. On the other hand, those who noted the flexibility inherent in a performance-based regulation would seem to contradict those who said that the regulation was one size fits all.

An industrial radiographer:

> Regarding the issue of whether Part 37 is too prescriptive or too performance-based, I like the rule. While I don't like some of the wording, it leaves us a lot of room to work. For example, not telling me how to do security zones is fine.

An Agreement State official:

> The new rule addresses a very diverse community possessing various radioactive materials. The rule must allow flexibility for the differing business models to comply with the rule. Based on this belief the rule is not too broadly written. The Agreement States and the USNRC have more than a decade of experience in performance-based regulation. Likewise, the regulated community has the same amount of experience complying with regulations through performance-based policies, procedures and programs. The new rule "tightens" up some of the initial orders with prescriptive requirements, while allowing performance-based implementation across a very diverse regulated community.

An Agreement State official:

> Some RSOs wanted a prescriptive order, but I told them that I didn't know the specifics of each facility, so they would need to develop a security system and RCP would then inspect it. If we found weaknesses in their system, we would not issue a violation notice but rather work with them to develop a corrective action plan. In practice, many RSOs would develop a plan, then call me to ask my opinion of the plan. … I think the rule strikes the right balance between being prescriptive and being performance-based.

A university RSO

> feels that the balance between the rule being prescriptive vs. performance-based has worked out well. Many stakeholders have lobbied NRC for more performance-based requirements in the rule, which is what NRC provided in this case. However, there is now complaint by some that they would like the rule to be more prescriptive. NRC and many other federal agencies have done an excellent job of providing detailed guidance on how to implement a rule in addition to the rule itself. NRC's draft guidance from 2010 for the draft of 10 CFR 37 provided a clear explanation of what the rule meant. As he understands it, NRC intends to publish supplemental guidance documents based on the experiences from the increased controls program to assist with implementation of the new rule. These guidance documents provide very useful information for licensees to successfully implement the regulation.

[34] U.S. Government Accountability Office, *Nuclear Nonproliferation: Further Actions Needed by U.S. Agencies to Secure Vulnerable Nuclear and Radiological Materials*, GAO-12-512T, March 14, 2012, pp. 16-18, http://www.gao.gov/assets/590/589345.pdf.

An Agreement State official:

> Compared to the orders, the final rule is much more prescriptive. … it is a one size fits all set of regulations. The orders were issued incrementally to licensees needing different levels of security, such as panoramic irradiators, manufacturers and distributors of radioactive sources, and other organizations such as hospitals. The rule mandates that all licensees have the same high level of security; that may not be necessary. Security should have been tailored to users, as the orders were. For example, a licensee with a half-dozen employees using soil moisture and density gauges, which have millicuries of radioactive material, do not need the same level of security as a panoramic irradiator, which may have hundreds of thousands of curies.

A university RSO:

> The rule is one size fits all: security plans, training, procedures, new concepts (like security zones). There were orders, and we implemented them. After we had been inspected a few times, we were able to understand how to comply with the orders. Now with the new rule, we will have to set the rule as the new baseline. We will be reinspected against the new standards. It will take significantly more time. There are 37 Agreement States plus NRC, so there will be 38 interpretations of what the rule means. We will have to start all over again.

In comments in January 2011 on the draft rule, the Advisory Council on the Medical Uses of Isotopes, an official advisory body to NRC, stated,

> The ACMUI understands the need to quickly develop and implement the Increased Controls License Orders required the NRC to establish a one-size-fits all model for all types and uses of Category 1 and 2 sources. The ACMUI is concerned that the proposed Part 37 builds off of and expands the requirements of a one-size-fits all model.[35]

Other

Scarcity of resources has affected radiation security programs. Several radiation professionals noted many ways in which scarcity of resources has affected their or other programs. This raises the question of whether it will be economically feasible to secure radioactive materials to the extent, and on the timeline, that the rule requires.

A university RSO:

> The lack of resources affects inspections. For example, budget cuts reduce the number of inspectors and the time they have for each inspection.

An industrial radiographer:

> Under the rule, we must verify that the receiving licensee has a valid license. On the surface, this makes sense. But I have to contact that licensee's jurisdiction to get this information. For me, that means I have to call [the state] and ask the radiation health bureau if the license is still valid and can receive the shipment. In reality, [the state] doesn't have enough money, so that bureau is understaffed and people don't answer the phone.

[35] D. Gilley, S. Langhorst, and D. Fisher, Advisory Committee on the Medical Use of Isotopes (ACMUI), "Comments on Proposed Part 37," January 5, 2011

NRC commented on the foregoing statement:

> Under 10 CFR Part 30, all licensees are required to verify that the recipient is authorized to possess the radioactive material. In the past, this was done by the recipient faxing the first page of their license to the sender. To prevent the use of counterfeit licenses, licensees will be required to verify the recipients' license with the appropriate regulator and the preferred way to comply with the regulation is use of the License Verification System.[36]

An Agreement State official:

> While there are no concerns about the new rule, there is the concern over the ability to promulgate the rule when required. I think all states including [mine] are experiencing that it is definitely harder to promulgate rules in this tough economic environment. Regulatory rule promulgation is perceived as anti-business and bad for the economy.

A university RSO:

> Unfortunately, at many institutions I've spoken with, the money estimated to implement the new rule is woefully inadequate.

A Nuclear Energy Institute representative:

> NRC's regulatory analysis with the final rule showed an average one-time cost of $23,375, and an average annual cost of $21,736, for each of the 1,400 or so licensees with category 1 or 2 sources. Most of these licensees are small business industrial radiographers, for whom these costs would be significant.

An Agreement State official:

> NRC can find a state inadequate for protecting public health and safety, and can put that state on "heightened oversight." A few years ago, [my state] was put on heightened oversight, after which more resources were devoted to the radiation control program and [the state] showed sufficient improvement to be taken off heightened oversight. The [state] radiation protection budget was cut approximately 20 percent for the 2011-12 biennium. In order to make sure the radioactive materials program has enough staff, resources are being shifted to ensure adequate support for radioactive materials.

Comments on Global Threat Reduction Initiative (GTRI). According to NRC, "The rule would impose the minimum requirements that the NRC believes are necessary to adequately protect the public health and safety and the common defense and security."[37] The National Nuclear Security Administration, a semiautonomous component of the Department of Energy, operates GTRI. The Domestic Materials Protection Program, a GTRI component, goes beyond the minimum requirements by providing security upgrades on a voluntary basis to facilities with radioactive material. To do so, it sends a team to a participating facility to assess its security situation. The team makes recommendations on security upgrades—such as iris scanners for access control, infrared cameras to provide video if the lights go out, a backup power supply, and communication links to police alarm stations—and negotiates with the facility's personnel on which to install. GTRI then contracts to have the agreed systems installed, and

[36] Information provided by Nuclear Regulatory Commission, August 7 and 14, 2012.

[37] U.S. Nuclear Regulatory Commission. "Regulatory Analysis for Final Rule: Physical Protection of Byproduct Material (10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73)," December 2011, Appendix C, Regulatory Analysis, p. C-6, http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0170scy.pdf, pdf page 531.

provides funds for maintenance for three years, after which time the facility is supposed to fund maintenance. GTRI also provides training at the Y-12 National Security Complex (TN) for law enforcement personnel,[38] and conducts training exercises at facilities around the country.

NRC and NNSA view their roles as complementary, with NRC setting minimum standards for securing radioactive material and GTRI providing a higher level of security. For example, a particularly worrisome threat is that posed by insiders. 10 CFR 37 deals with this threat by requiring licensees to grant unescorted access to category 1 and 2 material only to personnel the licensee deems trustworthy and reliable. So far, this system appears to have worked satisfactorily; since 9/11, there has been only one theft of a category 2 source of radioactive material, a radiography camera with 33.7 curies of iridium-192 stolen from a truck in Texas in 2011, and that theft was not done for terrorist purposes. In contrast, GTRI installs TV cameras, tamper-alarming seals, radiation detectors, and links to police alarm stations in order to indicate a theft of radioactive material in progress by anyone, including an insider, as breaking the seal, or radiation leaking out when the material was removed, would trigger an alarm.

GTRI is not a part of 10 CFR 37, and is not under NRC jurisdiction. Nonetheless, several radiation professionals interviewed for this memo commented on GTRI, and their comments seem worth including. Most of them found GTRI valuable; one declined to participate on grounds of personnel time, cost of maintaining GTRI-installed equipment, and complexity of equipment.

A university RSO:

> NNSA's Global Threat Reduction Initiative installed a full suite of equipment. [The university's] reactor building also houses a 30-year-old irradiator with less than 1000 curies. The construction people ripped everything in the building apart for months in order to install many alarms. However, the reactor people love the system, it's a great system.

An industrial radiographer:

> What level of security is needed? We do want operational security, but can't bust the bank for it. NNSA's Global Threat Reduction Initiative has the best way to approach this. They would like to come out to our facility. I signed up for it, and am hopeful that as their limited budget will allow, they will come here this year or next and help us with realistic workable approaches to enhancing our security both at our fixed facilities as well as our mobile fleet.

An Agreement State official:

> While it is the licensee's responsibility to develop and implement a compliant operational strategy, there are other resources available to assist them in this mission such as the Global Threat Reduction Initiative (GTRI). GTRI has performed a lot of security enhancements in [my state]. It has increased the security for many irradiators. [A] University, for example, has been very complimentary of the work that GTRI completed for them. It not only provided enhanced security devices, but also developed and implemented extensive tabletop exercises. Participants in these exercises included the FBI, the [state] Radiation Protection Section, universities, state and local response organizations, and other public and private sector stakeholders at local, state and federal levels. This exercise led to the development of many improved relationships among the participants.

[38] See Y-12 National Security Complex, Nuclear and Radiological Field Training Center, "Advanced Radiological Response Techniques (ARRT) Courses," http://www.y12.doe.gov/missions/complementarywork/nrftc/arrt_courses.php .

> As part of their voluntary security enhancement program, GTRI also provides opportunities for private and public sector security force response training at their Oak Ridge facility. This training specifically enhances the coordination of a facility's radiation safety staff and their responding security force, including LLEA. With real world staged environments in which the "players" form response plans and act them out, the value of pre-arranged cross-discipline response plans is evident and strong partnerships are formed.

An Agreement State official:

> Police departments in [various] cities send all of their officers to Advanced Radiological Response Techniques training courses at the Y-12 National Security Complex in Tennessee. This is not something that [the radiation control program] mandates.

An Agreement State official:

> NNSA has done a lot, including two tabletop exercises in [my state]. These have been eye-openers to emergency responders. They raised elements that the responders hadn't considered. For example, if it became necessary to evacuate 300,000 people from [city] because of a dirty bomb, where would they go? How would health workers treat them, given that emergency rooms would be flooded with people? The exercise helped the [city] learn what other assets were available to them in the event that they needed additional resources. Another exercise, at [a university], had a scenario with a two-pronged terrorist attack that stole a radioactive source and raided a reactor. This exercise gave an excellent opportunity to work through the issues and provided many lessons.

An Agreement State official:

> The Global Threat Reduction Initiative has been in [my state] a half-dozen times. They will install security systems for one of the state's larger licensees this summer. The program opens the eyes of licensees to security, and provides good training not only for the licensee, but also for the state inspectors who sit in on the training.

On the other hand, a university RSO does not use GTRI:

> I have thus far declined to use GTRI because of my organizations' concerns with the level of complexity with the security systems, their lack of personnel time to devote to this GTRI implementation, and uncertainty of the funds which will be needed to support maintaining the security systems after the three years in which GTRI provides that maintenance support.

Should trustworthiness and reliability (T&R) screening be enhanced? 10 CFR 37 would require every individual granted unescorted access to category 1 or 2 sources to be deemed T&R by his or her employer. Some radiation professionals interviewed for this memo were comfortable with their T&R procedures. They feel that their organizations are competent to adjudicate T&R decisions, are able to use outside investigators as needed, and have experience in adjudicating T&R through implementing the various security orders. They see their employees every day and can spot changes in behavior, and are aware that erroneously granting someone T&R status could ruin their organization. Others expressed concerns: how to determine who should adjudicate T&R decisions (a human resources specialist, an RSO, or a committee); standards used in making T&R decisions that varied from one organization to the next; the possibility of being sued by an individual not hired because he or she was denied T&R status; lack of clear standards in 10 CFR 37 for denying T&R status; the difficulty of making T&R decisions based on incomplete information, such as for foreign students; and inadequate training of individuals who make T&R determinations for evaluating background information.

It can be readily argued that the current system is satisfactory, given that there has been only one case of a theft of a category 2 source of radioactive material since 9/11. On the other hand, the issue is potentially serious: one individual erroneously deemed T&R could obtain material for a "dirty bomb" that could contaminate several square miles of a city and cost many billions of dollars in cleanup costs, relocation costs, and lost productivity, as well as societal disruption.

Should there be a desire to enhance T&R adjudication, several measures might be taken:

- NRC could make T&R standards clearer. For example, the State Department's "Adjudicative Guidelines for Determining Eligibility for Access to Classified Information" provide a detailed set of criteria for this purpose. The department notes, "The ability to develop specific thresholds for action under these guidelines is limited by the nature and complexity of human behavior. The ultimate determination of whether the granting or continuing of eligibility for a security clearance is clearly consistent with the interests of national security must be an overall common sense judgment based upon careful consideration of the following [thirteen] guidelines, each of which is to be evaluated in the context of the whole person."[39] The text presents these guidelines, along with a detailed discussion of security concerns and mitigating factors for each. Standards such as these could be used even if not in the context of granting a security clearance.
- The Federal Select Agents Program is operated by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service. Its registry program "oversees the activities of possession of biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products." [40] It may offer another model for adjudicating T&R decisions. According to a university RSO,

  > One alternative approach to the current Increased Controls T&R process is the one used for a bioterrorism security risk assessment to vet people for access to select agents or toxins. Under this program, an organization's biosafety officer (BSO) sends in an application for an individual to the Animal and Plant Health Inspection Service (APHIS) or CDC to obtain a unique identifying number (UIN). The BSO submits a completed FD-961 form[41] with the UIN and two fingerprint cards to the FBI. The FBI does a background check, and the FBI and APHIS or CDC make the decision and give the biosafety officer a yes or no decision, all for no charge.[42]

  NRC commented:

  > The FBI's Criminal Justice Information Service (CJIS) performs a fingerprint-based Security Risk Assessment (SRA) for access to select agents, transmits the result, which indicates whether an individual is authorized or restricted, and maintains a database of their determination. CJIS bases their determination primarily on whether the criminal history record indicates that the person has

[39] U.S. Department of State. "Adjudicative Guidelines for Determining Eligibility for Access to Classified Information," February 3, 2006, http://www.state.gov/m/ds/clearances/60321.htm.

