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

September 2014

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EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC) regulates the safe transportation of byproduct material under Part 71 of Title 10 of the Code of Federal Regulations (10 CFR), "Packaging and Transportation of Radioactive Material." In consultation with the U.S. Department of Transportation (DOT), the NRC is amending its regulations for the packaging and transportation of radioactive material. These amendments will make conforming changes to the NRC's regulations based on the International Atomic Energy Agency's (IAEA) regulations for the international transportation of radioactive material and to maintain consistency with DOT regulations. The final NRC rule, in combination with a final DOT rule amending Title 49 of the Code of Federal Regulations (49 CFR) (79 FR 40590; July 11, 2014), will bring United States regulations into general accord with the 2009 edition of the IAEA's "Regulations for the Safe Transport of Radioactive Material" (TS-R-1).

In addition, the NRC is making other revisions to 10 CFR Part 71. These other revisions include NRC-initiated changes that will: 1) update administrative procedures for the quality assurance (QA) program requirements described in subpart H of 10 CFR Part 71; 2) re-establish restrictions on material that qualifies for the fissile material exemption; 3) clarify the requirements for a general license; 4) clarify the responsibilities of certificate holders and licensees when making preliminary determinations; and 5) make other editorial changes.

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

The RA makes the following key findings:

- Total cost to Industry: The rule will result in a one-time cost to the industry of approximately $95,000 (approximately $400 per licensee). The rule will have a total annual savings to the industry of approximately $112,000 (approximately $450 per licensee).

- Total cost to the NRC: The rule will result in a one-time cost to the NRC of approximately $5,000, followed by annual cost savings of approximately $22,000.

- Total cost to Agreement States: Agreement States will be required to amend their regulations consistent with the final rule. The rule will result in a one-time cost to Agreement States of approximately $1.8 million.

- Decision Rationale: The final rule will make the NRC's Part 71 requirements compatible with IAEA and DOT regulations. The NRC-initiated regulatory changes will improve regulatory efficiency, thereby providing benefits to licensees and to the Agreement States. The final rule is expected to slightly reduce impacts to public health and safety.

The final rule is planned for publication in the *Federal Register* in 2015.

ACRONYMS

ADAMS	Agencywide Documents Access and Management System
AS	Agreement States
CFR	*Code of Federal Regulations*
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
FTE	Full Time Equivalent
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” 2009 edition

1. STATEMENT OF THE PROBLEM AND OBJECTIVE OF THE RULEMAKING

The NRC is amending its 10 CFR Part 71 regulations for packaging and transportation of radioactive material. These amendments will make NRC regulations consistent with 2009 revisions to the IAEA's transportation standards in TS-R-1. The TS-R-1 represents an accepted set of requirements that provides a high level of safety in the packaging and transportation of radioactive materials and provides 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 can reduce risks associated with the import and export of radioactive material.

The IAEA revises its transportation standards periodically to reflect acquired knowledge and experience. The NRC periodically updates its transportation regulations in10 CFR Part 71 to reflect the changes in the IAEA's transportation standards and to maintain compatibility with the DOT regulations.

The NRC co-regulates domestic transportation of radioactive material with the DOT. The DOT regulations regarding transportation of radioactive materials are in Title 49 Parts 107, and 171-180. The NRC and the DOT are publishing final rules with the dual purpose to achieve compatibility with IAEA's transportation standards and to improve regulatory efficiency by maintaining a consistent regulatory framework. To achieve compatibility with TS-R-1, the DOT published amendments to its regulations in a final rule dated July 11, 2014 (76 FR 40590). The NRC is also making other changes that do not affect compatibility with the IAEA TS-R-1 or the DOT hazardous material regulations, as discussed in more detail later in this document.

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 NRC rulemaking does not incorporate the 2012 IAEA SSR-6 changes. The NRC will review the SSR-6 changes to determine if additional future conforming changes to 10 CFR Part 71 are warranted.

In addition to making changes for compatibility with IAEA and DOT, the NRC is also revising 10 CFR Part 71 to: 1) update administrative procedures for the quality assurance program requirements described in subpart H of 10 CFR Part 71; 2) re-establish restrictions on material that qualifies for the fissile material exemption; 3) clarify the requirements for a general license; 4) clarify the responsibilities of certificate holders and licensees when making preliminary determinations; and 5) make editorial revisions to correct and clarify certain other requirements.

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 requirements 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."

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 and the DOT harmonized domestic transport regulations with changes made to TS-R-1 over the past several years. These changes will be implemented with a slight cost to the public and domestic regulatory authorities responsible for implementing the proposed changes.

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.

