Draft Regulatory Analysis for Proposed Rule: Physical Protection of Byproduct Material (10 CFR Parts 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	Code of Federal Regulations
DOT	Department of Transportation
FBI	Federal Bureau of Investigation
FR	*Federal Register*
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	Nuclear Regulatory Commission
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 proposed security requirements for use of category 1 and category 2 quantities of radioactive material. The U.S. Nuclear Regulatory Commission (NRC) is proposing to establish a new part 37 in Title 10 of the Code of Federal Regulations (CFR), which will contain 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 proposed rulemaking. Section 1.2 provides background information. Section 1.3 discusses the regulatory objectives of the proposed 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).

Commission regulations provide requirements for the safe use, transit, 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, 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 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 authorities (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.

Although a security 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 process. This proposed rulemaking would place the security requirements for use of category 1 and category 2 quantities of radioactive material into the regulations. In developing the proposed rule the staff considered the various security orders, lessons-learned during implementation, the recommendations of the Independent External Review Panel and the Materials Program Working Group, and

stakeholder comments
on the preliminary rule language. The proposed rule also considers a petition for rulemaking 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," put in place 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 put in place 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 only 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 gone. In some cases, months could elapse between uses; which is ample time for a terrorist to carry out a significant malevolent act. Nowhere do the 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.

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 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. The NRC 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 local law enforcement agency 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 security 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 were issued to manufacturing and distribution licensees (EA-03-225; January 12, 2004) (69 FR 5375; February 4, 2004). These orders require the implementation of additional security measures and the 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 our public website 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 known as Increased Controls. To effect nationwide implementation, each Agreement State issued legally binding requirements to

licensees under their regulatory jurisdiction.

These security 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 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 (EPAct). The EPAct 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.

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;

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

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, 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, necessitates 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 to licensees under their regulatory jurisdiction.

1.3 Regulatory Objectives

The objective of this proposed 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 by the NRC orders. Although a security 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 process. This proposed rulemaking would place the security requirements for use of category 1 and category 2 quantities of radioactive material into the regulations. In developing the proposed rule the staff considered the various security orders, lessons-learned during implementation, the recommendations of the Independent External Review Panel and the Materials Program Working Group, and stakeholder comments on the preliminary rule language. In addition a petition for rulemaking filed by the State of Washington was considered during the development of the proposed rule.

2. Identification and Preliminary Analysis of Alternative Approaches

This section presents preliminary analysis of the alternatives that the staff considered to meet the regulatory goals identified in the previous section. The NRC considered three alternatives for the proposed 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 Commission's security orders. This alternative would avoid certain costs that the rule would impose. However, taking no action would not address the lessons-learned, 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 be out of date and 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 the common defense and security.

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

Under Option 2, 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 30, 32, 33, 34, 35, 36, 39, 51, 71, and 73. The rule would apply to licensees that possess byproduct material in category 1 or category 2 quantities. Licensees that allow unescorted access to category 1 and category 2 quantities of radioactive material would need to develop and implement an access authorization program. Any licensee that is authorized to possess category 1 or category 2 quantities of radioactive material would need to develop a security program. Only those licensees that aggregate the radioactive material at the category 1 or category 2 level would be required to implement the security program and employ the security measures. 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, 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, 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 30, 32**,** 33, 34, 35, 36, 39, 51, 71, and 73. The rule would apply to licensees that are authorized to possess byproduct material that equals or exceeds the category 2 thresholds. 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, 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.

3. Evaluation of Benefits and Costs

This section examines the benefits and costs expected to result from the three options. 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.

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 NRC in Chapter 5 of its *Regulatory Analysis Technical Evaluation Handbook.*[2] 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 heath 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.

- Industry Operation - The action would require licensees to conduct additional security activities beyond those currently required such as notification of LLEA at temporary jobsites and for some licensees, develop security zones.

- NRC Implementation - Under the action, NRC will develop guidance and revise inspection procedures as a result of the new requirements.

- 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 suspicious activities. The action (options 2 and 3 only) would also require NRC staff to analyze

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

the fingerprint and criminal history record check results for the reviewing official for each licensee.

- Regulatory Efficiency - The action (options 2 and 3 only) would result in enhanced regulatory efficiency through regulatory and compliance improvements.

- 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. 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.[3] 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 proposed 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 proposed rule relative to the main analysis.