[40] U.S. Animal and Plant Health Inspection Service and Centers for Disease Control and Prevention. "National Select Agent Registry," http://www.selectagents.gov/.

[41] This form is the Federal Bureau of Investigation Bioterrorism Preparedness Act: Entity/Individual Information; it is available at http://www.fbi.gov/about-us/cjis/bioterrorism-security-risk-assessment-form/bioterrorism-security-risk-assessment-form-fd-961 .

[42] For further information on the Select Agent Program, see U.S. Centers for Disease Control and Prevention (CDC). Office of Public Health Preparedness and Response. "CDC Select Agent Program," July 2011, http://www.cdc.gov/phpr/documents/DSAT_brochure_July2011.pdf.

committed any of the offenses listed in section 817 of the USA PATRIOT ACT, that would make them a "restricted person". The Department of Justice is specifically authorized to perform this function by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. CJIS transmits the result of the SRA to the CDC, which in turn sends an authorization or denial letter to the entity's Responsible Official. The Responsible Official is ultimately responsible for controlling access to the agent. A legislative change would be required to apply a similar process to users of radioactive materials.[43]

- NRC could provide training for personnel making T&R decisions.
- Difficult cases could be resolved by denying an individual unescorted access to category 1 or 2 material. Such cases do arise. It may prove hard to do an adequate background investigation of foreign nationals because information may be incomplete or available in a form that is hard for U.S. personnel to evaluate. Some U.S. citizens may have committed a serious crime many years earlier, but have had a clean record since.
- A federal agency, such as NRC, the FBI, or the Office of Personnel Management, could adjudicate difficult cases. Referring such cases to a federal agency would permit a more thorough background investigation, could apply clear standards to the results, and could reduce the risk that a person denied T&R would sue the requesting organization.
- A federal agency could adjudicate all cases. NRC commented, "This would require a legislative change."[44]
- Individuals granted T&R status could be required to have a Secret clearance. The definition of Secret information is: "'Secret' shall be applied to information, the unauthorized disclosure of which reasonably could be expected to cause serious damage to the national security that the original classification authority is able to identify or describe."[45] In its regulatory analysis for the new rule, NRC states that in issuing several orders between 2003 and 2006 for securing radioactive material, "NRC noted that a deliberate malevolent act by an individual with unescorted access to these materials has a potential to result in significant adverse impacts to the public health and safety or the common defense and security and, thus, necessitated expeditious implementation of additional fingerprint requirements."[46] Yet an individual who stole certain radioactive material could take it to the roof of a building and disperse it in minutes using explosives, potentially inflicting large costs and societal disruption. While this release would not be "information," it "reasonably could be expected to cause serious damage to the national security."

  NRC commented:

  The 10 CFR Part 37 rule is being issued under the authority to protect public health and safety. "Secret" clearances apply to protecting the common defense and security. This recommendation would cause a change in the underpinnings of the 10 CFR Part 37 regulations and would result in a

[43] Information provided by Nuclear Regulatory Commission, August 7, 2012.

[44] Ibid.

[45] U.S. White House. Executive Order 13526, "Classified National Security Information," December 29, 2009, http://www.whitehouse.gov/the-press-office/executive-order-classified-national-security-information.

[46] U.S. Nuclear Regulatory Commission. "Regulatory Analysis for Final Rule: Physical Protection of Byproduct Material (10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73)," December 2011, p. 5, http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0170scy.pdf at pdf page 5.

> difference of costs to the licensees and regulators and change to the regulatory burden. … additional analysis would be needed (and possibly a legislative change) to implement such a recommendation. [47]

Measures such as these would arguably provide a higher level of assurance that individuals granted T&R status were in fact trustworthy and reliable. At issue is whether they are needed; if so, if they are worth any added cost they might incur; and whether Congress would wish to make the requisite legislative changes.

Wrap-up: Several general points emerge from the foregoing analysis.

- While the rule imposes many requirements on licensees, the previously-issued security orders did so as well. Since the rule includes many of the requirements of the orders, its incremental burden is much less than would have been the case had the orders not been issued first.
- Since many actions must be undertaken by all facilities with category 1 or 2 material regardless of facility size, the rule would appear to impose a proportionately larger burden on small licensees than on larger ones.
- Layered defense—in which no layer is perfect but each reduces the likelihood of a successful terrorist attack—is a cornerstone of post-9/11 homeland security. The rule puts into effect a layered defense using personnel reliability, ability to detect intrusion, police response, etc. Vulnerabilities are inevitable: someone deemed T&R might not be, security systems could fail, or police might not respond in time. Nonetheless, the ability of one layer to offset weaknesses in others can be expected to improve security, especially as terrorists would not necessarily know where vulnerabilities are or how to exploit them.
- Security can be expected to increase over time as more monitoring equipment is installed, as local law enforcement becomes more familiar with the need for rapid response, and as the T&R process becomes more effective. However, as with so many other aspects of enhanced security post-9/11, this gradual accretion of security measures has made the United States safer but cannot guarantee safety.
- Further steps might increase security further, such as a more rapid rollout of GTRI, a more uniform T&R policy, or federal adjudication of some or all T&R applications. Whether the costs of these measures are worth the potential benefit is a matter for political judgment.
- Radiation professionals who use or regulate radioactive material every working day express a wide range of views on how changes from orders to rule and details of each section of the rule affect them. NRC consulted with them and made many changes in moving from the draft to the final rule in response to their recommendations. Nonetheless, judging from comments presented throughout this memo, further changes—whether to the rule or the accompanying guidance document—may prove desirable. Such changes would benefit from further consultation with radiation professionals.

[47] Information provided by Nuclear Regulatory Commission, August 7, 2012.

Appendix A. Definition of "Byproduct Material."

10 CFR 37 regulates "byproduct material." This Appendix presents the definition of the term as contained in 10 CFR 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," at 10 CFR 30.4, "Definitions."[48]

Byproduct material means— (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

[48] 10 CFR 30.4, "Definitions," http://www.nrc.gov/reading-rm/doc-collections/cfr/part030/part030-0004.html.

Appendix B. Notes from Interviews with Radiation Professionals, May-July 2012

To obtain data for this memorandum, the author interviewed 14 radiation professionals, three of whom wish to remain anonymous, and wrote notes of each interview. The author sent the notes to the interviewee, who then edited them so that they express the interviewee's opinions. As such, the notes in this Appendix do not express the opinions of CRS.

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Eric Boeldt, Radiation Safety Officer, The Pennsylvania State University, May 29, 2012

Mr. Boeldt is the Radiation Safety Officer (RSO) at The Pennsylvania State University. This university has several devices containing radioactive material that are subject to NRC regulations. Penn State also has a nuclear research reactor, which is regulated and secured under 10 CFR 73.

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Mr. Boeldt has several concerns on 10 CFR 37. §37.57, reporting of events, requires the licensee to assess "suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate." Within 4 hours, the licensee must notify NRC operations center and submit a written report to NRC within 30 days. Mr. Boeldt had an experience in which these requirements were excessive.

"An unknown State Police Officer in uniform in his private car drove up to our reactor and requested admittance (wearing a side arm). This was very suspicious. The LLEA was notified. The LLEA sergeant responded very quickly. He knew the individual, a State Police captain. The State Police captain promised to NEVER do that again. According to §37.57 of the final rule, I must still notify the NRC within four hours."

The rule should offer some flexibility as to what incidents to report. If an event occurs that initially appears suspicious but proves not to be, there should be no requirement to contact NRC.

As a second concern Mr. Boeldt, in a comment to NRC, suggested that 10 CFR 37 should add a new paragraph (5) to § 37.23(f) to read as follows: "Procedures and policies meeting the requirements of the security plans required by part 73 meet the requirements of this subpart B of this chapter." In its response, NRC "agree[d] that a licensee does not need to maintain two sets of procedures; however, a provision is not needed in the regulations. As long as the part 73 procedure addresses the content of the required procedures under part 37, additional procedures are not necessary." Mr. Boeldt's comment is, "this means that a person performing checks under part 73 has to read and be totally aware of all the details and all the changes to part 37. The simple statement that I suggested would not reduce security or change the intent, but it would reduce the regulatory burden."

He likes the fact that 10 CFR 37 combines multiple orders into one new part of 10 CFR rather than codifying the orders as they were. Having them all in one place makes it easier to follow than if a licensee had to look in multiple orders, revisions to orders, Q&A, revisions to Q&A, etc. In effect, by combining the orders and adding material, NRC codified them. The orders have three main components: background investigations, alarms, and LLEA response, and so does 10 CFR 37.

RSOs don't have the knowledge to secure radioactive material. Police and security experts will look for very different things than Mr. Boeldt would as an RSO. While he would see that there was a door lock, security experts might notice that an intruder could enter the room through a crawl space above the room. Also, he doesn't understand the details of the electronics to transmit an alarm to LLEA; the IT people have to do that; he has the responsibility but must rely on other people. He is fortunate that Penn State police are sworn and armed. There was an incident, in response to a false alarm, where they showed up with shotguns and automatic weapons.

Mr. Boeldt feels that the rule must be broadly written, and would not want it to be more prescriptive. He would like more background documentation on how to do things, such as securing a room, in order to comply with the rule's requirements. Such documentation need not be part of the rule itself but could be included in an implementation document.

Pennsylvania has been an Agreement State for three years, but does not have its own regulations. Instead, it quotes 10 CFR and adopts that by reference. As an Agreement State, PA has its own inspectors. A lot of the inspections have been based on trust. Inspectors would look at paperwork, and then at alarms, locks, biometric equipment, etc., and say that everything looks fine. They do not necessarily visit the police to see how they would respond. The lack of resources affects inspections. For example, budget cuts reduce the number of inspectors and the time they have for each inspection. In addition, they must upgrade from being radiation safety inspectors to being security inspectors as well.

Mr. Boeldt worries about T&R. There is no analytic way to adjudicate T&R, it's ultimately a judgment call. T&R adjudicators at Penn State's nuclear reactor do all of his adjudications because they do anywhere from six to thirty a year, while he would need to do one every four years or so. The reactor people do T&R adjudications properly. He feels that the states could not do the job because they don't have enough highly qualified people, and budget cuts and a pay freeze prevent them from paying enough to attract such people. He is also concerned about subjectivity and the potential for bias. He feels that having a federal agency make T&R adjudications would eliminate bias, as the adjudicators would not know the individuals being submitted for T&R. Federal adjudicators would have extensive experience in this process, reducing subjectivity. However, the federal agency would need to process T&R decisions quickly.

Should there be a design basis threat (DBT)? No. A DBT would be so onerous that no one could comply with it. A reactor DBT involved multiple people and weapon types; it became clear that it was almost impossible to meet the requirement to defend against it. For radioactive material, Mr. Boeldt thinks it's sufficient to have cameras, an alarm, and a police response; a DBT is unnecessary. The guidance to implement 10 CFR 37 could state that the threat to guard against is removal of radioactive material by people with guns, or an insider threat.

NNSA's Global Threat Reduction Initiative installed a full suite of equipment. Penn State's reactor building also houses a 30-year-old irradiator with less than 1000 curies. The construction people ripped everything in the building apart for months in order to install many alarms. However, the reactor people love the system, it's a great system.

An earlier version of Part 37 required quarterly testing of alarms, or as recommended by the manufacturer. Quarterly was too frequent because of the number of alarms and the amount of documentation. Some items can break or be knocked out of alignment if tested, such as magnetic door position switches. And some plastic access controls can be damaged during disassembly to test the internal tamper alarm. These really do not have any method for breakage so they don't really need to be tested. Furthermore, testing can be complicated, as it sends alarms to police, distracting them from their

work. Section 37.51 of the final rule calls for testing in accordance with the manufacturer's recommendation, and if no recommendation then at least every 12 months. One manufacturer states: "This security system requires very little maintenance, however, test the system weekly to ensure it is working properly" The company then goes on to offer to sell the testing service to the customer. If Mr. Boeldt were the manufacturer, he would suggest frequent testing to be able to blame the owner if there is ever a failure. Thus, the change in the final rule is not an improvement. In some circumstances it requires much more frequent testing than the Draft Part 37 required. Mr. Boeldt suggests the following wording: "The equipment relied on to meet the security requirements of this part must be inspected and tested for operability and performance at a least annually."

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Scott Cargill, Radiation Safety Officer and Quality Assurance Manager, Valley Industrial X-Ray and Inspection Services, Inc., Bakersfield, CA, June 1, 2012

Valley Industrial provides non-destructive testing and inspection "in all aspects of the oil and gas industries, including exploration, transmission, refining, storage facilities, and all oil related support industries," onshore as well as offshore, "and power generation communities, steam generation plants, co-generation facilities and the hydroelectric industry," as well as supporting the aerospace industry.[49] It has over 100 mobile x-ray crews throughout California, Colorado, Wyoming, and Texas.

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Valley Industrial provides inspections for clients to verify that their product or process meets specifications. I have personally inspected everything from a dead body to a Delta 5 rocket during my tenure of nearly 20 years with Valley. We can inspect anything inanimate where the client needs to look inside to verify the dimensions or soundness of the internal structure. We use many disciplines, such as ultrasound, magnetic particles, x-rays, and gamma rays, to inspect manufactured materials. I'm responsible for over 100 radioactive sealed sources, which are out in the field every day. We provide critical support for the U.S. infrastructure—buildings, pipelines, power plants, and so on. All of our sources start out at about 100 curies of iridium-192, which is category 2.

