
**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)**

**U.S. Nuclear Regulatory Commission
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ACRONYMS AND ABBREVIATIONS

AEA	Atomic Energy Act
CFR	<i>Code of Federal Regulations</i>
DOT	U.S. Department of Transportation
EPAct	Energy Policy Act of 2005
FBI	Federal Bureau of Investigation
FR	<i>Federal Register</i>
GPS	global positioning satellite
HRCQ	highway route control quantities
IAEA	International Atomic Energy Agency
LLEA	local law enforcement agency
M&D	manufacturer and distributor
NRC	U.S. Nuclear Regulatory Commission
OMB	Office of Management and Budget
RDD	radiological dispersal device
RED	radiological exposure device
SGI	safeguards information
SGI-M	safeguards information – modified handling

1. Introduction

This document presents a regulatory analysis of the security requirements for category 1 and category 2 quantities of radioactive material. The U.S. Nuclear Regulatory Commission (NRC or Commission) is establishing a new Part 37 in Title 10 of the *Code of Federal Regulations* (10 CFR), which contains the physical protection requirements for certain byproduct material (category 1 and category 2 quantities of radioactive material). This introduction is divided into three sections. Section 1.1 states the problem and the reasons for the rulemaking. Section 1.2 provides background information. Section 1.3 discusses the regulatory objectives of the rule.

1.1 Statement of the Problem and Reasons for Rulemaking

The NRC has long participated in efforts to address radioactive source protection and security. The terrorist attacks of September 11, 2001, however, heightened concerns about the use of risk-significant radioactive materials in a malevolent act. Such an attack is of particular concern because of the widespread use of radioactive materials in the United States by industrial, medical, and academic institutions. The theft or diversion of risk-significant radioactive materials could lead to their unauthorized use in a radiological dispersal device (RDD) or a radiological exposure device (RED).

NRC regulations provide requirements for the safe use, transit, and control of licensed radioactive material. A licensee's loss of control of risk-significant radioactive material, whether it is inadvertent or through a deliberate act, has the potential to result in significant adverse impacts that could reasonably constitute a threat to the public health and safety or the common defense and security of the United States. After the attacks of September 11, 2001, the Commission determined that certain licensed material should be subject to enhanced security provisions and safeguarded during transport, and that individuals with unescorted access to risk-significant radioactive material should be subject to background investigations. The NRC issued several security orders to licensees that possessed category 1 and category 2 quantities of radioactive material. In general, the orders provided for enhanced security measures for such things as license verification before transfer, intrusion detection and response, use of security zones, access control, and coordination with local law enforcement agencies (LLEAs). The orders also contain requirements for the licensee to determine the trustworthiness and reliability of individuals permitted unescorted access to category 1 or category 2 quantities of radioactive material through fingerprinting and criminal history checks and other elements of a background investigation. The orders also provided additional security measures during transportation such as preplanning and coordinating shipments, advance notification of shipments, and control and monitoring of shipments.

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. This rulemaking promulgates the security requirements for use of category 1 and category 2 quantities of

radioactive material by NRC licensees. More specifically, the requirements address access authorization, security during use of the material, and security during transport. In developing the rule the NRC considered the various orders, lessons-learned during implementation of the orders, the recommendations of the Independent External Review Panel and the Materials Program Working Group, and stakeholder comments. The rule also considers a petition for rulemaking (PRM 71-13) submitted by the State of Washington that requested that the NRC adopt the use of global positioning satellite (GPS) tracking as a national requirement for vehicles transporting highly radioactive mobile or portable radioactive devices.

1.2 Background

1.2.1 Current Regulatory Framework

NRC regulations in 10 CFR 20.1801, "Security of stored material," and 10 CFR 20.1802, "Control of material not in storage," require licensees to: (1) secure, from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas; and (2) to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. NRC regulations in 10 CFR 20.2201, "Reports of theft or loss of licensed material," require licensees to report lost, stolen, or missing radioactive material. Further, throughout the NRC's regulations for licensing byproduct material, there are educational and training requirements to ensure that individuals with access to radioactive materials have adequate knowledge and skills to safely use the radioactive material as intended. These requirements, along with other safety regulations, were primarily intended to provide reasonable assurance for preventing and mitigating unintended exposure to radiation exceeding the applicable limits in 10 CFR Part 20, "Standards for Protection Against Radiation."

NRC regulations in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," establish requirements for packages used to transport radioactive material. NRC regulations in 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources," require licensees to report to the National Source Tracking System the manufacture, transfer, receipt, disassembly or disposal of a nationally tracked source. NRC regulations in 10 CFR 71.97, "Advance notification of shipment of irradiated reactor fuel and nuclear waste," require licensees to notify in advance the Governor of a State, or the Governor's designee, about shipments of highway route controlled quantities (HRCQ) of radioactive waste passing through the boundaries of the State. Further, NRC regulations in 10 CFR 71.5, "Transportation of licensed material," specifically require licensees transporting licensed material to comply with applicable regulations implemented by the U.S. Department of Transportation (DOT). These requirements, along with other safety regulations, were primarily intended to provide reasonable assurance for preventing and mitigating unintended radiation exposure of licensee personnel, workers involved in carriage and the general public during the transport of such materials.

The current regulations require a licensee to report lost, stolen, or missing material to the NRC, or the appropriate Agreement State, after it discovers the event has occurred. Usually, this would be the next time the licensee went to use the material and finds it missing. In some cases, months could elapse before discovery of the loss. This is ample time for a terrorist to carry out a significant malevolent act using the missing material. Nowhere do the current regulations designate how quickly a licensee must discover that its radioactive material is stolen or missing. For situations involving theft of material, the local police force needs to be called

quickly so it can interdict the adversaries or take appropriate protective measures to mitigate severe radiological consequences to the public. Therefore, a mechanism is needed to trigger earlier discovery of the loss.

If the loss, theft, or misplacement of materials takes place during transport, this report would occur when the material has not arrived at its destination. In some cases, hours or days could elapse before anyone notices that the shipment did not arrive at its destination and begins searching for it, which could be ample time for a terrorist to carry out a significant malevolent act. Currently, the regulations do not designate how quickly a licensee must identify that its radioactive material is lost or stolen during transport. Prompt reporting to the NRC or to an Agreement State of radioactive material lost during transport may be appropriate for ensuring that resources are in place to help find and secure the material, thereby protecting the public from possible exposure. Therefore, a mechanism is needed to trigger earlier discovery that a shipment did not arrive. The NRC's regulations provide reasonable assurance that the radioactive material will be transported in a safe manner and that the public will be protected from radiological exposure under normal conditions of transport and during transportation accidents. However, for situations involving the theft of material during transport, the LLEA and Federal Bureau of Investigation (FBI) should be called quickly so that they can interdict the adversaries and recover the material or take appropriate measures to mitigate radiological consequences to the public.

The regulations do not have provisions to provide reasonable assurance that individuals having access to the radioactive material are trustworthy and reliable to use the radioactive material as intended or will not aid or abet those who might attempt to steal or divert the radioactive material.

1.2.2 Commission Orders

The NRC imposed a series of security orders on licensees that were authorized to possess category 1 or category 2 quantities of radioactive material. The orders were issued using a graded approach, based on the relative risk and quantity of material possessed by the licensee. The NRC issued the first series of orders to panoramic and underwater irradiator licensees that possessed more than 370 Terabecquerels (10,000 Curies) of radioactive materials (EA-02-249; June 6, 2003) (68 FR 35458; June 13, 2003). The next series of orders was issued to manufacturing and distribution licensees (EA-03-225; January 12, 2004) (69 FR 5375; February 4, 2004). These orders require implementation of additional security measures and protection of the licensee's physical protection information as Safeguards Information – Modified Handling (SGI-M). The orders are not publicly available because they contain detailed security requirements that are designated as SGI-M. These orders were issued to both NRC and Agreement State licensees under the NRC's authority to protect the common defense and security.

Subsequently, the NRC issued Increased Control Orders (EA-05-090; November 14, 2005) (70 FR 72128; December 1, 2005) to other licensees authorized to possess category 1 and category 2 quantities of risk-significant radioactive material. The Increased Control Orders are available on the NRC's Web site at <http://www.nrc.gov/security/byproduct/orders.html>. These orders were issued under the NRC's authority to protect public health and safety and require licensees to implement enhanced security measures. To effect nationwide implementation,

each Agreement State issued legally binding requirements consistent with the Increased Control Orders to licensees under their regulatory jurisdiction.

These orders specifically addressed the security of byproduct material possessed in quantities greater than or equal to category 2. The category 1 and category 2 thresholds are based on the International Atomic Energy Agency (IAEA) Code of Conduct.¹ These additional security measures provided for enhanced security measures for such things as license verification before transfer, intrusion detection and response, use of security zones for some licensees, access control, and coordination with LLEA. The orders also contained requirements for the licensee to determine the trustworthiness and reliability of individuals permitted unescorted access to risk-significant radioactive materials. The determination involved a background investigation of the individual. The background investigations were limited to local criminal history records checks with law enforcement agencies, verification of employment history, education, personal references, and confirmation of employment eligibility (legal immigration status).

During the same time period, efforts were underway to enhance transportation security of category 1 and category 2 quantities of radioactive material. In 2005, the NRC issued two sets of orders to licensees transporting radioactive material in quantities of concern. The first set of transportation security orders was issued to licensees that might be expected to transport category 1 quantities of radioactive material (EA-05-006; July 19, 2005) (70 FR 44407; August 2, 2005). The orders require the implementation of additional security measures and the protection of the licensee's physical protection information as SGI-M and are not publicly available. These orders were issued to both NRC and Agreement State licensees under the NRC's authority to protect the common defense and security. The second set of orders was the Increased Control Orders mentioned above which also contain requirements for transporting category 2 quantities of radioactive material.