3.2.2 Data

To the extent practical, 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. NRC staff discussed its understanding of the potential differences between the proposed new requirements and the current requirements and has incorporated available, nonsafeguards, information into this draft regulatory analysis. The NRC is seeking additional insight from stakeholders on implementing costs and related issues.

3.2.3 Assumptions

The main analysis assumes that any one-time implementation costs are incurred in calendar year 2011. The main analysis and the no-action option assume that one-time costs have already occurred and are not factored into the analysis for those aspects required by the security orders. Ongoing costs of operation related to the rule are assumed to begin in 2011, 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, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 4. The detailed incremental cost and savings calculations are presented in Appendices A and B. Costs and savings are expressed in 2010 dollars.

For the main analysis, the NRC assumed that 1,400 licensees would fully implement the security provisions and another 1,550 licensees would need to conduct some documentation

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

under Option 2 and 2,950 licensees would be impacted under Option 3. 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 irradiators); teletherapy unit licensees; radiographers; well loggers; broad scope users; radioisotope thermoelectric generator licensees; and licensees that ship or prepare for shipment of category 1 or category 2 quantities of radioactive material. Because the licensees impacted by the rule vary so greatly, it is hard to estimate the burden that would be imposed by the proposed 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 assumes an average sized facility for calculating the costs.

The NRC assumes that three to five licensees would be issued security orders per year under the no-action alternative. This cost in 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 proposed rule assuming that the security orders were never issued. The analysis assumes full licensee compliance with existing NRC regulations, but not the security orders that have been issued. Section 4.2 presents the estimated incremental costs and savings of the proposed rule relative to the pre-order analysis.

3.3.2 Data

To the extent practical, 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. NRC staff discussed its understanding of the potential differences between the proposed new requirements and the current requirements and has incorporated available, nonsafeguards-information into this draft regulatory analysis. The NRC is seeking additional insight from stakeholders on implementing costs and related issues.

3.3.3 Assumptions

The pre-order analysis assumes that any one-time implementation costs are incurred in calendar year 2011. Ongoing costs of operation related to the rule are assumed to begin in 2011, 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, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 4. The detailed incremental cost and savings calculations are presented in Appendices A and B. Costs and savings are expressed in 2010 dollars.

For the pre-order analysis, the NRC assumed that 1,400 licensees would fully implement the security provisions and another 1,550 licensees would need to conduct some documentation under Option 2, and 2,950 licensees would be impacted under Option 3.

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 options. Option 2 would result in a net quantitative impact estimated between $450,996,566 and $612,347,047 (7-percent and 3-percent discount

rate, respectively), and option 3 would result in a net quantitative impact estimated between $1,102,164,007 and $1,452,904,865 (7-percent and 3-percent discount rate, respectively). The majority of the costs would be incurred by industry.

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
Option 1: No Action **Industry:** ($0) using a 7% discount rate ($0) using a 3% discount rate **NRC/Agreement States:** ($0) using a 7% discount rate ($0) using a 3% discount rate	<u>Qualitative Benefits:</u> Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded. Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material. Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material. Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material. On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material. <u>Qualitative Costs:</u> Regulatory Efficiency: Regulatory efficiency would be reduced by the need to issue security orders to new licensees and licensees increasing their possession limit above the category 2 threshold.
Option 2: Rulemaking(Possession Base) **Industry:** ($433,350,357) using a 7% discount rate ($588,956,864) using a 3% discount rate **NRC/State:** ($12,026,479) using a 7% discount rate ($16,575,368) using a 3% discount rate **Agreement States:**	<u>Qualitative Benefits:</u> Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded. Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material. Occupational Health (Accident): Reduced risk that

($5,619,730) using a 7% discount rate ($6,814,815) using a 3% discount rate	occupational health will be affected by radiological releases from unauthorized use of radioactive material. Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material. On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material. Regulatory Efficiency: Enhanced regulatory efficiency through regulatory and compliance improvements. <u>Qualitative Costs:</u> None.
Option 3: Rulemaking (Authorization Base) **Industry:** ($1,078,740,403) using a 7% discount rate ($1,421,576,173) using a 3% discount rate **NRC/State:** ($14,848,144) using a 7% discount rate ($20,363,061) using a 3% discount rate **Agreement States:** ($8,575,460) using a 7% discount rate ($10,965,631) using a 3% discount rate	<u>Qualitative Benefits:</u> Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded. Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material. Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material. Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material. On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material. Regulatory Efficiency: Enhanced regulatory efficiency through regulatory and compliance improvements. <u>Qualitative Costs:</u> None.