I'm on the Working Group on Industrial Radiography of the Conference of Radiation Control Program Directors and a member of the Radiation Safety Program of the American Society of Non-Destructive Testing. I, and my company, are aware of regulation as a double-edged sword. If we are not in business, we make no money. At the same time, we are 100 percent for good regulation. We agree with a lot of regulations and want regulations for the safety of employees.

The Increased Controls Order (ICO) belongs in regulation. Orders say, you will do this, while regulations can be changed. The ICO worked pretty well. When it was being crafted, it included a lot of provisions that wound up being jettisoned because of strong opposition. NRC included many of those items into a draft of Part 37 and, not surprisingly, they met with strong opposition. I and others testified before NRC on these points, and NRC accepted much of what we told them. But most of the industry didn't know about the draft Part 37 until very late. NRC could have sent notices to all its licensees, or to the Agreement States. I didn't see a strong NRC effort to pull in the stakeholders.

[49] Valley Industrial X-Ray and Inspection Services, Inc., "About Us," http://www.vxray.com/index.php?option=com_content&view=article&id=56&Itemid=49.

I am 100 percent for the new rule, but it does increase burden, just like any rule does. As a taxpayer, I'm concerned that when the federal government makes a rule and publishes it in the Federal Register, it has met its obligation. Part 37 is a sweeping, high-impact rule that affects the entire industry. There are two parts of the final rule that cause me heartache. First is the shipment and license verification issue. Under the rule, we must verify that the receiving licensee has a valid license. On the surface, this makes sense. But I have to contact that licensee's jurisdiction to get this information. For me, that means I have to call the State of California and ask the radiation health bureau if the license is still valid and can receive the shipment. In reality, California doesn't have enough money, so that bureau is understaffed and people don't answer the phone. NRC proposes a licensing database built into the National Source Tracking System. That is a great idea and needs to be done. Keep in mind, though, that it took five years to get NSTS running smoothly.

A second area of concern is that the rule takes us from a quarterly inventory of sources to a weekly inventory. On the surface, this is not a bad idea. For me, this is not a problem because most of my sources come back each night, and there is a benefit of source security, which is a top concern for us. But a sister company, JANX, works in all 50 states and its sources do not return to a centralized location. This provision of Part 37 is a nightmare for them, imposing a huge logistical burden.

Regarding the issue of whether Part 37 is too prescriptive or too performance-based, I like the rule. While I don't like some of the wording, it leaves us a lot of room to work. For example, not telling me how to do security zones is fine.

On whether RSOs have enough security training, security has always been part of our work. We would always report lost or stolen sources to the jurisdiction operations are conducted in immediately. RSOs are concerned about security and safety, and our concern for security of course increased after 9/11. Up until 2011, no one had stolen a source, though people occasionally stole trucks that incidentally had small radioactive sources on them. Last year, a radiography camera was stolen in Texas and was never recovered. However, since its radioactive material was iridium-192, with a half-life of 74 days, over 99 percent of that radionuclide will have decayed in about two years. That source, 33 curies of Iridium 192, would be approximately 2 curies now, so this clearly was not a theft for terrorist purposes. I am not a security consultant or an expert on security systems, but I have the knowledge I need and consult with security experts as necessary. For example, after the ICO was issued, we upgraded security, such as by adding alarms and GPS tracking.

The trustworthiness and reliability (T&R) provision is not really a concern. It is not overly prescriptive. I would really appreciate it if the FBI would allow us to use Livescan, a machine for taking and transmitting fingerprints electronically. Now, we must get fingerprint cards because Part 37 requires it. We send these cards to NRC, which sends them to the FBI, which then sends a report back to NRC, and NRC sends the report back to us. Other than that, the T&R system is good. We feel we're in a better position to decide whether to hire someone, and whether that person is T&R, than the U.S. government. We know the person.

The regulation is right not to specify a design basis threat (DBT). I'm aware of one source that has been stolen in the past 20 years. Should I hire people with M-16s to guard each of my radioactive sources? What level of security is needed? We do want operational security, but can't bust the bank for it. NNSA's Global Threat Reduction Initiative has the best way to approach this. They would like to come out to our facility. I signed up for it, and am hopeful that as their limited budget will allow, they will come here this year or next and help us with realistic workable approaches to enhancing our security both at our fixed facilities as well as our mobile fleet.

Regarding cooperation with local law enforcement agencies (LLEA), I called the local sheriff's office, and they were unaware of the radioactive-material security issue. They don't have the manpower. I later spoke briefly with a homeland security officer in the Kern County Sheriff's Office about threat management, but he was busy. I don't know what they are being trained on. I worked with the county sheriff, and assume they are being trained; I don't know what they are being told about terrorism.

Agreement State personnel are not security consultants. They have common sense. For example, they can see possible points of entry to a room with radioactive material. But they probably do not have sufficient training. The agency doesn't have the budget or people.

As a side note, an important thing that the U.S. government could do to improve the security of our mobile radioactive sources is to develop a GPS transceiver that is small enough, rugged enough, and inexpensive enough to attach to our devices, which are out in the field every day.

To summarize, I feel that Part 37 is a good step. I feel that the jurisdictions, not just the NRC, could all do better at reaching out to the licensees that their regulations affect. I give kudos to the NRC for listening to the users and adjusting the regulation in response to our comments. I strongly believe that input from the "experts" in the field, i.e., the end users, should have a large part in regulatory affairs as it is those in the field that see the real impact of regulations.

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W. Lee Cox III, Chief, Radiation Protection Section, Department of Health and Human Services, North Carolina, June 1 and 6, 2012

The Radiation Protection Section (RPS) "administers the following programs … : a Radon monitoring, mitigation and education program; an emergency response program for nuclear facilities; an environmental monitoring program; a radioactive material licensing, compliance and education program; a low level radioactive waste management oversight program; a progressive Homeland Security initiative; an effective radioactive material emergency response program; an X-ray registration, compliance and education program; a mammography registration, compliance and education program; a tanning registration, compliance and education program; an information resource location for other sources of non-ionizing radiation; and a comprehensive enforcement program."[50]

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I have been with RPS for almost 20 years as a Radioactive Material Inspector, a Radioactive Material Branch Manager and most recently as the Chief of the Section. I have represented the Organization of Agreement States (OAS) on several USNRC Working Groups, Task Forces and Steering Committees including Sealed Source and Device Registration, the Energy Policy Act of 2005, 10 CFR Part 37, and the Nuclear Safety Culture Policy Statement. I have been a member of several USNRC Integrated Material Performance Evaluation Program (IMPEP) teams auditing other state radiation programs for adequacy and compatibility. I have been serving on the OAS Executive Board as the Director of Emerging Issues and Advocacy for the past 6 years.

1. *What are your concerns, if any, about the new rule?*

[50] North Carolina. Department of Health and Human Services. Radiation Protection Section. "About the Radiation Protection Section." http://www.ncradiation.net/about.htm .

As the agency responsible for implementing the new rule, the N.C. Radiation Protection Section has no concerns about the new rule. N.C. will implement the regulation as required.

While there are no concerns about the new rule, there is the concern over the ability to promulgate the rule when required. I think all states including N.C. are experiencing that it is definitely harder to promulgate rules in this tough economic environment. Regulatory rule promulgation is perceived as anti-business and bad for the economy. In the past, we have had no problem getting rules through the N.C. process with regards to regulating radioactive material. While it is always a time-consuming process, we have generally been supported in the effort. Most recently N.C. and probably most states have made it as cumbersome as possible, if not impossible to pass more regulatory rules. I only bring this up, because any new rule requires resources to get it through the rulemaking process. It may be harder in this environment. Hopefully the N.C. Rules Review Commission will not hold up this rule when presented to them, due to the fact our regulated entities have been working under similar orders for years.

(a) What changes does it require as compared to the orders?

All of the changes are outlined in SECY 11-0170 Enclosure 2. http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0170scy.pdf

(b) Does it increase or decrease the burden compared to the previous orders?

The new rule increases some burdens while decreasing other burdens. In general, the new rule has more increases than decreases in oversight.

I think that we are all working under what Past Commissioner McGaffigan stated was the mandate from the Commission regarding security: “To provide reasonable assurance of adequate protection, not absolute assurance of perfect protection.”

Under that premise, it is my belief that the burden or costs of implementing the previous orders or Part 37 are not too great.

(c) Are the costs worth the benefits?

From a regulatory viewpoint, yes the benefits are worth the costs. N.C. will use this effort to maximize the cross-benefits of the new rule and enhance the safety cultures across regulated entities. One example is the opportunity for cross-awareness between regulators and LLEA. As an example of this cross-awareness, before NRC issued its security orders, there was often not a good relationship, if any, between licensees and LLEA. The orders, which require licensees to contact LLEA to try to work out a response plan, have in many cases led to the establishment of relationships between licensees and LLEA.

An example of how the relationship will be further developed—though more from the increase in security culture than the orders per se—is the Licensing Tracking System (LTS). LTS is an application for tracking radioactive materials licenses and inspection information being set up by NRC, and N.C. is one of the pilot states implementing it. LTS will be transitioning to a web version, accessible over the internet, in August 2012, and the name will change to Web Based Licensing (WBL). This database will eventually contain all radioactive material licensees in the U.S. WBL will share information with another application, the License Verification System (LVS), that is currently in development and planned for release in the spring of 2013. These two systems will work together to allow licensees to perform a license verification (required by Part 37) online. For example, if a manufacturer of radioactive sources receives an order for a source, the manufacturer can use LVS to see if the would-be recipient in fact has a

license. LVS will be faster and simpler than contacting NRC or an Agreement State, and will have the most up-to-date data. Another example of the use of WBL is that LLEA or a local fire department may want to know what radioactive sources are in their area, whether to make a response plan or in case of emergency. They can access WBL to find the information. They may find, for example, that the soft drink plant down the street is licensed for radioactive material. Information captured in LVS and WBL will be available to those with a need to know. Another component of the enhanced culture already being implemented is the National Source Tracking System (NSTS).

2. *Is it better to have a new rule, or would it have been better to simply codify the security orders?*

Initially, most Agreement States would have preferred to simply codify the security orders. The new rule, however, is a consensus of Agreement State and USNRC ideas learned from experience while using the orders. A rule established and enhanced from experience would seem to have a better foundation than orders issued to address an immediate security need. The new rule also combines all security rules into one regulation. It is more efficient for regulators and the regulated community.

3. *In testimony to the Senate Homeland Security and Governmental Affairs Committee on March 14, 2012, Gene Aloise of the Government Accountability Office (GAO), said, "We look at NRC's increased controls over hospitals and medical facilities over radiological materials. And, basically, I think we are coming to the conclusion that they are too broadly written and need to be tightened up. A lot of the people we visited in these hospitals and medical facilities needed more guidance on how to better secure these radiological sources. They also needed better training regarding security because they are not trained in security in the health services." Do you agree or disagree? Does the rule strike the right balance between being prescriptive vs. performance-based?*

The new rule addresses a very diverse community possessing various radioactive materials. The rule must allow flexibility for the differing business models to comply with the rule. Based on this belief the rule is not too broadly written. The Agreement States and the USNRC have more than a decade of experience in performance-based regulation. Likewise, the regulated community has the same amount of experience complying with regulations through performance-based policies, procedures and programs. The new rule "tightens" up some of the initial orders with prescriptive requirements, while allowing performance-based implementation across a very diverse regulated community. The USNRC is currently working on a guidance document to accompany the rule.

4. *Do radiation safety officers, Agreement State inspectors, and others have sufficient training, experience, and knowledge of radioactive source security to effectively implement 10 CFR 37?*

Agreement State inspectors and USNRC inspectors have sufficient training, experience, and knowledge of radioactive source security to effectively implement 10 CFR 37. N.C.'s experience inspecting against the orders, demonstrates that licensee radiation safety officers and personnel also have sufficient training, experience, and knowledge of radioactive source security to effectively implement 10 CFR 37. Those that need or desire additional education have discovered efficient opportunities available to them. Just as with the orders, there will be an opportunity for all to learn the different nuances between the initial orders and the new rule. All compliance issues will go through established Agreement State and USNRC enforcement procedures.

It is acknowledged that initially, regulators and licensees came to the orders with limited security real world/operational experience, but believe training, knowledge gained and partnerships formed while under the orders prepare everyone well for the implementation of 10 CFR 37. The orders and the new rule

are designed to motivate the integration of LLEA, by both regulators and licensees. LLEAs bring that real world security experience to the final safety culture product.

State resources for training would be an issue for most if the Agreement States had to pay for it themselves, but we are fortunate that the NRC has been funding training essential to the program for many years. NRC's security training prepares inspectors to determine if licensees are complying with the orders, and in the future with 10 CFR 37. It is possible to do health and safety inspections and security inspections at the same time, which would save money. However, RPS decided to separate these activities because the inspections are so different in terms of who the inspectors speak with and what they look for. RPS found that it could gain a better understanding of a licensee's security situation if its inspectors focused on the comprehensive security environment.

While it is the licensee's responsibility to develop and implement a compliant operational strategy, there are other resources available to assist them in this mission such as the Global Threat Reduction Initiative (GTRI). GTRI has performed a lot of security enhancements in N.C. It has increased the security for many irradiators. Wake Forest University, for example, has been very complimentary of the work that GTRI completed for them. It not only provided enhanced security devices, but also developed and implemented extensive tabletop exercises. Participants in these exercises included the FBI, the NC Radiation Protection Section, universities, state and local response organizations, and other public and private sector stakeholders at local, state and federal levels. This exercise led to the development of many improved relationships among the participants.

As part of their voluntary security enhancement program, GTRI also provides opportunities for private and public sector security force response training at their Oak Ridge facility. This training specifically enhances the coordination of a facility's radiation safety staff and their responding security force, including LLEA. With real world staged environments in which the "players" form response plans and act them out, the value of pre-arranged cross-discipline response plans is evident and strong partnerships are formed.

5. *Are licensees able to adjudicate personnel trustworthiness and reliability decisions effectively?*

Yes, but participants in the NRC-sponsored working group developing Part 37 had differing views on this question. Knowing that every licensee is different having dissimilar resources, it would be impractical for state or federal governments to develop T&R criteria that would be adequate in every case. Facilities know their business and their people best, and have the most to lose if they misjudge their people. Licensees are able to evaluate the whole person, such as if someone is a wonderful employee but had a less-than-perfect past record. The question becomes, Would a state or the NRC be able to weigh these and other factors?

