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**Regulatory Analysis for Proposed Rulemaking -  
Compatibility with IAEA Transportation Standards  
(10 CFR Part 71)**

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**U.S. Nuclear Regulatory Commission**

**November 2012**



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## EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC), in consultation with the U.S. Department of Transportation (DOT), is proposing to amend its regulations for the packaging and transportation of radioactive material. These amendments would 1) conform the NRC regulations to the 2009 edition of the International Atomic Energy Agency's (IAEA) international transportation standards, 2) maintain consistency with changes in the DOT regulations, and 3) make other changes to the requirements for the packaging and transportation of radioactive material. These changes are necessary to maintain a consistent regulatory framework for the transportation and packaging of radioactive material. In addition, these changes would make the regulation of Quality Assurance (QA) programs more efficient by removing the requirement for prior approval of QA programs for users of packages, allowing changes that do not change commitments to be made without prior NRC approval, and removing the requirement to renew a QA program.

This Regulatory Analysis (RA) provides an evaluation of three alternatives. The preferred alternative is Alternative 3 (see section 2.3 of this document) which would change regulations as specified in the proposed rule.

The RA makes the following key findings:

**Total cost to Industry:** The proposed rule would result in a one-time cost to the industry of approximately \$95,000 and would have a total annual savings of about \$112,000.

**Total cost to the NRC:** The rule would result in a one-time cost to the NRC of approximately \$367,000, followed by annual cost savings of approximately \$22,000.

**Total cost to Agreement States:** Agreement States would be required to review proposed rule language and to amend its regulations consistent with the final rule. The rule would result in a one-time cost to Agreement States of approximately \$1.8 million.

**Decision Rationale:** Based on the analysis described below, the NRC concludes that the proposed rule, if implemented, would provide compatibility with IAEA and DOT regulations and would make certain NRC-initiated regulatory changes to improve regulatory efficiency and to provide benefits to licensees and to the NRC and Agreement States with a small change to measures of impacts to public health and safety.

The proposed rule is planned for publication in the *Federal Register* in October 2012. Following a public comment period and several months to review the public comments, the NRC will revise the proposed rule and publish a final rule, as appropriate.

## ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AS	Agreement States
CFR	<i>Code of Federal Regulations</i>
CRCPD	Conference of Radiation Control Program Directors
CoC	Certificate of Compliance
CSI	Criticality Safety Index
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
IAEA	International Atomic Energy Agency
ISO	International Organization for Standardization
LSA	Low Specific Activity
NRC	U.S. Nuclear Regulatory Commission
NPV	Net Present Value
NUREG	Nuclear Regulatory Publication
OMB	Office of Management and Budget
QA	Quality Assurance
RA	Regulatory Analysis
SSR-6	IAEA Specific Safety Requirements Number SSR-6, "Regulations for the Safe Transport of Radioactive Material"
TS-R-1	IAEA Safety Requirements Number TS-R-1: "Regulations for the Safe Transport of Radioactive Material"

## 1. INTRODUCTION

The U.S Nuclear Regulatory Commission (NRC) is planning to publish a proposed rule amending its regulations for packaging and transportation of radioactive material. These amendments would make NRC regulations consistent with 2009 revisions to the International Atomic Energy Agency's (IAEA's) transportation standards, "Regulations for the Safe Transport of Radioactive Material," (TS-R-1). The NRC co-regulates domestic transportation of radioactive material with the U.S. Department of Transportation (DOT). DOT regulations regarding transportation of radioactive materials are in Title 49 of the *Code of Federal Regulations* (49 CFR) Parts 107, 171-180, and 390-397. The NRC and the DOT are publishing proposed rules with the dual purpose to achieve compatibility with IAEA's transportation standards and to improve regulatory efficiency by maintaining a consistent regulatory framework. The NRC is also proposing to make other changes which do not affect compatibility with the IAEA TS-R-1 or the DOT hazardous material regulations as discussed in more detail below.

This Regulatory Analysis (RA) presents background material, rulemaking objectives, alternatives, and input assumptions, and describes the consequences of the rule language and alternative approaches necessary to accomplish the regulatory objectives.

### 1.1 Statement of the Problem and Objective of the Rulemaking

The proposed amendments would revise NRC regulations for the packaging and transportation of radioactive material to: 1) make the NRC regulations compatible with the 2009 edition of the IAEA TS-R-1; 2) maintain consistency with changes in the DOT regulations; and 3) make other changes to the requirements for the packaging and transportation of radioactive material, which do not affect compatibility with the IAEA's TS-R-1 or the DOT's hazardous material regulations.

The IAEA revises its transportation standards periodically to reflect acquired knowledge and experience. The NRC periodically updates its transportation regulations at 10 CFR Part 71 to reflect the changes in the IAEA's transportation standards.

One objective of the proposed rule would be to achieve compatibility with the IAEA's transportation standards. DOT is proposing the same amendments in its proposed rule to achieve compatibility with TS-R-1. Amendments to achieve compatibility are referred to in this document as the "IAEA-DOT compatibility" alternative. The amendment would allow a licensee who transports special form radioactive material, and who is using a specimen to simulate radioactive material contained in a sealed capsule, to use an alternative impact test currently allowed by the IAEA in TS-R-1 as one of the acceptable impact tests cited in the regulations. The amendments in the "IAEA-DOT compatibility" alternative are expected to have little impact on the public and on licensees, and will have only a minor impact on the NRC due to the one-time implementation cost to prepare the final rule, and amend regulations. In November 2012, the IAEA issued new standards for the safe transport of radioactive material and designated them as "Specific Safety Requirements Number SSR-6" (SSR-6). This rulemaking does not incorporate the 2012 IAEA changes, which will undergo a comprehensive review by the NRC staff to determine if additional changes to 10 CFR Part 71 are warranted.

Another objective of the proposed rule is to increase the efficiency of the oversight of Quality Assurance (QA) program. The NRC requires licensees to comply with their own NRC approved

QA programs. The NRC is proposing changes that would 1) establish a mechanism to allow some changes to be made in an approved QA program without obtaining prior NRC approval and 2) remove the requirements for renewal of QA program approvals. These changes would increase the efficiency of the NRC oversight of quality assurance by removing the need for holders of the QA program approval to obtain prior NRC approval of amendments to QA program descriptions that do not reduce the commitments in an approved QA program. This would allow holders of QA program approvals to implement changes more quickly.

The proposed amendments to 10 CFR Part 71 that would permit holders of the QA program approval to make changes to their QA program without NRC approval are modeled after those in 10 CFR Part 50. Holders of a QA program approval would only need to submit to the NRC for prior approval those changes to their QA program that would reduce commitments made to the NRC. Under the proposed rule, holders of a QA program approval would be required to report to the NRC at least every 24 months any changes they have made to their approved QA program.

