Regulatory Analysis for Revision 2 of Regulatory Guide 7.4, “Leakage Tests on Packages for Shipment of Radioactive Material”

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Division of Rulemaking, Environmental, and Financial Support

December 2019

Abstract

The U.S. Nuclear Regulatory Commission (NRC) is revising Regulatory Guide (RG) 7.4, "Leakage Tests on Packages for Shipment of Radioactive Material," Revision 1, issued March 2012, to endorse the 2014 American National Standards Institute (ANSI) Standard N14.5, "American National Standard for Radioactive Materials—Leakage Tests on Packages for Shipment," dated June 19, 2014. The NRC has a well-established practice for endorsing consensus standards through the rulemaking process or revision of RGs. This practice increases consistency across the industry and demonstrates the NRC's willingness to support the use of the most updated and technically sound techniques developed to adequately protect the public.

This document is a regulatory analysis for Revision 2 of RG 7.4. The NRC's analysis demonstrates that the endorsement of the 2014 version of the ANSI standards results in negligible cost impacts compared to continuing to endorse the 1997 ANSI standards.

Table of Contents

Section Page

Abstract ..... **ii**

List of Tables ..... **v**

List of Figures ..... **v**

Executive Summary ..... **vi**

Abbreviations and Acronyms ..... **viii**

1. Introduction **1**

2. Statement of the Problem and Objective **1**

2.1 Background 1
2.2 Statement of the Problem 1
2.3 Objective 2

3. Identification and Preliminary Analysis of Alternative Approaches **2**

3.1 Alternative 1—No Action 2
3.2 Alternative 2—Revise Regulatory Guide 7.4 3

4. Estimation and Evaluation of Costs and Benefits **3**

4.1 Identification of Affected Attributes 3
4.2 Analytical Methodology 5
4.2.1 Regulatory Baseline *5*
4.2.2 Affected Entities *5*
4.2.3 Base Year *6*
4.2.4 Sign Conventions *6*
4.2.5 Analysis Horizon *6*
4.3 Data 7

5. Results **7**

5.1 Industry Implementation 8
5.2 Industry Operation 9
5.3 NRC Operation 9
5.4 Total Costs 9
5.5 Improvements in Knowledge 10
5.6 Regulatory Efficiency 10
5.7 Other Considerations—Increased Public Confidence 10
5.8 Uncertainty Analysis 11
5.9 Summary 11
5.9.1 Quantified Net Cost *12*
5.9.2 Nonquantified Benefits *12*
5.10 Safety Goal Evaluation 12

6. Decision Rationale **12**

7. Implementation Schedule **13**

8. References 13

Appendix A: Major Assumptions and Input Data.....15

List of Tables

Page

Table 1 CoC Holders and Potential Future Applicants Affected by RG 7.4 6
Table 2 Total Costs (Industry and NRC) for Alternative 2 10
Table 3 Summary of Totals 12

List of Figures

Figure 1 Total costs (industry and NRC) for Alternative 2—7-percent NPV 11

Executive Summary

The U.S. Nuclear Regulatory Commission (NRC) is revising Regulatory Guide (RG) 7.4, "Leakage Tests on Packages for Shipment of Radioactive Material," Revision 1, issued March 2012 (NRC, 2012), to endorse the 2014 American National Standards Institute (ANSI) standards in ANSI N14.5-2014, "American National Standard for Radioactive Materials—Leakage Tests on Packages for Shipment," dated June 19, 2014. ANSI N14.5-2014 has been updated and contains new information, corrections, and clarifications. The NRC issued Information Notice (IN) 2016-04, titled, "ANSI N14.5-2014 Revision and Leakage Rate Testing Considerations," dated March 28, 2016 (NRC, 2016), which highlights many changes (but not necessarily all) that enhance safety in the ANSI N14.5-2014 revision.

This regulatory analysis evaluates the costs and benefits associated with the RG revision relative to the baseline case (i.e., the no-action alternative). The staff makes the following key findings based on this analysis:

- Cost Analysis. The revision recommended by the staff is estimated to result in minimal net quantitative costs to the NRC, certificate of compliance (CoC) holders, and licensees. The staff estimates that the costs associated with following the 2014 ANSI standard is partially offset by the costs of additional communications (requests for additional information that are generally related to the qualification and certification of personnel performing leakage rate tests and approving leakage rate testing procedures) with the NRC and related inspection actions if a different approval path is followed. The estimated net cost per future licensee (or new or revised application from an existing licensee) of conforming to the revised RG is ($14,100), assuming that each new application occurs in conjunction with the licensee achieving American Society for Nondestructive Testing (ASNT) nondestructive testing (NDT) Level III training and certification for key personnel. Current licensees using an approved package where no portion of the containment boundary and no portion of the containment boundary leakage rate testing has changed will have no incremental costs from this RG revision. At least 15 applications from 7 of the 21 current licensees have used the 2014 ANSI standard, demonstrating that some applicants have already adopted the new ANSI standard. Therefore, the total cost for the remaining 14 licensees is estimated to be ($184,000) using a 7-percent discount rate, assuming these licensees transition to the 2014 ANSI standard over the next 3 years. This is a conservative estimate (high cost) because this analysis assumes licensees train and certify their own NDT Level III personnel, when it might be less costly to subcontract this work. Additionally, personnel and the environment benefit from potentially improved leak testing techniques and considerations that personnel who are not qualified to the latest ANSI standard might not recognize.

