
**Regulatory Analysis for Direct Final Rule:
Safeguards Information - Modified Handling
Categorization Change for Materials Facilities
(10 CFR Parts 30, 37, 73, and 150)**

**U.S. Nuclear Regulatory Commission
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Executive Summary

The U.S. Nuclear Regulatory Commission (NRC) is amending Title 10 of the *Code of Federal Regulations* (10 CFR) Part 73, "Physical Protection of Plants and Materials," to remove the Safeguards Information – Modified Handling (SGI-M) designation of the security-related information for large irradiators, manufacturers and distributors (M&Ds) of items containing source, byproduct, or special nuclear material in category 2 quantities or greater, and for transport of category 1 quantities of radioactive material. This rulemaking will also result in the removal of the SGI-M designation of security related information for the transportation of irradiated reactor fuel in net weights of 100 grams or less. The security-related information for these facilities and the transportation of certain materials will no longer be designated as SGI-M under 10 CFR Part 73, and will be protected under the information protection requirements of 10 CFR Part 37, which applies to all materials licensees that possess aggregated category 1 or category 2 quantities of radioactive material.

The purpose of this regulatory analysis is to measure the incremental costs of the rule. The baseline for the analysis is the no action alternative, or how things would be without the rule. The costs evaluated in the regulatory analysis are only those costs that would be incurred under the rule. Under these assumptions, the analysis presented in this document examines the benefits and costs of the new requirements. The analysis found:

- **Total Cost to Industry.** This rule will result in an annual savings for each NRC licensee of approximately \$302. The total industry annual savings is approximately \$33,850. The net present value of the savings to industry is approximately \$0.62 million (using a 7-percent discount rate) and \$.87 million (using a 3-percent discount rate) over a 20-year analysis period.
- **Costs to NRC.** There is an estimated \$25,000 annual savings for the NRC associated with the implementation of the rule. The NRC has a one-time cost associated with updating the associated guidance. The cost of this updating is estimated to be \$1,200.
- **Decision Rationale.** The NRC decision is to conduct this rulemaking to remove the SGI-M categorization of security-related information for large irradiators, M&D licensees, and licensees that transport category 1 quantities of radioactive material and irradiated reactor fuel in 100 grams or less net weight. The rationale for this decision is that this information will be protected under the information protection requirements of 10 CFR Part 37, which provides adequate protection of this information without needlessly maintaining an effectively redundant burden on the licensee to protect this information under 10 CFR Part 73.

No backfit analysis was conducted for this rule. As stated in the "Backfit Analysis" section in this Regulatory Analysis, a Backfit Analysis does not apply to this rule because this amendment does not add or modify any requirements as backfits are defined in 10 CFR 50.109 or 10 CFR 70.76.

Acronyms and Abbreviations

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
CFR	<i>Code of Federal Regulations</i>
Ci	curies
FR	<i>Federal Register</i>
M&D	manufacturer and distributor
NRC	U.S. Nuclear Regulatory Commission
OMB	Office of Management and Budget
RA	regulatory analysis
SGI	safeguards information
SGI-M	safeguards information – modified handling
TBq	Terabequerels

1. Introduction

The NRC is amending 10 CFR Part 73, "Physical Protection of Plants and Materials," to remove the SGI-M designation of the security-related information for panoramic and underwater irradiator licensees that possess more than 370 Terabequerels (TBq) (10,000 curies (Ci)) of radioactive material (large irradiators), M&D licensees, and licensees that transport category 1 quantities of radioactive material. This rulemaking will also result in the removal of the SGI-M designation of security-related information for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. The security information for these facilities will no longer be protected as SGI-M. The information will be protected under the information protection requirements of 10 CFR Part 37, which applies to all materials licensees possessing aggregated category 1 and category 2 quantities of radioactive material. This regulatory analysis (RA) is part of the Commission's analysis of options being considered and is a supporting document to the direct final rule. The purpose of this RA is to evaluate the costs and benefits associated with the regulatory changes to be imposed by this rule. The NRC considers the RA process an integral part of its statutory mission to ensure reasonable assurance for the protection of public health and safety, property, environmental quality, and common defense and security from civilian uses of nuclear materials. This document presents background material, describes the regulatory problem, the objective of the rule, outlines the alternatives being considered, and evaluates the values and impacts of the regulatory alternatives.