## **1.2 Background**

Hazardous materials, including radioactive material, are transported regularly as part of international commerce. Shipping companies that are active in the international transport of radioactive material must comply with international legal instruments that are often based on standards published by the IAEA and adopted by IAEA Member States. The U.S. adopts many of the IAEA international transportation regulations into its domestic transport regulations, with regulatory changes implemented through the rulemaking process. The NRC and the DOT strive to maintain consistency or compatibility between the domestic transport regulations and the IAEA's transportation standards. The effort to maintain consistency or compatibility between national regulations and internationally-accepted requirements is known as "harmonization." There is a need for the NRC and the DOT to harmonize<sup>1</sup> domestic transport regulations with changes made to the IAEA's TS-R-1 over the past several years. These changes can be implemented with slight cost to the public and domestic regulatory authorities responsible for implementing the proposed changes.

A second set of changes is being proposed to eliminate unnecessary administrative requirements that require licensees to submit documents to the NRC for approval. The current regulations require holders of a QA program approval to obtain prior NRC approval of every change to their QA program, of which some are administrative, such as the transfer of functional responsibility within organizations and generic organizational position titles. The proposed rule would amend this by making the 10 CFR Part 71 transportation QA requirements similar to the requirements for making changes to a QA program that apply to 10 CFR Part 50 licensees. The amended transportation requirements would require QA program changes to be submitted to

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<sup>1</sup> The regulations in the IAEA's TS-R-1 represent an accepted set of requirements that are considered to provide a high-level of safety in the packaging and transportation of radioactive materials and provide a basis and framework that facilitates the development of internationally-consistent regulations. Internationally-consistent regulations for the transportation and packaging of radioactive material reduce impediments to trade, facilitate international cooperation, and, when the regulations provide a high-level of safety, can reduce risks associated with the import and export of radioactive material. Harmonization represents the effort to increase the consistency or compatibility between national regulations and the internationally-accepted requirements, within the constraints of an existing national legal and regulatory framework.

the NRC only if the change results in a reduction in the commitments made to the NRC compared to the currently approved QA program. This change is being made to promote savings on the part of industry and regulators. The proposed amendments would require holders of the QA program approval to report to the NRC at least every 24 months any changes they have made to their approved QA program.

## **2. IDENTIFICATION OF ALTERNATIVE APPROACHES**

The following sections describe the regulatory options that the NRC is considering in order to meet the rulemaking objectives identified in the previous section. Section 3 presents a detailed analysis. The NRC considered three alternatives for the proposed rule, described in the following three sections. The full list of changes which indicate their relationship to the alternatives are provided in Table 4-3 which summarizes the costs by entity, over a 10-year analysis period.

### **2.1 Alternative 1: The No-Action Alternative**

The No-Action alternative would maintain the status quo. Under the No-Action Alternative, the NRC would make no changes to the current regulations in 10 CFR Part 71 and there would be no costs or benefits. Alternative 1 would avoid costs that the proposed rule would impose; however, it would allow greater divergence between the international standards and the domestic regulations. Radioactive material is imported and exported. Consistency between domestic and international transportation regulations facilitates international commerce. Differences in domestic and international regulations can make it more complicated and expensive to import or export radioactive material and inhibit trade. There would be no changes made that would enhance the current level of protection for public health and safety. Also, there would be no changes made to improve regulatory efficiency and the resulting benefits to certain segments of the transport industry. This is the baseline of the RA.

### **2.2 Alternative 2: IAEA-DOT Compatibility**

This alternative would amend the NRC regulations to increase consistency and compatibility with the 2009 edition of the IAEA's TS-R-1 and with changes proposed by the DOT.

- Section 71.4, Definitions. The definition of contamination would be added. The definitions for "Criticality Safety Index (CSI)," "Low Specific Activity (LSA) material," "special form radioactive material," and "uranium — natural, depleted, enriched" would be revised.
- Section 71.14, Exemption for low-level material. Paragraph (a) would be changed to revise the exemption to include natural material and ore that has been processed to qualify for the exemption. Paragraph (a)(3) would be added to provide an exemption for non-radioactive solid objects which have radioactive substances present on their surfaces, provided that the quantity of radioactive substances is below that which is used to define contamination.
- Paragraph 71.75(d), Qualification of special form radioactive material. This change would update the International Organization for Standardization (ISO) Class 4 impact test and ISO Class 6 temperature test to those prescribed in ISO 2919:1999(E), "Radiation

protection — Sealed radioactive sources — General requirements and classification,” and would allow the ISO Class 5 impact tests prescribed in ISO 2919:1999(E) to be used if the specimen weighs less than 500 grams.

- Appendix A., Table A-1,  $A_1$  and  $A_2$  Values for Radionuclides. The table would be revised by adding an entry for krypton-79 (Kr-79); revising entries for californium-252, iridium-192, krypton-81, and molybdenum-99; and revising footnotes to be consistent with the IAEA’s TS-R-1.
- Appendix A, Table A-2, Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides. The table would be revised by adding an entry for Kr-79, revising the entry (values) for tellurium-121m (Te-121m), and revising footnote b.

### **2.3 Alternative 3: IAEA-DOT Compatibility and NRC Initiated Changes**

This alternative includes 1) all of the proposed changes comprising Alternative 2, which would amend the NRC regulations to increase consistency and compatibility with the 2009 edition of the IAEA’s TS-R-1 safety standards, and maintain consistency with changes proposed by the DOT; and 2) implement NRC-initiated changes.

The changes listed below are consistent with Alternative 3 to Compatibility with IAEA Transportation Standards in 10 CFR Part 71.

- Section 71.15, Exemption from classification as fissile material. The exemption in paragraph (d) that applies to uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with total plutonium and uranium-233 content of up to 1 percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass, (hereafter referred to as uranium enriched to a maximum of 1 percent) would be revised to require the material to be distributed homogeneously and not form a lattice arrangement.
- Section 71.38, Renewal of a certificate of compliance. This section would be retitled and revised to remove references to renewals of QA program approvals, which would no longer be necessary.
- Section 71.85, Preliminary determinations. This section would be revised to replace “licensee” with “certificate holder” in paragraphs (a), (b), and (c); and paragraph (d) would be added to require that licensees ascertain that the preliminary determinations made by the certificate holder (paragraphs (a) – (c)) have been made.
- Section 71.106, Changes to quality assurance program. This section would be added to revise the process for holders of a QA program approval to make changes to an approved QA program and would require periodic reporting of those changes that do not require prior NRC approval.



- Section 71.135, Quality assurance records. This section would be revised to include changes made to an approved quality assurance program as a quality assurance record.

The NRC has estimated the benefits and costs of these alternatives. The costs and benefits are evaluated and described in Sections 3 and 4 of this RA. The rationale for the NRC decision to pursue Alternative 3 is discussed in Section 5.

### **3. ESTIMATION AND EVALUATION OF VALUES AND IMPACTS**

This section examines the values (benefits) and impacts (costs) expected to result from the proposed changes to 10 CFR Part 71. The benefits and costs are analyzed for Alternatives 2 and 3, and are set forth by the societal attributes that are considered important for the evaluation of the proposed amendments.