This analysis presents background material, rulemaking objectives, alternatives considered, input assumptions, analysis of the costs and benefits of the proposed rule, and decision rationale. It describes the consequences of the rule language and alternative approaches necessary to accomplish the regulatory objectives.

2. IDENTIFICATION OF ALTERNATIVE APPROACHES

The following sections describe the regulatory options that the NRC considered in order to meet the rulemaking objectives identified in the previous section. The NRC considered three alternatives for the rule, described in the following sections. The full lists of changes that 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

Alternative 1 is the No-Action alternative and would maintain the status quo. Under Alternative 1, 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 rule would impose; however, it would allow greater divergence between the international standards and the domestic regulations. Because radioactive material is routinely imported and exported, consistency between domestic and international transportation regulations benefits international commerce. Differences in domestic and international regulations can make it more complicated and expensive to import or export radioactive material and inhibit trade. Under this alternative, there would be no changes to 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 TS-R-1 and with changes implemented by the DOT and does not include any additional NRC-initiated changes. These amendments include:

- Section 71.4, Definitions. A definition of contamination is added, and the existing definitions of “Criticality Safety Index (CSI),” “Low Specific Activity (LSA) material,” “special form radioactive material,” and “Uranium ─ natural, depleted, enriched” are revised.

- Section 71.14, Exemption for low-level material. Paragraph (a) is revised to allow natural material and ores that contain naturally occurring radionuclides to qualify for the exemption, if such material has “been processed for purposes other than the extraction of the radionuclides.” Section 71.14(a)(3) is 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 stated in the new contamination definition.

- Section 71.75, Qualification of special form radioactive material. Paragraph (d) is amended to 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 will 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 is amended to add an entry for krypton-79 (Kr-79); revise listed values for californium-252 (Cf-252), and revise footnotes to be consistent with TS-R-1.

- Appendix A, Table A-2, “Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides.” The table is amended to add an entry for Kr-79, revise listed values for tellurium-121m (Te-121m), and revise footnote b.

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

This alternative includes all of the changes comprising Alternative 2 and additional NRC-initiated changes.

These NRC-initiated changes include:

- 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) is revised to additionally require that such material be distributed homogeneously and not form a lattice arrangement, in order to qualify for this exemption.

- Section 71.38, Renewal of a certificate of compliance. This section is retitled and revised to remove references to renewals of QA program approvals, which will no longer be required.

- Section 71.85, “Preliminary determinations.” This section is revised to replace “licensee” with “certificate holder” in paragraphs (a), (b), and (c); and paragraph (d) is 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 is added to revise the process for holders of a QA program approval to make changes to an approved QA program and requires periodic reporting of those changes that do not require prior NRC approval.

- Section 71.135, “Quality assurance records.” This section is 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. They 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 BENEFITS AND COSTS

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

3.1 Identification of Affected Attributes

This section identifies the factors within the public and private sectors that the final rule is expected to affect, using the list of potential attributes in Chapter 5 of NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook,” issued January 1997, and in Chapter 4 of NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” Revision 4, issued September 2004. This evaluation considered each attribute listed in Chapter 5 of NUREG/BR-0184[1]. The basis for selecting those attributes is presented later in this document.

Affected attributes include the following:

- **Industry Operation**: The NRC is making changes that will make the regulation of QA programs more efficient. The NRC will issue QA program approvals that will not expire, so that QA program renewal applications will no longer be required. The NRC is also allowing those changes that do not reduce the commitments in an approved QA program to be made without prior NRC approval. Additional natural material and ores that contain naturally occurring radionuclides might qualify for the exemption of low-level radioactive material, which will facilitate the transportation of these materials and reduce shipping costs. In aggregate, the NRC expects that the efficiencies gained from these regulatory changes will result in cost savings to the industry. Radioactive material is imported and exported and consistency between domestic and international transportation regulations reduces cost to the industry. This rule will allow industry to continue to benefit from harmonized regulations.

[1] (http://pbadupws.nrc.gov/docs/ML0501/ML050190193.pdf)

- **Industry Implementation**: When the final rule is adopted/promulgated, affected licensees 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 for compliance. Changes to 10 CFR 71.75(d), which will 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 affected licensees to incur a one-time cost for the purchase of equipment.

- **NRC Implementation**: With the publication of the final rule, the NRC will re-issue QA program approvals with no expiration date. The NRC will 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.

- **Other Governments**: Agreement States will 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 States will incur one-time costs to amend regulations to implement Alternative 2 or Alternative 3.

  The U.S. Department of Energy (DOE) certifies its packages, and it 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 will need to comply with amendments to the fissile material exemption.