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)	
	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	($8,400,000)	0	($17,700,000)	0
Background Investigations	0	0	($1,864,800)	0	($9,457,200)	($2,064,600)
Background Re-investigations	NA	NA	NA	($369,600)	NA	($7,788,000)
Access Lists	0	0	0	0	($465,,000)	0
Program Review	NA	NA	NA	($7,000,000)	NA	($14,750,000)
Subtotal for Access Authorization Program	$0	$0	($10,264,800)	($7,369,600)	($27,622,200)	($24,602,600)
Security Program						
Security Plan	0	0	($17,193,000)	0	($17,193,000)	0

Security Procedures	NA	NA	($8,400,000)	0	($17,700,000)	0
Information Protection Procedures	0	0	0	0	($4,650,000)0	0
Security Training	NA	NA	($11,480,000)	($5,880,000)	($24,190,000)	($12,390,000)
LLEA Coordination	0	0	0	0	($3,177,500)	($852,500)
Security Measures	0	0	0	0	($23,250,000)	($1,550,000)
Program Review	NA	NA	0	($7,000,000)	0	($14,750,000)
Maintenance and Testing	NA	NA	0	($7,000,000)	0	($14,750,000)
Physical Inventory Checks	NA	NA	0	($3,640,000)	0	($7,670,000)
LLEA Notification – Temporary Jobsites	NA	NA	0	($80,640)	0	($80,640)
Subtotal for Security Program	$0	$0	($237,073,000	($23,600,640)	($90,160,500)	($52,043,140)
Transportation Security						
Procedure Development	NA	NA	($28,000)	0	($28,000)	0
Training	NA	NA	($64,000)	0	($64,000)	0
License Verification	0	0	0	($375,000)	0	($375,000)

Preplanning and Coordination (Category 1)	0	0	0	0	0	0
Post Notification (Category 1)	0	0	0	0	0	0
Documentation (Category 1)	0	0	0	0	0	0
Advance Notifications	0	0	0	0	0	0
Protection of Category 1 Shipments	0	0	0	0	0	0
Preplanning and Coordination (Category 2)	0	0	0	0	0	0
Post Notification (Category 2)	0	0	0	0	0	0
Documentation (Category 2)	0	0	0	0	0	0
Protection of Category 2 Shipments	0	0	0	0	0	0
Notification of	0	0	0	0	0	0

Revisions						
Subtotal for transportation Security	$0	$0	($92,000)	$0	($92,000)	($375,000)
Records and Reporting						
Notification of Compliance	NA	NA	($368,750)	0	($368,750)	0
Records	-	0	($700,000)	($1,750,000)	($1,475,000)	($3,687,500)
Procedure Updates	NA	NA	0	($3,220,000)	0	($6,785,000)
Event Notification	0	0	0	($12,048)	0	($12,048)
Subtotal for Records and Reporting	$0	$0	($1,068,750)	($4,982,048)	($1,250,000)	($10,484,548)
TOTAL	$0	$0	($48,498,550)	($36,327,288)	($119,718,450)	($87,505,288)

Exhibit 4-3 Cost Comparison for Main Analysis

	OPTION 1 – (NO-ACTION)		OPTION 2 (RULEMAKING BASED ON POSSESSION)		OPTION 3 (RULEMAKING BASED ON AUTHORIZATION)	
	3% Discount	7% Discount	3% Discount	7% Discount	3% Discount	7% Discount
Industry One-Time Savings (Cost)	$0	$0	($48,498,550)	($48,498,550)	($119,718,450)	($119,718,450)
Industry Annual Savings (Cost)	$0	$0	($540,458,314)	($384,851,807)	($1,301,857,723)	($959,021,953)
NRC/State One-Time Savings (Cost)	$0	$0	($775,998)	($775,988)	($1,208,448)	($1,208,448)
NRC/State Annual Savings (Cost)	$0	$0	($15,799,370)	($11,250,481)	($19,154,613)	($13,639,696)
Agreement State One-Time Savings (Cost)	$0	$0	($2,664,000)	($2,664,000)	($2,664,000)	($2,664,000)
Agreement State Annual Savings (Cost)	$0	$0	($4,150,815)	($2,955,730)	($8,301,631)	($5,911,460)
Total Savings (Cost)	$0	$0	($612,347,047)	($450,996,566)	($1,452,904,865)	($1,102,164,007)