Throughout this RA, various labor rates are used. These labor rates are used consistently for all of the issues. The bases for the labor rates are described below. Labor rates for licensees — including holders of a Certificate of Compliance (CoC) or a QA program approval and applicants — and Agreement States were obtained from National Wage Data databases available on the Bureau of Labor Statistics Web site ([www.bls.gov](http://www.bls.gov)). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate was determined. The hourly cost was determined by multiplying the hourly labor rate by 1.5 to account for benefits (insurance premiums, pension, and legally required benefits). Nationwide mean hourly labor rates are used, because exact hourly rates are difficult to obtain and may not be sufficiently recent. For licensee labor rates, \$73.20/hour (\$48.80/hour X 1.5) is used, which is from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, “Nuclear Engineers.” For all Agreement State labor rates, \$60.80/hour (\$40.53/hour X 1.5) is used, which is from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, “Lawyers.”

The NRC labor rates are determined per the calculation methodology in Abstract 5.2, “NRC Labor Rates,” of NUREG/CR-4627, Rev.1, Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses.” Currently, the hourly labor rate for the NRC is \$119.

The estimation of costs for rulemaking is based on professional NRC staff full-time equivalent (FTE). Based on actual data from the NRC time and labor system, the number of hours in 1 year that directly relate to implementation of assigned duties is 1,451; this excludes hours on such things as leave, training, and completing administrative tasks. Therefore, an NRC professional staff FTE hourly rate is based on 1,451 hours per year.

The estimated costs for the Agreement States to amend and implement changes to their regulations are based on the number of productive hours in one year, as described in the Office of Management and Budget (OMB) Circular A-76, “Performance of Commercial Activities”, which is 1,776. The actual number of productive hours per year is likely to vary from state to state and no specific data are available. Costs for the Agreement States are calculated using the 1,776 productive hours per year from OMB Circular A-76 per FTE.

### 3.1 Identification of Affected Attributes

This section lists the significant attributes for this proposed rulemaking and describes the expected changes in the context of these attributes. The benefits and costs for each attribute are quantified using the methodology described in Section 3.2. Those attributes that are not expected to be affected by the proposed amendments are listed at the end of the Section 3.1. NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," identifies a set of attributes to be evaluated. All of the attributes listed in NUREG/BR-0184 are addressed below. No additional attributes that would inform the evaluation of values and impacts for this proposed rulemaking were identified.

- **Industry Operation:** The NRC is proposing to make changes that would make the regulation of QA programs more efficient. The NRC is proposing to issue QA program approvals that would not expire, removing the need for the approval to be renewed, and would revise the current QA program approvals so that they would not expire. The NRC is also proposing to allow those changes that do not reduce the commitments in an approved QA program to be made without prior NRC approval. Additional material might qualify for the exemption of low-level radioactive material, which would facilitate the transportation of these materials and reduce shipping costs. In aggregate, industry operations are anticipated to be improved, resulting in savings.
- **Industry Implementation:** If the proposed action is adopted/promulgated the licensee will need to purchase a copy of the ISO standards as well as maintain awareness of changes to the relevant transportation regulations. Each licensee will need to read the new regulations and determine actions necessary. Changes to 10 CFR 71.75(d), which would incorporate by reference the alternate Class 4 impact test and Class 6 temperature test and allow the Class 5 impact tests to be used if the specimen weighs less than 500 grams, will require the licensee to incur a one-time cost for the purchase of equipment.
- **NRC Implementation:** Under the proposed action, the NRC would publish the draft rule for public comment. The NRC plans to consider any public comments received, develop a final rule and amend guidance to be consistent with the new requirements. With the publication of the final rule, the NRC would re-issue QA program approvals with no expiration date. The NRC would also review and evaluate State regulations developed by the Conference of Radiation Control Program Directors (CRCPD) and will review amendments to Agreement State regulations for compatibility. Under Alternative 2 and Alternative 3, the NRC would need to update guidance.
- **Other Governments:** Agreement States would incur costs associated with efforts to amend their regulations and guidance, which may also include costs associated with the CRCPD development of Suggested State Regulations for Control of Radiation. Agreement State governments will incur one-time costs to amend regulations to implement Alternative 2 or Alternative 3, and annual savings due to improved regulatory efficiency from Alternative 3.

The U.S. Department of Energy (DOE) certifies their own packages and may use them for the transportation of Class 7 (radioactive) material when evaluated, approved and certified using standards equivalent to those specified in 10 CFR Part 71. The DOT also requires that for Class 7 material shipped by the DOE, that the packages be marked and prepared

for shipment in a manner equivalent to that required of NRC licensees. Consequently, the DOE would need to comply with proposed amendments to the fissile material exemption.

The NRC and the DOT adopted a memorandum of understanding (44 FR 38690; July 2, 1979) to delineate their respective roles in the regulation of the transportation of radioactive material. The NRC, in consultation with the DOT, develops safety standards for the design and performance of packages for fissile materials and for quantities of other radioactive materials, other than LSA materials, exceeding Type A limits. The areas where the NRC develops safety standards include: criticality control and quality assurance of packaging design, fabrication, testing, maintenance, and use.

- **Regulatory Efficiency:** The proposed amendments include changes to harmonize 10 CFR Part 71 with the international standards and to maintain consistency with the DOT regulations. This will help to achieve and maintain regulatory efficiency. The proposed rule will incorporate by reference consensus standards used for the qualification of special form material, which also contributes to regulatory efficiency. Changes to the general license provisions would provide additional clarity as to the responsibilities of the general licensee, which will improve compliance and regulatory oversight. Changes to the requirements for making preliminary determinations would make the requirements more consistent with current practice and improve compliance. In Appendix A, improving the row headings in Table A-3 for clarity, and correcting and adding equations for calculating values for mixtures of radionuclides will also contribute to improved regulatory efficiency by making it easier for licensees to comply.

The proposed rulemaking would modify the process for making changes to QA programs, which will increase efficiency for holders of a QA program approval and the NRC oversight of QA programs. Holders of a QA program approval would not need to apply to renew their approval and the NRC would not have to review future renewals of QA program approvals. With the publication of a final rule, the NRC would re-issue QA program approvals with no expiration date.

- **Environmental Considerations:** The proposed rulemaking would involve changes that could have environmental impacts. The proposed amendments would expand the low-level material exemption for natural material and ores containing naturally occurring radionuclides to allow material that has been processed to qualify for the exemption. These changes would increase the number of shipments of low specific activity radioactive material that would be exempt from the NRC and the DOT transport regulations (i.e., would not be shipped as hazardous material). The Environmental Assessment (Agencywide Document Access and Management System (ADAMS) Accession No. ML12187A109) discusses the environmental considerations in greater detail. After evaluating the potential impacts, the NRC determined that there would be no significant impact to the public from the proposed amendments.
- **NRC Operations.** Holders of a QA program approval would not need to apply to renew their approval and the NRC would not have to review future renewals of QA program approvals. With the publication of a final rule, the NRC would re-issue QA program approvals with no expiration date. The NRC would need to review the biennial reports of changes to QA programs that do not reduce commitments to the NRC. The proposed action would result in a small annual savings to the NRC in the oversight of QA programs.