(a) Would it be better to have NRC or another federal agency make T&R adjudications?

No. The regulatory posturing of Agreement State programs is to ensure regulated entities are responsible for implementing a safety culture that is in-step with the regulations. Shifting that responsibility to the USNRC or another federal agency would transfer that burden and undermine the foundation of responsibility.

6. *Should there be a design basis threat to guide licensees in determining what security measures should be implemented at each facility?*

While the new rule does not require the formulation and documentation of a formal design basis threat (DBT), the licensees would no doubt have to evaluate threats in order to comply with the rule's general security program requirements outlined in Part 37, Section 43. Implementation of these requirements will be evaluated during performance-based inspections by Agreement States and the USNRC.

7. *Has local law enforcement been cooperative in working out plans for responding to an alarm that someone has stolen radioactive material?*

N.C.'s experience has been that local law enforcement has generally been very cooperative in working out plans for responding to an alarm that someone has stolen radioactive material. Those that have established relationships and funding tied to homeland security through the Department of Homeland Security (DHS) have been most cooperative.

The Department of Homeland Security (DHS) has provided homeland security grants for many LLEAs. LLEAs receiving these grants are more sensitized to the issue and are more motivated to become involved in it. For example, the grants enable them to obtain equipment and training. These grants generally go to larger cities. Charlotte, for example, received a substantial amount of money to beef up its counterterrorism program, including an awareness of threats from radioactive materials. Smaller cities have required more attention from RPS to make them aware of such threats.

Prior to 9/11, RPS provided training to all N.C. Highway Patrol and other first responders with basic radioactive material awareness training. Post-9/11 DHS initiatives taken on by RPS include (1) Responding to and adjudicating scrap yard radiation alarm trips to ensure the removal and security of any source of radiation from the public waste stream; (2) Partnering with other state and federal agencies, such as Secret Service, FBI, EPA, etc for special "terrorist target" events such as the upcoming Democratic National Convention in Charlotte; (3) 24/7 availability to Border and Custom Patrol for adjudication of Border Radiation alarms and licensing verification issues; (4) Participation in the National Source Tracking System (NSTS); and (5) Maintaining a 24/7 statewide environmental radiation monitoring program.

It is expected that with the continuation of the many federally sponsored post-9/11 radiation response training opportunities, the law enforcement discipline will become increasingly aware and capable within the "radiation event" response arena. Programs such as the preventive radiological/nuclear detection equipment program operated by the Domestic Nuclear Detection Office of DHS, GTRI-hosted Security Force Response Training, and the National Guard Civil Support Team (CST) stand-up teams will provide consistent standardized awareness and response training which will further the overall intent of 10 CFR 37.

(a) Would local law enforcement give highest priority to such an alarm?

Local law enforcement priorities change from event to event. It would be impossible to indicate whether a radioactive material alarm would be given highest priority without knowing exactly what other response events may be happening at that moment. For example, it would be highly improbable that law enforcement would respond first to a radioactive material alarm over the twin towers being attacked. Each individual law enforcement agency would need to be queried to understand priorities.

That said, LLEA is absolutely much more aware of the need for radioactive material security post-9/11. LLEA, especially in cities containing licensees under increased security controls, understand the significance of theft of radioactive material, and understand that responding to such theft requires high

priority. For "radiation events" LLEA is becoming increasingly capable of local adjudication of threat based on appropriate assessment of the variables discovered at the scene.

8. *According to March 2012 testimony by GAO, "We also found that Agreement States lacked sufficient staff and adequate training to ensure the security of radiological sources, according to recent NRC reviews of two Agreement States' inspection programs." (http://www.gao.gov/assets/590/589345.pdf , p. 21) Do you agree or disagree?*

While the statement must have been made, N.C. has demonstrated that it has sufficient staff and adequate training to ensure the security of radiological sources. While more resources are always welcomed, N.C. is sensitive to doing more with less during these tough economic times.

RPS is self-supporting through fees; it receives no taxpayer funds. As a result, it is better positioned than most state agencies to withstand tough economic times due to having dedicated funds. At the same time, RPS has responded to the economic situation by becoming more efficient without jeopardizing effectiveness. RPS evaluated all of its processes and organization and found ways to build-in efficiencies while delivering greater services to its regulated community and the public. For example, RPS evolved from a centralized office to one with regionalized home-based inspectors. That change not only saved a large amount of money by avoiding the need for overnight travel, but also allowed RPS to respond more quickly to events and be more readily available to its licensees. N.C. volunteered to be a pilot state of LTS because RPS knew that that system would be more efficient and effective than its obsolete Access database. N.C. RPS could never afford to develop such a database on its own. A seemingly minor change, allowing licensees to pay license fees by credit card rather than by check, saves a large sum of money and resources given that the state regulates 10,270 facilities, ranging from irradiators to tanning salons. RPS is driving more of its requests to its website, which will include blogs and other social media, to reduce the number of calls it must handle, while also giving it the ability to push out more useful information quicker and to a greater audience. RPS is creating its own IT "cloud," driving IT efficiencies such as remote device access, allowing the use of less expensive dummy laptops and tablets[51] and all the while building in added security. These efficiencies have not come at the expense of losing valuable radioactive material inspectors. RPS has not reduced the number of personnel in its radioactive materials branch, but in fact shifted two people from environmental monitoring to this branch.

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Robert Gallaghar, Acting Director, Massachusetts Radiation Control Program, June 14, 2012

Massachusetts is an Agreement State. Its Radiation Control Program (RCP) describes itself as "the Massachusetts agency having exclusive authority and responsibility in the Commonwealth for protecting people from the harmful aspects of radiation, we meet this mission by implementing and enforcing regulations for the licensing, registration and inspection of radiation sources and their users; and, by maintaining technical expertise and assets for responding to the unique characteristics of radiological incidents in the Commonwealth." It has promulgated "numerous regulations and statutes in the area of

[51] According to Mr. Cox, "A dummy laptop or tablet is one that only has the capability of getting you to the cloud. There is no software installed on it. All applications are on the cloud. It makes for a cheaper 'gateway' device, because the laptop or tablet is basically a blank slate containing no software other than software allowing an interface to the internet and cloud. Basically when you connect to the cloud, you access your desktop there. It is also a much more secure device. If a laptop or tablet gets lost or stolen, there is no information on the device. All information is contained on the secure cloud servers. It is also a more efficient business process. If a laptop or tablet malfunctions or is lost or stolen, it just requires the replacement of the device, not reconfiguring and restoration of device software and data. All software and data is contained on the cloud."

ionizing radiation, information concerning radon, mammography, x-rays, emergency planning, environmental monitoring, radiological technologist licensing, radioactive materials licensing, low-level radioactive waste, and various other radiation issues."[52] Mr. Gallaghar has been the Acting Director of RCP for over two years, and previously worked with the NRC on working groups as the representative from the Organization of Agreement States on the development of security orders. He taught a security course at Sandia National Laboratories and was in a pilot course for training radiation security inspectors. He also represents the states in the Nuclear Sector Governmental Coordinating Council, a federal organization that brings together representatives of numerous federal agencies as well as agreement states to discuss nuclear and materials security issues.[53]

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I have no concerns with 10 CFR 37. NRC and the states worked on it, and NRC modified it so as to be acceptable to it and the states. It is important to have it as a rule rather than orders. My legal staff is of the opinion that it is easier to conduct enforcement of a rule than of an order. Specifically, the staff says, if a licensee violates a rule, the state is in a stronger position in a court case than if the licensee violates an order. While there are added costs, such as for staff time and resources, I feel that the benefits are worth the cost.

While GAO testified at the March 14, 2012, hearing before the Senate Homeland Security and Governmental Affairs Committee that NRC's Increased Controls order for medical facilities need to be tightened up, I disagree. GAO is looking at small pieces of an overall security program. Clearly, writing the combination to a door lock on the door frame is a violation, but that by itself doesn't provide access because NRC's security orders, and 10 CFR 37, provide security in depth, with multiple layers of security. Overall, the orders and rule do a good job of limiting access. I also disagree with the GAO statement that personnel in medical facilities need better training in security. Even before NRC issued the Increased Controls Order, I arranged a meeting with all Massachusetts licensees affected by the order to meet with NRC, LLEA, and FBI to discuss how to work together to improve security of radioactive sources. Some RSOs wanted a prescriptive order, but I told them that I didn't know the specifics of each facility, so they would need to develop a security system and RCP would then inspect it. If we found weaknesses in their system, we would not issue a violation notice but rather work with them to develop a corrective action plan. In practice, many RSOs would develop a plan, then call me to ask my opinion of the plan. Joseph Ring, Harvard University's RSO, had a security professional develop a plan. Harvard could afford to spend much more on security than could other organizations, but the latter often asked the Harvard Police Department for advice. In sum, I think the rule strikes the right balance between being prescriptive and being performance-based.

LLEA know a lot about security of radioactive sources and take it seriously. I work closely with the Boston Police Department. Their special operations group conducts security inspections of licensees in Boston, and whenever there is a movement of radioactive material, even inside a facility, the Boston Police Department requires armed officers to be present. At the state level, Massachusetts State Police take radiation security seriously as well. For example, in a recent movement of category 2 material from another state to Boston, Massachusetts State Police escorted the transport vehicle to Boston and Boston Police continued to guard the material until it was installed and the security systems were operational.

[52] Massachusetts. Executive Office of Health and Human Services. "Radiation Control Program." http://www.mass.gov/eohhs/gov/departments/dph/programs/radiation-control.html .

[53] For further information, see U.S. Department of Homeland Security. "More About SSA EMO and Sectors," section on the Nuclear Reactors, Materials, and Waste Sector, http://www.dhs.gov/xabout/structure/gc_1260478706680.shtm#nuclear.

I think that licensees are able to adjudicate trustworthiness and reliability (T&R). They have better knowledge of the individuals and see them every day. They can spot changes in a person, such as heavy drinking. In terms of what is required to do an adequate T&R adjudication, when we inspect we often find that licensees have done much more than is required. For example, Harvard has an outside security firm doing its background investigations. The firm has even been able to conduct investigations of foreign nationals, which is important for a university that has students and faculty from all over the world. The fact that many licensees have gone beyond the requirements of the ICO in adjudicating T&R is another example of the value of non-prescriptive regulations.

I don't think there has to be a design basis threat (DBT) for each facility. When people look at a facility to see how to harden it, they are in effect doing a DBT, as they are looking for vulnerabilities specific to each room. The Boston Police Department conducts security inspections of facilities. (Most of the radioactive sources requiring implementation of the ICO in Massachusetts are in Boston and Cambridge.) RCP inspectors also look for vulnerabilities; they prefer to do separate inspections for safety and for security because the two types of inspections are so different. In my experience, when an organization needs to design a security system, RSOs consult with security professionals. This approach guards against a plausible threat that is specific to each room or facility, rather than a DBT. This is a better approach.

Many LLEAs, not only in Boston and Cambridge, have been very cooperative in working out plans for responding to an alarm that someone has attempted unauthorized entry into a secured facility, and would give an alarm high priority. In many cases, alarms are linked directly to police headquarters to help determine an appropriate response. Police departments in Boston, Cambridge, and some other Massachusetts cities send all of their officers to Advanced Radiological Response Techniques training courses at the Y-12 National Security Complex in Tennessee.[54] This is not something that RCP mandates. I periodically retrain police officers and RCP inspectors. RCP also has a Nuclear Incident Advisory Team, and we all have equipment in our vehicles to assess radiological conditions anywhere in the state.

At the March 14 hearing, GAO testified, "We also found that Agreement States lacked sufficient staff and adequate training to ensure the security of radiological sources, according to recent NRC reviews of two Agreement States' inspection programs." This statement is probably based on IMPEP data. IMPEP is NRC's Integrated Materials Performance Evaluation Program to assess the licensing and inspection programs of Agreement States and states that fall directly under NRC's jurisdiction.[55] It would not be surprising if IMPEP found problems in two states because it goes to a very detailed level of scrutiny. I know this because of IMPEP reviews in my state and because I have participated in many IMPEP reviews of agreement states and NRC Regional offices. In Massachusetts, all RCP inspectors are trained, and I periodically test their knowledge of physical security and the increased controls by challenging them with hypothetical scenario questions.

[54] See Y-12 National Security Complex, Nuclear and Radiological Field Training Center, "Advanced Radiological Response Techniques (ARRT) Courses," http://www.y12.doe.gov/missions/complementarywork/nrftc/arrt_courses.php .

[55] For information on IMPEP, see Nuclear Regulatory Commission, Office of Federal & State Materials & Environmental Management Programs, "Integrated Materials Performance Evaluation Program (IMPEP) Toolbox," http://nrc-stp.ornl.gov/impeptools.html .

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Tony LaMastra, President, Health Physics Associates, Inc., May 24, 2012

"Health Physics Associates, Inc. is a professional radiation protection consulting company, started in January 1985 by Anthony LaMastra. Mr. LaMastra is a Certified Health Physicist (American Board of Health Physics) and serves as the company president. The company is licensed by the US Nuclear Regulatory Commission and the Pennsylvania Department of Environmental Protection to perform radiation related services for clients."[56]

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(1) 10 CFR 37 will be burdensome in terms of cost and what it requires. I am particularly concerned about security zones. Most of my clients are in industries, such as steel and petrochemicals, and use radioactive sources in the form of gauges, such as to measure thickness of steel or flow of chemicals. These gauges are small, typically less than 10 curies of cesium-137 chloride, though there may be one to five sources in a room or building. There are some locations where there are sources of 50 to 250 curies. (The Category 2 threshold for cesium-137 is 27 curies.) Unlike mobile gauges, someone trying to gain access to a fixed gauge would have a difficult time. In a steel mill, a gauge for measuring the thickness of a plate of steel would have radioactive material inside a housing, and the housing would be inside a steel frame to protect the gauge from damage. Stealing the material would take a lot of coordination with the plant. A crane would be needed to lift the source from the gauge, thereby requiring coordination with a crane operator. Additionally, the terrorists would have to damage the security cameras and coordinate with operators in the "pulpit," a glass-enclosed control room in which the operators watching the rolling process are located. The mill could not be in operation because the steel plates going through the gauge are 1200 to 1300 degrees F, and considerable time would be needed for the rolls that squeeze the plates down to the proper size to cool down. There are cameras in the mill room. If the gauge is off-line, it is locked in a steel building when not in use, with cameras linked to the plant security force. Workers would report an attempted attack on radioactive sources, and plant security would notify the LLEA in the event of an attack. While terrorists might be able to get into the plant and blow up a source in place, they would have a hard time getting it out. It should be kept in mind that any large scale explosion could also involve hazardous chemicals that could be more toxic than the dispersed radioactivity, even from a large source exceeding 27 curies. The security features already in place should be sufficient to keep people from gaining unauthorized access to the material. It seems excessive to require the licensee to set up a security zone, which is a barrier that absolutely prevents people from getting to that area. It is even more burdensome for licensees if the security zone extends well beyond the gauge itself.