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 $939,259,048 and $1,276,425,028 (7-percent and 3-percent discount rate, respectively), and option 3 would result in a net

quantitative impact estimated between $1,616,863,568 and $2,197,090,772 (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 proposed 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
Option 1: No Action $0	Qualitative Benefits and Costs: None.
Option 2: Rulemaking **Industry:** ($921,254,790) using a 7% discount rate ($1,252,676,795) using a 3% discount rate **NRC:** ($12,384,528) using a 7% discount rate ($16,933,418) using a 3% discount rate **Agreement States:** ($5,619,730) using a 7% discount rate ($6,814,815) using a 3% discount rate	Qualitative Benefits: Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive material are safeguarded. Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material. Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material. Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material. On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material. Regulatory Efficiency: Enhanced regulatory efficiency through regulatory and compliance improvements. Qualitative Costs: None.
Option 3: Rulemaking	Qualitative Benefits: Safeguards and Security: Increased level of assurance that category 1 and category 2 quantities of radioactive

Industry: ($1,593,073,014) using a 7% discount rate ($2,165,395,130) using a 3% discount rate **NRC:** ($15,215,094) using a 7% discount rate ($20,730,010) using a 3% discount rate **Agreement States:** ($8,575,460) using a 7% discount rate ($10,965,631) using a 3% discount rate	material are safeguarded. Public Health (Accident): Reduced risk that public health will be affected by radiological releases from unauthorized use of radioactive material. Occupational Health (Accident): Reduced risk that occupational health will be affected by radiological releases from unauthorized use of radioactive material. Off-site Property: Reduced risk that off-site property will be affected by radiological releases from unauthorized use of radioactive material. On-site Property: Reduced risk that on-site property will be affected by radiological releases from unauthorized use of radioactive material. Regulatory Efficiency: Enhanced regulatory efficiency through regulatory and compliance improvements. <u>Qualitative Costs:</u> None.

Exhibit 4-5

Industry Savings and Costs for Pre-Order Analysis

	OPTION 2 (RULEMAKING BASED ON POSSESSION)		OPTION 3 (RULEMAKING BASED ON AUTHORIZATION)	
	One-Time Savings (Cost)	Annual Savings (Cost)	One-Time Savings (Cost)	Annual Savings (Cost)
Access Authorization Program				
Access Authorization Program Procedures	($8,400,000)	-	($17,700,000)	-
Background Investigations	($11,188,800)	($1,864,800)	($23,576,400)	($8,991,000)
Background Reinvestigations (every 10 years)	-	($369,600)	-	($7,788,000)
Access Lists	($420,000)	-	($885,000)	-
Program Review	-	($7,000,000)	-	($14,750,000)
Subtotal for Access Authorization Program	($20,008,800)	($9,234,400)	($42,161,400)	($31,529,000)
Security Program				
Security Plan	($32,450,000)	-	($32,450,000)	-

Security Procedures	($8,400,000)	-	($17,700,000)	-
Information Protection Procedures	($4,200,000)	-	($8,850,000)	
Security Training	($11,480,000)	($5,880,000)	($24,190,000)	($12,390,000)
LLEA Coordination	($2,870,000)	($770,000)	($6,047,500)	($1,622,500)
Security Measures	($21,000,000)	($1,400,000)	($44,250,000)	($2,950,000)
Program Review	-	($7,000,000)	-	($14,750,000)
Maintenance and Testing	-	($7,000,000)	-	($14,750,000)
Physical Inventory Checks	-	($3,640,000)	-	($7,670,000)
LLEA Notification – Temporary Jobsites	-	($80,640)	-	($80,640)
Subtotal for Security Program	($80,400,000)	($25,770,640)	($133,487,500)	($54,213,140)
Transportation Security				
Procedure Development	($28,000)	-	($28,000)	-
Training	($64,000)	-	($64,000)	-
License Verification	-	($758,750)	-	($758,750)
Preplanning and Coordination (Category 1)	-	($105,000)	-	($105,000)