- Benefits. There are no quantified benefits. Other benefits include the NRC's continued ability to meet its goal of providing reasonable assurance of adequate protection of public health and safety and the environment through the agency's endorsement of the new ANSI standard. This encourages CoC holders and licensees to use the most current methods and technology to design, construct, and test packages while maintaining NRC oversight of these activities, which increases public confidence. Industry and the staff gain experience and knowledge with the more specific training and qualifications related to leak testing, for example in ASNT Recommended Practice No. SNT-TC-1A. Improved knowledge and training results in better leakage rate testing, which may lead to identifying small leaks that could otherwise have gone unnoticed and

cause exposure to personnel and the environment. Further, knowing personnel are qualified to a higher standard could create better workplace safety and employee confidence. Developing greater knowledge and a common understanding of the latest ANSI standard supports the industry and staff in producing desired on-the-job results. The RG revision is consistent with the provisions of the National Technology Transfer and Advancement Act of 1995 and implementing guidance in U.S. Office of Management and Budget Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," dated January 27, 2016 (OMB, 2016), which encourage Federal regulatory agencies to consider adopting voluntary consensus standards as an alternative to *de novo* agency development of standards affecting an industry.

- Uncertainty Analysis. The staff conducted an uncertainty analysis that estimated total costs to industry and the NRC range from ($12,000) to ($391,000) using a 7-percent discount rate, with a 90-percent confidence interval.

- Decision Rationale. Relative to the no-action baseline, the NRC concludes that the RG revision is acceptable when considering all costs and benefits, because the nonquantified benefits justify the minor costs. The analysis considers quantitatively the current staff practice to issue a request for additional information when the training of personnel and certification of procedures are unclear. The related inspection actions are a qualitative averted cost due that results from the revision of RG 7.4 to recommend ANSI N14.5-2014, and further justifies the minor costs of issuing this revision.

Abbreviations and Acronyms

ADAMS	Agencywide Documents Access and Management System
ANSI	American National Standards Institute
ASNT	American Society for Nondestructive Testing
BLS	Bureau of Labor Statistics
CFR	*Code of Federal Regulations*
CoC	certificate of compliance
DG	draft regulatory guide
IN	information notice
MD	management directive
NDT	nondestructive testing
NRC	U.S. Nuclear Regulatory Commission
NTTAA	National Technology Transfer and Advancement Act of 1995
OMB	U.S. Office of Management and Budget
RAI	request for additional information
RG	regulatory guide

1. Introduction

This document presents the regulatory analysis for the issuance of Regulatory Guide (RG) 7.4, "Leakage Tests on Packages for Shipment of Radioactive Material," as Revision 2 of the RG.

2. Statement of the Problem and Objective

2.1 Background

Since 1975, the U.S. Nuclear Regulatory Commission (NRC) has used RG 7.4 to endorse the American National Standards Institute (ANSI) standard for leakage tests of Type B packages for shipment, as described below. This RG revision continues that practice.

The National Technology Transfer and Advancement Act of 1995 (Public Law 104-113, 1995) (NTTAA) mandates the following:

> All Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.

In carrying out this legislation, Federal agencies are to consult with voluntary consensus standards bodies and participate with such bodies in developing technical standards when such participation is in the public interest and compatible with the agency mission, priorities, and budget resources. If the technical standards are inconsistent with applicable law or otherwise impractical, a Federal agency may elect to use technical standards that are not developed or adopted by voluntary consensus bodies.

2.2 Statement of the Problem

The NRC originally published RG 7.4 in June 1975 (NRC, 1975) to endorse the guidance in ANSI N14.5-1973 as an acceptable industry standard for leakage tests of Type B packages for shipment in accordance with the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material." The NRC has revised 10 CFR Part 71 several times. In 2012, the staff revised RG 7.4, Revision 1 (NRC, 2012) to endorse ANSI N14.5-1997, which was reaffirmed in 2008.

Experiences in package design and leakage rate testing has improved leakage rate testing techniques and considerations related to package and seal design and materials. Under certain conditions, better seal design and leakage rate testing can prevent or detect leaks. The result is a potential for lower dose and less rework (i.e., preventing the need for repackaging of radioactive material) and reduced associated costs. The initial intent of the previous standard was not met; therefore, the staff asked for additional information to address safety concerns. During this time the NRC staff became aware of these new findings and better understood the importance of certain variables in leakage rate testing procedures and their application. Therefore, the staff has been engaging with industry via requests for additional information (RAIs) and inspection actions to provide reasonable assurance that personnel are adequately trained, qualified, and certified to write, approve, and qualify leakage rate test procedures and conduct leakage rate tests in accordance with the previous version of the ANSI N14.5 standard.

Considering these new findings and knowledge, ANSI updated ANSI N14.5 in 2014, clarifying a level of training for leakage rate testers and for those who write, approve, and qualify the procedures. The NRC staff has determined that, in adhering to ANSI N14.5-2014, the procedures and testing would provide reasonable assurance that packages and leakage rate testing procedures are adequate to avoid undetected leaks, without the staff needing to further clarify via RAIs, and may reduce the need for the NRC to perform related inspection actions. The inspection costs are considered qualitatively in this analysis. The NRC issued Information Notice (IN) 2016-04, "ANSI N14.5-2014 Revision and Leakage Rate Testing Considerations," dated March 28, 2016 (NRC, 2016), to make industry aware of these issues and the updated ANSI standard as well as the NRC's intention to revise RG 7.4. This revision endorses ANSI N14.5-2014 as a clear path to qualification of leakage rate testing personnel and leakage rate testing procedure performance.

2.3 Objective

The objective of this regulatory action is to update RG 7.4 to endorse the current version of a consensus standard, ANSI N14.5, which contains new information, corrections, and clarifications, to demonstrate compliance with 10 CFR Part 71 requirements.