(2) A related concern I have about 10 CFR 37 is that licensees have already complied with the Increased Controls order. It has taken some time and effort, but licensees have prepared plans, been inspected, made changes as necessary, and gotten into the whole program of doing what NRC wanted. To comply with the new rule, plans will have to be changed, and people covered by security orders will have to be retrained to the new terms. This will impose a financial burden on licensees, but without benefit. One of my clients is pulling his hair out because of the added burden. His feeling is that his organization has a good program, it has been inspected three or four times, and everything is up to snuff. Why change it? NRC should have simply codified the orders and then changed them as necessary.

(3) In 10 CFR 37, the balance between prescriptiveness and performance-based is reasonable.

[56] Health Physics Associates, Inc., "Introduction," http://www.radprotection.com/ .

(4) I would like more explanation of the rule, as it doesn't have sufficient guidance. NRC will probably put these explanations in their guidance, which will accompany the rule.

(5) Regarding T&R, many of the workers who use the gauges are electronics technicians. From my experience, they tend to be reasonable and honest. So far, my clients haven't had a problem in determining that they are T&R. A potential problem, one that hasn't happened yet, comes from the fact that steel mill jobs are union jobs. If an electronics technician retires and a slot opens up, almost anyone in the union can bid for the job. Even if that person isn't an electronics technician, he can go through the training program the plant offers and become an electronics technician. If someone with high seniority in the union wants the job, he can usually get it. Even if the person is not a good worker and management and the workers in that area don't want him in that job, it may be hard to keep him out unless he has a felony conviction as revealed by the FBI criminal records check.

(6) Yet another concern I have is that 10 CFR 37 requires limiting information on security to people with a need to know, but in practice information is often widely disseminated. At the steel mill, all 200 electronics technicians know that there is a storage room where spare devices are stored. Same story in a hospital, where most of the doctors and nurses know if their hospital has a gamma knife. Limiting information can be tough to implement in practice.

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Andrew Mauer, Senior Project Manager, Fuel & Materials Safety, Nuclear Energy Institute, May 23, 2012

NEI describes itself as "the policy organization of the nuclear energy and technologies industry and participates in both the national and global policy-making process. NEI's objective is to ensure the formation of policies that promote the beneficial uses of nuclear energy and technologies in the United States and around the world."[57] NEI addresses issues relating to all aspects of the nuclear fuel cycle, including radioactive materials and devices using such materials and commercial nuclear power plants.

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NEI had concerns about implementation of some provisions of NRC's draft 10 CFR 37, but NRC dropped some of the more controversial provisions in the final rule. Is the final rule too burdensome? NEI's view is that NRC should have codified the security orders, and then done a careful analysis of enhancements beyond the orders, including vulnerability assessments. The rule imposes burden beyond that of the existing orders. The current security orders include security requirements based on vulnerability assessments. NRC says it used lessons learned from implementing the security orders, but concedes that it had not done vulnerability assessments in preparing the rule. Without the assessments, the justification for the enhancements and inclusion of some categories of licensees is unclear. NRC's regulatory analysis with the final rule showed an average one-time cost of $23,375, and an average annual cost of $21,736, for each of the 1,400 or so licensees with category 1 or 2 sources. Most of these licensees are small business industrial radiographers, for whom these costs would be significant. Without a clear assessment of the benefits of the rule, it is not possible to evaluate whether the benefits are worth the cost. It is also unclear why some provisions were placed in the rule instead of in the guidance document or a best practices document as this practice of placing detailed prescriptive provisions in a rule is not consistent with a performance-based approach to regulating licensed activities.

[57] Nuclear Energy Institute, "About NEI," http://www.nei.org/aboutnei/.

The rule imposes compliance requirements but does not necessarily increase physical security. In addition, the rule covers some facilities that were not covered by the security orders, such as nuclear power reactors. These are among the most secure industrial facilities in the United States. What is the need for them to have added security measures for low level waste?

NRC provides training for both NRC and Agreement State inspectors. It would be helpful if the Federal Government could support security training for the radiological/nuclear industry. Videoconference workshops, for example, would provide significant benefit at low cost. There are also opportunities to provide examples/templates of policies and procedures. For example, if NRC supplied a template for writing a security plan to comply with §37.43(a), and writing implementing procedures to comply with §37.43(b), that would help ease the implementation burden of the final rule. It could still be done.

NRC issued security orders for panoramic and underwater irradiator licensees and for manufacturer and distributor licensees, and increased controls for other licensees. Each order provided separate requirements for each type of licensee. Licensees have been operating within the security orders. NRC merged the three sets of requirements and imposed this merged set on every licensee, including nuclear power plants and licensees operating other parts of the nuclear fuel cycle. As a result, the rule is quite complicated. It would have been better if NRC had codified the orders and made revisions later in a risk-informed manner, as necessary, based on objective vulnerability assessments.

Regarding trustworthiness and reliability (T&R), there is no unanimous position in the nuclear industry on who should adjudicate the decision, whether by licensees, the NRC or another government agency. It is worth having further discussion on this point. In response to the proposed rule, NEI suggested applying CDC's Select Agents Program, but NRC never engaged on that. The FBI criminal history record check for a T&R candidate goes through NRC to the licensee, and NRC would flag potential problems. However, NRC does not adjudicate T&R even for difficult cases, and it has not published criteria that would disqualify someone as T&R even though that would be helpful. At a minimum, NRC needs to provide clear guidance on T&R to its licensees.

One quirk in the T&R process is that the Energy Policy Act of 2005 amends the Atomic Energy Act of 1954, §149, to require personnel to undergo fingerprinting for a criminal history record check in order to be granted unescorted access to certain radioactive materials or to have access to certain safeguards information. Personnel who make T&R decisions, such as HR personnel, must be T&R, but they can only be judged T&R if they undergo fingerprinting and a background check, but that can only happen, according to the Energy Policy Act, if they are to be granted unescorted access to radioactive material or access to safeguards information. HR people do not need such access, yet NRC had to structure 10 CFR 37 (e.g. 37.27) around that provision. NRC has previously requested a change in the legislation to avoid this problem.

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Joseph Ring, Radiation Safety Officer, Harvard University, June 7, 2012

Dr. Ring has been with Harvard for 26 years, and has been its Radiation Safety Officer (RSO) for 10 years. As such, he is responsible for the safety and security of all of the university's radioactive sources and the 2,400 people who use them. He holds a Ph.D. in physics/radiological science. He responded to these questions in his current capacity and on behalf of the Health Physics Society.

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At first glance, 10 CFR 37 appeared to impose additional burdens compared to the Increased Controls Order. For example, it required security system reviews each quarter and a performance review every year. Despite the burden, at Harvard, the university police department mandated these periodic security system reviews two years ago. The university police has experts in security, security systems and a capable police force, so their judgment on security matters is well-respected in the local law enforcement authority (LLEA) community. The security reviews have proven to be of great value. These quarterly assessments proved useful for both myself as RSO, and the security force staff. For example, some users were having problems with the system but it was not clear why. In these assessments, a security specialist found the problem: the internet timing was off by a couple of milliseconds. Making fixes like this makes it easier for users to use the system. The security systems work very well now, in part due to the added requirements.

Weighing cost (in dollars and burden) vs. benefit for the rule is difficult due to the complex nature of the materials and risks. The vendor cost of doing a background investigation is $125 through a contract service, which is small in the scope of business costs where a piece of lab equipment can cost $50,000 or more. This compares to the extensive dollar costs and other consequences of a successful dirty bomb attack . Another difficulty of assessing cost-benefit is that there is no satisfactory metric: the probability of malevolent use is very low, but the potential consequences are very high. As a result, it is incumbent on RSOs to do something to mitigate the risk. On balance, Dr. Ring feels that the rule entails burdens but that they are reasonable and doable.

Dr. Ring feels it is better to have the provisions in a rule rather than as Orders. While NRC's various security orders include most of the provisions that are in 10 CFR 37, people don't like orders because they are orders, i.e., something nonnegotiable that people must do immediately. In contrast, regulations provide for input from stakeholders through an open and transparent, reviewable process.

Dr. Ring feels that the balance between the rule being prescriptive vs. performance-based has worked out well. Many stakeholders have lobbied NRC for more performance-based requirements in the rule, which is what NRC provided in this case. However, there is now complaint by some that they would like the rule to be more prescriptive. NRC and many other federal agencies have done an excellent job of providing detailed guidance on how to implement a rule in addition to the rule itself. NRC's draft guidance from 2010 for the draft of 10 CFR 37 provided a clear explanation of what the rule meant. As he understands it, NRC intends to publish supplemental guidance documents based on the experiences from the increased controls program to assist with implementation of the new rule. These guidance documents provide very useful information for licensees to successfully implement the regulation.

Dr. Ring feels that he does not have sufficient training to design and implement security enhancements by himself, but that that is an unreasonable expectation. He is not a security professional, a police officer, or a human resource specialist (HR), but he doesn't need to be. He knows how to effectively coordinate and find these people to use their expertise in these areas for enhanced security. Since NRC says that licensees must enhance the security of sources, and users say they need access to the sources, security professionals and other experts constitute a necessary business expense. Most businesses already have access to these types of professionals.

There is no need to have NRC, FBI, or another federal agency make T&R decisions. Dr. Ring asked his HR office if they felt they were capable of assessing the T&R status of people. They replied that is what HR specialists do and had no question about their ability to do the T&R. He noted that the background investigations for T&R are done by a private company for $125 per person. The company checks personal history, court records, criminal history, interviews references, etc., and gives a package with the resulting data to an HR officer at the university. The officer reviews all the pieces, and makes the final

adjudication. The Energy Policy Act of 2005 (P.L. 109-58), Section 652, amended the Atomic Energy Act of 1954 to require that persons granted unescorted access to radioactive material in quantities of concern be fingerprinted and subject to an FBI criminal history records check. Officials who make T&R decisions must also be fingerprinted and have a criminal history records check to ensure that they are T&R, but the only way that these officials can be subject to these requirements is if they are granted unescorted access to radioactive material in quantities of concern. HR personnel clearly do not need such access for their work. The university solves this dilemma by having HR people go through a background investigation so that they are qualified as T&R, but not issuing them key cards for access. The HR people felt that going through the T&R investigation themselves was worthwhile because it helped them undertand what T&R applicants go through. CDC has the Select Agent Program, in which the FBI adjudicates applicants who need to work with selected biological agents and toxins that might be used in bioterrorism, but people who have gone through the Select Agent Program and the university's T&R program say that the latter is faster and produces the same results.

The rule does not specify a design basis threat but NRC has clearly communicated what a security program needs to do, potential scenario and the timeframes in which a police response is required. He said that the NRC has included security assessments into the Increased Controls Orders and the new 10 CFR 37. Even without prescribing a DBT for materials licensees, Dr Ring believes that NRC has been crystal clear in what threats must be countered. Dr. Ring and others have met with the local FBI WMD coordinator, who also provided the same guidance and advice that recognized the differences in types of radiological systems. For example, a radiographic camera is mobile, but might have 35 curies of iridium-192, a modest amount, while a blood irradiator with several thousand curies of cesium-137, a large amount, is heavy and stationary. Dr. Ring does not see the need for additional guidance or a DBT.

Dr. Ring commented that the LLEA has been very responsive to the need to secure radioactive material. This applies to small towns as well as metro areas. Dr. Ring does not need more cooperation from LLEA in the Boston area because they have done everything he has asked them to and developed a strong working relation. When working with the LLEAs, he found the officers do not need to know additional details of radiation; instead, their mantra is: Tell me what I need to know, what I need to watch out for, and what I need to do. They understand potential consequences of a theft of this type of radioactive material. For example, Dr. Ring has trained the entire Harvard University Police Department, Boston Police Department's (BPD) command staff, and an additional 200+ BPD officers and Boston Emergency Medical Services personnel in radiation protection issues and radioactive materials security.

Regarding differences between Agreement States and states regulated directly by NRC, Dr. Ring feels that the Massachusetts Agreement State program well understands the increased controls program. The head of that program is very involved, has the necessary skills. Dr. Ring has no experience with other Agreement State programs. In contrast, he feels that NRC has been "fantastic." He noted that NRC has strong technically capable staff, create requirements based on a comprehensive review and technically sound criteria, and clearly communicate/craft the regulations. While he may not always agree with their selection, he says they have done very well and he is able to support their position.

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Alice Rogers, Radiation Inspections Branch Manager, Texas Department of State Health Services (DSHS), May 29, 2012

Ms. Rogers is in charge of 55 radiation inspectors and other radiation control professionals for Texas. These inspectors inspect radioactive materials, x-ray equipment, mammography equipment, and lasers. Her Branch would also handle response to a nuclear emergency. Texas has about 1,900 licensees for

possessing nuclear material. It has 468 sites licensed for one or more category 1 or 2 sources. It has 2,500 radiographers. Ms. Rogers was the Chair of the Conference of Radiation Control Program Directors (CRCPD) for two years, and is currently the Past Chair.