1.1 Background

1.1.1 Current Regulatory Framework

Safeguards Information (SGI) is a special category of sensitive unclassified information authorized by Section 147 of the Atomic Energy Act, as amended (AEA), to be protected from unauthorized disclosure. Safeguards Information – Modified Handling is a subset of SGI. Part 73 contains requirements for the protection of SGI and SGI-M. Specifically, 10 CFR 73.21, "Protection of Safeguards Information: Performance requirements" and 10 CFR 73.23, "Protection of Safeguards Information-Modified Handling: Specific requirements" apply to SGI-M. An individual's access to SGI-M is controlled by a valid "need-to-know" determination, a criminal history records check (which includes fingerprinting), and a background check to determine trustworthiness and reliability. Information designated as SGI-M must be withheld from public disclosure and must be physically controlled and protected. Physical protection requirements include (1) secure storage, (2) document marking, (3) access restrictions to authorized individuals who have been fingerprinted, (4) limited reproduction, (5) protected transmission, (6) controls for information processing on electronic systems, and (7) prescribed information destruction procedures.

Examples of the types of information designated as SGI-M include security plans for a facility or site, scheduling and itinerary information for shipments of category 1 quantities of radioactive material, and security implementing procedures.

Section 73.23 requires that the security-related information for large irradiators, M&D licensees, and those licensees that transport category 1 quantities of radioactive material be designated as SGI-M and be protected accordingly.

On March 16, 2012, the Commission approved publication of a new 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." The final rule was published in the *Federal Register* on March 19, 2013 (78 FR 16922). NRC licensees will be required to implement 10 CFR Part 37 on March 19, 2014. Part 37 rulemaking (10 CFR Part 37) establishes security requirements for the protection of aggregated category 1 and category 2 quantities of radioactive material. The rule also contains information protection requirements for the licensee's security plan, implementing procedures, and other information. Part 37 rulemaking (10 CFR Part 37) requires that an individual seeking access to security-related information have a valid need-to-know before gaining such access. Part 37 rulemaking (10 CFR Part 37) requires licensees to limit access to and prevent unauthorized disclosure of their security plans and implementing procedures. When not in use, the security plan and implementing procedures must be stored in a manner to prevent its unauthorized removal. Information stored in non-removable electronic form must be password-protected. Part 37 rulemaking (10 CFR Part 37) also requires a background investigation to determine the trustworthiness and reliability of an individual seeking access to protected information. Although fingerprinting and a criminal history records check are not required for access to the protected information, most individuals with access to the information do undergo fingerprinting and a criminal history records check because they also have unescorted access to the radioactive material, which requires fingerprinting. The trustworthiness and reliability determination must be conducted by a reviewing official who has also been determined to be trustworthy and reliable.

1.1.2 Commission Orders

The NRC has issued four sets of security orders for the protection of category 1 and category 2 quantities of radioactive material. The first set of orders was issued to large irradiators. The second set of orders went to M&D licensees. The third set went to licensees that transport category 1 quantities of radioactive material.

The orders issued to large irradiators, M&D licensees, and licensees transporting category 1 quantities of radioactive materials, require these licensees to perform specified actions within specific timeframes. The security-related information related to these timeframes is designated SGI-M. Some licensees have developed security plans incorporating these timeframes. Therefore, these security plans have been designated as SGI-M. Furthermore, the orders to licensees transporting category 1 quantities of radioactive material require these licensees to develop transportation security plans and coordinate itinerary information with the States through which the shipment will be traveling. These transportation security plans and itinerary information are also designated as SGI-M. The orders also applied to the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel.