The following attributes are not expected to be affected:

**Public Health (Accident)**  
**Public Health (Routine)**  
**Antitrust Considerations**  
**Improvements in Knowledge**

**Offsite Property**  
**Onsite Property**  
**General Public**

**Occupational Health (Accident)**  
**Occupational Health (Routine)**  
**Safeguards and Security**

Section 4 presents the results, in constant 2012 dollars. The results are shown for the one-time costs (or benefits) and the annual operating expense (or savings) to implement Alternatives 2 and 3. The total benefits and costs over the 10-year analysis period are estimated using 7 percent and 3 percent real discount rates.

The estimated total cost for Alternative 3 is approximately \$1.1 million and \$1.3 million, discounted at 3 percent and 7 percent, respectively for the preferred approach. The 3 percent discounted value is less than the 7 percent discount value because of the large amount of annual cost savings to the industry and the NRC.

### **3.2 Analytical Methodology**

This section describes the methodology used to analyze the values and impacts associated with the proposed rule. The values (benefits) consist of any desirable changes in the affected attributes. The impacts (costs) consist of any undesirable changes in the affected attributes. To the extent practical, quantitative information (e.g., costs and savings) and qualitative information on attributes affected by the proposed rule have been obtained from NRC staff.

As described in Section 3.1, the attributes expected to be affected include the following:

- Industry Operation
- Industry Implementation
- NRC Implementation
- NRC Operation
- Other Governments
- Regulatory Efficiency
- Environmental Considerations

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 pretax 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. The

NRC seeks public comments on the accuracy of these RA assumptions and on the validity of the proposed rule's value and impact estimation methods. The NRC has specifically requested comments from the public on this assumption in the RA.

The RA includes assumptions and estimates. The NRC staff relied on referenced sources for the assumptions and estimates when these were available. In some cases, the NRC was not aware of any input data and in these cases the NRC staff made an estimate based on best professional judgment. These are noted as "staff judgment" in the descriptions of the input data. The NRC seeks public comments on the accuracy of the assumptions and estimates used in this RA, and on the validity of the method to estimate values and impacts of the proposed rule.

### **3.2.1 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. The RA calculates costs over a 10-year analysis period, with the annual costs in each year beyond 2012 discounted back at a 7-percent and 3-percent discount rate, in accordance with NUREG/BR-0058, Rev. 4.

The [NRC staff's] general input assumptions for the analysis are discussed below.

- The NRC 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 staff determined Licensee labor rates using National Wage Data available on the Bureau of Labor Statistics Web site ([www.bls.gov](http://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 rates, \$73.20/hour is used, which is from Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Nuclear Engineers."
- The NRC staff determined Agreement State labor rates using National Wage Data available on the Bureau of Labor Statistics Web site ([www.bls.gov](http://www.bls.gov)). Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates are used. For all Agreement State labor rates, \$60.80/hour is used, which is from Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Lawyers".
- The DOE hourly labor rates will match the NRC rate, i.e., \$119/hour.
- The NRC staff estimates there are 290 entities – 210 general licensees or users of packages, 40 certificate holders/applicants for certificate holders, 37 Agreement States, DOE, DOT, and CRCPD – would be directly impacted by the proposed amendments. The CRCPD impacts – development of Suggested State Regulations for Control of Radiation – would be a subset of, and considered as part of, the Agreement State impacts, because it would be Agreement State staff working to develop the Suggested State Regulations for Control of Radiation.

- The time period for the analysis is 10 years. Renewals of QA program approvals are required every 10 years. The 10-year period for the analysis was selected to cover one complete QA program approval renewal period.
- Estimates were made for one-time implementation costs. It is assumed that the costs will be incurred in the first year of the analysis. This will provide a conservative estimate of the one-time implementation costs, because one-time costs that may occur later (e.g., rulemaking conducted by the Agreement States would not be discounted).
  - There are one-time implementation costs assumed for the NRC and the Agreement States.
  - One time implementation costs for the transportation industry may be incurred in response to amendments to 10 CFR Part 71. The area's most likely to contribute to one-time implementation costs include: 1) exemption of low-level materials, 2) preliminary determinations, 3) qualification of special form material; and 4) quality assurance.
- Estimates were 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 10 years in the analysis. The annuity formula used to discount the annual expense values is on page B.3 of NUREG/BR-0184.

### **3.2.2 Specific Assumptions for Alternative 2**

Under Alternative 2, the NRC would amend two sets of domestic transport regulations to maintain compatibility with the IAEA's TS-R-1 transportation standards revised in 2009. These changes will impact licensee shipping costs as well as rulemaking costs for the NRC and the Agreement States. The specific [NRC staff] assumptions for Alternative 2 are:

- There are one-time costs that may be incurred in response to changes to 10 CFR Part 71.
  - It is assumed that licensees and certificate holders maintain awareness of changes to the relevant transportation regulations, but would incur costs associated with this effort. It is estimated that 50 percent of licensees would obtain materials relating to training on the current requirements, with commercial references estimated to cost \$60 and a total cost of \$7,500.
  - It is assumed that some effort would be made to review the changes in the regulations. The proposed rulemaking includes 24 proposed amendments. It is estimated that an average of 2 hour per licensee or certificate holder would be spent reviewing the changes, for a total of approximately \$35,000.
- The changes to 71.14(a) would allow some additional material and objects to be shipped under the exemption. Natural material and ore containing naturally occurring radionuclides that has been processed could be shipped without being classified as hazardous material if it meets the expanded exemption. The material would not be

shipped for the use of its radionuclides. Licensees would need to ensure correct labeling and placarding for their shipments. This would require them to determine whether material can be shipped under the exemption if it is to be treated as radioactive material.

- Because the material is not being shipped for use of its radionuclides, it is assumed that most licensees would be unaffected by this change. It is assumed that about 2 percent of licensees (five licensees) would be affected by this change.
- The number of DOE shipments affected is estimated to be 0.5 percent of the low-level wastes and “other” radioactive material shipments in 2004. This corresponds to approximately 6 rail shipments and 74 truck shipments.
- The quantity of material shipped by industry is based on the average consumption for the following: tantalite ore, niobium ore, and rare earth concentrates for the years (2006 – 2010) where consumption amounts are available in the U.S. Geological Survey Mineral Commodity Summaries after being adjusted to better approximate the amount of material affected by the proposed change. It is also assumed that the tantalite slag and niobium slag are transported in the same quantities as tantalite ore and niobium ore, respectively.
- The fraction of tantalite ore and tantalite slag affected by the proposed change is estimated using information from the Tantalum-Niobium International Study Center that was included in the IAEA Coordinated Research Program and the activity levels listed in “The Trade in Radioactive Materials – Potential Problems and Possible Solutions” by Nick Tsurikov (2008) and “Regulation of Natural Radioactivity in International Transport and Trade” by N. Tsurikov, et. al. (2006). The estimates for niobium and niobium slag assume the fraction of material less than 10 Bq/g of uranium-238 and thorium-232 are the same as that estimated by the Tantalum-Niobium International Study Center for tantalite ore and tantalite slag.
- It is assumed that the material is processed, but not for its radionuclides. Because assuming that the material, with the exception of the slag, has been processed is likely to overestimate the quantity of material evaluated that would qualify for the exemption, the volume of material and the number of shipments would include the shipment of some material not specifically evaluated.
- It is estimated that approximately 12,000 metric tons of material is shipped by rail in approximately 125 railroad cars (or shipments).
- It is assumed that annual fees and permits would not be affected by this change, because some material would still be shipped as class 7 (radioactive) hazardous material.
- It is estimated that approximately \$500 per shipment would be saved, because the material would not be shipped as radioactive material.