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Ms. Rogers has no concerns left about the new rule, 10 CFR 37. CRCPD had serious concerns on the draft rule but the concerns have been removed. For example, NRC removed the requirement to check credit history as part of T&R; CRCPD felt that credit checks do not give good information and that other tools were sufficient. The regulatory burden for Texas under the new rule will be about the same as in the last few years under the various NRC security orders. Texas will have to write new rules but that is not a big burden. As a result, the cost vs. benefit of the new rule as compared to the orders is a wash.

NRC's intent in writing the new rule was to put into the rule what the orders said, but it grew from that. It's easy for working groups like the ones working on the rule to experience scope creep, such as adding credit checks. NRC did a good job in pulling back from scope creep.

Regarding prescriptive vs. performance-based rules, Ms. Rogers has been in regulatory programs for 30 years, and prefers performance-based rules because they focus on goals rather than a checklist and records. The key is to observe people to see how they are doing their work day to day.

The tone and content of the March 14, 2012, hearing before the Senate Homeland Security and Governmental Affairs Committee was that NNSA is good and NRC is bad, but in reality they are complementary. NNSA has done a lot, including two tabletop exercises in Texas. These have been eye-openers to emergency responders. They raised elements that the responders hadn't considered. For example, if it became necessary to evacuate 300,000 people from Houston because of a dirty bomb, where would they go? How would health workers treat them, given that emergency rooms would be flooded with people? The exercise helped the City of Houston learn what other assets were available to them in the event that they needed additional resources. Another exercise, at Texas A&M, had a scenario with a two-pronged terrorist attack that stole a radioactive source and raided a reactor. This exercise gave an excellent opportunity to work through the issues and provided many lessons.

Exercises, though, are only part of securing radioactive material. Ms. Rogers's inspectors look at safety and security. Initially, some licensees had done nothing in response to the new security requirements. The goal of inspectors in Texas is to help licensees get into compliance or out of business. After the first couple of inspections, licensees understood the need for security. Most licensees are compliant now. So, the regulations plus inspections have increased security awareness.

As to knowledge of security, none of Texas' radioactive materials inspectors had expertise in security when the security requirements of the orders went into effect. But they have all been to NRC's Increased Controls course.

Regarding T&R, Ms. Rogers was on the Fingerprinting Working Group with NRC. (Fingerprinting also includes a criminal records check by the FBI.) A huge topic of discussion was the criteria to use in judging T&R issues. It's very difficult to say that a particular crime makes a person untrustworthy forever. The licensees asked NRC to provide T&R criteria. They asked over and over again, including for examples, but NRC wouldn't do it, though it's not clear as to why. At this point, however, licensees have so much experience in adjudicating T&R that there would not be much value added if NRC provided criteria. Ms. Rogers does not think that people need a security clearance to be declared T&R.

Regarding a design basis threat, Texas licensees are so diverse that it would be difficult to have a single DBT. There would have to be a number of different ones.

In the beginning, LLEA was not so cooperative in coordinating security plans with licensees; this was a common violation. Often, they were not interested. But as LLEA awareness of radioactive threats increased and as regulators tried to help licensees contact the right people in law enforcement, LLEA now "gets it" and wants to know if there is radioactive material in their jurisdictions. Ms. Rogers can't say what priority LLEA would give to a radiological incident. But there are other problems. A radiography camera with 33.8 curies of iridium-192 was stolen from a truck on July 19, 2011. The licensee notified LLEA, which sent investigators, and Texas reported the incident to NRC's operations center, but it took the FBI a week to figure out that they needed to investigate. Once the FBI understood the issue, they began investigating the case. Texas continued its search for the camera including flyovers by the DOE and search assistance from the 6th Civil Support Team. The FBI has discussed wanting to do a memorandum of understanding with Texas DSHS so that there would be better communication.

Texas has sufficient staff and adequate training to conduct inspections, and uses procedures that NRC reviews. The NRC program with Agreement States is called Integrated Materials Performance Evaluation Program, or IMPEP, which does a performance-based audit of Agreement States. The last one for Texas was in 2010. IMPEP looks at technical staffing and training, the status of the inspection program (frequency), the technical quality of the inspections (from reviewing the inspection reports, and observing inspectors), etc. IMPEP inspectors accompanied Texas inspectors on inspections to observe the inspections in detail, such as asking licensees to show how they do their jobs (the goal being to observe if they're actually using the radiation protection procedures they're supposed to) and where the login/logout sheet was, and conducting physical inspections.

The technical quality of Texas's licensing actions is high. When a would-be licensee submits an application for a license, Texas DSHS staff reviews the adequacy of the application and imposes conditions if necessary. For example, if the licensee submits an operating plan for a facility, the office directs that, as a condition of the license, the licensee must operate its facility according to the plan, otherwise it's a violation of the license. Ms. Rogers provided CRS with NRC's report on its most recent IMPEP review of the Texas program; CRS will forward it to the committee.

IMPEP also looked at the Texas enabling statutes and rules to assure compatibility with those of NRC. 10 CFR 37 requires Agreement States to come into compliance with the new rule three years after it is published in the Federal Register. The Texas rulemaking process takes at least a year. Texas has its version of the federal Administrative Procedures Act. DSHS seeks additional input before publishing a rule in the Texas Register (analogous to the Federal Register). There is input from licensees, the public, advisory boards, the Commissioner of Health and Human Services; this all takes time. Some states must change statutes when they adopt a new rule, and most state legislatures meet every other year. NRC's orders continue to apply until an Agreement State adopts its own rules. (Texas calls its Agreement State orders "license conditions.") Thus a three-year delay is not unreasonable and does not increase the risk to the public health and safety.

When NRC does an IMPEP review, it may find that some states are understaffed and do not have enough training. NRC can find a state inadequate for protecting public health and safety, and can put that state on "heightened oversight." A few years ago, Texas was put on heightened oversight, after which more resources were devoted to the radiation control program and Texas showed sufficient improvement to be taken off heightened oversight. The Texas radiation protection budget was cut approximately 20 percent for the 2011-12 biennium. In order to make sure the radioactive materials program has enough staff, resources are being shifted to ensure adequate support for radioactive materials.

A recent GAO report stated that the RSO at a university hospital—the report did not indicate which state it was in, but it was in Texas—"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." But this misstates the situation. The hospital, M.D. Anderson, is a large research and teaching facility. It has over 450 labs and has many large radioactive sources—13 irradiators, a gamma knife, and a cobalt-60 source. Access to each of these sources has an iris scanner, limiting access to each irradiator to people who need to use it. Texas conducted an inspection in April 2012 for compliance with the Increased Controls requirements, and did two others previously, and found no violations of the requirements. GAO found that people at that hospital have access limited to the facility they need.

Also regarding GAO, that agency interviewed radiation control program directors and accompanied inspectors. Many questions asked by GAO centered on NNSA's program. Answers provided by Texas stressed that NNSA's Global Threat Reduction Initiative would benefit from added funding. None of the answers provided by Texas were intended to imply that the NRC security efforts were lacking.

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Cheryl Rogers, Chair, Organization of Agreement States (OAS), and Radioactive Materials Program Supervisor, Wisconsin Department of Health Services, May 25 and June 8, 2012

There are 37 Agreement States in the United States. Each has entered into an agreement with NRC pursuant to Section 274 of the Atomic Energy Act of 1954 (42 USC 2021), as amended. Under this agreement, the state is responsible for regulating licensees within the state that possess many types of radioactive materials. The state's regulations and other processes must be "adequate to protect the public health and safety" and "compatible with the [Nuclear Regulatory] Commission's program for regulation of such materials." OAS is a professional society; its members are radiation control directors and staff from the Agreement States who are responsible for implementing their Agreement State programs. "The purpose of the OAS is to provide a mechanism for these Agreement States to work with each other and with [NRC] on regulatory issues associated with their respective agreements."[58] All told, the Agreement States regulate 85 percent of radioactive material licensees. In her work for Wisconsin, Ms. Rogers supervises the state's Agreement State program. She is in charge of licensing, and inspection of licensees, excepting nuclear power plants and federal facilities such as the VA Hospitals. Wisconsin has 330 licensees, of which 27 have category 1 or 2 materials in quantities of concern.

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10 CFR 37 has followed a different rulemaking procedure than typical regulations. NRC issues most regulations without having issued similar orders previously. It makes a draft rule, then seeks comments. NRC issued the Increased Controls Order (ICO) in 2005. The Agreement States, not NRC, are the regulators for their states. The Agreement States put the same requirements as the ICO, using the same language, on their licensees, generally through imposing licensing conditions. They implemented these requirements a few months after NRC issued the order. As a result, Wisconsin and the other Agreement States have lived with the requirements of the ICO for some years. I'd say they have been living with 85 percent of part 37. This has made for an easier transition from order to rule. This model has worked out well for Agreement States, all of which have now had experience with implementation. If the rule had

[58] Organization of Agreement States, "About OAS," http://www.agreementstates.org/page/about-oas.

been issued five years ago, implementing it might have been too burdensome, but given our experience in implementing the ICO that is not the case.

We worked closely with NRC to develop the rule. We were co-regulators and had a good partnership with NRC. For example, we were involved in developing parts of the rule concerning fingerprinting and reviewing officials. We feel that the ICO and the rule provide reasonable assurance—not certainty—about the security of radioactive material. We are quite satisfied with the rule, and were able to get our input in; it was an excellent experiment in rulemaking. We feel that the rule is pretty clear.

There are some differences between the ICO and the rule. Under the order, people who were deemed trustworthy and reliable (T&R) were approved indefinitely, while under the rule they must be approved every 10 years. The rule requires training every year, which is a good thing. The rule establishes security zones, which are not in the ICO and are confusing to the Agreement States as to where a zone must be established. Licensees will have to learn about establishing these zones. The rule imposes requirements on maintaining equipment, which is a good thing. The rule has a few enhancements, but is basically not much different than the order. The rule adds a slight burden, but not much. Regarding cost vs. benefit, the rule does not add much cost. There are benefits in shoring up the ICO and closing a few gaps, but benefits are hard to quantify because there has been no issue of malevolent use of radioactive material in the United States.

We would have preferred to have NRC review the credentials of the reviewing official, the person at each licensee who is responsible for reviewing the results of personnel investigations and deciding whether or not individuals should be granted T&R status.

At a hearing of the Senate Homeland Security and Governmental Affairs Committee on March 14, 2012, the following exchange occurred between Senator Daniel Akaka and Ann Harrington, Deputy Administrator for Defense Nuclear Nonproliferation, National Nuclear Security Administration:

> Senator Akaka: Are you aware of any actual incidents of potential theft or sabotage of radiological sources in the U.S. medical facilities in the last several years?
>
> Deputy Administrator Harrington: There are some examples but they would not be something that I could discuss here.

This statement is not true. There has been no potential sabotage, and no actual sabotage, either. We have a continuous cycle of inspections. Egregious security gaps are not there.

[Subsequently, NRC provided the following statement to CRS:

"NRC Staff reviewed records contained in the Nuclear Materials Events Database (NMED) going back 4 years and found that there have been no incidents of theft or sabotage of risk significant (IAEA category 1 and 2) radiological sources at US medical facilities. The record review was then expanded to include IAEA category 3 sources, and again no incidents of theft or sabotage were found."[59]]

OAS likes the performance-based approach. Now that licensees have implemented ICO and gotten input from local law enforcement agencies (LLEAs), they have shored things up and have improved security within ICO. It's fine if NNSA wants to go beyond ICO to harden facilities with the Global Threat Reduction Initiative program.

[59] Nuclear Regulatory Commission, "Questions from Jonathan Medalia," June 14, 2012.

We have a three-legged defense against malevolent use of radioactive material: ensuring personnel trustworthiness and reliability; having licensees assess and detect an incident and notify LLEA; and having LLEA respond. LLEAs have usually been cooperative in setting up a response ahead of time, but sometimes NRC or the state regulator must make contact with an LLEA. As to the priority LLEAs are to give to a potential threat of radioactive material, Agreement States and NRC expect LLEAs to show up [very quickly].

Regarding T&R, there are two main types of licensees, medical facilities and industrial radiographers. Medical facilities necessarily have a thorough process of vetting people if for no other reason than liability issues that could arise, for example, if they hired a pedophile. Industrial radiographers use radioactive sources out in the field, where they are more vulnerable. In my state, once ICO went into effect, some industrial radiography companies lost a few staff members who did not qualify as T&R. On the other hand, a licensee had an employee with a good record but who had some trouble awhile ago. The licensee weighed these factors and decided to grant this person T&R status. I think that licensees can adjudicate T&R decisions. They know the people they work with. I would have preferred to have NRC doing the adjudication, but having licensees do it is satisfactory.

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Kate Roughan, Director, Regulatory Affairs and Quality Assurance, QA Global, Inc., Burlington, MA, June 1, 2012

QSA Global is a manufacturer and distributor of radioactive sources and devices. It obtains radioactive materials, such as iridium-192, americium-beryllium, and cobalt-60, from Russia, Netherlands, and Poland, and encapsulates them into sealed sources for such uses as oil well logging, industrial radiography and medical brachytherapy. As Director of Regulatory Affairs and QA, Ms. Roughan has had extensive experience with implementing the various NRC security orders and has looked in detail at 10 CFR 37.

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10 CFR 37 has a large impact on QSA Global. The company receives amounts of radioactive material exceeding the category 1 threshold two or three times a month. They also receive, manufacture and ship thousands of category 2 sources a year. As a manufacturer and distributor (M&D), the company had to comply with seven NRC orders, such as the M&D, fingerprinting, SGI-M,[60] transportation security, and Increased Controls. Ms. Roughan is glad that NRC is putting these orders into a rule but noted that NRC added many things to part 37 as compared to the orders. These things impose a large administrative burden. NRC estimates the cost of implementing the rule at $500 million, but the benefit is not clear and

[60] SGI-M, or Safeguards Information—Modified Handling, was issued as part of an NRC order, "In the Matter of All Licensees Authorized To Manufacture or Initially Transfer Items Containing Radioactive Material for Sale or Distribution and Possess Certain Radioactive Material of Concern and All Other Persons Who Obtain Safeguards Information Described Herein; Order Issued on November 25, 2003 Imposing Requirements for the Protection of Certain Safeguards Information (Effective Immediately)" (69 FR 3397, January 23, 2004). According to the order, "Information and material that the U.S. Nuclear Regulatory Commission (NRC) determines are safeguards information must be protected from unauthorized disclosure. In order to distinguish information needing modified protection requirements from the safeguards information for reactors and fuel cycle facilities that require a higher level of protection, the term ''Safeguards Information-Modified Handling'' (SGI–M) is being used as the distinguishing marking for certain materials licensees. Each person who produces, receives, or acquires SGI–M shall ensure that it is protected against unauthorized disclosure." See also U.S. Nuclear Regulatory Commission, "Modified Handling Requirements for the Protection of Certain Safeguards Information (SGI-M) General Requirement," no date, http://pbadupws.nrc.gov/docs/ML0911/ML091120156.pdf.

the threat is not proven. One example of the burden is a requirement to do a weekly check of all sealed radioactive sources. This may be workable for a company with a few dozen sources, but QSA Global has thousands of sources. It would be impossible to check them all each week, and someone doing the checking would receive too much radiation exposure.