A fourth set of orders, commonly called the Increased Controls Order, was issued to all other licensees that possessed greater than category 2 quantities of radioactive material. The Increased Control Orders require licensees to immediately detect, assess, and respond to any unauthorized access to category 2 or greater quantities of radioactive material. These orders do not contain any specific response times or other SGI-M information. Because these licensees' security plans are based on the Increased Controls Order, and these orders do not contain SGI-M information, the security plans for licensees' subject only to the Increased Controls Order are not designated as SGI-M. Once Part 37 rulemaking (10 CFR Part 37) or

equivalent Agreement State requirements are effective, all of the security orders will be rescinded.

1.2 Statement of the Problem and Reasons for Rulemaking

The actual security requirements in 10 CFR Part 37 are the same for all licensees. These security requirements do not contain any of the information from the security orders that was designated as SGI-M. The SGI-M timeframes that were in the orders are replaced in the 10 CFR Part 37 rule by terms such as prompt, immediate, and without delay. Therefore, disclosure of a licensee's response times would not compromise other licensees' security-related information because the response time designated in the rule is already public knowledge, *i.e.* immediate.

Currently, itinerary information for the transportation of category 1 quantities of material is designated as SGI-M under 10 CFR Part 73. Licensees are required to coordinate this information with States through which the shipment will pass. Shipment information is shared on a need-to-know basis for preplanning, coordination, and advance notification purposes and need not be designated as SGI-M; however, once it is received, it must be handled as SGI-M. If the SGI-M designation for these licensees is revised, the licensees will be able to communicate freely with the States possessing a need-to-know and without exception, under no SGI-M restrictions.

The security orders for the transportation of category 1 quantities of material, large irradiator licensees, and M&D licensees were issued under NRC's common defense and security authority. The new Part 37 rulemaking (10 CFR Part 37) security requirements, however, were issued under the NRC's authority to protect the public health and safety. The security requirements for protection of security-related information for large irradiators, M&Ds, and licensees that transport category 1 quantities of radioactive material will now be set forth in the new 10 CFR Part 37. The NRC has determined that the information protection requirements set forth in the new rule are adequate to protect the security information associated with large irradiators, M&Ds, and licensees that transport category 1 quantities of radioactive material. Therefore, once the SGI-M rule is effective, the security information requirements associated with these licensees is no longer required to be handled as SGI-M. Furthermore, this will ensure that all the information security requirements are consistent across all areas that are regulated under public health and safety.

Protection of information at a level less than SGI-M would allow licensees to communicate more easily with regulators regarding implementation of the 10 CFR Part 37 requirements, but still require licensees to limit access to specific security plans. For example, licensees would be required to limit access to the plans to those employees who need access to perform a job function. Licensees would also be required to store their security plans in locked cabinets while not in use, but could use normal lines of communication with the NRC or an Agreement State to discuss security questions or concerns. This approach achieves meaningful information protection without unduly burdening licensees' and regulators' ability to achieve effective implementation of the 10 CFR Part 37 requirements.

If the security-related information for these facilities remains designated as SGI-M, NRC will be responsible for inspection and enforcement of the SGI-M programs at those facilities regulated

by an Agreement State. This can result in confusion for licensees. Results of many aspects of the security inspections would be SGI-M and could not be discussed in an open environment. Because some security-related information at these facilities would be SGI-M and some would not be, licensees would need to maintain two systems to protect security-related information, which needlessly increases the burden on the licensee.

1.3 Regulatory Objectives

The objective of this rule is to remove the SGI-M designation for the security-related information for large irradiators, M&D licensees, and licensees transporting category 1 quantities of radioactive material. The security-related information would be protected under 10 CFR Part 37 information protection requirements. This would allow all licensees subject to 10 CFR Part 37 to be treated the same in regards to information protection.