These transportation security orders specifically addressed the transportation security of category 1 and category 2 quantities of radioactive material. The orders required enhanced security measures during transportation, including enhanced security in preplanning and coordinating shipments, advance notification of shipments to the NRC and States through which the shipment will pass, control and monitoring of shipments that are underway, trustworthiness and reliability of personnel, information security considerations, and control of mobile or portable devices.

In 2005, Congress passed, and the President signed, the Energy Policy Act of 2005 (EPAAct). The EPAAct amended Section 149 of the Atomic Energy Act (AEA) to authorize the Commission to require the fingerprinting of any individual who is permitted unescorted access to radioactive material or other property subject to regulation by the Commission that the Commission determines to be of such significance to the public health and safety or the common defense and security as to warrant fingerprinting and background checks. Under this new authority, the Commission determined that individuals with access to category 1 and category 2 quantities of radioactive material warrant fingerprinting and background checks.

¹ International Atomic Energy Agency Code of Conduct on the Safety and Security of Radioactive Sources, IAEA, Vienna, 2004.

On October 17, 2006, the NRC issued orders to panoramic and underwater irradiator licensees (EA-06-248) (71 FR 63043; October 27, 2006), M&D licensees (EA-06-250) (71 FR 53046; October 27, 2006), and licensees making shipments of category 1 quantities of radioactive material (EA-06-249) (71 FR 62302; October 24, 2006) to require fingerprinting and FBI criminal history records checks for unescorted access to risk-significant quantities of radioactive material at their facilities. In issuing these orders, the 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. The orders were issued to both NRC and Agreement State licensees under the NRC's authority to protect the common defense and security. On December 5, 2007, the NRC issued orders to all other NRC licensees who were authorized to possess category 1 or category 2 quantities of radioactive material (EA-07-305) (72 FR 70901; December 13, 2007). These orders were issued under the NRC's authority to protect the public health and safety. To effect nationwide implementation, each Agreement State issued legally binding requirements consistent with the orders to licensees under their regulatory jurisdiction.

In November 2009, the NRC issued the Increased Control Order and the Fingerprint Order to power reactor licensees that are undergoing decommissioning (EA-09-204 and EA-09-205; November 23, 2009) (74 FR 66168 and 74 FR 66164; December 14, 2009). In December 2009, the NRC issued orders to service provider licensees that were not manufacturers or distributors (EA-09-293; December 16, 2009) (75 FR 160; January 4, 2010). The order required service provider licensees to implement specific measures to ensure the trustworthiness and reliability of their service representatives that have unescorted access to category 1 or category 2 quantities of radioactive materials.

1.3 Regulatory Objectives

The objective of this rule is to provide reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material by establishing generally applicable security requirements similar to those previously imposed on certain licensees by the NRC orders. Although an order is legally binding on the licensee receiving the order, a rule makes requirements generally applicable to all licensees. In addition, notice and comment rulemaking allows for public participation and is an open and transparent process. This rulemaking places the security requirements for use of category 1 and category 2 quantities of radioactive material into the regulations. In developing the rule the NRC considered the various orders, lessons-learned during implementation of the orders, the recommendations of the Independent External Review Panel and the Materials Program Working Group, and stakeholder comments on the proposed rule. In addition, this rule considers a petition for rulemaking filed by the State of Washington that requested that the NRC adopt the use of global positioning satellite tracking as a national requirement for vehicles transporting highly radioactive mobile or portable radioactive devices was considered during the development of the rule.

2. Identification and Preliminary Analysis of Alternative Approaches

This section presents preliminary analysis of the alternatives that the NRC considered to meet the regulatory goals identified in the previous section. The NRC considered four alternatives for the rule as discussed below.

2.1 Option 1: No Action

Option 1 is the no-action alternative. Under the no-action alternative, the Commission would make no changes to the current regulations. Licensees would continue to comply with the NRC's orders. This alternative would avoid certain costs that the rule would impose. However, taking no action would not address the lessons-learned during implementation of the orders and various recommendations from the Independent External Review Panel and Materials Program Working Group, and orders would need to be issued to new licensees and licensees that amend their licenses to increase their possession limit. The NRC's regulations would not reflect current Commission policy for the minimum requirements that the Commission deems necessary to ensure the adequate protection of public health and safety and security.

2.2 Option 2: Amend the Regulations to Enhance Security (Possession Base)

Under Option 2, the NRC would conduct a rulemaking to include security measures for use of category 1 and category 2 quantities of radioactive material. This would involve creating a new Part 37 that would contain the security measures for use of category 1 and category 2 quantities of radioactive material. Conforming changes would be made to Parts 20, 30, 32, 33, 34, 35, 36, 39, 51, 71, and 73. The rule would apply to licensees that actually possess byproduct material in category 1 or category 2 quantities and are not just authorized to possess the material. If a licensee is authorized to possess byproduct material in category 1 or category 2 quantities, but does not actually possess a category 1 or category 2 quantity the rule would not apply to the licensee. Licensees that allow unescorted access to an aggregated category 1 and category 2 quantity of radioactive material would need to develop and implement an access authorization program. Any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material would need to develop and implement a security program. Any licensee that ships category 1 or category 2 quantities of radioactive material or small quantities of irradiated reactor fuel would be subject to the transportation security provisions.

A comprehensive rulemaking would provide a means of addressing the issues and concerns associated with the physical protection of category 1 and category 2 quantities of radioactive material. Through a comprehensive revision of the regulations, the NRC could ensure that all licensees that possess category 1 and category 2 quantities of radioactive material would be subject to uniform regulatory requirements in order to consistently implement measures to enhance security and safety.

The NRC has estimated the benefits and costs of this option, as described in Sections 3 and 4 of this regulatory analysis, and has pursued Option 2 for the reasons discussed in Section 5.

2.3 Option 3: Amend the Regulations to Enhance Security (Authorization Base)

Under Option 3, the NRC would conduct a rulemaking to include security measures for use of category 1 and category 2 quantities of radioactive material. This would involve creating a new Part 37 that would contain the security measures for use of category 1 and category 2 quantities of radioactive material. Conforming changes would be made to Parts 20, 30, 32, 33, 34, 35, 36, 39, 51, 71, and 73. The rule would apply to any licensee that is authorized to possess byproduct material that equals or exceeds the category 2 thresholds, even if the licensee does not actually possess the material. This approach would impact more licensees than option 2. Any licensee authorized to possess category 1 or category 2 quantities of radioactive material would be required to develop and implement an access authorization program and a security program. Any licensee that ships category 1 or category 2 quantities of radioactive material or small quantities of irradiated reactor fuel would be subject to the transportation security provisions.

A comprehensive rulemaking would provide a means of addressing the issues and concerns associated with the physical protection of category 1 and category 2 quantities of radioactive material. Through a comprehensive revision of the regulations, the NRC could ensure that all licensees that are authorized to possess category 1 or category 2 quantities of radioactive material would be subject to uniform regulatory requirements in order to consistently implement measures to enhance security and safety.

The NRC has estimated the benefits and costs of this option, as described in Sections 3 and 4 of this regulatory analysis.

2.4 Option 4: Amend the Regulations to Enhance Security (Order Base)

Under Option 4, the NRC would conduct a rulemaking to include security measures for use of category 1 and category 2 quantities of radioactive material that are identical to the orders. This would involve creating a new Part 37 that would contain the security measures for use of category 1 and category 2 quantities of radioactive material. Conforming changes would be made to Parts 20, 30, 32, 33, 34, 35, 36, 39, 51, 71, and 73. The rule would apply to licensees that are implementing the orders and would be identical to the orders. The rule would not include provisions for licensees that ship small quantities of irradiated reactor fuel.

A comprehensive rulemaking would provide a means of addressing the issues and concerns associated with the physical protection of category 1 and category 2 quantities of radioactive material. Through a comprehensive revision of the regulations, the NRC could ensure that all licensees that possess category 1 or category 2 quantities of radioactive material would be subject to uniform regulatory requirements in order to consistently implement measures to enhance security and safety. This alternative does not address any of the recommendations or lessons learned from implementing the orders.

The NRC has estimated the benefits and costs of this option, as described in Sections 3 and 4 of this regulatory analysis.

3. Evaluation of Benefits and Costs

This section examines the benefits and costs expected to result from the four options described in the previous section. The information is presented in three subsections. Section 3.1 identifies the attributes that are expected to be affected by the rulemaking. Section 3.2 describes how the benefits and costs have been analyzed for the main analysis. Section 3.3 describes how the benefits and costs have been analyzed for the pre-order analysis.

Throughout this analysis, various labor rates are used. These rates are used consistently for all of the issues and their derivations are described below.

Licensee labor rates were obtained from National Wage Data available on the Bureau of Labor Statistics Web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate is selected. The rate is then increased using a multiplier of 1.5 to account for benefits (insurance premiums, pension, and legally required benefits). Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates are used. For all licensee labor rates, \$55/hour is used, which is from Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Health and Safety Engineers, Except Mining Safety Engineers and Inspectors,"² however, some of the actions evaluated may be conducted by lower paid employees, such as clerical staff.

The NRC labor rates are determined per the calculation methodology in Abstract 5.2 of NUREG/CR-4627, Revision.1, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses." This methodology considers only variable costs that are directly related to the implementation, operation, and maintenance of the requirement. Currently, this hourly labor rate for the NRC is \$119.

Agreement States' labor rates vary in amount and in how each rate is determined. A survey of a particular industry would reveal a labor rate that can be compared to the NRC's labor rate, or the Bureau of Labor Statistics Web site can be used to obtain an hourly labor rate. Either of these methods is likely to yield similar results. For the purpose of this analysis, the average Agreement State hourly labor rate of \$33.17 was obtained from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Management, professional, and related occupations" limited to State and local government workers³. This wage was then increased by the same factor of 1.5 described earlier to obtain an hourly labor rate of \$50 and an annual labor rate of \$89,000.