- The NRC is proposing to incorporate by reference ISO 9978:1992(E), “Radiation protection — Sealed radioactive sources — Leakage test methods” and ISO 2919:1999(E), “Radiation protection — Sealed radioactive sources — General requirements and classification.” The NRC is allowing the use of certain ISO tests as an alternative to the tests prescribed by 10 CFR Part 71. The NRC is allowing the use of the Class 4 and Class 5 impact tests and the Class 6 temperature test. The ISO Class 5 impact test can be used for a specimen weighing less than 500 grams. The ISO tests are more rigorous than the tests prescribed in 10 CFR Part 71, so they are not the most common tests used to qualify special form material.
  - It is assumed that each licensee would obtain a copy of the ISO standards. It is also assumed that they would acquire the standards at the non-member rate. These estimates would be conservative in estimating the costs. Purchasing the two standards from the distributor in the U.S. would cost each licensee \$200.
  - The NRC staff estimates there are 60 Class 4 and Class 6 tests performed each per year. Although the ISO standard that includes these tests has been updated, it is assumed that no new equipment is needed to perform these tests.
  - The Class 5 impact tests allow a smaller hammer to be used for smaller specimens. It is assumed that acquiring the testing equipment would cost \$500 for each licensee who acquires the equipment. It is assumed that about 5 percent of the licensees (rounded up to 5 licensees) would purchase the equipment, for a total cost of \$2,500.
  - It is estimated that licensees would perform 50 Class 5 impact tests each year instead of the Class 4 impact at an equivalent savings of the costs for one labor hour per test, for a total savings of \$3,660.

Other changes would amend certain values in 10 CFR Part 71, Tables A-1, A-2, and A-3, Appendix A. See chart in Appendix 1 for a summary of the proposed changes and estimates for the effect of each change. These changes would result in an estimated net savings of \$20,000 annually for the industry.

The NRC will require approximately 2031 labor hours (1.4 FTE) to develop a final rule and update guidance. The NRC would develop the final rule following the close of the public comment period for the proposed rule. The effort to develop the final rule and update the guidance is modeled as a one-time labor cost.

- It is assumed that CRCPD will update Part T to the Suggested State Regulations for Control of Radiation, which addresses the requirements of 10 CFR Part 71. It is assumed that this effort will take approximately 2 FTE. It is assumed that in addition to supporting the development of the Suggested State Regulations for Control of Radiation, the Agreement States will average about 444 labor hours (0.25 FTE) each to review proposed rule language and to amend regulations consistent with the final rule. An estimate of 16,428 labor hours for all 37 Agreement States is made and modeled as a one-time labor cost.
- No quantitative costs or benefits accrue to industry as a result of the Alternative 2 regulatory changes.



The input assumptions for Alternative 2 are in Appendix 1.

### 3.2.3 Specific Assumptions for Alternative 3

Under Alternative 3, the NRC would make the changes identified above for Alternative 2 and other conforming changes. The specific assumptions for Alternative 3 are listed below.

- The proposed changes to 10 CFR 71.15(d) would revise the exemption that applies to uranium enriched to a maximum of one percent to require the material to be distributed homogeneously and not form a lattice arrangement. The type of material that would be affected by this change is more likely to be possessed by the DOE than by a licensee. It is not typically shipped. Therefore, it is assumed that only the DOE would ship this material.
  - Shipments of material that would be affected by the changes to the fissile material exemption for uranium enriched to a maximum of one percent are unlikely and estimated to occur once every 10 years. Accordingly, the NRC estimates there will be one shipment in the 10-year period. It is assumed that this shipment would occur midway through the analysis period.
  - The effect of this amendment would be to preclude uranium enriched to a maximum of one percent that is not distributed homogeneously or that forms a lattice arrangement from being shipped under the fissile material exemption. It is assumed that the material would be able to be shipped under a general license for fissile material, which would require the calculation of the CSI and appropriate labeling, and on an exclusive use conveyance. It is estimated that the labor associated with determining the appropriate CSI, which involves determining the mass of fissile materials for the shipment, and labeling would take 40 hours. It is assumed that the CSI would not exceed 100, so the shipment would not need to be shipped using separate conveyances.
- The NRC is proposing to amend 10 CFR 71.38 to remove the need for QA program approvals to be renewed. These proposed changes would result in a savings for the NRC, general licensees, and holders of, or applicants for, a CoC. These are related to changes to 10 CFR 71.106.
- It is estimated that an average of 25 QA program approvals would not be required each year. Holders of the QA program approval would not need to prepare a request for a renewal, because the NRC will be issuing QA program approvals that will not expire for all existing QA program approvals. It is estimated that each renewal request takes about 20 hours to prepare. The estimated total annual savings for holders of a QA program approval would be 500 labor hours (or \$36,600). The NRC estimates that it averages 10 hours of effort per renewal.
- Existing QA program approvals will expire. The NRC would need to issue new QA program approvals that would not have an expiration date. The NRC estimates that issuing the replacement QA program approvals would require 40 hours to complete.
- The NRC is proposing to add requirements to make it more efficient for holders of a QA program approval to make changes to their QA program that do not reduce their commitments to the NRC.

- The proposed requirements in 10 CFR 71.106(a) would result in a savings for holders of a QA program approval and the NRC. Holders of a QA program approval would no longer be required to obtain prior NRC approval for changes to their QA program description that do not reduce their commitments to the NRC. The NRC estimates that 14 holders of QA program approvals would benefit from the proposed amendments each year. It is estimated that, on average, 25 labor hours would be saved each time a QA program approval holder does not need to obtain prior NRC approval for their changes. It is estimated that the NRC takes 5 hours to review each request.
  - The proposed amendments in 10 CFR 71.106(b) would require that respondents periodically report changes that they made that did not reduce their commitments to the NRC. The NRC estimates 250 entities will be affected every 2 years. The NRC estimates that QA program approval holders will spend 1 hour every 2 years to comply with this proposed requirement. The NRC estimates it will spend 1 hour to review each submittal.
  - Holders of a QA program approval would be required to maintain records created in response to the proposed changes to § 71.106. The NRC estimates that each QA program approval holder would spend 0.5 hours annually to maintain these records.
- There will be a one-time labor cost for the NRC and the Agreement States to implement Alternative 3. It is assumed that implementing Alternative 3 would require 50 percent more staff hours than the effort required to implement Alternative 2. This means about 3,047 labor hours will be required of the NRC and about 24,642 labor hours by the Agreement States. This is modeled as a one-time labor cost.