- **Regulatory Efficiency**: The 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 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 will 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 will 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 rule modifies 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 will not need to apply to renew their approval and the NRC will not have to review future renewals of QA program approvals. With the publication of a final rule, the NRC will re-issue QA program approvals with no expiration date.

- **Environmental Considerations:** The amendments will 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 will increase the number of shipments of low specific activity radioactive material that will be exempt from

the NRC and the DOT transport regulations (i.e., will 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 environmental impacts, the NRC determined that there will be no significant impact to the public from the amendments.

- **NRC Operations**: Since QA program renewal applications will no longer be required, holders of a QA program approval will not need to apply to renew their approval, thereby reducing the expenditure of NRC resources needed to review such applications. With the publication of a final rule, the NRC will re-issue QA program approvals with no expiration date. The NRC will need to review the biennial reports of changes to QA programs that do not reduce commitments to the NRC. The action will 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)	***Offsite Property***	***Occupational Health (Accident)***
Public Health (Routine)	***Onsite Property***	***Occupational Health (Routine)***
Antitrust Considerations	***General Public***	***Safeguards and Security***
Improvements in Knowledge		

3.2 Analytical Methodology

This section describes the methodology used to analyze the benefits and costs associated with the rule. The benefits consist of any desirable changes in the affected attributes. The 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 rule have been identified by the NRC.

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[2] 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

[2] (http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/)

and 7 percent real discount rates. The 3 percent rate approximates the real rate of return on longterm 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 RA includes assumptions and estimates. The NRC relied on referenced sources for the assumptions and estimates when these were available.

3.2.1 General Assumptions

Costs are expressed in 2014 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 2014 discounted back at a 7-percent and 3-percent discount rate, in accordance with NUREG/BR-0058, Rev. 4.

Here is a discussion of the NRC's general input assumptions for this analysis.

- 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 amendments. Currently, the NRC hourly labor rate is $121.

- Licensee labor rates were determined 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 rates, $73.20/hour is used, which is from Bureau of Labor Statistics Employer Costs for Employee Compensation data set, "Nuclear Engineers."

- The NRC-determined Agreement State labor rates are based on National Wage Data available on the Bureau of Labor Statistics Web site (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., $121/hour.

- The time period for the analysis is 10 years, because licenses are on a 10-year cycle for renewals.

- Estimates were made for one-time implementation costs. It is assumed that the costs will be incurred in the first year after the rule becomes effective. 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 will not be discounted).

- 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 will amend the 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 Agreement States. Appendix 1 details the licensee costs for Alternative 2. The specific NRC assumptions for Alternative 2 costs are as follows:

- 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 will incur costs associated with this effort. It is estimated that 50 percent of licensees will 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 will be made to review the changes in the regulations. The rule includes 24 amendments. It is estimated that an average of 2 hours per licensee or certificate holder will be spent reviewing the changes, for a total of approximately $35,000.
- The changes to § 71.14(a) will 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 will not be shipped for the use of its radionuclides. Licensees will need to ensure correct labeling and placarding for their shipments. This will 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 will be unaffected by this change. It is assumed that about 2 percent of licensees (5 licensees) will 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 estimated annual 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[3] after being adjusted to better approximate the amount of material affected by the 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 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)[4]. 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 will qualify for the exemption, the volume of material and the number of shipments will include the shipment of some material not specifically evaluated.

- It is estimated that approximately 12,000 metric tons of material is shipped annually by rail in approximately 125 railroad cars (or shipments).

- It is assumed that annual fees and permits will not be affected by this change; because some material will still be shipped as class 7 (radioactive) hazardous materials.

- It is estimated that approximately $500 per shipment will be saved, because the material will not be shipped as radioactive material.

- The NRC is incorporating 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."[5] 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 of the 250 impacted licensees will obtain a copy of the ISO standards. It is also assumed that they will acquire the standards at the non-member rate. These estimates will be conservative in estimating the costs.

[3] http://minerals.usgs.gov/minerals/pubs/mcs
[4] http://calytrix.biz/papers/07.NORM_trade.pdf
[5] (http://pbadupws.nrc.gov/docs/ML0036/ML003686268.pdf)

Purchasing the two standards from the distributor in the U.S. will cost each licensee $200 for a total cost of $50,000.

- The NRC estimates there are 60 Class 4 and 60 Class 6 tests performed 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 will cost $500 for each licensee who acquires the equipment. It is assumed that 5 licensees will purchase the equipment, for a total cost of $2,500.

- It is estimated that licensees will perform 50 Class 5 impact tests each year instead of the Class 4 impact test at an equivalent savings of the costs for one labor hour per test, for a total savings of $3,660.