Post Notification (Category 1)	-	($5,600)	-	($5,600)
Documentation (Category 1)	-	($18,900)	-	($18,900)
Advance Notifications	-	($142,200)	-	($142,200)
Protection of Category 1 Shipments	-	($3,500,000)	-	($3,500,000)
Preplanning and Coordination (Category 2)	-	($1,500,000)	-	($1,500,000)
Post Notification (Category 2)	-	($480,000)	-	($480,000)
Documentation (Category 2)	-	($870,000)	-	($870,000)
Protection of Category 2 Shipments	-	($30,000,000)	-	($30,000,000)
Revision Notifications	-	($4,800)	-	($4,800)
Subtotal for transportation Security	($92,000)	($37,385,250)	($92,000)	($37,385,250)
Records and Reporting				
Licensee Notification on Compliance	($368,750)	0	($368,750)	0
Records	($700,000)	($1,750,000)	($1,475,000)	($3,687,500)
Procedure Updates	-	($3,220,000)	-	($6,785,000)

Event Notification	-	($12,198)	-	($12,198)
Subtotal for Records and Reporting	($1,068,750,000)	($4,982,198)	($1,843,750)	($10,484,698)
TOTAL	($101,569,550)	($77,372,488)	($177,584,650)	($133,612,088)

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 $450,996,566 (total present value over a 20-year period), assuming a 7-percent discount rate, or approximately $612,347,047 assuming a 3-percent discount rate. Option 3 would result in a net cost estimated as approximately $1,102,164,007 (total present value over a 20-year period), assuming a 7-percent discount rate, or approximately $1,452,904,865 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. Options 2 and 3 would also result in enhanced regulatory efficiency and effectiveness and would 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 has selected Option 2 as it would impose less burden on industry and still meet the objectives of the rule.

The typical licensee would have a one-time cost of approximately $27,000 and an annual cost of approximately $25,700 to fully implement the proposed 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 security 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 weekly physical check of the category 2 sources and the annual program review. The NRC believes that the weekly check is a vital part of the security program, particularly for materials that are used infrequently. The program review is important for licensees to review the effectiveness of the program and to ensure that requirements are being implemented.

As noted earlier, some of the licensees that would be impacted by the proposed rule are small businesses. The proposed rule would impose 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 could not grant relief to small entities to allow them to implement less effective measures. The proposed rule would provide some flexibility in the particular measures that a licensee could choose to employ.

6. Implementation

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

6.1 Schedule

The action would be implemented through a proposed rule, resolution of public comments, and a final rule. The final rule would be effective 180 days from the date of publication. The staff has not identified any impediments to implementing the recommended alternative. Agreement States would have 3 years to issue compatible regulations.

6.2 Impacts on Other Requirements

As discussed in Section 4.1, affected licensees will experience most of the impact of the proposed rule. The NRC estimates that it will spend 0.7 FTE to revise implementation guidelines and inspection procedures. Each Agreement State would be expected to spend 0.5 FTE to establish regulations. The NRC estimates that on average an additional 3 hours per licensee will be needed to conduct the security-related inspections. This will result in approximately 1,200 hours for NRC inspection and approximately 3,000 hours 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 access authorization program.

Hours of staff time for procedures	50
Wage of staff per hour	$100
Cost of staff time for procedures	$5,000
Hours of clerical time for procedures	20
Wage of clerical worker per hour	$50
Cost of clerical time for procedures	$1,000

Total cost for access authorization program procedures $6,000

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 check	6
Wage of manager per hour	$100
	$600
Cost of credit history	$20
Cost of taking fingerprints	$10
Cost for fingerprint submission	$36
Cost of background check	$666
Number of individuals needing background checks per licensee	10
Number of reviewing officials needing background checks	2

Total cost of background investigation per licensee $7,992

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

Hours of staff time for lists
3
Wage of staff per hour
$100

Total cost for documenting access per licensee
$300

Notification on Compliance
Licensees would need to notify NRC on compliance.

Hours of staff time for notification
1
Wage of staff per hour
$100

Cost of staff time for procedures
$100

Hours of clerical time for notification
0.5
Wage of clerical worker per hour $50

Cost of clerical time for procedures
$25

Total Cost of Notification per Licensee **$125**

Security Program

Preparation of security plan

Hours of staff time for plan 100
Wage of staff per hour $100

Cost of staff time for plan
$10,000

Hours of clerical time per set of plans
20
Wage of clerical worker per hour $50

Cost of clerical worker time for security plan $1,000

Total cost for security plans

$11,000

Procedures will be necessary to implement the security program.