The estimates for the effect of each change for Alternative 3 are in Appendix 2.

### **3.2.4 Data on Affected Entities**

The analysis makes the following assumptions regarding the entities affected:

- The NRC staff estimates 290 entities — 210 general licensees or users of packages, 40 certificate holders/applicants for certificate holders, 37 Agreement States, DOE, DOT, and CRCPD — would be directly impacted by the proposed amendments. The CRCPD impacts — development of Suggested State Regulations for Control of Radiation — would be a subset of, and considered as part of, the Agreement State impacts, because it would be Agreement State staff working to develop the Suggested State Regulations for Control of Radiation.

The NRC staff would develop the rule package and revise guidance to accommodate the requirements that would be added or modified by the rulemaking process.

## **4. PRESENTATION OF RESULTS**

This section presents results of values and impacts that are expected to be derived from the proposed rule. The results are shown for each of the following attributes:

- Industry Operation
- Industry Implementation
- NRC Implementation
- NRC Operation
- Other Government Implementation (Agreement States)

The rule is expected to provide values in other attributes, such as Improvements in Knowledge, Regulatory Efficiency, Environmental Considerations, and Public Confidence, but these are not quantified because they are expected to be small. The quantified values are presented in constant 2012 dollars, for both implementation and annual operating expenses. The impact of the proposed rule over a 10 year analysis period is estimated using 3 percent and 7 percent real discount rates to show an overall effect in terms of 2012 dollars. Alternative 1, the No-Action Alternative, provides a baseline against which the other two alternatives are assessed.

#### 4.1 Summary of Results

This section presents results of the benefits and costs that are expected to be derived from the proposed rule. To the extent that the affected attributes could be analyzed quantitatively, the costs have been calculated and are presented below. Some values and impacts are addressed qualitatively for reasons discussed in Section 3.2. Exhibits 3-1 and 3-2 summarize these results.

Table 4-1 presents the net impact of the proposed rule for each of the three alternatives, at 3 percent and 7 percent real discount rates, including all benefits and costs over the 10-year analysis period. A positive value for net impact is a cost.

**Table 4-1: Net Impact of Alternatives 1, 2, and 3**

3 percent discount rate		7 percent discount rate	
Alternative 1	\$0	Alternative 1	\$0
Alternative 2	\$1,008,576	Alternative 2	\$1,104,488
Alternative 3	\$1,142,677	Alternative 3	\$1,344,380

There are no costs or benefits associated with Alternative 1, the No Action Alternative. The estimated cost of approximately \$1 million (3 percent discount rate) for Alternative 2 is to implement the proposed rule in NRC and Agreement State regulations as well as a small industry shipping savings.

Alternative 3 includes the costs in Alternative 2 and the NRC initiated changes resulting in a small overall cost savings over the 10-year analysis period. The major contributing costs and benefits under Alternative 3 are due to:

- The removal of the requirement to submit QA related information to the NRC, which the NRC does not need, equal to an annual industry savings of approximately \$50,000.
- As a result of removing the requirements to submit QA information, the NRC will save approximately \$20,000 annually in operating expenses.

The cost to the NRC and Agreement States to implement amended regulations is about 50 percent higher for Alternative 3 compared to Alternative 2 because of the larger scope of activity.

Table 4-2 shows the estimated costs and benefits, by attribute, over the 10-year analysis period for Alternative 1, 2, and 3 at a three percent discount rate.

**Table 4-2: Estimated Values and Impacts by Attribute for Alternative 1, 2 and 3**

	Alternative 1	Alternative 2	Alternative 3
Industry Implementation	\$0	\$95,136	\$95,136
Industry Operation	\$0	-\$543,033	-\$954,207
NRC Implementation	\$0	\$241,689	\$367,365
NRC Operation	\$0	\$0	-\$187,792
Agreement States	\$0	\$1,214,784	\$1,822,176
Total	\$0	\$1,008,576	\$1,142,677

Table 4-3 summarizes the costs by entity, over a 10-year analysis period.

**Table 4-3: Summary of Values and Impacts for Alternatives 2 and 3**

Alternative 3

	One-time Implementation Costs	Annual Operating Costs	Total Combined Implementation and Annual Cost for 10-year period at 3%	Total Combined Implementation and Annual Cost for 10-year period at 7%
Industry Costs	\$95,136	-\$111,862	-\$859,071	-\$690,537
Agreement States	\$1,822,176	\$0	\$1,822,176	\$1,822,176
NRC Costs	\$367,365	-\$22,015	\$179,573	\$212,741
Total	\$2,284,677	-\$133,877	\$1,142,677	\$1,344,380

Alternative 2

	One-time Implementation Costs	Annual Operating Costs	Total Combined Implementation and Annual Cost for 10-year period at 3%	Total Combined Implementation and Annual Cost for 10-year period at 7%
Industry Costs	\$95,136	-\$63,660	-\$447,897	-\$351,985
Agreement States	\$1,214,784	\$0	\$1,214,784	\$1,214,784
NRC Costs	\$241,689	\$0	\$241,689	\$241,689
Total	\$1,551,849	-\$63,660	\$1,008,576	\$1,104,488

Table 4-4 shows all of the amendments that are included in the proposed rule, and whether or not the amendment is estimated as a cost (or savings) to industry and to regulators, or is insignificant and not included in the cost-benefit calculations.

**Table 4-4: Proposed Rule Amendments and Significance in the Cost-Benefit Analysis**

<b>10 CFR Part 71 Proposed Amendment Description</b>		Cost of amendment estimated as a licensee and/or NRC cost and included in cost-benefit analysis	Cost of amendment NOT estimated as a licensee and/or NRC cost and NOT included in cost-benefit analysis
71.0	Purpose and Scope. A section is deleted from the list of sections for which general licenses are issued without a required NRC package approval.		•
71.4	Definitions. Add definition of “contamination.” Revise definitions of “Criticality Safety Index (CSI),” “Low Specific Activity (LSA) material,” “special form radioactive material,” and “uranium – natural, depleted, enriched.”		•
71.6	Information Collection Requirements: OMB Approval. A new section that would have an information collection would be added.		•

71.14(a)(2) and (3)	Exemption for low-level materials. The exemption for natural material and ores containing naturally occurring radionuclides would be revised to include material that has been processed, but is not intended to be processed for the use of the radionuclides. A reference to Table A-3 would be added. An exemption would be added for non-radioactive solid objects which have radioactive substances present on its surfaces, provided that the quantity of radioactive substances are below the quantity used to define contamination.	•	
71.15(d)	Exemption for classification as fissile material. The exemption that applies to uranium enriched to a maximum of one percent would be revised to require the material to be distributed homogeneously and not form a lattice arrangement.	•	
71.17(c)	General license: NRC-approved package. Would be revised to clarify that the general licensee must comply with the requirements in paragraphs (c)(1) through (c)(3).		•
71.19(a)	Previously approved package. Paragraphs would be redesignated and paragraph (b)(2), which would be redesignated as paragraph (a)(2), would be changed to delete the phrase "December 31, 2003".		•
71.21(a)	General license: Use of a foreign approved package. This paragraph would be revised to update the reference to 49 CFR 171.12.		•
71.21(d)	General license: Plutonium-beryllium special form material. This paragraph would be revised to clarify that the general licensee must comply with the requirements in paragraphs (d)(1) and (d)(2).		•