Revising this RG to endorse a consensus standard is consistent with the NRC policy of evaluating the latest versions of national consensus standards to determine their suitability for RG endorsement, if the benefits justify the costs. This is in accordance with Public Law 104-113, "National Technology Transfer and Advancement Act of 1995," and the approach described in the NRC's Management Directive (MD) 6.5, "NRC Participation in the Development and Use of Consensus Standards," dated October 28, 2016 (NRC, 2016).

3. Identification and Preliminary Analysis of Alternative Approaches

This section analyzes the two alternatives that the NRC considered for RG 7.4: (1) do not revise RG 7.4, and (2) revise RG 7.4 to address current methods and procedures.

3.1 Alternative 1—No Action

Under this alternative, the NRC would not revise this guidance document, and applicants (including current CoC holders and licensees) would continue to use Revision 1 of this RG. This alternative is considered the "no-action" alternative and provides a baseline condition from which any other alternatives will be assessed. This alternative would not align the RG to the process recommended in IN 2016-04 of updating RG 7.4 by endorsing ANSI N14.5-2014, potentially continuing a lack of clarity on this issue.

It is important to note that since 2016, at least 15 applications from 7 of the 21 current licensees have voluntarily used ANSI N14.5-2014, which the NRC has not yet endorsed. A reasonable conclusion might be that applicants will continue to voluntarily use ANSI N14.5-2014 without further action from the NRC. Even so, the "no-action" alternative would not address identified problems with the 1997 ANSI N14.5 standard (e.g., deficiencies associated with qualification and certification of personnel performing leakage rate tests and writing leakage test procedures, and lack of qualification of leakage rate testing procedures themselves), and the NRC would continue to review each application on a case-by-case basis to ensure the requirements of 10 CFR Part 71 related to these areas were met.

3.2 Alternative 2—Revise Regulatory Guide 7.4

Under this alternative, the NRC would revise RG 7.4. This revision would endorse the ANSI N14.5-2014 standard and its appendices and RG 7.4, Revision 1 would no longer be applicable to new licensing actions. By doing so, the NRC would ensure that the RG relies upon the best available information and practices.

Current CoC holders and licensees may continue to use the guidance that the NRC has already found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged. For an approved package as long as the current licensing basis remains unchanged, ANSI N14.5-1997 can continue to be used as an acceptable means to meet the requirements of 10 CFR Part 71.

The proposed action would provide updated guidance on leakage tests of packages for shipment of radioactive material to comply with 10 CFR Part 71 requirements. Based on this regulatory analysis, the NRC staff concludes that a revision of RG 7.4 to endorse ANSI N14.5-2014 is warranted because this alternative:

- Encourages future applicants to use the latest ANSI N14.5 standard for leakage testing.
- Supports the NRC's commitment to participating in the national consensus standards process (when clear benefits result.)
- Results in a minimal burden on industry and the NRC.
- Provides a path for CoC holders, licensees, and applicants that would result in fewer RAIs and related inspections than the status quo, because the ANSI N14.5 2014 ensures licensees consider recent findings and new information on leak rate testing.

Section 5 of this analysis discusses the costs and benefits of this alternative compared to the regulatory baseline (Alternative 1).

4. Estimation and Evaluation of Costs and Benefits

This section describes the process for evaluating the costs and benefits expected to result from Alternative 2 relative to the regulatory baseline (Alternative 1). This regulatory analysis monetizes costs and benefits where meaningful quantification is possible.

4.1 Identification of Affected Attributes

This section identifies the components of the public and private sectors, commonly referred to as "attributes," that the staff expects the alternatives identified in Section 3 to affect. The alternatives would apply to CoC holders, licensees, and applicants for the transportation and storage of nuclear materials. The NRC developed an inventory of the impacted attributes using the list provided in NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4, dated September 2004 (NRC, 2004), as augmented with Commission direction provided in SRM SECY 18-0042 dated March 28, 2018 (NRC, 2018).

The rule would affect the following attributes:

- Industry Implementation. This attribute accounts for the projected net economic effect on the affected existing CoC holders and licensees, in addition to new applicants using the revised guidance. Costs include procedural and administrative activities related to inspection, testing, and training that might occur as a result of the RG revision. Additional costs above the regulatory baseline are considered negative, and cost savings and averted costs are considered positive.

- Industry Operation. This attribute accounts for the projected net economic effect caused by routine and recurring activities required by the alternative on new applications and applicants. For example, an alternative that endorses an ANSI standard that provides a path for the affected existing CoC holders and licensees, in addition to new applicants to submit an application with reduced regulatory uncertainty due to improved standards would provide a net benefit (i.e., averted cost) to the affected existing CoC holders and licensees, in addition to new applicants.

  The effect on industry operation would be the changes to the CoC holder or licensee's design, testing, and inspection practices because of the new ANSI standard endorsed by this RG revision. Some of the changes may result in an increase in burden, and some of the changes may result in a decrease in burden.

- NRC Operation. This attribute accounts for the projected net economic effect on the NRC after the rule is implemented. If, based on the new findings discussed in this regulatory analysis, the requirements of 10 CFR 71 were more clearly communicated in regulatory guidance documents (because applications use the latest ANSI standard, thus providing a clear basis for procedure qualification and testing,) NRC would realize a net benefit.

- Improvements in Knowledge. This attribute accounts for improvements in knowledge as industry and the staff gain experience with training, qualifications, design, and test procedures as a result of implementing the updated ANSI N14.5 standard.

- Regulatory Efficiency. This attribute accounts for regulatory and compliance improvements resulting from the implementation of Alternative 2 relative to the regulatory baseline. Alternative 2 would constitute a best practice by aligning NRC regulations with the ANSI standard, and it would provide new applicants, and CoC holders and licensees using new applications, with regulatory certainty via a path for approval that addresses the latest findings on testing and test procedures.