² Department of Labor (U.S.), Bureau of Labor Statistics. Occupational Employment Statistics, Occupational Employment and Wages, May 2009 17-2111 Health and Safety Engineers, Except Mining Safety Engineers and Inspectors. Mean hourly wage is $\$36.45 \times 1.5 = \$55/\text{hour}$.

³ Department of Labor (U.S.), Bureau of Labor Statistics, Employer Costs for Employee Compensation, September 2010, Table 3 - Employer costs per hour worked for employee compensation and costs as a percent of total compensation: State and local government workers, by major occupational and industry group, September 2010.

The estimation of costs for rulemaking is based on professional staff full-time equivalent (FTE). Based on actual data from the NRC's time and labor system, the number of hours in 1 year that directly relate to implementation of assigned duties is 1,451; this excludes hours on such things as leave, training, and completing administrative tasks. Therefore, an NRC professional staff FTE hour rate is based on 1,451 hours. As described in the Office of Management and Budget (OMB) Circular A-76, "Performance of Commercial Activities," the number of productive hours in one year is 1,776. As this actual value is likely to vary from State to State and no specific data are available, the FTE costs for the Agreement States are based on the number of hours estimated in OMB Circular A-76. Costs are determined by multiplying the number of FTEs by 1,451 hours for NRC (1,776 hours for Agreement States) times the hourly labor rate.

3.1 Identification of Affected Attributes

This section identifies the factors within the public and private sectors that the regulatory alternatives (discussed in Section 2) are expected to affect. These factors are classified as "attributes" using the list of potential attributes provided by the NRC in Chapter 5 of its *Regulatory Analysis Technical Evaluation Handbook*.⁴ Affected attributes include the following:

- Safeguards and Security Considerations - The action is intended to establish requirements that will provide assurance that activities involving category 1 and category 2 quantities of radioactive material are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety.
- Public Health (Accident) - The action would reduce the risk that public health and safety will be affected by radiological releases resulting from unauthorized use of the radioactive material.
- Occupational Health (Accident) - The action would reduce the risk that occupational health will be affected by radiological releases resulting from unauthorized use of the radioactive material.
- Industry Implementation - The action may require licensees to make facility modifications, develop a security plan, and conduct background investigations, among other implementation activities. Option 4 would have few impacts as the action has already been completed in response to the orders.
- Industry Operation - The action would require licensees to conduct additional activities beyond those currently required such as training, maintenance and testing of security equipment, and for some licensees, develop security zones. Option 4 would have fewer impacts as it is already being implemented.
- NRC Implementation - Under the action, the NRC will revise inspection procedures and the inspector training program as a result of the new requirements.

⁴ *Regulatory Analysis Technical Evaluation Handbook, Final Report*, NUREG/BR-0184, Office of Nuclear Regulatory Research, January 1997.

- NRC Operation - The action would require the NRC Operations Center to answer calls from licensees when they discover an imminent or actual threat against the category 1 or category 2 quantities of radioactive material, as well as calls regarding suspicious activities.
- Regulatory Efficiency - The action (Options 2, 3, and 4 only) would result in enhanced regulatory efficiency through regulatory and compliance improvements. The NRC would not need to issue orders to additional licensees.
- Off-site Property - The action would reduce the risk that off-site property would be affected by radiological releases resulting from unauthorized use of the radioactive material.
- On-Site Property - The action would reduce the risk that on-site property would be affected by radiological releases resulting from unauthorized use of the radioactive material.
- Other Government - Agreement States would need to issue compatible requirements. The LLEA interaction with licensees could increase which would result in an expenditure of resources but would result in a more informed and prepared LLEA.

Attributes that are not expected to be affected under any of the options include the following: public health (routine), occupational health (routine), general public, environmental, improvements in knowledge, and antitrust considerations.

3.2 Analytical Methodology for Main Analysis

This section describes the process used to evaluate benefits and costs associated with the various regulatory options. The benefits (values) include desirable changes in affected attributes, e.g., monetary savings and improved security and safety. The costs (impacts or burdens) include undesirable changes in affected attributes, e.g., increased monetary costs and increased radiation exposure levels.

The analysis evaluates several attributes on a quantitative basis. (These include industry implementation, industry operation, NRC implementation, and NRC operation.) Quantitative analysis requires a baseline characterization, including factors such as the number of licensees affected, the nature of activities being conducted, and the types of new activities that licensees will implement as a result of the rule. However, licensees may respond to the rule in different ways depending on their licensed activities. It is beyond the scope of this analysis to characterize and analyze the individually affected licensees. The analysis proceeds quantitatively for these attributes by making general assumptions. Sections 3.2.1 – 3.2.3 describe the most significant analytical data and assumptions used in the quantitative analyses of these attributes. Additional details regarding the calculations used in the analysis are presented in the appendices to the analysis.

This analysis relies on a qualitative evaluation of several of the affected attributes (safeguards and security considerations, public and occupational health, and off- and on-site property) due

to the difficulty in quantifying the impact of the current rulemaking.⁵ These attributes would be affected by the regulatory options through the associated reduction in the risks of damage from unauthorized use of the radioactive material. Quantification of any of these attributes would require estimation of factors such as: (1) the frequency of attempted theft or diversion, (2) the frequency with which theft or diversion attempts are (i.e., pre-rule) and will be (i.e., post-rule) successful, and (3) the impacts associated with successful theft or diversion attempts.

3.2.1 Baseline for Main Analysis

This regulatory analysis measures the incremental impacts of the rule relative to a baseline, which reflects anticipated behavior in the event that the regulation is not imposed. The analysis assumes full licensee compliance with existing NRC requirements, including current regulations and relevant orders. This is consistent with NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 4, which states that, "in evaluating a new requirement..., the staff should assume that all existing NRC and Agreement State requirements have been implemented." Section 4.1 presents the estimated incremental costs and savings of the final rule relative to the main analysis.

3.2.2 Data

To the extent practicable, quantitative information (e.g., costs and savings) and qualitative information (e.g., the nature and magnitude of safeguards and security impacts) on attributes affected by the rule have been obtained from NRC staff and from commenters on the proposed rule. The NRC staff considered the potential differences between the new requirements and the current requirements and has incorporated available, nonsafeguards, information into this regulatory analysis.

3.2.3 Assumptions

The main analysis assumes that any new one-time implementation costs are incurred in calendar year 2013. For those aspects required by the security orders, the main analysis and the no-action option assume that one-time costs have already occurred and are not factored into the analysis. Ongoing costs of operation related to the rule are assumed to begin in 2014, and are modeled on an annual cost basis. The analysis calculated cost and savings over a 20-year period, with each year's costs or savings discounted back at a 7-percent and 3-percent discount rate, in accordance with NUREG/BR-0058. The detailed incremental cost and savings calculations are presented in Appendices A and B. Costs and savings are expressed in 2011 dollars.

For the main analysis, the NRC assumed that 1,400 licensees would fully implement the security provisions under Option 2; 2,950 licensees would be impacted under Option 3; and 1,400 licensees would be impacted under Option 4. These licensees include a wide range of licensees, including pool-type irradiator licensees; manufacturer and distributor licensees; medical facilities with gamma knife devices; self-shielded irradiator licensees (including blood

⁵ The regulatory efficiency attribute also is evaluated qualitatively by definition. See NRC's *Regulatory Analysis Technical Evaluation Handbook*, Section 5.5.14.

irradiators); teletherapy unit licensees; radiographers; well loggers; broad scope users; radioisotope thermoelectric generator licensees; decommissioning reactors; and licensees that ship or prepare for shipment of category 1 or category 2 quantities of radioactive material. The rule could also impact some operating reactors, fuel cycle facilities, and gauge licensees. Because the licensees impacted by the rule vary so greatly, it is hard to estimate the burden that would be imposed by the rule for a typical licensee. Licensees can select different methods for many of the security measures. Many of the licensees may be small businesses. The regulatory analysis uses small, medium, and large facilities for calculating the costs. It is assumed that 26 percent of the licensees are considered small; 59 percent are considered medium; and 15 percent are considered to be large facilities.

The NRC assumes that two licensees would be issued security orders per year under the no-action alternative. This cost is not included in the analysis.

3.3 Analytical Methodology for Pre-Order Analysis

This section describes the process used to evaluate benefits and costs associated with the various regulatory options. The benefits (values) include desirable changes in affected attributes, e.g., monetary savings and improved security and safety. The costs (impacts or burdens) include undesirable changes in affected attributes, e.g., increased monetary costs and increased radiation exposure levels.

The analysis evaluates several attributes on a quantitative basis. (These include industry implementation, industry operation, NRC implementation, and NRC operation.) Quantitative analysis requires a baseline characterization, including factors such as the number of licensees affected, the nature of activities being conducted, and the types of new activities that licensees will implement as a result of the rule. However, licensees may respond to the rule in different ways depending on their licensed activities. It is beyond the scope of this analysis to characterize and analyze the individually affected licensees. The analysis proceeds quantitatively for these attributes by making general assumptions. Sections 3.3.1 – 3.3.3 describe the most significant analytical data and assumptions used in the quantitative analysis of these attributes. Additional details regarding the calculations used in the analysis are presented in the appendices.