71.31 (b)	Contents of application. Would be revised to update a reference to another section.		•
71.38	Renewal of a certificate of compliance. Would be retitled and revised to remove references to renewals of quality assurance program approvals, which would no longer be necessary.	•	
71.70	Incorporation by reference. This section would be added to consolidate the incorporation by reference language; the costs associated with the consensus standards that would be incorporated by reference are discussed as part of 10CFR 71.75.		•
71.75(a)(5)	Qualification of special form radioactive material. Would incorporate by reference ISO 9978 for the alternate leak test methods.		• <sup>1</sup>
71.75(b)(2)	Qualification of special form radioactive material. Paragraphs (b)(2)(ii) and (b)(2)(iii) would be revised to make corrections in the description of the billet and the lead sheet.		•
71.75(d)	Qualification of special form radioactive material. Would incorporate by reference the alternate Class 4 impact test and Class 6 temperature test and would allow the Class 5 impact tests to be used if the specimen weighs less than 500 grams.	• <sup>2</sup>	•
71.85	Preliminary determinations. Would be revised to make certificate holders responsible for making preliminary determinations and durably marking the package. Licensees would be responsible for ensuring that the preliminary determinations have been made.		• <sup>3</sup>

71.91(a)	Records. Would correct the reference from 10 CFR 71.10 to 10 CFR 71.14.		•
71.101(a)	Quality assurance requirements. Would clarify the responsibilities of certificate holders and licensees to reflect the activities that they conduct and would clarify when the NRC is to be notified that a previously approved quality assurance program is to be applied to transportation activities.		•
71.101(c)(2)	Quality assurance requirements. Would clarify that this section only applies to certificate holders and applicants.		•
71.103(a)	Quality assurance organization. Would delete a footnote, which is considered unnecessary.		•
71.106	Changes to quality assurance program. Would be added to revise the process for obtaining NRC approval to make changes to an approved quality assurance program and to report to the NRC those changes that do not require prior NRC approval.	•	
71.135	Quality assurance records. This section would be revised to include changes made to an approved quality assurance program as a quality assurance record.	•	
Appendix A, paragraph IV	Determination of $A_1$ and $A_2$ . Clarifications and corrections would be made to the process for calculating values for $A_1$ and $A_2$ .		•
Appendix A, paragraph V	Determination of $A_1$ and $A_2$ . Direction would be provided for calculating exempt activity concentration and exempt consignment activity for certain mixtures of radionuclides.		•



Appendix A, Table A-1	A <sub>1</sub> and A <sub>2</sub> Values for Radionuclides. Would be revised by adding entries, revising entries, and revising footnotes.	•	
Appendix A, Table A-2	Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides. Would be revised by adding an entry for Kr-79, revising the entry (values) for Te-121m, and revising footnote b.	•	
Appendix A, Table A-3	General Values for A <sub>1</sub> and A <sub>2</sub> . Would be revised to clarify the descriptive phrases for the contents and add a footnote to clarify the calculation of A <sub>1</sub> for a group containing both alpha emitting radionuclides and beta or gamma emitting radionuclides when the groups are based on the total alpha activity and the total beta and gamma activity.		•

<sup>1</sup> The alternate tests allowed by the incorporation by reference are more stringent and costly to perform than the tests prescribed in 10CFR 71.75. Because they are alternative approaches and current practice is to use the tests prescribed in 10 CFR 71.75(c), it is estimated that there are no costs associated with this change.

<sup>2</sup> The alternate tests allowed by the incorporation by reference are more stringent and costly to perform than the tests prescribed in 10 CFR 71.75(b)(1) and (2). Because they are alternative approaches and current practice is to use the tests prescribed in 10 CFR 71.75, it is estimated that there are no costs associated with this change, with the exception of the alternate test allowed for specimens weighing less than 500 grams. The added flexibility for the test for specimens weighing less than 500 grams may have additional benefits and may be more likely to be used. The costs/benefits for this test have been estimated for this RA.

<sup>3</sup> The changes to the preliminary determinations involve changes that would reflect that package marking and testing is done by certificate holders, rather than the user of the package. Licensees would be required to ensure that the preliminary determinations have been made. The changes do not change the preliminary determinations that are to be performed before the first use of the package, so it is estimated that there will be no costs associated with these changes, which also reflect current industry practice.

## 5. DECISION RATIONALE

The assessment of costs and benefits discussed previously leads the NRC to the conclusion that the proposed rule, if implemented, would improve regulatory efficiency and effectiveness for transportation of radioactive material, and would benefit industry with small changes to measures of public health and safety. There is a need to amend regulations to achieve compatibility with the IAEA's TS-R-1 safety standards. Finally, there is a benefit to amend the regulatory requirements that result in holders of a QA program approval having to submit all changes to their QA program description to the NRC for prior approval. Under the proposed rule, holders of a QA program approval would only need to submit to the NRC changes to their QA program description if the change would result in a reduction in the commitments that they have made to the NRC.

Three alternatives were evaluated in this RA. Alternative 1 would take No Action and would maintain the regulations as currently written.

Alternative 2 would amend regulations to provide compatibility with the IAEA's TS-R-1 safety standards and with changes proposed by the DOT. These changes can be done through rulemaking with a one-time implementation cost to the NRC, Industry, and the Agreement States equal to about \$1.5 million followed by an annual operating cost savings of approximately \$63,000.

Alternative 3 would amend regulations as described in the proposed rule. These amendments would provide compatibility with IAEA and DOT regulations and would make certain NRC-initiated regulatory changes to improve regulatory efficiency and to provide benefits to licensees and to the NRC and Agreement States with a small change to measures of impacts to public health and safety. The implementation cost would be equal to approximately \$2,284,000 followed by an annual savings to industry of an estimated \$112,000 (in 2012 dollars). The NRC has determined that Alternative 3 is superior to either of the other alternatives, and improves regulatory efficiency.

## 6. IMPLEMENTATION

The proposed rule is planned for publication in the *Federal Register* in November 2012. Following a public comment period and several months to review the public comments, the NRC staff will revise the proposed rule as appropriate and submit to the Commission in 2013 a proposed final rule.