- Other Considerations. This attribute accounts for considerations not captured in the preceding attributes. Specifically, it accounts for how Alternative 2 would improve public confidence.

- Attributes with No Effects. Attributes not expected to be affected under any of the alternatives include NRC implementation, considerations of public health (accident and routine), occupational health (accident and routine), offsite property, onsite property, other governments, the general public, safeguards and security, and the environment.

4.2 Analytical Methodology

This section describes the process used to evaluate costs and benefits associated with the alternatives. The benefits include any desirable changes in affected attributes (e.g., monetary savings, and improved safety and security). The costs include any undesirable changes in affected attributes (e.g., monetary costs and increased exposures).

The analysis evaluates industry implementation, industry operation, and NRC operation on a quantitative basis, and the remaining three of the six affected attributes on a qualitative basis because those benefits are not quantifiable or because the data necessary to quantify and monetize the impacts on these attributes are not available.

The staff documents its assumptions throughout this regulatory analysis.

4.2.1 Regulatory Baseline

This regulatory analysis identifies the incremental impacts of Alternative 2 compared to a baseline that reflects anticipated behavior if the NRC does not undertake regulatory or nonregulatory action. The regulatory baseline assumes full compliance with existing NRC requirements, including current regulations and relevant orders. This is consistent with NUREG/BR-0058, Revision 4 (NRC,2004), as augmented by SRM SECY 18-0042 (NRC,2018), which states that “in evaluating a new requirement…, the staff should assume that all existing NRC and Agreement State requirements have been implemented.” Section 5 of this regulatory analysis presents the estimated incremental costs and benefits of Alternative 2 compared to this baseline.

4.2.2 Affected Entities

The RG revision affects 21 Type B transportation package current CoC holders as long as their current licensing basis has changed, and any future applicants, as shown in Table 1.

Table 1 CoC Holders and Potential Future Applicants Affected by RG 7.4

Type B Transportation Package CoC Holders Affected by RG 7.4
Alpha-Omega Services, Inc.
AREVA Inc.
Best Theratronics
BWXT Nuclear Operations Group, Inc.
Croft Associates Limited
EnergySolutions
Framatome Inc.
GE-Hitachi Nuclear Energy Americas, LLC
General Atomics
Global Nuclear Fuel—Americas, LLC
Holtec International
Industrial Nuclear Company
NAC International, Inc.
National Nuclear Security Administration
Neutron Products, Inc.
Orano Federal Services, LLC
QSA Global Inc.
Robatel Technologies, LLC
Source Production and Equipment Company, Inc.
TN Americas, LLC
U.S. Department of Energy

* Current licensees are impacted as long as their current licensing basis has changed.

4.2.3 Base Year

The NRC assumes that the RG will be effective in 2020. The staff assumes that the ongoing costs of operation related to the alternative being analyzed begin no earlier than 30 days after publication of the RG unless otherwise stated and models these costs on a per-applicant basis.

One-time NRC implementation costs related to RG issuance are considered sunk costs at this stage.

4.2.4 Sign Conventions

The sign conventions used in this analysis are that all favorable consequences for the alternative are positive and all adverse consequences for the alternative are negative. Negative values are shown using parentheses (e.g., negative $500 is displayed as ($500)).

4.2.5 Analysis Horizon

This RG will remain in effect as long as the NRC regulates nuclear materials CoC holders and licensees. This analysis assumes that all licensees will eventually use ANSI N14.5-2014 as a result of this guidance, across the next 3 years. At that point, all current licensees would have transitioned to American Society for Nondestructive Testing (ASNT) nondestructive testing

(NDT) Level III certification and would not be expected to incur further incremental costs from this RG revision.

4.3 Data

Analysts obtained qualitative (i.e., nonquantified) information on attributes affected by the alternatives from the staff and from comments on the regulatory analysis provided with the RG revision. The NRC considered the potential differences between the new guidance and the current guidance and incorporated the incremental changes into this regulatory analysis. Subject matter experts provided quantitative information on the costs of ASNT NDT Level III training and certification, as well as level of effort estimates for RAIs. The labor rate for the NRC is a calculation the NRC performs annually, and the labor rate for industry is a blended labor rate from the most recent data from the Bureau of Labor Statistics (BLS) (2018). Appendix A to this regulatory analysis shows the data inputs.

5. Results

This section presents the qualitative results by attribute for Alternative 2, relative to the regulatory baseline (Alternative 1). As described in the previous sections, costs and benefits are quantified when possible and are shown to be either positive or negative, depending on whether the alternative has a favorable or adverse effect compared to the regulatory baseline. Those attributes that are not presented in monetary values are discussed in qualitative terms.

The NRC staff tabulated the applications from Type B transportation package CoC holders affected by RG 7.4 to document the usage of ANSI N14.5-2014. Since 2016, when the NRC issued IN 2016-04, at least 15 applications from 7 of the 21 current licensees have voluntarily applied to the NRC using ANSI N14.5-2014, as opposed to the 1997 standard endorsed in the current revision of RG 7.4. Eight of these applications were amendments for existing CoCs, and seven were new applications. This evidence of CoC holders voluntarily using the 2014 ANSI standard indicates that CoC holders consider the benefits of using the 2014 ANSI standard to outweigh the costs. This regulatory analysis assumes that, if the costs of conforming to ANSI N14.5-2014 exceeded the benefits in any clear, measurable way, the staff would not see so many applications voluntarily conforming to the 2014 ANSI standard.