Hours of staff time for procedures
50
Wage of staff per hour
$100

Cost of staff time for procedures
$5,000

Hours of clerical time for procedures
20
Wage of clerical worker per hour $50

Cost of clerical time for procedures
$1,000

Total cost for security procedures $6,000

Training on Security Related Aspects:

Hours of staff time
8
Wage of staff per hour
$100
Number of people requiring training
10

Cost of training per licensee
$8,000

Number of hours for a training manager to document all training per year
2
Wage of training manager
$100

Cost for training documentation
$200

Total cost of security training $8,200

Procedures will be necessary for information protection.

Hours of staff time for procedures
25
Wage of staff per hour
$100

Cost of staff time for procedures
$2,500

Hours of clerical time for procedures
10
Wage of clerical worker per hour $50

Cost of clerical time for procedures
$500

Total cost for information protection procedures $3,000

LLEA Coordination on Security

Hours of staff time
20
Wage of staff per hour
$100

$2,000

Documentation of coordination activities

Hours of staff time
0.50
Cost of staff time per hour
$100

$50

Total cost of LLEA coordination $2,050

Cost of Physical Protection Elements

Equipment, system cost, etc, per licensee
$15,000

Total cost of equipment, systems, etc, per licensee $15,000

Transportation Security

Preparation of procedures for category 1 shipments

Hours of staff time for procedures
15
Wage of staff per hour
$100

Cost of staff time for procedures
$1,500

Hours of clerical time for procedures
5
Wage of clerical worker per hour $50

Cost of clerical time for procedures
$250

Number of licensees
16

Total cost for transportation procedures

$28,000

Training on procedures for category 1 shipments

Hours of staff time
4
Wage of staff per hour
$100
Number of people requiring training
10

Cost of training per licensee
$4000

Number of licensees
16

Total cost of transportation training $64,000

Total Cost of Transportation Security **$92,000**

Records

Licensee must retain additional records based on the new requirements

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 4

Wage of staff per hour $100

Number of people requiring training 10

$4,000

Number of hours for a training manager to document and certify all training per year 2

Wage of training manager $100

Cost for training documentation $200

Total Cost of Refresher Training per Licensee **$4,200**

Alarm Monitoring

Cost per licensee for security firm to monitor alarms $1,000

Total Cost of Alarm Monitoring per licensee **$1,000**

Procedure Development

The procedures will need to be periodically updated.

Hours of staff time for procedures
20
Wage of staff per hour
$100

Cost of staff time for procedures
$2,000

Hours of clerical time for procedures
6
Wage of clerical worker per hour $50

Cost of clerical time for procedures
$300

Total Cost for Procedure Updates per Licensee

$2,300

LLEA Coordination on Security

Hours of staff time 5
Wage of staff per hour
$100

$500

Documentation of coordination activities

Hours of staff time
0.50
Cost of staff time per hour
$100

$50

Total Cost of LLEA Coordination per Licensee **$550**

Maintenance and Testing Program

Security equipment will need to be tested and maintained.

Hours of staff time
50

Cost of staff per hour
$100

Cost of staff time
$5,000

Total Cost for Maintenance and Testing per Licensee

$5,000

Records

Industry must retain additional records based on the new requirements.

Hours of manager time
10
Wage of manager per hour
$100

Cost of manager time $1,000

Hours of clerical time for records
5
Wage of clerical worker per hour
$50

Cost of clerical time for records
$250

Total Cost for Records per Licensee

$1,250

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.

Number of new hires needing background checks per year
2
Cost of each background check
$666

Cost of background check $1,332

Total Cost of Background Investigations per Licensee $1,332

Individuals are subject to reinvestigation every 10 years.

Number of hours to conduct a background check 2

Wage of manager per hour $100

$200

Cost of credit history $20

Cost of background check $220

Number of individuals needing background checks per licensee 12

Total Cost of Background Reinvestigation per Licensee $2,640

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 $100

Number of calls per year 6

Cost of notifications per year $150

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

Hours of staff time per written report 20

Wage of staff per hour $100

Number or written reports per year 6

-

Cost of staff time for written reports
$12,000

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

Hours of staff time per call
0.08
Cost of staff time per hour
$100
Number of calls per year
6

Cost of recovery notifications per year
$48

Total Cost for Event Notification **$12,198**

LLEA Notification for Temporary Job Sites

Hours of staff time to notify LLEA
1
Cost of staff time per hour
$100
Number of notifications per licensee per year
2
Number of licensees
336

$67,200

Hours of clerical staff time to file documents .
0.8
Cost of clerical time per hour
$50
Number of licensees
336

$13,440

Total Cost for LLEA Notifications **$80,640**

Physical Inventory Checks

Hours of staff time to check inventory
0.5
Cost of staff time per hour
$100
Number of checks
52

2,600

Total Cost of Physical Inventory Check per Licensee $2,600

Category 1 Shipments

Industry has averaged 317 shipments of category 1 quantities of radioactive material per year over the last 3 years. For purposes of the regulatory analysis, an assumption of 350 shipments per year is used.