This pre-order analysis relies on a qualitative evaluation of several of the affected attributes (safeguards and security considerations, public and occupational health, regulatory efficiency, and off- and on-site property) due to the difficulty in quantifying the impact of the current rulemaking. These attributes would be affected by the regulatory options through the associated reduction in the risks of damage from unauthorized use of the radioactive material. Quantification of any of these attributes would require estimation of factors such as: (1) the frequency of attempted theft or diversion, (2) the frequency with which theft or diversion attempts are (i.e., pre-rule) and will be (i.e., post-rule) successful, and (3) the impacts associated with successful theft or diversion attempts.

3.3.1 Pre-Order Analysis

The pre-order analysis measures the incremental impacts of the rule assuming that the orders were never issued. The analysis assumes full licensee compliance with existing NRC

regulations, but not the orders that have been issued. Section 4.2 presents the estimated incremental costs and savings of the rule relative to the pre-order analysis.

3.3.2 Data

To the extent practicable, quantitative information (e.g., costs and savings) and qualitative information (e.g., the nature and magnitude of safeguards and security impacts) on attributes affected by the rule have been obtained from NRC staff and from commenters on the proposed rule. The NRC staff considered the potential differences between the new requirements and the current requirements and has incorporated available, nonsafeguards-information into this regulatory analysis.

3.3.3 Assumptions

The pre-order analysis assumes that any one-time implementation costs are incurred in calendar year 2013. Ongoing costs of operation related to the rule are assumed to begin in 2014, and are modeled on an annual cost basis. The analysis calculated cost and savings over a 20 year period, with each year's costs or savings discounted back at a 7-percent and 3-percent discount rate, in accordance with NUREG/BR-0058. The detailed incremental cost and savings calculations are presented in Appendices A and B. Costs and savings are expressed in 2011 dollars.

For the pre-order analysis, the NRC assumed that 1,400 licensees would fully implement the security provisions under Option 2; 2,950 licensees would be impacted under Option 3; and 1,400 licensees under Option 4.

4. Results

This section presents the analytical results. Section 4.1 presents findings on the overall benefits and costs of the three options under the main analysis, and Section 4.2 presents the findings for the pre-order analysis.

4.1 Benefits and Costs for Main Analysis

This section summarizes the benefits and costs estimated for the regulatory options under the main analysis. To the extent that the affected attributes could be analyzed quantitatively, the net effect of each option has been calculated and is presented below. However, some values and impacts could be evaluated only on a qualitative basis.

The results of the value-impact analysis are summarized in Exhibits 4-1 and 4-2. Exhibit 4-3 provides the cost comparison for the three main options. Option 2 would result in a net quantitative impact estimated over a 20-year period between \$357,857,528 and \$488,473,538 (7-percent and 3-percent discount rate, respectively); Option 3 would result in a net quantitative impact estimated between \$1,445,580,046 and \$1,936,568,404 (7-percent and 3-percent discount rate, respectively); and Option 4 would result in a net quantitative impact estimated at \$1,794,500 (both 7-percent and 3-percent discount rate, respectively). The majority of the costs would be incurred by industry, except for Option 4 where the cost would be incurred by the Agreement States.

There are no quantifiable values (i.e. Benefits) associated with the rule. The qualitative values of the rule are associated with safeguard and security considerations of the decreased risk of a security-related event, such as theft or diversion of radioactive material and subsequent use for unauthorized purposes. Increasing the security of high-risk radioactive material decreases this risk and increases the common defense and security of the nation. Other qualitative values that are positively affected by the decreased risk of a security-related event include public and occupational health due to an accident or event and the risk of damage to on-site and off-site property. In addition, regulatory efficiency is enhanced by the rule.

Exhibit 4-1
Summary of Benefits/Savings and Costs/Burdens for Main Analysis

NET MONETARY SAVINGS (OR COSTS) – TOTAL PRESENT VALUE	NON-MONETARY BENEFITS/COSTS
<p>Option 1: No Action</p> <p>Industry: (\$0) using a 7% discount rate (\$0) using a 3% discount rate</p> <p>NRC/Agreement States: (\$0) using a 7% discount rate (\$0) using a 3% discount rate</p>	<p><u>Qualitative Benefits:</u></p> <p>Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded.</p> <p>Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p><u>Qualitative Costs:</u></p> <p>Regulatory Efficiency: Regulatory efficiency would be reduced by the need to issue orders to new licensees and licensees increasing their possession limit above the category 2 threshold.</p>
<p>Option 2: Rulemaking(Possession Base)</p> <p>Industry: (\$355,111,140) using a 7% discount rate (\$485,461,006) using a 3% discount rate</p> <p>NRC/State: (\$415,437) using a 7% discount rate (\$524,520) using a 3% discount rate</p>	<p><u>Qualitative Benefits:</u></p> <p>Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded. Reduces good faith presumption.</p> <p>Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material.</p>

NET MONETARY SAVINGS (OR COSTS) – TOTAL PRESENT VALUE	NON-MONETARY BENEFITS/COSTS
<p>Agreement States: (\$2,330,951) using a 7% discount rate (\$2,488,012) using a 3% discount rate</p>	<p>Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Regulatory Efficiency: Enhanced regulatory efficiency through regulatory and compliance improvements.</p> <p><u>Qualitative Costs:</u> None.</p>
<p>Option 3: Rulemaking (Authorization Base)</p> <p>Industry: (\$1,442,114,420) using a 7% discount rate (\$1,932,545,825) using a 3% discount rate</p> <p>NRC/State: (\$704,558) using a 7% discount rate (\$930,541) using a 3% discount rate</p> <p>Agreement States: (\$2,761,068) using a 7% discount rate (\$3,092,038) using a 3% discount rate</p>	<p><u>Qualitative Benefits:</u></p> <p>Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded. Reduces good faith presumption.</p> <p>Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Regulatory Efficiency: Enhanced regulatory efficiency through regulatory and compliance improvements.</p> <p><u>Qualitative Costs:</u> None.</p>
<p>Option 4: Rulemaking (Order Base)</p> <p>Industry: (\$0) using a 7% discount rate (\$0) using a 3% discount rate</p> <p>NRC/State:</p>	<p><u>Qualitative Benefits:</u></p> <p>Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded.</p> <p>Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material.</p>

NET MONETARY SAVINGS (OR COSTS) – TOTAL PRESENT VALUE	NON-MONETARY BENEFITS/COSTS
(\$0) using a 7% discount rate (\$0) using a 3% discount rate Agreement States: (\$1,794,500) using a 7% discount rate (\$1,794,500) using a 3% discount rate	<p>Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p><u>Qualitative Costs:</u></p> <p>Regulatory Efficiency: Enhanced regulatory efficiency through regulatory improvements</p>

Exhibit 4-2
Industry Savings and Costs for Main Analysis

	OPTION 1 (NO-ACTION)		OPTION 2 (RULEMAKING BASED ON POSSESSION)		OPTION 3 (RULEMAKING BASED ON AUTHORIZATION)		OPTION 4 (RULEMAKING BASED ON ORDERS)	
	One-Time Savings (Cost)	Annual Savings (Cost)	One-Time Savings (Cost)	Annual Savings (Cost)	One-Time Savings (Cost)	Annual Savings (Cost)	One-Time Savings (Cost)	Annual Savings (Cost)
Access Authorization Program								
Access Authorization Program Procedures	NA	NA	(\$3,850,000)	\$0	(\$12,375,000)	\$0	\$0	\$0
Background Investigations - Large	\$0	\$0	\$0	\$0	(\$23,452,615)	(\$2,288,060)	\$0	\$0
Background Re-investigations - Large	NA	NA	\$0	(\$456,330)	\$0	(\$962,639)	NA	NA
Background Investigations - Medium	\$0	\$0	\$0	\$0	(\$23,785,022)	(\$2,243,870)	\$0	\$0

Background Re-investigations - Medium	NA	NA	\$0	(\$464,046)	\$0	(\$977,532)	NA	NA
Background Investigations - Small	\$0	\$0	\$0	\$0	(\$4,353,206)	(\$395,746)	\$0	\$0
Background Re-investigations - Small	NA	NA	\$0	(\$84,884)	\$0	(\$178,864)	NA	NA
Access Lists	\$0	\$0	\$0	\$0	(\$341,000)	(\$170,500)	\$0	\$0
Program Review	NA	NA	\$0	(\$7,000,000)	\$0	(\$14,750,000)	NA	NA
Subtotal for Access Authorization Program	\$0	\$0	(\$3,850,000)	(\$8,005,260)	(\$64,306,843)	(\$21,967,211)	\$0	\$0
Security Program								
Security Plan	\$0	\$0	\$0	\$0	(\$10,230,000)	\$0	\$0	\$0

Security Procedures	NA	NA	(\$7,700,000)	\$0	(\$16,225,000)	\$0	NA	NA
Information Protection Procedures	\$0	\$0	\$0	\$0	(\$2,983,750)	\$0	\$0	\$0
Security Training - Large	NA	NA	(\$9,505,650)	(\$4,758,600)	(\$20,052,295)	(\$10,038,380)	NA	NA
Security Training - Medium	NA	NA	(\$9,767,450)	(\$4,906,440)	(\$20,575,500)	(\$10,335,600)	NA	NA
Security Training - Small	NA	NA	(\$1,901,900)	(\$920,920)	(\$4,007,575)	(\$1,940,510)	NA	NA
LLEA Coordination	\$0	NA	\$0	(\$423,500)	(\$1,790,250)	(\$892,375)	\$0	NA
Security Measures - Large	\$0	\$0	\$0	\$0	(\$23,300,000)	(\$11,650,000)	\$0	\$0
Security Measures - Medium	\$0	\$0	\$0	\$0	(\$54,840,000)	(\$27,420,000)	\$0	\$0