Public Comments

The NRC received public comments on Draft Regulatory Guide (DG)-7010, issued April 2019 (NRC, 2019), including several that raised issues with the draft regulatory analysis. The comments and NRC's response are summarized below.

(1) One public comment asserts that the NRC has imposed ANSI N14.5-2014 in the renewal process for a current transportation package CoC, resulting in costs to the CoC holder.

The NRC staff does not intend to impose implementation of the ANSI N14.5-2014 standard on existing CoC holders and licensees. These current CoC holders and licensees may continue to use the guidance that the NRC has already found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

ANSI N14.5-2014 supersedes ANSI N14.5-1997 and contains new information, corrections, and clarifications. The NRC has discussed and made known the issuance of the updated ANSI

N14.5-2014 consensus standard in public meetings and in IN 2016-04; the NRC staff does not intend to impose implementation of the ANSI N14.5-2014 standard on existing CoC holders and licensees.

(2) A second public comment states that utilities have expended resources to meet the temperature and insolation controls of the 2014 ANSI standard because of a lack of controls and indoor space, resulting in temporary storage areas and additional relocations of casks for testing. The comment characterizes the final RG as imposing the new standard.

ANSI N14.5-2014 does not add or modify any temperature or insolation control specifications from those in the 1997 standard. For an approved package as long as the current licensing basis remains unchanged, ANSI N14.5-1997 can continue to be used.

(3) A third public comment mentioned the new training and qualification that would be necessary to meet the 2014 ANSI standard and stated that this would be burdensome—costly and resource intensive—to licensees.

The importance of having qualified individuals approving leakage rate test procedures and performing leakage rate tests is due to the sensitivity of leakage rate test variables, sophistication of leakage rate testing equipment, subtleties of achieving accurate measurements, and often rigorous leakage rate test acceptance criteria. ANSI N14.5-2014 states that leakage rate testing procedures shall be approved by personnel whose qualification and certification in the nondestructive method of leak testing includes certification by a nationally recognized society at a level appropriate to the writing or review, or both, of leakage rate testing procedures. An individual who has obtained certification as an ASNT NDT Level III in leak testing has the qualification necessary to develop and approve written instruction for conducting leakage rate testing as well as the knowledge to consider practical leakage rate testing issues. This regulatory analysis demonstrates that this training is not a significant burden to an applicant.

RG 7.4 endorses the 2014 ANSI N14.5 standard that specifies the minimum qualification necessary for personnel approving leakage rate testing procedures and personnel performing leakage rate testing. By this endorsement, the NRC provides a clear, detailed path to simplified acceptance of new package designs, leakage rate test procedures, and performance of leakage rate tests. Absent meeting the standard of ANSI N14.5-2014, an affected CoC holder, licensee, or new applicant might not avoid RAIs or associated inspection actions during the approval process.

In consideration of these comments, the NRC staff reviewed recent CoC applications and amendments and found that seven licensees have voluntarily used the ANSI N14.5-2014 standard. This evidence supports the conclusion that either the ANSI N14.5 standard is not onerous, or CoC holders or licensees benefit from complying with the standard.

5.1 Industry Implementation

This regulatory analysis assumes licensees have personnel trained to ASNT NDT Levels I and II, which subject matter experts have stated is highly likely. The NRC staff consulted with ASNT NDT Level III subject matter experts and estimates the undiscounted costs per applicant to train personnel and certify procedures to this level at ($24,600). This is a conservative (high cost) estimate because it assumes licensees will train and certify NDT Level III personnel in house,

when it might be less costly to subcontract out these activities. These costs are offset in part by a more streamlined regulatory review if the application has adopted the 2014 ANSI standard. This regulatory analysis shows these averted costs in the industry operation and NRC operation sections, assumed to take place in the same year as the implementation costs, as undiscounted averted costs.

5.2 Industry Operation

This attribute accounts for the projected net economic effect of routine and recurring activities required by the alternative for all affected CoC holders and licensees. The proposed RG 7.4, Revision 2, does not require CoC holders and licensees to meet ANSI N14.5-2014; RGs are not substitutes for regulations, and compliance with them is not required. For an approved package as long as the current licensing basis remains unchanged, ANSI N14.5-1997 can continue to be used. As noted in the public comments for DG-7010, CoC holders or licensees could potentially incur costs if, for example, those who are not qualified according to the ASNT Recommended Practice No. SNT-TC-1A subsequently underwent training. However, those applicants that meet ANSI N14.5-2014 could experience savings during the application process, because the additional clarity in the NRC's guidance document may obviate the need to request additional information on their leakage rate testing personnel qualification and leakage rate testing procedures. Additionally, the NRC may not need to use inspection actions to verify the adequacy, safety, or usefulness of these procedures and testing. Depending on the number of applications, these averted costs could counter the initial qualification costs estimated in this regulatory analysis, but this is a speculative calculation and therefore is considered qualitatively.

A clear path to avoiding additional costs associated with the RAIs mentioned above would be following the 2014 ANSI N14.5 standard. The NRC staff estimates the undiscounted averted costs of no longer having to respond to these RAIs as $6,800 per applicant. **Table 2** shows this estimate using a mean hourly labor rate for industry of $120 (based on BLS data) and an hourly estimate of 56.7 hours to respond to RAIs.

For an approved package as long as the current licensing basis remains unchanged, the existing leak test procedures and procedural qualifications hold and can continue to be used without modification or any expectation of RAIs or inspection actions. RG 7.4 is guidance; existing licensees and future applicants are not required to take any actions as a result of the NRC endorsing the 2014 ANSI N14.5 standard but instead would expect a streamlined application process if the 2014 ANSI N14.5 standard were used.