2. Identification and Preliminary Analysis of Alternative Approaches

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

2.1 Option 1: No Action

Option 1 is the no action alternative. The no-action alternative is how the world would look absent the rule. Under the no action alternative, the Commission would make no changes to the current regulations. Licensees would continue to comply with the SGI-M provisions in 10 CFR 73.21 and 10 CFR 73.23 and NRC would continue to inspect the information protection programs of both NRC and Agreement State licensees. Some licensees would be required to maintain two information protection programs. The no action alternative would require the NRC to conduct inspections of Agreement State licensees solely due to the need to conduct the inspection of the SGI-M information protection program. The no-action alternative serves as the baseline against which other options are measured.

2.2 Option 2: Revise the SGI-M Categorization for Certain Licensees

Option 2 is the NRC's modification to revise the regulations (10 CFR Part 73) to remove the SGI-M designation of the security-related information for large irradiators, M&Ds, and for transport of category 1 quantities of radioactive material. The security-related information for these facilities will no longer be protected as SGI-M and will be protected under the information protection requirements that apply to other materials licensees that possess category 1 and category 2 quantities of radioactive material, *i.e.*, 10 CFR Part 37. Conforming changes are made to 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 10 CFR Part 150, "Exemptions and continued regulatory authority in Agreement States and in offshore waters under section 274," and 10 CFR Part 37. The specific changes are listed below:

- § 30.4 is removed;
- § 30.32(k) is removed;
- § 30.34(l) is removed;
- § 37.29(a)(10) is revised to add category 1 drivers;
- § 37.43(d)(9) is removed;
- § 37.77(f) is revised to change the reference for protection of the information from § 73.21 to § 37.43(d);
- § 73.21(a)(1)(ii) is revised to remove the discussion of large irradiators, M&D licenses, and transportation of category 1 quantities of concern;
- § 73.23 is revised to remove discussion of large irradiators, M&D licenses, and transportation of byproducts, source material and special nuclear material in category 1 quantities of concern in the introductory text;
- § 73.23(a)(2) is revised to remove the discussion of transport of category 1 quantities of concern; and
- Appendix 1 to 10 CFR Part 73 is removed;
- § 150.15(a)(9) is removed.

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.

3. Evaluation of Benefits and Costs

This section examines the benefits and costs expected to result from the two options described in the previous section. The information is presented in two 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.

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*. Affected attributes include the following:

- Safeguards and Security Considerations – Option 2 could be viewed as reducing the level of protection of security-related information.
- Industry Implementation – Under Option 2, large irradiators, M&D licensees, and licensee that transport category 1 quantities of radioactive material will no longer need to protect security-related information as SGI-M. All security-related information will be protected under the requirements of 10 CFR Part 37.
- Industry Operation – Under Option 2, communications with States, NRC, or other entities related to security information will be easier to accomplish. Licensee will not need to maintain two information protection processes.

- NRC Implementation – Under Option 2, NRC will revise 10 CFR Part 37 guidance to remove any references to SGI-M.
- NRC Operation – Under Option 2, the NRC will no longer inspect the SGI-M program at facilities regulated by the Agreement States.
- Regulatory Efficiency - Option 2 results in enhanced regulatory efficiency. There is no split in responsibility between the NRC and the Agreement States for the affected licensees. All of the security-related information related to category 1 and category 2 quantities of radioactive material will be protected under the same requirements.
- Other Government – Under Option 2, Agreement States will not need to revise their regulations, but will be responsible for inspecting all of the information protection aspects for the affected licensees.

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

3.2 Analytical Methodology for 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.

This analysis relies on a qualitative evaluation of several of the safeguards and security considerations due to the subjective nature of the impact.¹

¹ The regulatory efficiency attribute also is evaluated qualitatively by definition. See NRC's *Regulatory Analysis Technical Evaluation Handbook*, Section 5.5.14.

3.2.1 Analysis

This RA measures the incremental impacts of the rule relative to a baseline, which reflects anticipated behavior in the event that the regulation is not revised. 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 presents the estimated incremental costs and savings of the direct final rule relative to the no action or baseline.