Security Measures - Small	\$0	\$0	\$0	\$0	(\$10,075,000)	(\$6,045,000)	\$0	\$0
Program Review	NA	NA	\$0	(\$7,000,000)	\$0	(\$14,750,000)	NA	NA
Maintenance and Testing	NA	NA	\$0	(\$3,850,000)	\$0	(\$8,112,500)	NA	NA
Subtotal for Security Program	\$0	\$0	(\$28,875,000)	(\$21,859,460)	(\$164,079,370)	(\$91,184,365)	\$0	\$0
Transportation Security								
Procedure Development	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Training (Category 1)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
License Verification	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Preplanning and Coordination (Category 1)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0

Post Notification (Category 1)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Documentation (Category 1)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Advance Notifications	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Protection of Category 1 Shipments	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
License verification (Category 2)	\$0	\$0	\$0	(\$206,250)	\$0	(\$206,250)	\$0	\$0
Preplanning and Coordination (Category 2)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Post Notification (Category 2)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Documentation (Category 2)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0

Protection of Category 2 Shipments	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Notification of Revisions	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Subtotal for transportation Security	\$0	\$0	\$0	(\$206,250)	\$0	(\$206,250)	\$0	\$0
Records and Reporting								
Records	\$0	\$0	\$0	(\$350,000)	(\$775,000)	(\$1,125,000)	\$0	\$0
Event Notification	\$0	\$0	\$0	(\$8,626)	\$0	(\$8,626)	\$0	\$0
Suspicious Activity Reports	NA	NA	\$0	(\$1,375)	\$0	(\$2,750)	NA	NA
Subtotal for Records and Reporting	\$0	\$0	\$0	(\$360,001)	(\$775,000)	(\$1,136,376)	\$0	\$0
TOTAL	\$0	\$0	(\$32,725,000)	(\$30,430,971)	(\$229,161,213)	(\$114,494,202)	\$0	\$0

Exhibit 4-3
Cost Comparison for Main Analysis

	OPTION 1 – (NO-ACTION)		OPTION 2 (RULEMAKING BASED ON POSSESSION)		OPTION 3 (RULEMAKING BASED ON AUTHORIZATION)		OPTION 4 (RULEMAKING BASED ON ORDERS)	
	3% Discount	7% Discount	3% Discount	7% Discount	3% Discount	7% Discount	3% Discount	7% Discount
Industry One-Time Savings (Cost)	\$0	\$0	(\$32,725,000)	(\$32,725,000)	(\$229,161,213)	(\$229,161,213)	\$0	\$0
Industry Annual Savings (Cost)	\$0	\$0	(\$452,736,006)	(\$322,386,140)	(\$1,703,384,612)	(\$1,212,953,207)	\$0	\$0
NRC One-Time Savings (Cost)	\$0	\$0	(\$145,650)	(\$145,650)	(\$145,650)	(\$145,650)	\$0	\$0
NRC/State Annual Savings (Cost)	\$0	\$0	(\$24,786)	(\$17,650)	(\$38,949)	(\$27,735)	\$0	\$0
NRC Annual Savings (Cost)	\$0	\$0	(\$354,520)	(\$252,137)	(\$745,942)	(\$531,173)	\$0	\$0
Agreement State One-Time Savings (Cost)	\$0	\$0	(\$1,942,500)	(\$1,942,500)	(\$1,942,500)	(\$1,942,500)	(\$1,794,500)	(\$1,794,500)
Agreement State Annual Savings (Cost)	\$0	\$0	(\$545,512)	(\$388,451)	(\$1,149,538)	(\$818,568)	\$0	\$0
Total Savings (Cost)	\$0	\$0	(\$488,473,538)	(\$357,857,528)	(\$1,936,568,404)	(\$1,445,580,046)	(\$1,794,500)	(\$1,794,500)

4.2 Benefits and Costs for Pre-Order Analysis

This section summarizes the benefits and costs estimated for the regulatory options under the pre-order analysis. To the extent that the affected attributes could be analyzed quantitatively, the net effect of each option has been calculated and is presented below. However, some values and impacts could be evaluated only on a qualitative basis.

The results of the value-impact analysis are summarized in Exhibits 4-4 and 4-5. Option 2 would result in a net quantitative impact estimated between \$1,366,936,042 and \$1,847,064,192 (7-percent and 3-percent discount rate, respectively); option 3 would result in a net quantitative impact estimated between \$2,455,634,036 and \$3,296,528,945 (7-percent and 3-percent discount rate, respectively); and option 4 would result in a net quantitative impact estimated between \$1,012,359,344 and \$1,361,866,686 (7-percent and 3-percent discount rate, respectively). The majority of the costs would be incurred by industry.

Although there are no quantifiable values (i.e., Benefits) associated with the rule alternative, there are significant qualitative benefits of the rule relative to the pre-order baseline. The qualitative values of the rule are associated with safeguard and security considerations of the decreased risk of a security-related event, such as theft or diversion of radioactive material and subsequent use for unauthorized purposes. Increasing the security of high-risk radioactive material decreases this risk and increases the common defense and security of the nation. Other qualitative values that are positively affected by the decreased risk of a security-related event include public and occupational health due to an accident or event and the risk of damage to on-site and off-site property.

Exhibit 4-4
Summary of Benefits/Savings and Costs/Burdens for Pre-Order Analysis

NET MONETARY SAVINGS (OR COSTS) – TOTAL PRESENT VALUE	NON-MONETARY BENEFITS/COSTS
<p>Option 1: No Action</p> <p>Industry: (\$0) using a 7% discount rate (\$0) using a 3% discount rate</p> <p>NRC/Agreement States: (\$0) using a 7% discount rate (\$0) using a 3% discount rate</p>	<p><u>Qualitative Benefits:</u></p> <p>Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded.</p> <p>Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material.</p>

NET MONETARY SAVINGS (OR COSTS) – TOTAL PRESENT VALUE	NON-MONETARY BENEFITS/COSTS
	<p>On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p><u>Qualitative Costs:</u></p> <p>Regulatory Efficiency: Regulatory efficiency would be reduced by the need to issue orders to new licensees and licensees increasing their possession limit above the category 2 threshold.</p>
<p>Option 2: Rulemaking (Possession Base)</p> <p>Industry: (\$1,359,585,832) using a 7% discount rate (\$1,837,965,551) using a 3% discount rate</p> <p>NRC/State: (\$4,166,588) using a 7% discount rate (\$5,792,368) using a 3% discount rate</p> <p>Agreement States: (\$2,913,622) using a 7% discount rate (\$3,306,273) using a 3% discount rate</p>	<p><u>Qualitative Benefits:</u></p> <p>Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded. Reduces good faith presumption</p> <p>Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Regulatory Efficiency: Enhanced regulatory efficiency through regulatory and compliance improvements.</p> <p><u>Qualitative Costs:</u></p> <p>None.</p>
<p>Option 3: Rulemaking (Authorization Base)</p> <p>Industry: (\$2,446,859,112) using a 7% discount rate (\$3,285,050,370) using a 3% discount rate</p> <p>NRC/States: (\$4,786,010) using a 7% discount rate (\$6,662,238) using a 3% discount rate</p> <p>Agreement States: (\$3,988,914) using a 7% discount rate (\$4,816,337) using a 3% discount rate</p>	<p><u>Qualitative Benefits:</u></p> <p>Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded. Reduces good faith presumption</p> <p>Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material.</p>

NET MONETARY SAVINGS (OR COSTS) – TOTAL PRESENT VALUE	NON-MONETARY BENEFITS/COSTS
	<p>Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Regulatory Efficiency: Enhanced regulatory efficiency through regulatory and compliance improvements.</p> <p><u>Qualitative Costs:</u></p> <p>None.</p>
<p>Option 4: Rulemaking (Order Base)</p> <p>Industry: (\$1,006,275,517) using a 7% discount rate (\$1,354,048,562) using a 3% discount rate</p> <p>NRC/State: (\$3,751,151) using a 7% discount rate (\$5,267,848) using a 3% discount rate</p> <p>Agreement States: (\$2,377,171) using a 7% discount rate (\$2,612,761) using a 3% discount rate</p>	<p><u>Qualitative Benefits:</u></p> <p>Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded.</p> <p>Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material.</p> <p>Regulatory Efficiency: Enhanced regulatory efficiency through regulatory improvements.</p> <p><u>Qualitative Costs:</u></p> <p>None.</p>

Exhibit 4-5
Industry Savings and Costs for Pre-Order Analysis

	OPTION 2 (RULEMAKING BASED ON POSSESSION)		OPTION 3 (RULEMAKING BASED ON AUTHORIZATION)		OPTION 4 (RULEMAKING BASED ON ORDERS)	
	One-Time Savings (Cost)	Annual Savings (Cost)	One-Time Savings (Cost)	Annual Savings (Cost)	One-Time Savings (Cost)	Annual Savings (Cost)
Access Authorization Program						
Access Authorization Program Procedures	(\$7,700,000)	\$0	(\$16,225,000)	\$0	(\$3,850,000)	\$0
Background Investigations - Large	(\$21,137,550)	(\$2,062,200)	(\$44,590,165)	(\$4,350,260)	(\$21,137,550)	(\$2,062,200)
Background Reinvestigations (every 10 years) - Large	\$0	(\$456,330)	\$0	(\$962,639)	NA	NA
Background Investigations - Medium	(\$21,494,998)	(\$2,027,830)	(\$45,280,020)	(\$4,271,700)	(\$21,494,998)	(\$2,027,830)