## 7. REFERENCES

- SECY-01-0057, dated March 29, 2001, (ADAMS Accession No. ML010810303), and Attachment 2, "NORM and TENORM Producers, Users, and Proposed Regulations" by P. Egidi and C. Hull, Table 5A, Page 16 (ADAMS Accession No. ML010670073).
- IAEA Safety Standards Series. IAEA SSR-6, 2012, "Regulations for the Safety Transport of Radioactive Material," IAEA, Vienna.
- IAEA Safety Standards Series. IAEA TS-R-1, Amended 2009, "Regulations for the Safe Transport of Radioactive Material," IAEA, Vienna.
- NRC, "RA Technical Evaluation Handbook, Final Report," NUREG/BR-0184, January 1997.
- U.S. Department of Labor, Bureau of Labor Statistics. Occupational Employment Statistics, Occupational Employment and Wages.
- DOE, "A Resource Handbook on DOE Transportation Risk Assessment," DOE/EM/NTP/HB-01, July 2002.
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- DOT, "The U.S. Department of Transportation's Comprehensive Truck Size and Weight Study: Volume II: Issues and Background," FHWA-PL-00-029 (Volume II), HPTS, August 2000.
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- Tsurikov, N., "The Trade in Radioactive Materials – Potential Problems and Possible Solutions," NORM-V Proceedings, IAEA, 2008.
- Schwela, U. and Chambers, D., "Transportation of Tantalum Raw Materials, Other NORM, and Waste," presented at the EAN-NORM 2<sup>nd</sup> Workshop, Dresden, [http://www.ean-norm.net/lenya/ean\\_norm/images/pdf/Transport\\_tantalum\\_raw\\_materials\\_NORM\\_waste\\_Schwela\\_Chambers.pdf](http://www.ean-norm.net/lenya/ean_norm/images/pdf/Transport_tantalum_raw_materials_NORM_waste_Schwela_Chambers.pdf), Germany, 2009.
- U.S. Geological Survey, 2011, Mineral commodity summaries 2011: U.S. Geological Survey.

- L.D. Cunningham, "Columbium (Niobium) and Tantalum," Minerals Yearbook Volume 1. Metals and Minerals, U.S. Bureau of Mines, 1992, pp. 435-436.

## Appendix 1: Input Assumptions and Line Item Results relating to Alt 2

	Hours	\$ Per Hour	Total One-time Cost (2012)
NRC effort to develop final rule and amend guidance	2031	119	\$241,689
Agreement States' effort to develop final rule and amend guidance	19,980	60.80	\$1,214,784

- 37 Agreement States X 444 hours (.25) gives us the AS hours plus and additional 3,552 hours for the CRCPD efforts.

Change	Truck Shipments/Year	Licensee Cost or Savings to Comply with Transportation Regulations (\$/truck shipment)	Annual Cost of Shipments (20121\$)
Table A-1			
cf-252	5	(500)	(2,500)
lr-192			
kr-79	25	(500)	(12,500)
kr-81	0	0	0
mo-99	0	0	0
Table A-2			
kr-79	25	(100)	(2,500)
kr-81	0	0	0
Te-121m	25	(100)	(2,500)
Totals			(20,000)

## Detailed Quantitative Results relating to Licensee Costs/Savings for Alt 2

Citation	Description	Number Licensees	Annual Responses	Cost per Shipment/Hours Per Response	Annual hours per change	Total Annual Cost	One Time Cost	Total 10 Year 3% NPV	Total 10 Year 7% NPV
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### ALTERNATIVE # 2

71.14(a)	Natural material/ore could be shipped without being classified as hazardous material if it meets the expanded exemption.	5	80	-500		-\$40,000		-\$341,208	-\$280,943
	Purchase copy of ISO standards.	250					\$50,000		
	Maintain awareness of changes to the relevant transportation regulations.						\$7,500		
	240 licensees will need to read the new regulations and will determine actions necessary	240	240	2	480		\$35,136		
71.75(d)	Would incorporate by reference the alternate Class 4 impact test and Class 6 temperature test and would allow the Class 5 impact tests to be used if the specimen weighs less than 500 grams.	50	-50	1	-50	-\$3,660	\$2,500	-\$31,221	-\$25,706
Appendix A						-\$20,000	\$0	-\$170,604	-\$140,472
Total Alternative 2						-\$63,660	\$95,136	-\$543,033	-\$447,121
							+one time cost	\$95,136	\$95,136
							TOTAL	-\$447,897	-\$351,985

## Appendix 2: Detailed Quantitative Results relating to Licensee and NRC Costs/Savings for Alt 3

### Licensee

Citation	Description	Number Licensees	Annual Responses	Hours Per Response	Annual hours per change	Total Annual Cost	One Time Cost	Total 10 Year 3% NPV	Total 10 Year 7% NPV
<b>ALTERNATIVE # 3</b>									
71.15(d)	*Revises the exemption that applies to uranium enriched to a maximum of 1 percent.	1	0.1	40	4	\$293	\$0	\$2,498	\$2,057
71.38(c)	Renewal of a CoC would be revised to remove references to renewals of QA program approvals, which would no longer be necessary.	25	-25	20	-500	-\$36,600	\$0	-\$312,205	-\$257,063
71.106(a)	Allows certificate holders and applicants for a COC to make changes to their approved QA program if the changes do not reduce the commitments in the QA program previously approved by NRC.	14	-14	25.00	-350	-\$25,620	\$0	-\$218,544	-\$179,944
71.106(b)	Changes to quality assurance program. Added to revise the process for obtaining NRC approval to make changes to an approved quality assurance program and to report to the NRC those changes that do not require prior NRC approval	250	125	1.00	125	\$9,150	\$0	\$78,051	\$64,266
71.135	Recordkeeping	250	125	0.5	63	\$4,575	\$0	\$39,026	\$32,133
							\$95,136		
						-\$111,862	<b>TOTAL</b>	-\$954,207	-\$785,673
							+ one-time costs	\$95,136	\$95,136
	<b>Total Alternative # 3</b>						<b>TOTAL</b>	-\$859,071	-\$690,537

<sup>1</sup> Note Alternative 3 includes all cost and benefits for "Alternative 2" in Appendix 1.

**NRC Alternative # 3**

Citation	Description	Number Licensees	Response Per Year	Total Annual Responses	Labor Hours Per Response	Total Annual Costs	One Time Cost Per	Total 10 Yr 3 Percent NPV	Total 10 Yr 7 percent NPV
	RA rule prep Alternative 3					\$0	\$362,605	\$362,605	\$362,605
71.38	Issue new QA program approvals.	240	0	0	0.17	\$0	\$4,760	\$4,760	\$4,760
71.38( c)	Review renewals of QA program.	24	(1)	(24)	10	-\$28,560	\$0	-\$243,623	-\$200,593
71.106 (a)	Holders of a QA Program Approval would no longer be required to obtain prior NRC approval of changes to their QA program description that do not reduce their commitments to the NRC.	14	(1)	(14)	5	-\$8,330	\$0	-\$71,057	-\$58,506
71.106(b)	Report to the NRC those changes that do not require prior NRC approval.	125	1	125	1	\$14,875	\$0	\$126,887	\$104,476
							Total One Time Cost		
							\$367,365		
						-\$22,015	<b>TOTAL</b>	\$179,573	\$212,741