In accordance with guidance from the Office of Management and Budget (OMB) and NUREG/BR-0058, Rev. 4, this RA presents the results of the analysis using both 3-percent and 7-percent real discount rates. The real discounted rates or present-worth calculation simply determines how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future. By using present-worth, costs and benefits, regardless of when averted in time, are valued equally. Based on OMB guidance (OMB Circular No. A-4, September, 17, 2003), present-worth calculations are presented using both 3-percent and 7-percent real discount rates. The 3-percent rate approximates the real rate of return on long-term government debt which serves as a proxy for the real rate of return on savings. This rate is appropriate when the primary effect of the regulation is on private consumption. Alternatively, the 7-percent rate approximates the marginal pre-tax real rate of return on an average investment in the private sector, and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector.

3.2.2 Data

Information (e.g., the nature and magnitude of safeguards and security impacts) on attributes affected by the rule have been obtained from NRC staff. The NRC staff considered the potential differences between the new requirements and the current requirements and has incorporated available, non-safeguards information into this regulatory analysis. Information on the cost of implementing the SGI-M for these facilities was taken from the RA for the final rule on protection of SGI (73 FR 63546; October 24, 2008). The RA is available in the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession No. ML072190656.

There are 112 licensees that will be impacted by the rule, 27 are licensed by the NRC and 85 are licensed by Agreement States. The costs of these licensees to implement the information protection requirements of 10 CFR Part 37 were captured by the RA conducted for 10 CFR Part 37 final rule (ADAMS Accession No. ML112920114) and, therefore, are not included in this analysis.

One-time costs for these 112 licensees to develop and implement an SGI-M program have already been expended and are considered sunk costs. The NRC inspection costs were not calculated as part of the 2008 rulemaking because it was assumed that the inspection would occur at the same time as the security inspection and there would be no additional costs. However, after 10 CFR Part 37 is adopted by an Agreement State, NRC will no longer be responsible for the routine security inspections and would need to schedule inspections just to review the SGI-M program. Typically, NRC would conduct this inspection every 2 years. The

total NRC cost to conduct inspections for the 85 Agreement State licensees that currently have SGI-M programs is \$25,288.

The States should not have any costs associated with this rule. Agreement States already inspect the 85 state licensees impacted by the rule and would not need to make a special trip. As part of the inspection, the Agreement State already reviews the non-SGI protection program. States would continue to maintain their SGI program because they receive other SGI, therefore, there would be no savings from the elimination of the SGI program as there is for licensees. Although, there should be fewer documents that are considered to be SGI-M, the NRC is not including this as a savings.

3.2.3 General Assumptions

Costs are expressed in 2012 dollars and are modeled either on an annual recurring cost basis or on a one-time implementation basis. Ongoing costs of operation related to the options are assumed to begin in 2014, and are modeled on an annual cost basis. The RA calculates costs over a 20-year analysis period, with the annual costs in each year beyond 2014 discounted back at a 7-percent and 3-percent discount rate, in accordance with NUREG/BR-0058, Rev. 4.

The general input assumptions for the analysis are discussed below.

- The NRC's labor rates are determined using the methodology in Abstract 5.2, "NRC Labor Rates," of NUREG/CR-4627, Rev. 1. This methodology considers only variable costs that are directly related to the implementation, operation, and maintenance of the proposed amendments. Currently, the NRC hourly labor rate is \$119.
- The NRC will update guidance to support this rulemaking, this is a minor task and will require only 10 hours of staff time.
- 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. 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 a rate, \$41.86/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."
- The NRC staff estimates 112 entities will be directly impacted by the amendments.
- The NRC staff estimates that each licensee will save 5.5 labor hours annually. The breakdown of the functions are presented in the below table.

Licensees with Radioactive Materials in Quantities of Concern	Hours
Establishing SGI program	0
Background checks	1
Training Staff	2
Marking SGI	2.5
Total	5.50

- The NRC staff estimates that each licensee will save \$72 annually for the cost of background checks, additional storage of SGI, and document stamps for marking SGI.
- Licensees will incur a one-time cost to decontrol current documents. The NRC staff estimates this will be on average 2 hours per licensee.
- The time period for the analysis is 20 years. The 20-year period for the analysis was selected to cover the estimated timeframe the affected entities will be impacted.
- Estimates have been made for one-time implementation costs. It is assumed that the costs will be incurred in the first year of the analysis.
- Estimates have been made for recurring annual operating expenses to support implementation of the rule. The values for annual operating expenses are assumed to be identical for each of the 20 years in the analysis. The annuity formula used to discount the annual expense values is on page B.3 of NUREG/BR-0184.
- On NRC inspection costs assume 1 hour of inspection time and 4 hours of travel time for a total of 5 labor hours.