Background Reinvestigations (every 10 years) - Medium	\$0	(\$464,046)	\$0	(\$977,532)	NA	NA
Background Investigations - Small	(\$3,931,928)	(\$357,448)	(\$8,285,134)	(\$753,194)	(\$3,931,928)	(\$357,448)
Background Reinvestigations (every 10 years) - Small	\$0	(\$84,884)	\$0	(\$178,864)	NA	NA
Access Lists	(\$308,000)	(\$154,000)	(\$649,000)	(\$324,500)	(\$308,000)	(\$154,000)
Program Review	\$0	(\$7,000,000)	\$0	(\$14,750,000)	NA	NA
Subtotal for Access Authorization Program	(\$54,572,476)	(\$12,606,738)	(\$115,029,319)	(\$26,568,689)	(\$50,722,476)	(\$4,601,478)
Security Program						
Security Plan	(\$9,240,000)	\$0	(\$19,470,000)	\$0	(\$9,240,000)	\$0
Security Procedures	(\$7,700,000)	\$0	(\$16,225,000)	\$0	NA	NA

Information Protection Procedures	(\$2,695,000)	\$0	(\$5,678,750)	\$0	(\$2,695,000)	\$0
Security Training - Large	(\$9,505,650)	(\$4,758,600)	(\$20,052,295)	(\$10,038,380)	NA	NA
Security Training - Medium	(\$9,767,450)	(\$4,906,440)	(\$20,575,500)	(\$10,335,600)	NA	NA
Security Training - Small	(\$1,901,900)	(\$920,920)	(\$4,007,575)	(\$1,940,510)	NA	NA
LLEA Coordination	(\$1,617,000)	(\$423,500)	(\$3,407,250)	(\$892,375)	(\$3,080,000)	NA
Security Measures - Large	(\$21,000,000)	(\$10,500,000)	(\$44,300,000)	(\$22,150,000)	(\$21,000,000)	(\$10,500,000)
Security Measures - Medium	(\$49,560,000)	(\$24,780,000)	(\$104,400,000)	(\$52,200,000)	(\$49,560,000)	(\$24,780,000)
Security Measures - Small	(\$9,100,000)	(\$5,460,000)	(\$19,175,000)	(\$11,505,000)	(\$9,100,000)	(\$5,460,000)
Program Review	\$0	(\$7,000,000)	\$0	(\$14,750,000)	NA	NA

Maintenance and Testing	\$0	(\$3,850,000)	\$0	(\$8,112,500)	NA	NA
Subtotal for Security Program	(\$122,087,000)	(\$62,599,460)	(\$257,291,370)	(\$131,924,365)	(\$94,675,000)	(\$40,740,000)
Transportation Security						
Procedure Development	(\$17,600)	\$0	(\$17,600)	\$0	(\$17,600)	\$0
License Verification Cat 1	\$0	(\$4,813)	\$0	(\$4,813)	\$0	(\$4,813)
Training (Category 1)	\$0	\$0	\$0	\$0	(\$64,000)	\$0
Preplanning and Coordination (Category 1)	\$0	(\$57,750)	\$0	(\$57,750)	\$0	(\$57,750)
Post Notification (Category 1)	\$0	\$0	\$0	\$0	\$0	(\$3,080)
Documentation (Category 1)	\$0	(\$11,165)	\$0	(\$11,165)	\$0	(\$11,165)
Advance Notifications	\$0	(\$78,980)	\$0	(\$78,980)	\$0	(\$78,980)

Protection of Category 1 Shipments	\$0	(\$3,500,000)	\$0	(\$3,500,000)	\$0	(\$3,500,000)
License Verification – Cat 2	\$0	(\$412,500)	\$0	(\$412,500)	\$0	(\$206,250)
Preplanning and Coordination (Category 2)	\$0	(\$825,000)	\$0	(\$825,000)	\$0	(\$825,000)
Post Notification (Category 2)	\$0	(\$264,000)	\$0	(\$264,000)	\$0	(\$264,000)
Documentation (Category 2)	\$0	(\$544,500)	\$0	(\$544,700)	\$0	(\$544,700)
Protection of Category 2 Shipments	\$0	(\$30,000,000)	\$0	(\$30,000,000)	\$0	(\$30,000,000)
Revision Notifications	\$0	(\$2,640)	\$0	(\$2,640)	\$0	(\$2,640)
Subtotal for Transportation Security	(\$17,600)	(\$35,701,348)	(\$17,600)	(\$35,701,348)	(\$52,800)	(\$35,498,178)

Records and Reporting						
Records	(\$700,000)	(\$700,000)	(\$1,475,000)	(\$1,475,000)	(\$700,000)	(\$350,000)
Event Notification	\$0	(\$8,709)	\$0	(\$8,709)	\$0	(\$83)
Suspicious Activity Reports	\$0	(\$1,375)	\$0	(\$2,750)	NA	NA
Subtotal for Records and Reporting	(\$700,000)	(\$710,084)	(\$1,475,000)	(\$1,486,459)	(\$700,000)	(\$350,083)
TOTAL	(\$177,377,076)	(\$111,617,629)	(\$373,813,289)	(\$195,680,860)	(\$146,150,276)	(\$81,189,738)

5. Decision Rationale

The decision rationale is based on the main analysis. The pre-order analysis is provided for informational purposes only. Relative to the no-action alternative, option 2 would result in a net cost estimated as approximately \$357,857,528 (total present value over a 20-year period), assuming a 7-percent discount rate, or approximately \$488,473,538 assuming a 3-percent discount rate. Option 3 would result in a net cost estimated as approximately \$1,445,580,046 (total present value over a 20-year period), assuming a 7-percent discount rate, or approximately \$1,936,568,404 assuming a 3-percent discount rate. Option 4 would result in a net cost estimated as approximately \$1,794,500 (total present value over a 20-year period), assuming a 7-percent discount rate, or approximately \$1,794,500 assuming a 3-percent discount rate. Offsetting the net cost, the NRC believes that options 2 and 3 would result in substantial nonquantified benefits related to safety and security. Option 4 would result in fewer nonquantified benefits related to safety and security as it would not address some of the issues identified with the orders and the recommendations on byproduct material security. Most of the costs associated with option 4 have already occurred and are therefore considered sunk costs. Options 2, 3, and 4 would also result in enhanced regulatory efficiency and effectiveness and provide for public involvement. Although significant costs are incurred as a result of the rule, the qualitative benefits associated with the rule outweigh its cost. The NRC selected Option 2 as it addresses the lessons-learned from implementing the orders and better addresses the various security-related recommendations from the Independent External Review Panel and the Materials Program Working Group. Option 3 would impose unnecessary burden on licensees that are authorized to possess the material but might not actually possess the material and on licensees that don't aggregate the material into a category 1 or category 2 quantity.

The average for licensees (the total cost divided by 1400 licensees) is a one-time cost of approximately \$23,375 and an annual cost of approximately \$21,736 to fully implement the final rule. The NRC acknowledges that for some licensees the cost will be much higher and for some the costs will be lower than the average. Costs for a specific licensee depends on the number of individuals that are granted unescorted access, the number of procedures that must be developed, the actual security measures that are used to meet the requirements, and the extent of the training. The actual costs also depend on the number of sources possessed by a licensee and the location of the sources relative to other sources. The average value does not include the costs that have already been expended to meet the orders. Much of the cost would result from the requirements to have procedures and conduct training. Although not required by the various orders, many licensees would have developed procedures and conducted training and may only require minor revisions; therefore, the actual cost may be lower. Additional large costs are the annual program review and the maintenance and testing of the security-related equipment. The program review is important for licensees to review the effectiveness of the program and to ensure that requirements are being implemented. Maintenance and testing is essential to assure that the equipment is operational and available when needed.

As noted earlier, some of the licensees that will be impacted by the rule are small businesses. The rule imposes the minimum requirements that the NRC believes is necessary to adequately protect the public health and safety and the common defense and security. Therefore, the NRC cannot grant relief to small entities to allow them to implement less effective measures. The rule provides some flexibility in the particular measures that a licensee can choose to employ.

This final rule will result in maximum annual impact to the economy of approximately \$17.9 million (using a 7 percent discount rate, annualizing the one-time costs over 20 years, and adding these “annualized” one-time costs to the annual costs) or \$24.4 million (using a 3 percent discount rate). The OMB has indicated that the annual cost of the orders should be included in the annual impact to the economy calculation. The estimated annual cost to the industry using the pre-order was \$111.6 million. Therefore, this final rule is considered a major rule as defined by the Congressional Review Act.

6. Implementation

This section identifies how and when the final rule action will be implemented, the required NRC actions to ensure implementation, and the impact on NRC resources.

6.1 Schedule

The action will be implemented through a final rule. The final rule will be effective 1 year from the date of publication. The NRC has not identified any impediments to implementing the recommended alternative. Agreement States would have 3 years from the publication date to issue compatible regulations or other legally binding requirements.

6.2 Impacts on Other Requirements

As discussed in Section 4.1, affected licensees will experience most of the impact of the rule. The NRC estimates that it will spend 0.45 FTE to revise inspection procedures and the training program. Inspectors will need to attend the revised training course. Each Agreement State would be expected to spend 0.5 FTE to establish regulations. The NRC estimates that on average an additional 2 hours per licensee will be needed to conduct the security-related inspections. This will result in approximately 600 hours over 3 years for NRC inspection and approximately 2,200 hours over 3 years for Agreement State inspection. The actual impact on any given Agreement State will depend on the number of licensees and the frequency of inspection.

Appendix A:

INDUSTRY ACTIVITIES AND COST EQUATIONS

A.1 ONE-TIME COSTS FOR INDUSTRY

Access Authorization Program

Procedures will be necessary to implement the access authorization program.

Hours of staff time for procedures	80
Wage of staff per hour	<u>\$55</u>
Cost of staff time for procedures	\$4,400
Hours of clerical time for procedures	20
Wage of clerical worker per hour	<u>\$55</u>
Cost of clerical time for procedures	\$1,100

Total cost for access authorization program procedures \$5,500

Individuals whose assigned duties and responsibilities permit the individual to have unescorted access to category 1 or category 2 quantities of radioactive material are subject to a background investigation.