- Other changes will amend certain values in 10 CFR Part 71, Tables A-1 and A-2. These changes will result in an estimated net savings of $20,000 annually for the industry.

- 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 rule language and to amend regulations consistent with the final rule. An estimate of 19,980 labor hours for all 37 Agreement States is made and modeled as a one-time labor cost.

3.2.3 Specific Assumptions for Alternative 3

Under Alternative 3, the NRC will make the changes identified above for Alternative 2 plus other NRC-initiated changes. Appendix 2 details the additional costs for Alternative 3. The specific assumptions for Alternative 3 costs are listed below.

- The changes to 10 CFR 71.15(d) will revise the exemption 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. Within the transportation packages, the material must be distributed homogeneously and must not form a lattice arrangement, in order to qualify for the exemption. The type of material that will be affected by this change is more likely to be possessed by the DOE than by a licensee. Uranium of this enrichment is not used in commercial power reactors, and therefore is not typically shipped. Therefore, it is assumed that only the DOE will ship this material.

    - Shipments of material that will be affected by the revised exemption are expected to be infrequent – one shipment every 10 years. The NRC's cost estimate is based on this assumption, and it is further assumed that this shipment will occur midway through the analysis period.

    - Material which does not meet the revised exemption will likely be able to be shipped under a general license for fissile material, which will 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 will take 40 hours. It is assumed that the CSI will not exceed 100, so the shipment will not need to be shipped using separate conveyances.

- The NRC is amending 10 CFR 71.38, and adding a new 10 CFR 71.106, to remove the need for QA program approvals to be renewed. These changes will result in a savings for the NRC, general licensees, and holders of, or applicants for, a CoC.

- Based on these changes, the NRC estimates there will be an average of 25 fewer QA program approval reviews each year. Holders of the QA program approval will 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 will 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 will need to issue new QA program approvals that will not have an expiration date. The NRC estimates that issuing the replacement QA program approvals will require 40 hours to complete for a one-time NRC cost of approximately $4,800.

- The NRC is adding 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 new requirements in 10 CFR 71.106(a) will result in a savings for holders of a QA program approval and the NRC. Holders of a QA program approval will 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 will benefit from the amendments each year. It is estimated that, on average, 25 labor hours will 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 new requirements in 10 CFR 71.106(b) will 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 by these new requirements. The NRC estimates that QA program approval holders will spend 1 hour every 2 years to comply with this requirement. The NRC estimates it will spend 1 hour to review each submittal.

    - Holders of a QA program approval will be required to maintain records created in response to the changes to § 71.106. The NRC estimates that each QA program approval holder will 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 will require 50 percent more Agreement State staff hours than the effort required to implement Alternative 2. This means about 29,970 labor hours will be required of the Agreement States. This is modeled as a one-time labor cost.

3.2.4 Data on Affected Entities

The analysis makes the following assumptions regarding the entities affected:

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

This rule affects NRC licensees who transport or deliver to a carrier for transport, relatively large quantities of radioactive material in a single package; holders of a quality assurance program description issued under 10 CFR parts 50, 71, or 72; and holders of a certificate of compliance for a transportation package. These companies do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards adopted by the NRC in 10 CFR 2.810, "NRC size standards."

4. PRESENTATION OF RESULTS

This section presents results of benefits and costs that are expected to be derived from the 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 benefits in Regulatory Efficiency and Environmental Considerations, but these are not quantified because they are expected to be small.

The quantified benefits are presented in constant 2014 dollars, for both implementation and annual operating expenses. The impact of the 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 2014 dollars. Alternative 1, the No-Action Alternative, provides a baseline against which the other two alternatives are assessed. The baseline assumes full compliance with existing NRC requirements. This baseline is consistent with NUREG/BR-0058, which states that, "in evaluating a new requirement...the staff should assume that all existing NRC requirements have been implemented."

4.1 Summary of Results

This section presents results of the benefits and costs that are expected to be derived from the rule. To the extent that the affected attributes could be analyzed quantitatively, the costs have been calculated and are presented below. Some benefits and costs are addressed qualitatively for reasons discussed in Section 3.1.

Table 4-1 presents the net impact of the 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	$766,887	Alternative 2	$862,799
Alternative 3	$776,916	Alternative 3	$979,176

There are no costs or benefits associated with Alternative 1, the No Action Alternative. The estimated cost of approximately $0.8 million (3 percent discount rate) for Alternative 2 is to implement the 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 as follows:

- The removal of the requirement to submit QA related information to the NRC, which equals 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.