NRC did not give adequate guidance on T&R, and imposes some real burdens. As part of the documentation for background checks, prospective employees must provide references, but employers must actively seek out people who are not included in the list of references. This can be quite difficult. Another concern is that it is difficult to make T&R assessments. NRC did not even provide guidelines on what factors should lead to rejecting someone as T&R. The rule poses a dilemma. A company may incur liability if it denies someone a job based on a judgment that the person is not T&R, but it may also incur liability if a person who the company deems T&R steals radioactive material and makes a dirty bomb. More guidance on when not to adjudicate someone as T&R would be helpful. It also seems arbitrary that an employee moving to another company can have his or her background investigation data transferred to the new employer, but not the first company's adjudication of the person as T&R.

Having all the security requirements in a new rule entails difficulties. NRC's orders were based on the type of licensee, such as for a panoramic irradiator or a manufacturer and distributor. The rule, in contrast, is one size fits all. This puts extra work on smaller companies. There is a large administrative burden to carry out the rule, such as documenting the security program, having an annual assessment of the security program, and some of the training requirements for the security program. There are some onerous requirements for the shipment notifications requiring followup on each shipment and notifications if shipment is not where expected. To do this for more than 50 sources a day is a 24/7 job for one individual. But these administrative tasks provide no tangible security benefits. Under the orders, document requirements were less stringent: licensees would implement but not document.

On the issue of whether the rule should be more performance-based or prescriptive, NRC has a set of documents (NUREG 1556) that tell a prospective licensee in detail what a safety program should look like and they are issued specifically for the different types of licensees. It would be useful if NRC did something similar for the security requirements for the different types of licenses. This would allow NRC to have some of the basic security requirements in a rule and then have different subsections for the different licensees, such as was in the orders. This will make it clear that the NRC will allow for different levels of detail in how licensees implement the new rule, fitting the level of the program to the level of risk for that particular type of license.

RSOs and other radiation professionals did not have adequate training in security when the orders were implemented. RSOs are trained in safety and had to learn a new way to view practices. NRC should have provided more training on the orders and should provide training including many more workshops when they implement Part 37. GTRI has a different mindset on security as that is their expertise. When GTRI staff came to QSA Global, they presented many new and useful ideas as they were trained and experienced in security issues.

Should NRC have promulgated a design basis threat (DBT) in the rule? In theory, a DBT would help licensees determine if they were doing enough for security by indicating what they were supposed to guard against. But NRC hasn't indicated what the risks are, and there is no DBT for any other type of license except the reactors. There should be some type of risk analysis for the different licenses and this be communicated to the licensees, sort of a limited DBT, as a full DBT seems excessive for NRC or Agreement State licensees. Ms. Roughan noted a disparity in regulation. The nuclear industry is very heavily regulated, while other industries that pose significant health and safety risks are much less

stringently regulated. For example, tanker trucks carrying large quantities of dangerous chemicals can go through large cities.

QSA Global has a facility in Burlington, MA. LLEA can respond in [a short time] if need be. They understand the significance of a threat to the plant, or theft of radioactive materials from it, and have assigned a very high priority to such events. Ms. Roughan understands that LLEA in other jurisdictions is less responsive.

Massachusetts is an Agreement State. This provides a huge benefit to QSA Global as the Agreement State personnel have undergone the NRC training so that the state is responsible for the security inspections, not NRC. They also maintain a lot of contacts in Massachusetts that are also connected with security, such as the FBI and Immigration and Customs Enforcement, that we have met with and they are now familiar with our operations and potential security risk.

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Jared Thompson, Radioactive Materials Program, Arkansas Department of Health, and Agreement State Director for Arkansas, May 30, 2012

Note: Mr. Thompson's views are his own and do not represent the opinion of the Arkansas Department of Health.

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Mr. Thompson served on the NRC's rulemaking working group for 10 CFR 37 as a representative of the Conference of Radiation Control Program Directors. Compared to the orders, the final rule is much more prescriptive. In his opinion, it is a one size fits all set of regulations. The orders were issued incrementally to licensees needing different levels of security, such as panoramic irradiators, manufacturers and distributors of radioactive sources, and other organizations such as hospitals. The rule mandates that all licensees have the same high level of security; that may not be necessary. Security should have been tailored to users, as the orders were. For example, a licensee with a half-dozen employees using soil moisture and density gauges, which have millicuries of radioactive material, do not need the same level of security as a panoramic irradiator, which may have hundreds of thousands of curies. NRC should have modified the orders, then codified them. The state members of the rulemaking working group kept asking NRC if there was some particular threat, and if so, shouldn't they tailor the rule to the threat and the users. NRC did not provide an answer. As a result, the rule has overkill in terms of the level of security. The orders were put in place between 2003 and 2007, and security of radioactive sources in the United States has been extremely high since then. There has been only one theft of a source with a modest amount of radioactive material, a radiography camera that was stolen from a truck in Texas in 2011. This incident was not terrorist-related, as it did not result in the release of radioactive material to the public. It is therefore unclear why NRC's intense need for enhanced security came about.

Continuing the point about the rule being much too prescriptive, hospitals are not an environment where security is high on their agenda. NRC must realize the characteristics of their audiences. It is not possible to make hospitals security experts. They need more guidance in this matter. The guidance needs to be better than it was with the orders. For example, personnel are in labs with blood irradiators often around the clock, so security is already high there; the greatest security concern is a radioactive source that is used every few months or less and is not constantly monitored.

Radiation Safety Officers (RSOs) and inspectors from NRC and Agreement States have training for health and safety, and less for security. Inspectors have always looked at security a little. Since 9/11 and the NRC orders, inspectors have learned much more about security. NRC has a security training course for inspectors; all of Mr. Thompson's inspectors have taken the course. The inspectors get enough security information to do their jobs. They can evaluate whether something is protected and can enforce NRC's security orders, and hopefully Part 37 as well. They do not need to know technical details; for example, they can check to see if an alarm system is working even if they don't know how it works.

Licensees are the ones best positioned to adjudicate trustworthiness and reliability (T&R). They work with their employees and know them well, so they can evaluate their character more easily and accurately than someone in Little Rock or Washington. The determination of T&R should be made by people who know the individual and not have the T&R determined based on review of fingerprint results only by regulators. The ability of licensees to judge T&R is critical, and particularly so for small companies. They realize they have only a few people and understand that a single T&R misjudgment could cause a major problem for their company, if not the end of it. Smaller companies appear to be at least as careful as large ones, and want to make sure everything is in order regarding T&R.

A Design Basis Threat (DBT) is easy to construct for a nuclear power plant. There could be a DBT for a panoramic irradiator (with perhaps hundreds of thousands of curies) or for manufacturers and distributors of radioactive material, but it's not plausible to apply a DBT to other radioactive sources. Licensees having few employees and modest amounts of radioactive material could not handle a DBT. Terrorists could seize such sources, or mobile sources. But they could also attack tanker trucks carrying chlorine or gasoline, many of which are on the roads; should there be a DBT for them, too?

Mobile industrial radiography sources can have, for example, 120 curies of iridium-192 or 330 curies of cobalt-60. These sources are self-shielded cameras. (Self-shielded means that the device itself has enough shielding, such as a thick layer of lead, to protect users.) The trucks that carry them are alarmed and have two barriers against being driven off. NRC and Arkansas have stringent guidelines to protect them.

Local law enforcement agencies (LLEAs) are cooperative up to a limit. They want to cooperate but don't want to be pinned down to certain requirements, such as responding within [a specified time]. NRC would like the theft of a radioactive source to be high on the LLEA priority list, but that probably won't happen. Some state troopers cover several hundred miles on their routes. If an event happens at one end of their route, it's unrealistic to expect them to drop everything and rush to the other end in [a specified time]. LLEA is committed to assisting if feasible, but if there's a bank robbery or other emergency situation, should they disregard it to respond to a radiological event? They need to make a choice. As a regulator, neither the NRC nor the Agreement States have any control over LLEA. Licensees also have no control. They try to get LLEA to participate, and document their efforts to do so.

A GAO report of March 2012 said, "We also found that Agreement States lacked sufficient staff and adequate training to ensure the security of radiological sources, according to recent NRC reviews of two Agreement States' inspection programs." Mr. Thompson was surprised by this statement, and feels that Arkansas has a sufficient number of staff to do the necessary inspections. "Sufficient" depends on the number of licensees. The state has 21 licensees affected by the rule (that is, with one or more category 1 or category 2 sources) and 5 inspectors. While Arkansas has 220 licensees in total, only the 21 require security inspections. Without evaluating the staffing and licenses of all 37 Agreement States, this statement is erroneous. Individual states may have issues but in general the Agreement States are aggressive and active in security efforts.

The Global Threat Reduction Initiative has been in Arkansas a half-dozen times. They will install security systems for one of the state's larger licensees this summer. The program opens the eyes of licensees to security, and provides good training not only for the licensee, but also for the state inspectors who sit in on the training.

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A Radiation Safety Officer and Certified Health Physicist at a company that transports radioactive material, June 25, 2012

These comments pertain mainly to 10 CFR 37, Subpart D, "Physical Protection in Transit."

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The company uses various networks, such as the Nuclear Energy Institute, to keep on top of transportation regulations and changes to them. Agreement States have three years to implement the requirements of 10 CFR 37, while licensees located in states regulated by the NRC must come into compliance within one year of issuance of the final rule. Some differences between the Part 37 rule and the RAMQC Order (EA-05-006) [61] may complicate compliance during the implementation period if some Agreement States have adopted the Part 37 rule while others are operating under the Order.

It seems more appropriate for Subpart D of Part 37 to be in Title 49 - Transportation of the U.S. Code instead of Title 10. While there is a memorandum of understanding (MOU) between NRC and the Department of Transportation (DOT) on regulating radioactive materials in transit, it is not clear as to why the regulation of category 1 and 2 quantities of radioactive materials in transit would fall under the NRC's jurisdiction given the language of the Section IIA MOU.[62]

It is important to note that the Agreement States will have some flexibility in how they implement the Part 37 requirements. This flexibility may result in Agreement State implementation of Part 37 Subpart D regulations in a manner that would otherwise result in preemption if the regulations were contained in Title 49. For example, in the early 1990's the State of Washington attempted to establish highway routing restrictions for radioactive materials that limited the locations that trucks hauling radioactive material could enter the State. This regulation was preempted by the DOT under the dual compliance and obstacle tests, reference 58 FR 31580. My concern is that given the pre-planning and coordination requirements

[61] NRC issued an order (EA-05-006) imposing requirements on transportation of radioactive material quantities of concern (RAMQC) on July 19, 2005; the order itself was not released to the public because it contained security-sensitive information. See U.S. Nuclear Regulatory Commission. Letter from Jack R. Strosnider, Director, Office of Nuclear Material Safety and Safeguards, to Holders of Material Licenses Authorized to Possess and Transfer Items Containing Radioactive Material Quantities of Concern as listed in Attachment A to Enclosure 1, Subject: Issuance of Order for Additional Security Measures on the Transportation of Radioactive Material Quantities of Concern, December 16, 2005, http://pbadupws.nrc.gov/docs/ML0533/ML053350222.pdf.

[62] "The DOT will adopt regulations imposing on shippers and carriers subject to its jurisdiction those standards developed by the DOT and the NRC pursuant to Section I of this Memorandum of Understanding and any additional requirements necessary to protect the public health and safety. The DOT will require NRC approval of designs of packages for shipment of fissile materials and other radioactive materials in quantities exceeding Type A limits (except LSA [low specific activity] materials) by all persons subject to the jurisdiction of the DOT. The DOT will issue complete and comprehensive Federal regulations for the packaging and transportation of all radioactive materials as a part of its overall body of Federal regulations (49 CFR Parts 100-199) for the packaging and transportation of all hazardous materials." U.S. Nuclear Regulatory Commission. "MOU Between the NRC and DOT," 44 FR 38690 (July 2, 1979), available at http://www.nrc.gov/about-nrc/regulatory/enforcement/moudot.pdf.

contained in Part 37 Subpart D, an Agreement State could effectively restrict the routing of radioactive materials through the State. Another concern is that states may charge unreasonable fees for transporting category 1 and category 2 materials through the state; in these cases the NRC could not challenge the fees, but the DOT could. Differences in escorting and vehicle inspections requirements could also place undue burdens on the shippers and carriers of category 1 and 2 quantities of materials. Generally speaking, when transportation requirements are set by many regulators and by federal interstate commerce rules as well, compliance with transportation regulations can become very complicated.

Subpart D does not add burdens beyond the existing NRC orders. There are minor things, such as updating the transportation security plan, and developing procedures to ensure compliance with the regulation but these are administrative activities that we do not consider burdensome because the Part 37 requirements for route notifications, estimation of when a shipment is going to cross state borders, delivery time, revised delivery time if there are changes, and so on are already in the RAMQC order.