5.3 NRC Operation

The NRC may experience incremental averted costs due to a reduction in RAIs and inspection actions in cases where CoC holders with new package designs or changes to leakage rate testing, or new CoC applicants choose to meet the ANSI N14.5-2014 standard. The staff estimates the averted costs to the NRC per applicant at $3,700, using the NRC labor rate of $131 per hour and 28.3 hours for generating the RAIs. **Table 2** shows this calculation. Inspection actions associated with these RAIs were not quantified yet should be considered qualitatively as an additional averted cost.

5.4 Total Costs

The staff estimates undiscounted costs of ($14,100) for each applicant as a result of Alternative 2, issuing the revised RG. Across 3 years following the issuance of the RG, the staff

estimates the total cost to industry and the NRC to range from ($184,000) using a 7-percent discount rate to ($191,000) using a 3-percent discount rate.

Table 2 Total Costs (Industry and NRC) for Alternative 2

Year	Activity	Number of Applicants	Labor Hours	Hourly Rate	Unit Cost	Undiscounted Cost	7% NPV Cost	3% NPV Cost
2020	Training and Certification to ANSI NDT III	4	NA	NA	$24,600	($98,400)	($98,400)	($98,400)
2020	RAIs (NRC)	4	28.3	$131	NA	$14,800	$14,800	$14,800
2020	RAIs (Industry)	4	56.7	$120	NA	$27,200	$27,200	$27,200
2021	Training and Certification to ANSI NDT III	5	NA	NA	$24,600	($123,000)	($114,953)	($119,417)
2021	RAIs (NRC)	5	28.3	$131	NA	$18,600	$17,383	$18,058
2021	RAIs (Industry)	5	56.7	$120	NA	$34,000	$31,776	$33,010
2022	Training and Certification to ANSI NDT III	5	NA	NA	$24,600	($123,000)	($107,433)	($115,939)
2022	RAIs (NRC)	5	28.3	$131	NA	$18,600	$16,246	$17,532
2022	RAIs (Industry)	5	56.7	$120	NA	$34,000	$29,697	$32,048
					Total:	**($197,200)**	**($183,700)**	**($191,100)**

5.5 Improvements in Knowledge

Compared to the regulatory baseline (Alternative 1), Alternative 2 would improve knowledge by encouraging industry and the staff to gain experience and knowledge with new training and qualifications related to leakage rate testing. Improved knowledge and training result in better leakage rate testing that may lead to identification of small leaks that could otherwise have gone unnoticed. The overall result is a potential reduction in dose or rework (i.e., preventing the need for repackaging of radioactive material) and reducing costs that come with rework or decontamination. In addition, knowing personnel are qualified to the latest standard can result in higher confidence in workplace safety. Developing greater knowledge and a common understanding of the latest version of the ANSI N14.5 standard would support the industry and staff in producing desired on-the-job results.

5.6 Regulatory Efficiency

Compared to the regulatory baseline (Alternative 1), Alternative 2 is consistent with the provisions of the NTTAA and its implementing guidance, which encourage Federal regulatory agencies to consider adopting voluntary consensus standards as an alternative to *de novo* agency development of standards affecting an industry. Alternative 2 is also consistent with the NRC policy of evaluating the suitability for endorsement by regulations of the latest versions of consensus standards. Finally, Alternative 2 is consistent with the NRC's goal to harmonize with international standards to improve regulatory efficiency for both the NRC and international standards groups.

5.7 Other Considerations—Increased Public Confidence

The NRC's regulatory analysis guidelines (NRC, 2018) state that the NRC's periodic review and endorsement of consensus standards, such as new versions of the ANSI standard, is a special case because consensus standards have already undergone extensive external review and have been endorsed by industry. Furthermore, NRC endorsement of the ANSI standard is consistent with the NTTAA, because the NRC has determined that sound regulatory reasons exist for establishing regulatory guidance for leak testing procedures and the conduct of leakage rate tests, in this case. Note that endorsing the ANSI N14.5 standard in RG 7.4, Revision 2, does not create a requirement but instead demonstrates a path toward approval.

Alternative 2 incorporates the current ANSI N14.5 standard for the leakage testing of radioactive material packages. Individuals with the qualifications and certifications described in

ANSI N14.5-2014 would provide reasonable assurance of an accurate test and a well-designed package. Experiences in leakage rate testing, which formed some of the clarifications in ANSI N14.5-2014, show that design and leakage rate testing practices can impact achieving acceptable leakage rate test performance. Personnel trained to ASNT Recommended Practice No. SNT-TC-1A as an ASNT NDT Level III in leak testing would have gained knowledge and experience of these more complex issues and would be able to review a leakage rate test procedure to verify the procedure would adequately detect leaks to the level intended by the requirements of NRC regulations, thus resulting in benefits to personnel and the environment. This alternative would encourage applicants to use the most current methods and technology to design, fabricate, and test packages while maintaining NRC oversight of these activities, which increases public confidence.

5.8 Uncertainty Analysis

The NRC conducted an uncertainty analysis based on the costs and averted costs of Alternative 2, using a Monte Carlo analysis. The uncertainty analysis showed that the alternative has a 96.6-percent chance of resulting in costs to the industry and the NRC, totaling an estimated ($184,000) using a 7-percent net present value (NPV). This assumes that applicants would adopt ANSI N14.5-2014 as a result of the revision to RG 7.4, which is a conservative assumption given that at least 15 applications (from 7 out of 21 licensees) have already adopted the newer standard. Appendix A shows the inputs for the uncertainty analysis.