Number of hours to conduct a background investigation	8
Wage of manager per hour	<u>\$55</u>
	\$440
Cost of taking fingerprints	\$25
Cost for fingerprint submission	\$26
Cost of background check per individual	\$491

Small licensee 20 individuals and 2 reviewing officials
Medium licensee 50 individuals and 3 reviewing officials
Large licensee 200 individuals and 5 reviewing officials

Total cost of background investigation per licensee	
Small licensee (26%)	\$10,802
Medium licensee (59%)	\$26,023
Large licensee (15%)	\$100,655

Cost of documenting determinations and access lists (material and information)

Hours of staff time for lists	4
Wage of staff per hour	<u>\$55</u>
Total cost for documenting access per licensee	\$220

Security Program

Preparation of security plan

Hours of staff time for plan	100
Wage of staff per hour	<u>\$55</u>
Cost of staff time for plan	\$5,500
Hours of clerical time per set of plans	20
Wage of clerical worker per hour	<u>\$55</u>
Cost of clerical worker time for security plan	\$1,100

Total cost for security plans \$6,600

Procedures will be necessary to implement the security program.

Hours of staff time for procedures	80
Wage of staff per hour	<u>\$55</u>
Cost of staff time for procedures	\$4,400
Hours of clerical time for procedures	20
Wage of clerical worker per hour	<u>\$55</u>
Cost of clerical time for procedures	\$1,100

Total cost for security procedures \$6,600

Training on Security Related Aspects:

Hours of staff time	4
Wage of staff per hour	\$55
Number of hours for a training manager to document all training per year	3
Wage of training manager	<u>\$55</u>
Cost for training documentation	\$165
Cost of training per licensee	
Small licensee	\$5,225
Medium licensee	\$11,825
Large licensee	\$45,265

Procedures will be necessary for information protection.

Hours of staff time for procedures	25
Wage of staff per hour	<u>\$55</u>
Cost of staff time for procedures	\$1,375

Hours of clerical time for procedures		10
Wage of clerical worker per hour		<u>\$55</u>
Cost of clerical time for procedures		\$550
Total cost for information protection procedures	\$1,925	
LLEA Coordination on Security		
Hours of staff time		20
Wage of staff per hour		<u>\$55</u>
		\$1,100
Documentation of coordination activities		
Hours of staff time		1
Cost of staff time per hour		<u>\$55</u>
		\$55
Total cost of LLEA coordination	\$1,155	
LLEA pre-arranged plan		
Hours of staff time		40
Cost of staff time per hour		<u>\$55</u>
Cost of pre-arranged plan		\$2,200
Cost of Physical Protection Elements		
Equipment, system cost, etc, per licensee	small - \$25,000, medium - \$60,000,	
large - 100,000		
<u>Transportation Security</u>		
Preparation of procedures for category 1 shipments		
Hours of staff time for procedures		15
Wage of staff per hour		<u>\$55</u>
Cost of staff time for procedures		\$825
Hours of clerical time for procedures		5
Wage of clerical worker per hour		<u>\$55</u>
Cost of clerical time for procedures		\$275
Number of licensees		16
Total cost for transportation procedures	\$17,600	

Records

Licensee must retain additional records

Cost of additional file cabinets etc. \$500

Total Cost for Records per Licensee \$500

A.2 ANNUAL COSTS

Program Review

Industry must conduct a performance evaluation of the security and access authorization program.

Cost of the security program review on an annual basis \$5,000

Cost of access authorization program review on annual basis \$5,000

Total Program Review Cost per Licensee \$10,000

Training on Security Related Aspects

Industry will need to conduct refresher training.

Hours of staff time 2
Wage of staff per hour \$55

Number of hours for a training manager to document
and certify all training per year 2
Wage of training manager \$55
Cost for training documentation \$110

Total Cost of Refresher Training per Licensee

Small Licensee \$2,530
Medium Licensee \$5,940
Large Licensee \$22,660

LLEA Coordination on Security

Hours of staff time 5
Wage of staff per hour \$55
\$275

Documentation of coordination activities

Hours of staff time	0.50
Cost of staff time per hour	<u>\$55</u>
	\$27.50

Total Cost of LLEA Coordination per Licensee \$302.50

Maintenance and Testing Program

Security equipment will need to be tested and maintained.

Hours of staff time	50
Cost of staff per hour	<u>\$55</u>
Cost of staff time	\$2,750

Total Cost for Maintenance and Testing per Licensee \$2,750

Records

Industry must retain additional records based on the new requirements.

Hours of clerical time for records	10
Wage of clerical worker per hour	<u>\$55</u>
Cost of clerical time for records	\$550

Total Cost for Records per Licensee \$550

Access Authorization Program

Any newly hired individual whose assigned duties and responsibilities permit the individual to have unescorted access to category 1 or category 2 quantities of radioactive material is subject to a background investigation.

Cost of each background check \$491

Cost of background check per licensee	
Small Licensee (2)	\$982
Medium licensee (5)	\$2,455
Large Licensee (20)	\$9,820

Individuals are subject to reinvestigation every 10 years.

Number of hours to conduct a background check	1
Wage of manager per hour	<u>\$55</u>
	\$55

Cost of fingerprints and FBI check		\$51
Cost of background check		\$106
Total Cost of Background Reinvestigation per Licensee		
Small licensee	\$2,332	
Medium licensee	\$5,618	
Large licensee	\$21,730	
Update access list 4 times a year		\$110

Event Notifications

Industry must notify the NRC Operations Center of missing or lost material, suspicious activities, and theft or diversion. The average number of calls for these types of events has been 5.7 averaged over 10 years. (57 calls related to category 2 radioactive material and 0 for category 1 radioactive material)

Hours of staff time per call		0.25
Cost of manager's time per hour		\$55
Number of calls per year		<u>6</u>
Cost of notifications per year		\$82.50

Industry must provide a written follow-up report for notifications.

Hours of staff time per written report		20
Wage of staff per hour		\$55
Number or written reports per year		<u>6</u>
Cost of staff time for written reports		\$6,600

Industry must call when lost/missing radioactive material is found.

Hours of staff time per call		0.08
Cost of staff time per hour		\$55
Number of calls per year		<u>6</u>
Cost of recovery notifications per year		\$26.40

Industry will now be required to report suspicious activities

Hours of staff time per call		0.25
Cost of manager's time per hour		\$55
Number of calls per year		<u>100</u>
Cost of notifications per year		\$1,375

Security Measures

Cost of measures per year (security company monitoring, etc.) small - \$15,000, medium - \$30,000, large - \$50,000

Category 1 Shipments

Industry has averaged 317 shipments of category 1 quantities of radioactive material per year (2005-2008). The number of shipments for 2009 and 2010 were well below the average for previous years. For purposes of the regulatory analysis, an assumption of 350 shipments per year is used.

Licensee Verification

Hours of staff time per verification	0.25
Cost of staff time per hour	\$55
Number of calls per year	<u>350</u>
Cost of license verification for category 1 shipments	\$4,812.50

Preplanning and Coordination

Hours of staff time with receiving licensee (0.25 x 2)	0.50
Cost of staff time per hour	\$55
Number of shipments per year	<u>350</u>
Cost of coordination with receiving licensee	\$9,625
Hours of staff time with State through which shipment passes	0.25
Cost of staff time per hour	\$55
Number of States through which shipment passes	10
Number of shipments per year	<u>350</u>
Cost of coordination with States	\$48,125
Cost of Preplanning and coordination	\$57,750

Notification of shipping licensee upon receipt

Hours of staff time with shipping licensee (0.08 x 2)	0.16
Cost of staff time per hour	\$55
Number of shipments per year	<u>350</u>
Cost of post notification with shipping licensee	\$3,080

Document preplanning and coordination activities

Hours of staff time	0.50
Cost of staff time per hour	\$55
Number of shipments per year	<u>350</u>
	\$9,625
Hours of clerical staff to file documents	0.08

Cost of clerical time per hour	\$55
Number of shipments per year	<u>350</u>
	\$1,540
Cost for documenting and filing for coordination activities	\$11,165
Advance Notifications	
Hours of staff time to prepare and send advance notification	4
Cost of staff time per hour	\$55
Number of notifications per year	<u>350</u>
	\$77,000
Hours of staff time for revision notice	0.25
Cost of staff time per hour	\$55
Number of revisions per year	32
	\$440
Hours of clerical staff to file documents	0.08
Cost of clerical time per hour	\$55
Number of shipments per year	<u>350</u>
	\$1,540
Total cost of advance notifications	\$78,980
Total Cost for Category 1 Shipment Arrangements	\$152,707.50
Physical protection of shipments	\$10,000
Number of shipments per year	<u>350</u>
	\$3,500,000
Total Cost of Protection for Category 1 Shipments	\$3,500,000
<u>Category 2 Shipments</u>	
Licensee Verification	
Hours of staff time per to verify license	0.25
Cost of staff time per hour	\$55
Number of verifications per year	<u>30,000</u>
Cost of license verification for category 2 shipments	\$412,500
Preplanning and Coordination	
Hours of staff time with receiving licensee (0.25 x 2)	0.50
Cost of staff time per hour	\$55
Number of shipments per year	<u>30,000</u>
Cost of coordination with receiving licensee	\$825,000
Notification of shipping licensee upon receipt	