Because of the larger scope of activity, the cost to the Agreement States to implement amended regulations is about 50 percent higher for Alternative 3 compared to Alternative 2.

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 and seven percent discount rate.

Table 4-2: Estimated Benefits and Costs by Attribute for Alternative 1, 2 and 3

3% Discount Rate	Alternative 1	Alternative 2	Alternative 3
Industry Implementation	$0	$95,136	$95,136
Industry Operation	$0	-$543,033	-$954,207
NRC Implementation	$0	$0	$4,760
NRC Operation	$0	$0	-$190,949
Agreement States	$0	$1,214,784	$1,822,176
Total	$0	$766,887	$776,916

7% Discount Rate	Alternative 1	Alternative 2	Alternative 3
Industry Implementation	$0	$95,136	$95,136
Industry Operation	$0	-$447,121	-$785,673
NRC Implementation	$0	$0	$4,760
NRC Operation	$0	$0	-$157,223
Agreement States	$0	$1,214,784	$1,822,176
Total	$0	$862,799	$979,176

Table 4-3 summarizes the costs by entity, over a 10-year analysis period. Appendices 1, 2 and 3 give details to the results presented in Table 4-2

Table 4-3: Summary of Benefits and Costs for Alternatives 2 and 3

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	$0	$0	$0	$0
Total	$1,309,920	-$63,660	$766,887	$862,799

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	$4,760	-$22,385	-$186,189	-$152,463
Total	$1,922,072	-$134,247	$776,916	$979,176

*****Agreement States do not have annual operating cost saving because NRC reviews the QA program

4.2 Backfitting

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) and the issue finality provisions in 10 CFR part 52 do not apply to this final rule, because this final rule does not contain any provisions that will impose backfits as defined in 10 CFR Chapter I. Therefore, a backfit analysis is not required for this final rule, and the NRC did not prepare a backfit analysis for this final rule.

5. DECISION RATIONALE

There is a need to amend the NRC's regulations to achieve compatibility with the IAEA's TS-R-1 safety standards. The assessment of costs and benefits discussed above leads the NRC to the conclusion that this final rule will improve regulatory efficiency and effectiveness for transportation of radioactive material, and will be cost-beneficial to the NRC and industry. The final rule is expected to slightly reduce impacts to public health and safety.

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 made by the Amending the NRC's regulations can be done through rulemaking with a one-time implementation cost to the NRC, Industry, and the Agreement States equal to about $1.3 million, followed by an annual operating cost savings of approximately $64,000.

Alternative 3 would amend NRC regulations as described in the *Federal Register* notice that has been prepared for the final rule. These amendments would provide compatibility with IAEA and DOT regulations and would make certain NRC-initiated regulatory changes to improve regulatory efficiency as well as make small improvements to public health and safety. The implementation cost would be approximately $1.9 million, followed by an annual savings to industry of an estimated $134,000 (in 2014 dollars). The NRC has determined that Alternative 3 is superior to the other two alternatives, and improves regulatory efficiency.

6. IMPLEMENTATION

Compliance with the amendments adopted in the NRC's final rule is required beginning July 13, 2015. However, the Agreement States have 3 years from the effective date of the final rule to adopt compatible regulations.

7. REFERENCES

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Appendix 1 Alternative 2 Licensee costs

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
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)	Will incorporate by reference the alternate Class 4 impact test and Class 6 temperature test and will 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	Shipment cost savings detailed below					-$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

Shipment Cost Savings

Change	Truck shipments/year	Discussion and Basis for Estimates	Licensee cost or savings to comply with transportation regulations ($/ truck shipment)	Annual Cost of shipments (2014$)
Table A-1				
Cf-252	5		(500)	(2,500)
Kr-79	25		(500)	(12,500)
Table A-2		-		
Kr-79	25	-	(100)	(2,500)
Te-121m	25	-	(100)	(2,500)
Totals		-		(20,000)

Appendix 2: Alternative 3 Costs

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
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 will be revised to remove references to renewals of QA program approvals, which will 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	**TOTAL**	-$954,207	-$785,673
							+ one-time costs	$95,136	$95,136
	Total Alternative # 3						**TOTAL**	-$859,071	-$690,537

[1] 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
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	-$29,040	$0	-$247,717	-$203,965
71.106 (a)	Holders of a QA Program Approval will 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	-$8,470	$0	-$72,251	-$59,490
71.106(b)	Report to the NRC those changes that do not require prior NRC approval.	125	1	125	1	$15,125	$0	$129,019	$106,232
							Total One Time Cost		
							$4,760		
						-$22,385	**TOTAL**	$186,189	$152,463