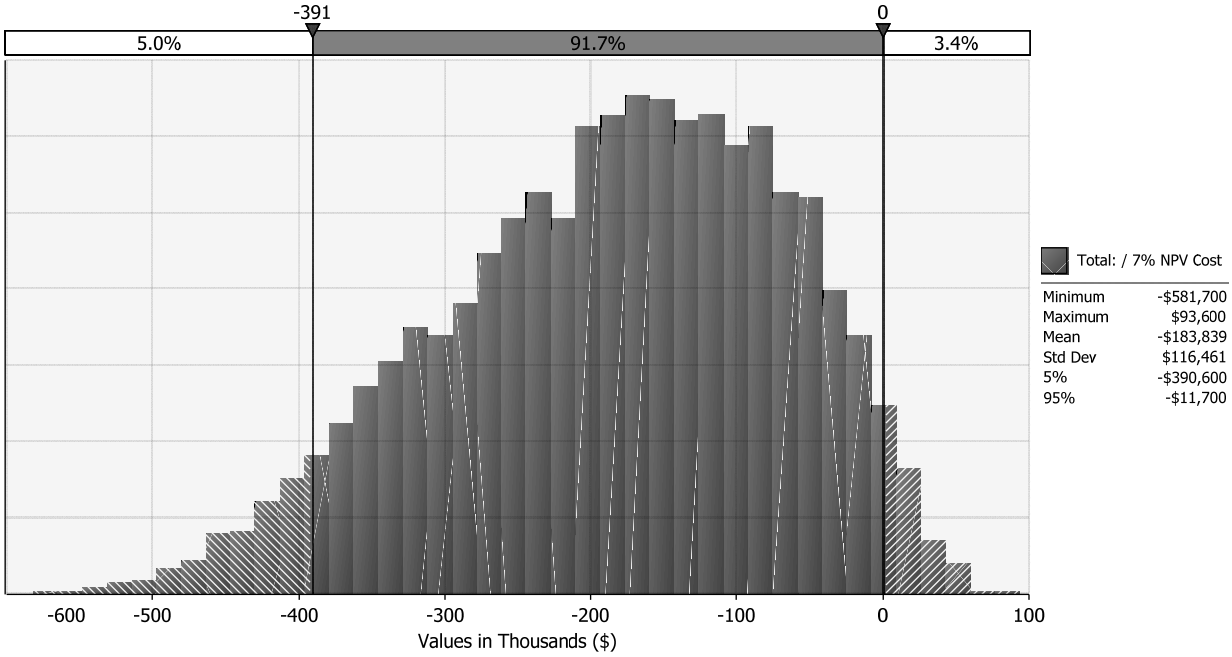

Figure 1 Total costs (industry and NRC) for Alternative 2—7-percent NPV

5.9 Summary

This regulatory analysis identified both quantifiable and nonquantifiable costs and benefits that would result from endorsing ANSI N14.5-2014 through the issuance of RG 7.4, Revision 2. The NRC staff asserts that the nonquantifiable benefits of the revised RG justify the small quantified costs per applicant.

5.9.1 Quantified Net Cost

The staff estimates a quantified net cost of ($184,000) as a result of issuing RG 7.4, Revision 2.

5.9.2 Nonquantified Benefits

The attributes of improvements in knowledge, regulatory efficiency, and other considerations (public confidence) would produce a number of nonquantified benefits for the industry and the NRC. Sections 5.6, 5.7, and 5.8 detail these benefits.

5.10 Safety Goal Evaluation

Issuing RG 7.4, Revision 2, would encourage applicants to apply the most recent ANSI N14.5 standard. The NRC's safety goal evaluation applies only to regulatory initiatives considered to be generic safety enhancement backfits subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). The NRC does not regard the endorsement of ANSI N14.5 standard to be backfitting or to represent an inconsistency with any issue finality provisions in 10 CFR Part 52, "Licensees, Certifications, and Approvals for Nuclear Power Plants," which do not apply to materials licensees. Based on the reasons described, a safety goal evaluation is not appropriate for this regulatory analysis.

6. Decision Rationale

Table 3 provides the quantified and qualified costs and benefits for Alternative 2. The quantitative analysis used best estimate values.

Table 3 Summary of Totals

Net Monetary Savings or (Costs)—Total Present Value	Nonquantified Benefits or (Costs)
Alternative 1: No Action $0	None
Alternative 2: Issue RG 7.4, Revision 2 Industry: ($232,000) using a 7% discount rate ($241,000) using a 3% discount rate NRC: $48,000 using a 7% discount rate $50,000 using a 3% discount rate Net Benefit (Cost): ($184,000) using a 7% discount rate ($191,000) using a 3% discount rate	Benefits: • **Improvements in Knowledge:** Industry and the staff would gain experience and knowledge with new training and qualifications related to leakage rate testing. Improved knowledge and training result in better leakage rate testing that may lead to identification of small leaks that could otherwise have gone unnoticed. The overall result is a potential reduction in dose or rework (i.e., preventing the need for repackaging of radioactive material) and reducing costs that come with rework or decontamination. In addition, knowing personnel are qualified to the latest standard can result in higher confidence in workplace safety. Developing greater knowledge and a common understanding of the latest version of the ANSI N14.5 standard would support

Net Monetary Savings or (Costs)—Total Present Value	Nonquantified Benefits or (Costs)
Alternative 2 (continued)	the industry and staff in producing desired on-the-job results. • **Regulatory Efficiency:** Issuing RG 7.4, Revision 2, is consistent with the provisions of the NTTAA and its implementing guidance, which encourage Federal regulatory agencies to consider adopting voluntary consensus standards. Alternative 2 is consistent with the NRC's goal to harmonize with international standards to improve regulatory efficiency for both the NRC and international standards groups. • **Increased Public Confidence:** Alternative 2 incorporates the ANSI N14.5-2014 standard for the leakage testing of radioactive material packages. This alternative would encourage CoC holders and licensees to use the most current methods and technology to design, fabricate, and test packages while maintaining NRC oversight of these activities, which increases public confidence.