Hours of staff time with shipping licensee (0.08 x 2)	0.16
Cost of staff time per hour	\$55
Number of shipments per year	<u>30,000</u>
Cost of post notification with shipping licensee	\$264,000
Document preplanning and coordination activities	
Hours of staff time	0.25
Cost of staff time per hour	\$55
Number of shipments per year	<u>30,000</u>
	\$412,500
Hours of clerical staff to file documents	0.08
Cost of clerical time per hour	\$55
Number of shipments per year	<u>30,000</u>
Cost for documenting coordination activities	\$132,000
Total Cost of Category 2 Shipment Arrangements	\$2,046,000
Physical protection of shipments	\$1,000
Number of shipment per year	<u>30,000</u>
	\$30,000,000
Total Cost of Protection for Category 2 Shipments	\$30,000,000
Notification of revisions	
Hours of staff time with (0.08 x 2)	0.16
Cost of staff time per hour	\$55
Number of shipments per year	<u>300</u>
Cost of revision notifications	\$2,640

Appendix B:

NRC/STATE ACTIVITIES AND COST EQUATIONS

B.1 ONE-TIME COSTS FOR NRC/STATE

Infrastructure

Revision of Inspection Procedures

FTE of staff time	0.2
Cost of FTE	<u>\$165,000</u>
Cost for inspection procedure revisions	\$33,000

Rule Development

FTE for State to develop rule	0.5
Cost of FTE	\$89,000
Number of Agreement States	<u>37</u>
Cost for Agreement States to develop rules	\$1,646,500

Training

FTE to revise training	0.25
Cost of FTE	<u>\$165,000</u>
Cost for training development	\$41,250
NRC Staff training hours	40
Number of NRC Staff	15
Cost of staff time per hour	<u>\$119</u>
Cost of NRC training	\$71,400
Number of Agreement State Staff (4 per)	148
Cost of staff time per hour	<u>\$50</u>
Cost of Agreement State staff training	\$296,000

B.2 ANNUAL COSTS FOR NRC/STATE

Event Notifications

NRC will answer calls from licensees reporting loss/missing, diversion, etc.

Hours of NRC/State staff time per call	0.08
Cost of NRC/State staff time per call	\$119
Number of calls per year	<u>6</u>
Cost of NRC/State staff time per year for handling calls	\$57.12

Review of 30-day reports

Hours of NRC/State time per report	1
Cost of NRC/State time per hour	\$119
Number of reports	<u>6</u>
Cost of NRC/State time to review 30-day reports	\$714

Total Cost of Handling Event Reports \$771.12

NRC will answer calls from licensees reporting suspicious activities

Hours of NRC/State staff time per call	0.08
Cost of NRC/State staff time per call	\$119
Number of calls per year	<u>100</u>
Cost of NRC/State staff time per year for handling calls	\$952.00

Verification of license

Hours of NRC/State time	0.25
Cost of NRC/State time	\$119
Number of verifications per year (assume 10%)	<u>3000</u>
Cost of license verification	\$89,250.00

Handling advance notifications

Hours of NRC time	0.50
Cost of NRC time	\$119
Number of notifications	<u>350</u>
Cost of NRC for advance notifications	\$20,825

Hours of State time	0.50
Cost of State time	\$50
Number of notifications	350
Number of States	<u>10</u>
Cost of State for advance notifications	\$175,000

Total Cost of Advance Notification \$195,825

Issuance of New Orders

NRC/State staff time	2
Cost of NRC/State time per hour	<u>\$119</u>
Cost of new order issuance	\$238

NRC/State Inspection

Additional time for conducting security-related inspections

NRC/State staff time	2
Cost of NRC time per hour	\$119
Cost of State time per hour	\$50

Additional cost of NRC inspection per licensee	\$238
Additional cost of State inspection per licensee	\$100

Appendix C:

REGULATORY FLEXIBILITY ANALYSIS

REGULATORY FLEXIBILITY ANALYSIS FOR THE AMENDMENTS TO 10 CFR PARTS 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, AND 73 (PHYSICAL PROTECTION OF BYPRODUCT MATERIAL)

I. Background.

The Regulatory Flexibility Act (RFA), as amended 5 U.S.C. 601 *et seq.*, requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply.

The NRC has established standards for determining which NRC licensees qualify as small entities (10 CFR 2.810). These size standards were based on the Small Business Administration's most common receipts-based size standards and include a size standard for business concerns that are manufacturing entities.

Description of the reasons that action by the agency is being considered.

The NRC has long participated in efforts to address radioactive source protection and security. The terrorist attacks of September 11, 2001, heightened concerns about the use of risk-significant radioactive materials in a malevolent act. Such an attack is of particular concern because of the widespread use of radioactive materials in the United States by industrial, medical, and academic institutions. The theft or diversion of risk-significant radioactive

materials could lead to their unauthorized use in a radiological dispersal device or a radiological exposure device.

Commission regulations provide requirements for the safe use, transport, and control of licensed material. A licensee's loss of control of risk-significant radioactive material, whether it is inadvertent or through a deliberate act, could result in significant adverse impacts that could reasonably constitute a threat to the public health and safety or the common defense and security of the United States. After the attacks of September 11, 2001, the Commission determined that certain licensed material should be subject to enhanced security provisions and safeguarded during transport, and that individuals with unescorted access to risk-significant radioactive material should be subject to background investigations. For additional information see the Discussion portion of the Statements of Consideration (SOC).

Succinct statement of the objectives of, and legal basis for, the final rule.

The objective of this rule is to establish generically applicable security requirements for the protection of category 1 and category 2 quantities of radioactive materials possessed by certain NRC and Agreement State licensees. These security requirements are similar to the requirements imposed on these licensees through the NRC's applicable previously issued security orders. The NRC has determined that it is preferable to regulate through rulemaking rather than order because notice and comment rulemaking is an open and transparent process that facilitates public participation. In developing the final rule, the NRC considered, among other things, the various orders, lessons-learned during implementation, the recommendations from the Independent Review Panel and the Materials Working Group, and stakeholder

comments. The rule also considered a petition for rulemaking submitted by the State of Washington. For additional information see the Discussion portion of the SOC. The authority citation sections of the final rule contain the statutory authority for the rule.

Description of and, where feasible, an estimate of the number of small entities to which the final rule will apply.

The final rule would affect about 300 NRC licensees and about 1,100 Agreement State licensees. This includes a wide range of licensees, including pool-type irradiator licensees; manufacturer and distributor licensees; medical facilities with gamma knife devices; self-shielded irradiator licensees (including blood irradiators); teletherapy unit licensees; radiographers; well loggers; broad scope users; radioisotope thermoelectric generator licensees; and licensees that ship or prepare for shipment category 1 or category 2 quantities of radioactive material. Some of these licensees would be considered small entities. In fiscal year 2008, about 26 percent of materials licensees qualified as small entities. Using the same percentage, approximately 364 of the licensees that will be affected by the rule would be considered small entities.

Description of the projected reporting, recordkeeping, and other compliance requirements of the final rule, including an estimate of the classes of small entities that will be subject to the requirements, and the type of professional skills necessary for preparation of reports and records.

Licensees will be required to: (1) develop procedures for implementation of the security provisions; (2) develop a security plan that describes how security is being implemented; (3)

conduct training on the procedures and security plan; (4) conduct background investigations for those individuals permitted access to category 1 or category 2 quantities of radioactive material; (5) coordinate with local law enforcement agencies (LLEAs) so the LLEAs would be better prepared to respond in an emergency; (6) conduct preplanning and coordination activities before shipping radioactive material; and (7) implement security measures for the protection of the radioactive material. Licensees will be required to promptly report any attempted or actual theft or diversion of the radioactive material. Licensees will be required to keep copies of the security plan, procedures, background investigation records, training records, and documentation that certain activities have occurred. For additional information on the requirements, see the SOC or the final rule text. No special skills are necessary for the preparation of reports or records.

On average, a licensee would have a one-time cost of approximately \$23,375 and an annual cost of approximately \$21,736 to fully implement the final rule. Much of this cost would result from the requirements to have procedures, conduct training, and to develop a security plan. Although not required by the various orders, many licensees may have developed procedures and conducted training that may require only minor revisions; if so, the actual cost may be lower. Additional large costs are the annual program review and the maintenance and testing of the security-related equipment. The program review is important for licensees to review the effectiveness of the program and to ensure that requirements are being implemented. Maintenance and testing is essential to ensure that the equipment is operational and available when needed. More information on the cost of the rule is contained in the Regulatory Analysis

Identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the final rule.

Several U.S. Government programs involve fingerprinting and an FBI identification and criminal history records check. These include the National Agency Check; Transportation Worker Identification Credentials in accordance with 49 CFR 1572; Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances in accordance with 27 CFR 555; Health and Human Services security risk assessments for possession and use of select agents and toxins in accordance with 42 CFR 73; Hazardous Material security threat assessment for hazardous material endorsement to commercial drivers license in accordance with 49 CFR 1572; and Customs and Border Protection's Free and Secure Trade Program. Any individual that has favorably undergone the background investigation required by these programs would be relieved from the fingerprinting and FBI criminal history records check element of the final rule as long as the licensee has appropriate documentation. Any individual who has an active Federal security clearance would also be relieved assuming appropriate documentation is provided.

The Department of Transportation requires security plans for the transport of highway route control quantities of radioactive material in accordance with 49 CFR 172.800. This provision covers only a small portion of the category 1 and category 2 quantities of radioactive material covered by the rule.

The NRC is not aware of any other relevant Federal rules that may duplicate, overlap, or conflict with the final rule.

Description of any significant alternatives to the final rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the final rule on small entities, including alternatives considered, such as: (1) establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements under the rule for small entities; (3) use of performance rather than design standards; and (4) any exemption from coverage of the rule, or any part thereof, for such small entities.

As noted earlier, some of the licensees that would be impacted by the final rule are small businesses. 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. Therefore, the NRC could not generically grant relief to small entities to allow them to implement less effective measures. The final rule provides some flexibility in the particular measures that a licensee can choose to employ. Licensees affected by the rule have already implemented the bulk of the rule's requirements in response to various orders.