The RAMQC order and the new Part 37 Rule permit the use of common carriers, but compliance with the current Order and Part 37 is the responsibility of the licensee and not the carrier. If the carrier did not comply with the Order, the shippers—not the carriers—were the ones in violation of NRC's orders. The carriers faced no penalty except the loss of business

Section 37.71 requires the shipper to confirm that a recipient of category 1 and 2 radioactive material has a license, using the license verification system. However, that system is not operational yet. For new customers, we must verify with the recipient's licensing authority. This should be straightforward for licensees linked into the Council of Radiation Control Program Directors, which issues an annual directory of State points of contact. It is simple to go to these lists and send an email to the licensing authority to obtain authorization. §37.71(c) provides an alternative method for obtaining permission in an emergency situation, but I don't know when that would arise. We haven't had that happen. We typically plan category 1 shipments months in advance; sufficient advanced planning is associated with category 2 shipments as well. We don't transport highway route control quantity shipments.[63]

Section 37.79(b) provides for security of transportation of category 1 and 2 radioactive material by rail, but I don't know of any instances where such material is transported by rail.

Section 37.75 of the rule provides for safe havens, but doesn't provide a list of safe havens. It is up to us to identify safe havens. We identify truck stops along the routes. They are not as safe as, say, a police barrack, but they are not deserted and are well lit.

Domestic shipments are straightforward, going from point A to point B. Imports and exports by air are also straightforward because Part 37 applies to the domestic portion of the highway (or rail) shipment, so once we deliver the shipment to the airport we are relieved of the transportation security burden. As a result, we use FedEx for exports as much as possible and deliver the source directly to the carrier at an airport. Imports and exports by sea are much more difficult because we have to coordinate the arrival or departure of our shipment with the arrival or departure of a ship. This is difficult because ships may encounter delays enroute and marine terminals are reluctant to authorize early access of cargo containing radioactive materials until the ship has called into port. Delays as long as 48 hours have been encountered, requiring the truck to remain at a truck stop while the drivers maintained constant

[63] This term is defined in 49 CFR 173.403, http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=23d0d2b1bc9e2cb244c6792146564158&rgn=div5&view=text&node=49:2.1.1.3.9&idno=49#49:2.1.1.3.9.9.25.2. A highway route control quantity is a large quantity of radioactive material.

surveillance. If delivery of the cargo to the port had been authorized, compliance with the NRC order would have been met, and the port would have been much more secure than the truck stop. The licensee importing category 1 and 2 sources is responsible for complying with Part 37.

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A Radiation Safety Officer at a large university that has multiple radioactive sources, May 18, 2012

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NRC says that security of radioactive material was adequate before 9/11, but it issued orders post-9/11. Everyone scrambled to implement the orders. Now, NRC says the orders are adequate but it is issuing the new rule in part because it prefers to implement policy through rules rather than orders. The final rule makes it easier for NRC or Agreement State inspectors to inspect facilities, and to cite them for noncompliance. Unfortunately, at many institutions I've spoken with, the money estimated to implement the new rule is woefully inadequate.

10 CFR 37 is very administratively driven. There are a great many administrative requirements, such as for record-keeping, written security plans, and a requirement for annual reviews of these plans. Some of these are excessive, but we agree with other parts of 10 CFR 37, such as the need to verify that systems work. The university has a robust security program.

An NRC manager said NRC thinks that the new rule will not be much of a burden to licensees because they have already implemented many of the requirements in 10 CFR 37. I strongly disagree. The rule is one size fits all: security plans, training, procedures, new concepts (like security zones). There were orders, and we implemented them. After we had been inspected a few times, we were able to understand how to comply with the orders. Now with the new rule, we will have to set the rule as the new baseline. We will be reinspected against the new standards. It will take significantly more time. There are 37 Agreement States plus NRC, so there will be 38 interpretations of what the rule means. We will have to start all over again. A big problem will be the paperwork. The idea that any university could determine if someone is a terrorist is silly. Universities are not in that business. It would be better to have T&R standardized so that a person's T&R determination could be transferrable. A Federal agency authorization, similar to CDC's Select Agent program, would be preferable.

Nothing in the rule says you must do a certain thing so it is difficult, in advance, to highlight the implementation headaches. But there are more burdens than in previous orders, especially administrative burdens. If the orders were adequate, why spend an estimated $500M to implement the rule? I believe the $500 million is a gross underestimation of the actual costs. NRC says it is incorporating lessons learned in the rule, and that it issued orders because it had to get them out quickly. But if the orders provide adequate security, why not codify the orders and modify them later as needed? NRC is making fundamental changes to the orders in 10 CFR 37, with additional requirements and burdens for licensees. If the Orders were adequate, why change?

Regarding the security plan that the new rule requires (§37.43), we didn't write the plan under the orders because anything we documented would have to be protected, and it's very difficult to impose document security on a university campus. A concern is that writing a detailed security plan creates a vulnerability: if a terrorist gained access to it, the plan could outline the strengths and potentially weaknesses. It is easier for NRC to inspect a written plan than to sit down and discuss (orally) what the plan is. This puts the burden on the licensee.

For our gamma knife, with several thousand curies of cobalt-60, the typical useful life of the cobalt (because of radioactive decay) is 6 or 7 years. At that point, the manufacturer exchanges the old sources for the new ones. But the rule provides no guidance on if we should raise the security level for this activity, by how much or for how long. It simply requires someone cleared for T&R, unarmed, to stand there while individuals who are not T&R are in the area. That is not much security.

Training is a problem. Inspectors have one week of training at Sandia, while radiation safety officers have no formal training. We will attempt to implement 10 CFR 37, to the best of our ability, and hope the money we spend will pass inspection. In the interest of national security, a different approach should be taken. In discussions with colleagues from Great Britain, all hospital security plans are centrally reviewed by a police agency PRIOR to paying for the new equipment or installations. Therefore, there is agreement between groups of the necessary security before any money is spent. While not every site is the same and some flexibility is required, it would be really nice to know if the systems being paid for will be deemed adequate before they are installed.

Finally, there is no design basis threat or discussion of adversary capabilities provided to the licensee. Without a common security education, each site will develop their security in accordance of their understanding of the regulations AND their guess of the potential threat. This variation in security implementation combined with the variation in inspection practices will produce widely varying security levels and practices.

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A radiation safety officer at a large university, PhD, Certified Health Physicist, May-July 2012

The RSO has a Ph.D. in nuclear engineering/health physics.

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NRC doesn't typically regulate by orders to licensees but decided to do so after re-evaluating the threat environment in the wake of 9/11, I feel the orders were the best that NRC could do at the time. However, I find 10 CFR 37 too burdensome. The rule is one size fits all, which causes a lot of problems. For example, radioactive sources in medical therapy units may be hard to steal, but have the same security requirements under the rule as self-shielded irradiators, which may be easier to break into.

I'm frustrated that more emphasis was not placed on physical protection within devices, and too much was placed on people. This is burdensome and some parts of Part 37 do not make sense. NRC requires a reviewing official to be granted unescorted access to certain types and quantities of radioactive material even if the reviewing official does not need such access to perform his or her job. Section 652 of the Energy Policy Act of 2005 amends Section 149 of the Atomic Energy Act of 1954 to require NRC to fingerprint any individual granted unescorted access to certain types and quantities of radioactive material, and individuals in certain other categories. NRC does not have authority to fingerprint other individuals. As a result, the only way NRC can require a reviewing official to have an FBI fingerprint and criminal history records check is to approve the official for unescorted access. Some institutions use Human Resources to do T&R adjudications, but HR people have no reason to have such access. When regulations are so convoluted, it's hard to justify them. The NRC Advisory Committee on Medical Uses of Isotopes (ACMUI) recommended a two-step process in response to the proposed Part 37: codify the Increased Controls (IC) security orders with as little change as possible, then examine them carefully and make whatever changes are needed.

Can HR people adjudicate T&R? The T&R requirements in Part 37 are similar to what some organizations review for new hires, which is done by the organization's HR people. For some licensees, the HR people have refused to participate in the license orders T&R process and RSOs must do the total T&R adjudication. I do not want to have people's SSNs and related personal information under my purview and I am thankful for the assistance of the HR groups involved in my IC program. I rely on their expertise; they would not hire people who are not considered T&R. One alternative approach to the current Increased Controls T&R process is the one used for a bioterrorism security risk assessment to vet people for access to select agents or toxins Under this program, an organization's biosafety officer (BSO) sends in an application for an individual to the Animal and Plant Health Inspection Service (APHIS) or CDC to obtain a unique identifying number (UIN). The BSO submits a completed FD-961 form[64] with the UIN and two fingerprint cards to the FBI. The FBI does a background check, and the FBI and APHIS or CDC make the decision and give the biosafety officer a yes or no decision, all for no charge. Instead, my institutions can only use NRC fingerprint cards, at a cost of $26 per FBI background check request (if more than two cards are needed by FBI, up to an additional $52 may be required). When establishing the required fingerprinting program, I investigated use of a vendor to provide electronic fingerprinting service similar to that used by the state's Department of Elementary & Secondary Education. I ultimately learned that the NRC would only accept electronic fingerprints if sent directly from the licensee, and not a vendor (equipment like this is cost prohibitive for materials licensees). I have had several hundred people go through FBI fingerprint background checks, which is quite burdensome. Why pay NRC to be the middleman instead of going directly to the FBI? Why can't one central federal agency make these kinds of T&R adjudications? The NRC would not be the right agency to make T&R decisions because their security job only relates to radioactive material and reactors. A central federal agency making T&R decisions would avoid another problem as well. Now, if someone who is adjudicated as T&R goes to a different licensee, the T&R process must start over again. 10 CFR 37.31(c) permits one licensee to transfer background investigation information to another licensee with the written consent of the individual who is the subject of the investigation. In practice, however, no HR organization would send out information on which its T&R decision was based because of privacy and liability issues, nor would they accept this kind of information from another licensee. Having a federal agency do T&R would remove the requirement from licensees.

In general, I believe that limited funds should be spent more to augment physical security, especially internally to the devices, and less on T&R. Indeed, by spending more on physical security, there is less concern about T&R. If devices are made harder to penetrate, or if there are more alarms, it would be harder for anyone to steal radioactive material.

Regarding changes in the final rule vs. the Increased Controls orders, there is a new requirement to train people every year on security. This is a large time commitment for individuals with unescorted or need-to-know access and for me as compared to the orders. For example, staff can have refresher courses in health and safety online, but security training cannot be done online because of the security nature of the material. Since the institutions for which I am the RSO have several hundred people currently granted unescorted access to category 1 and 2 material, several training sessions must be done so as to cover all the people needing training every year. The requirement to re-do background checks (FBI fingerprint check is not required) every 10 years will add some additional burden. There are many long-term employees in my institutions, but there is also a lot of turnover; as a result, some employees will be checked every 10 years, and others will be checked once, when they arrive, and will be gone within 10

[64] This form is the Federal Bureau of Investigation Bioterrorism Preparedness Act: Entity/Individual Information; it is available at http://www.fbi.gov/about-us/cjis/bioterrorism-security-risk-assessment-form/bioterrorism-security-risk-assessment-form-fd-961 .

years. There has not been a reduction in burden with 10 CFR 37 compared to the orders. There is more burden, such as documenting a written security plan describing all security systems. The documentation is more formal under the rule than under the orders. My state is not an Agreement State, so is regulated by NRC. One problem with the formality is that some NRC inspectors will cite a violation if everything is not done precisely as described in the written security plan, though I recognize that the inspectors have little leeway.

Because of the difficulties of complying with the rule, I am urging researchers and users at my organizations to plan to switch to x-ray based irradiators rather than current ones that use radioactive materials. Since x-ray-based irradiators do not use radioactive material, they do not fall under the IC orders or 10 CFR 37. A blood bank I oversee plans to move to a new facility. It will replace one cobalt-60 irradiator with two x-ray irradiators; two are needed because of operational reliability issues that do not arise with radioactive material irradiators. The hospital will not get rid of its gamma knife or another teletherapy unit, both of which use cobalt-60.

Are the costs worth the benefits? The security people say yes, the rule could forestall terrible events. I'm not in a position to judge on threats.

I feel that it is useful to have the security requirements in regulations; orders are not meant to function as regulations.

NRC needs to provide much better guidance. The guidance so far just says what the regulations say. I don't want the regulations themselves to be prescriptive because the regulations cannot be made to fit every licensee's circumstance.

Another concern is that it's unclear where the line is on controlling information pursuant to the regulation. Researchers have to publish, and hospitals have to advertise their equipment in order to attract patients. Does someone who might see the database of security procedures need to be T&R? What about vendors or university business people who might see the database? Where does it end?

I am not able to do all the background checking needed to adjudicate T&R; I have legal concerns about adjudicating someone as not T&R. HR people are trained in doing these kinds of background checking and maintaining security over this kind of personal information and I appreciate their help with the T&R process. I am confident that they are competent to do T&R, as they help me as the T&R Official to handle a wide range of adjudications, such as for medical staff and foreign nationals. I am considering having some HR staff become Reviewing Officials when the new Part 37 is implemented. As a practical matter, my institutions have had very few issues with T&R. The FBI reports are pretty boring. One difference between the rule and the orders is that, under the rule, applicants for T&R must provide a personal history disclosure form providing details on their backgrounds.

Requiring a licensee to develop a design basis threat would not work. How would a licensee know and guard against the DBT for each different Category 1 or 2 device? Requiring armed guards at every irradiator or other source would put research and medical licensees out of business for use of these devices. Also, if information on a DBT leaked out, it could reveal to terrorists what sort of attack was being defended against, and would imply that a somewhat greater threat would succeed. The most effective way to secure radioactive sources is to have the company building equipment (such as irradiators) build in security features to make it much more difficult to get the source out. Licensees using these devices would not need to, and probably should not, know this information

I am in a fortunate position regarding LLEA. I am in a big medical center with multiple security groups. The officers in the groups have the power to make arrests. They are licensed by the city police department. These officers understand the significance of the theft of radioactive material. All have been trained in the Increased Controls orders. Part of their job is to provide physical protection for radioactive material and respond to alarms. They know every alarm and know that an alarm requires an immediate response; their goal is to respond within [a short time] of receiving an alarm.

The licensees' current radiation safety staffs have adequate training to implement the security requirements of the new rule. However, the many new security requirements of the rule add considerable burden to the staff. As a result, I have a budget request for additional staff to manage all the documentation, training, and coordination needed to implement Part 37.