Qualification guidance under the 2014 ANSI N14.5 standard would result in higher costs for training and qualification. However, this would be balanced by fewer RAIs and inspection actions, affecting CoC holders, licensees, and the NRC, as well as the benefit of greater certainty in the integrity of new package seals. Therefore, industry and the NRC are expected to have net costs of approximately ($14,100) per applicant from Alternative 2. For CoC holders and licensees that continue using the same standard, there would be no change from the status quo of RAIs and inspections to guarantee procedural and testing effectiveness. Alternative 2 would also have the qualitative benefits of an improvement in knowledge, regulatory efficiency, and public confidence.

Considering quantified and nonquantified costs and benefits, the regulatory analysis shows that issuing RG 7.4, Revision 2, is justified because of the number and significance of the nonquantified benefits weighed against the small quantified costs.

7. Implementation Schedule

The RG will become effective upon publication, as announced in the *Federal Register*.

8. References

Bureau of Labor Statistics (BLS), 2019a. "NAICS Code: North American Industry Classification System Code," January 2019. Available at http://www.bls.gov/bls/naics.htm; last accessed on April 1, 2019.

BLS, 2019b. "Databases, Tables & Calculators by Subject: CPI Inflation Calculator," January 2019, accessible at http://www.bls.gov; last accessed on April 1, 2019.

Office of Management and Budget (OMB), 2016. Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," January 27, 2016. Available at https://www.federalregister.gov/documents/2016/01/27/2016-01606/revision-of-omb-circular-no-a-119-federal-participation-in-the-development-and-use-of-voluntary.

Public Law 104-113, National Technology Transfer and Advancement Act of 1995, as amended, accessible at http://www.gpo.gov/fdsys/pkg/PLAW-104publ113/pdf/PLAW-104publ113.pdf.

U.S. Code of Federal Regulations, "Domestic Licensing of Production and Utilization Facilities," Part 50, Chapter 1, Title 10, "Energy."

U.S. Code of Federal Regulations, "Licensees, Certifications, and Approvals for Nuclear Power Plants," Part 52, Chapter 1, Title 10, "Energy."

U.S. Code of Federal Regulations, "Packaging and Transportation of Radioactive Material," Part 71, Chapter 1, Title 10, "Energy."

U.S. Nuclear Regulatory Commission (NRC), 1975. Regulatory Guide (RG) 7.4, "Leakage Tests on Packages for Shipment of Radioactive Material," June 1975, Agencywide Documents Access and Management System (ADAMS) Accession No. ML003739407.

NRC, 2004. NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 4, September 2004, ADAMS Accession No. ML042820192.

NRC, 2012. RG 7.4, "Leakage Tests on Packages for Shipment of Radioactive Material," Rev. 1, March 2012, ADAMS Accession No. ML112520023.

NRC, 2016. Information Notice (IN) 2016-04, "ANSI N14.5-2014 Revision and Leakage Rate Testing Considerations," March 28, 2016, ADAMS Accession No. ML16063A287.

NRC, 2016. Management Directive 6.5, "NRC Participation in the Development and Use of Consensus Standards," October 28, 2016, ADAMS Accession No. ML18073A164.

NRC, 2018. NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," draft Rev. 5, March 28, 2018, ADAMS Accession No. ML17221A000.

NRC, 2019. Draft Regulatory Guide (DG) 7.4, "Leakage Tests on Packages for Shipment of Radioactive Material," April 2019, ADAMS Accession No. ML19042A172.

Appendix A: Major Assumptions and Input Data

Data Element	Mean Estimate	Distribution	Low Estimate	Best Estimate	High Estimate
Meeting ASNT NDT Level III Requirements					
Training and certification	$24,613	PERT	$7,275	$21,188	$55,650
Issue RAI (NRC)					
Weighted hourly rate (NRC)	$131				
Hours to generate RAI	28.3	PERT	10	30	40
Respond to RAI					
Weighted hourly rate (Industry)	$120.07	PERT	$90.34	$120.70	$147.31
Hours to respond to RAI	56.7	PERT	20	60	80
Nuclear engineer	$134.56	PERT	$104.27	$134.56	$156.69
Administrative staff	$54.07	PERT	$38.51	$54.07	$65.16
Licensing staff	$120.69	PERT	$71.67	$120.69	$199.10
Manager	$126.59	PERT	$88.29	$126.59	$158.91

ANSI: American National Standards Institute
NDT: nondestructive testing
RAI: request for additional information

SUBJECT: **Regulatory Analysis for Revision 2 of Regulatory Guide 7.4, Leakage Tests on Packages for Shipment of Radioactive Material**

DISTRIBUTION:
ASanders, NMSS FSchofer, NMSS

ADAMS Accession No: **PKG**: **ML19240B377; RA: ML20034F254** *concurred via email

OFFICE	NMSS/REFS/RASB	QTE*	NMSS/REFS /RASB/RAT*	NMSS/REFS/RASB/BC*	NMSS/REFS/D*
NAME	ASanders	Jay Dougherty	FSchofer	CBladey	KCoyne for JTappert
DATE	11/14/2019	11/21/2019	11/14/2019	11/26/2019	1/23/2020
OFFICE	OGC	NMSS/DFM/D*			
NAME		TInverso for AKock			
DATE		1/30/2020			

OFFICIAL RECORD COPY