4. Results

This section presents the analytical results and findings on the overall benefits and costs of the two options under the 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 Exhibit 4-1. Option 2 results in a net quantitative impact estimated between -\$615,934 and -\$869,246 (7-percent and 3-percent discount rate over the 20-year analysis period, respectively).

Exhibit 4-1

Summary of Benefits/Savings and Costs/Burdens

	One-time Implementation Costs	Annual Operating Costs	Total Combined Implementation and Annual Cost for 20-year period at 3%	Total Combined Implementation and Annual Cost for 20-year period at 7%
Industry Costs	\$9,377	-\$33,850	-\$494,222	-\$349,228
NRC Costs	\$1,190	-\$25,288	-\$375,024	-\$266,706
Total	\$10,567	-\$59,137	-\$869,246	-\$615,934

Exhibit 4-2 shows the estimated annual cost and benefit, by attribute, for Options 1 and 2, for the first year of implementation.

Exhibit 4-2

Summary of Annual Benefits/Savings by Attribute

	Option 1	Option 2
Industry Implementation	\$0	\$9,377
Industry Operation	\$0	-\$33,850
NRC Implementation	\$0	\$1,190
NRC Operation	\$0	-\$25,288
Total	\$0	-\$48,571

4.1 Backfit Analysis

The NRC has determined that the Backfit Rule does not apply to this rule, because this amendment does not add or modify any regulations to impose backfits as defined in 10 CFR 50.109 or 10 CFR 70.76. Part 50.109 (a)(1) of 10 CFR defines backfitting as the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility. This rulemaking will not make any modification or addition to any systems, structures or components or the design of a facility, affect the design approval or manufacturing license of a facility, or affect the procedures or organization required to design, construct or operate a facility. Therefore, it is the NRC's determination that a backfit analysis is not required.

5. Decision Rationale

The NRC decision is to conduct the rulemaking to remove the SGI-M categorization of the security-related information for large irradiators, M&D licensees, and licensees that transport category 1 quantities of radioactive material. The information will be protected under the information protection requirements of 10 CFR Part 37. This will provide adequate protection of the security-related information without needlessly imposing burden on the licensee. The change will result in an annual savings of \$33,850 for industry and savings of \$25,288 for the NRC while still providing adequate protection of the security-related information.

Therefore, this direct final rule is not considered a major rule as defined by the Congressional Review Act.

6. Implementation

The action will be implemented through a direct final rule. The direct final rule will be effective on the compliance date of the 10 CFR Part 37 final rule. The NRC has not identified any impediments to implementing the recommended alternative.

7. References

NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 4.

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

U.S. Department of Labor, Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Health and safety engineers, except mining safety engineers and inspectors."

Appendix A: Regulatory Flexibility Analysis

The NRC is required by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) as amended by the Small Business Regulatory Enforcement Fairness Act to consider the impact of its rulemakings on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition.

The NRC has established size standards that it uses to determine which NRC licensees qualify as small entities (60 FR 18344; April 11, 1995). These size standards are codified in 10 CFR 2.810. The size standards pertinent to licensees impacted by this rulemaking include the following: Under 10 CFR 2.810 (a)(1), a small business is a for-profit concern and is a concern that provides a service or a concern not engaged in manufacturing with average annual gross receipts of \$5 million or less over its last 3 completed fiscal years. The NRC estimates that this rule will affect 112 licensees some of which may be considered small entities. However, the rule will reduce the burden on affected licensees as they will no longer be required to protect security-related information as SGI-M.