Licensee Verification

Hours of staff time per call to agency to verify license
0.25
Cost of staff time per hour
$100
Number of calls per year
350

Cost of license verification for category 1 shipments
$8,750

Preplanning and Coordination

Hours of staff time with receiving licensee (0.25 x 2)
0.50
Cost of staff time per hour
$100
Number of shipments per year
350

Cost of coordination with receiving licensee
$17,500

Hours of staff time with State thru which shipment passes
0.25
Cost of staff time per hour
$100
Number of States through which shipment passes
10

Number of shipments per year
350

Cost of coordination with States
$87,500

Cost of Preplanning and coordination $105,000

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
$100
Number of shipments per year
350

Cost of post notification with shipping licensee
$5,600

Document preplanning and coordination activities

Hours of staff time
0.50
Cost of staff time per hour
$100
Number of shipments per year
350

17,500

Hours of clerical staff to file documents
0.08
Cost of clerical time per hour
$50
Number of shipments per year
350

$1,400

Cost for documenting and filing for coordination activities $18,900

Advance Notifications

Hours of staff time to prepare and send advance notification
4

Cost of staff time per hour
$100
Number of notifications per year
350

$140,000

Hours of staff time for revision notice
0.25
Cost of staff time per hour
$100
Number of revisions per year
32

$800

Hours of clerical staff to file documents
0.08
Cost of clerical time per hour
$50
Number of shipments per year
350

$1,400

Total cost of advance notifications $142,200

Total Cost for Category 1 Shipment Arrangements **$280,450**

Physical protection of shipments
$10,000
Number of shipments per year
350

$3,500,000

Total Cost of Protection for Category 1 Shipments **$3,500,000**

Category 2 Shipments

Licensee Verification

Hours of staff time per call to agency to verify license
0.25

Cost of staff time per hour
$100
Number of calls per year
30,000

_____

Cost of license verification for category 2 shipments
$750,000

Preplanning and Coordination

Hours of staff time with receiving licensee (0.25 x 2) .
0.50
Cost of staff time per hour
$100
Number of shipments per year
30,000

_____

Cost of coordination with receiving licensee
$1,500,000

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
$100
Number of shipments per year
30,000

_____

Cost of post notification with shipping licensee
$480,000

Document preplanning and coordination activities

Hours of staff time
0.25
Cost of staff time per hour
$100
Number of shipments per year
30,000

_____

$750,000

Hours of clerical staff to file documents
0.08

Cost of clerical time per hour
$50
Number of shipments per year
30,000

_____
Cost for documenting coordination activities
$120,000

Total Cost of Category 2 Shipment Arrangements **$3,600,000**

Physical protection of shipments $1,000
Number of shipment per year 30,000

_____

$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
$100
Number of shipments per year
300

_____

Cost of revision notifications
$4,800

Appendix B:

NRC/STATE ACTIVITIES AND COST EQUATIONS

B.1 ONE-TIME COSTS FOR NRC/STATE

Infrastructure

NRC revises/develops implementation guidance.

FTE of staff time	0.5
Cost of FTE	$148,000
Cost of guidance documents	$74,000

Revision of Inspection Procedures

FTE of staff time	0.2
Cost of FTE	$148,000
Cost for inspection procedure revisions	$29,600

Total Cost of Infrastructure **$103,600**

Rule Development

FTE for NRC to develop final rule	3.42
Cost of FTE	$148,000
Cost for NRC to develop final rule	$506,160
FTE for State to develop rule	0.5
Cost of FTE	$148,000
Number of Agreement States	36
Cost for Agreement States to develop rules	$2,664,000

Total Cost of Rule Development **$3,170,160**

NRC Fingerprint Processing

Review of fingerprints for reviewing officials

NRC/State time to review fingerprints	0.25
Cost of NRC/State time per hour	$93
Number per licensee	2
Cost of review per fingerprint set	$46.50

Processing of fingerprints

NRC processing time	0.25
Cost of NRC time per hour	$93
Cost of processing per fingerprint set	$23.25
Number of fingerprints per licensee	10

Compliance Notifications

NRC/State processing time	0.25
Cost of NRC/State time per hour	$93
Cost of processing for 2,950 licensees	$68,587.50

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	$93
Number of calls per year	6

Cost of NRC/State staff time per year for handling calls
$44.64

Review of 30-day reports

Hours of NRC/State time per report
1
Cost of NRC/State time per hour
$93
Number of reports
6

Cost of NRC/State time to review 30-day reports
$558

Total Cost of Handling Event Reports **$602.64**

Verification of license

Hours of NRC/State time
0.25
Cost of NRC/State time
$93
Number of category 1 verifications per year
350

Cost of license verification
$8137.50

Hours of NRC/State time
0.25
Cost of NRC/State time
$93
Number of category 2 verifications per year
30,000

Cost of license verification
$697,500

Total Cost of License Verification **$705,637.50**

Handling advance notifications

Hours of NRC time	0.50
Cost of NRC time	$93
Number of notifications	350
Cost of NRC for advance notifications	$16,275

Hours of State time		0.50
Cost of State time		$93
Number of notifications		350
Number of States		10
Cost of State for advance notifications		$162,750
Total Cost of Advance Notification	**$179,025**	

Issuance of New Orders

NRC/State staff time	2
Cost of NRC/State time per hour	$93
Cost of new order issuance	$186

NRC Fingerprint Processing

Processing of Fingerprints

NRC processing time	0.25
Cost of NRC time per hour	$93
Cost of processing per fingerprint set	$23.25

NRC/State Inspection

Additional time for conducting security-related inspections

NRC/State staff time	3
Cost of NRC/State time per hour	$93
Additional cost of inspection per licensee	$279

Appendix C:

Regulatory Flexibility Analysis

REGULATORY FLEXIBILITY ANALYSIS FOR THE PROPOSED AMENDMENTS TO 10 CFR PARTS 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, 73, AND 150 (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, 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 or a radiological exposure device.

Commission regulations provide requirements for the safe use, transit, 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 proposed rule.

The objective of this proposed rule is to provide reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material for unauthorized use by establishing generally applicable security requirements similar to those previously imposed by NRC orders. Although an order is legally binding on the licensee receiving the order, a rule makes the requirements generally applicable to all affected licensees. In addition, notice and comment rulemaking is an open process that allows for public participation. This proposed rulemaking would place security requirements for category 1 and category 2 quantities of radioactive material into the regulations. In developing the proposed rule, the staff considered, among other things, the various security orders, lessons-learned during implementation, the recommendations from the Independent Review Panel and the Materials Working Group, and stakeholder comments. The proposed 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 proposed rule contain the statutory authority for the proposed rule.

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

The proposed rule would afect 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, 364 of the licensees that would be affected by the proposed rule would be considered small entities.

Description of the projected reporting, recordkeeping, and other compliance requirements of the proposed 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 would 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 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 would be required to promptly report any attempted or actual theft or diversion of the radioactive material. Licensees would 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 proposed rule text. No special skills are necessary for the preparation of reports or records.

The average licensee would have a one-time cost of approximately $27,000 and an annual cost of approximately $25,700 to fully implement the proposed 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 security orders, many licensees have already developed procedures and conducted training and may only require minor revisions; therefore, the actual cost for some licensees may be lower. Additional large costs are the weekly physical check of the category 2 sources and the annual program review. The NRC views that the weekly check is a vital part of the security program, particularly for materials that are used infrequently. The program review is important for licensees to review the effectiveness of the program and to ensure that requirements are being implemented. More information on the cost of the proposed 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 proposed 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 Patrol's Free and Secure Trade Program. Any individual that has favorably undergone the background investigation required by these programs would be relieved from the background investigation elements of the proposed 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 proposed rule.

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

Description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the proposed 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 proposed rule are small businesses. The proposed rule would impose 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 could not grant relief to small entities to allow them to implement less effective measures. The proposed rule would provide some flexibility in the particular measures that a licensee could choose to employ. Licensees affected by the proposed rule have already implemented the bulk of the requirements in response to various security orders.