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DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-6008

(Proposed Revision 2 of Regulatory Guide 6.7, dated June 1976)

PREPARATION OF AN ENVIRONMENTAL REPORT TO SUPPORT A RULEMAKING PETITION SEEKING AN EXEMPTION FOR A RADIONUCLIDE-CONTAINING PRODUCT

A. INTRODUCTION

This guide provides general procedures for the preparation of environmental reports (ERs), which are submitted to support a rulemaking petition for an exemption for a radionuclide-containing product, and it amends Revision 1 of Regulatory Guide 6.7, issued June 1976. Use of this regulatory guide will help to ensure the completeness of the information provided in the ER, assist the staff of the U.S. Nuclear Regulatory Commission (NRC) and others in locating pertinent information, and facilitate the environmental review process. However, the NRC does not require conformance with the procedures, which are provided for guidance only.

The National Environmental Policy Act of 1969 (83 Stat. 852) (Ref. 1), implemented by Executive Order 11514, "Protection and Enhancement of Environmental Quality," dated March 5, 1970 (Ref. 2), and the Council on Environmental Quality's Guidelines of August 1, 1973 (Ref. 3), requires that all agencies of the Federal Government prepare detailed environmental statements on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment. The principal objective of the National Environmental Policy Act is to build into the agency's decisionmaking process an appropriate and careful consideration of environmental aspects of proposed actions.

As part of its policy and procedures for achieving this objective, Title 10, of the *Code of Federal Regulations*, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions" (10 CFR Part 51) (Ref. 4), the NRC must address the requirements of the National Environmental Policy Act. In the case of a person petitioning the NRC to establish an exemption from licensing for the use of radioactive material in a product, 10 CFR 51.68, "Environmental Report—Rulemaking," requires submittal of an ER. The purpose of this guide is to assist petitioners in developing ERs.

This guide is intended to be comprehensive in scope. However, the petitioner may need additional clarification. Therefore, if a petitioner or a person considering submission of a petition has questions about the applicability of certain recommendations of this guide to his or her product, he or she is encouraged to contact the NRC's Rulemaking and Directives Branch, Office of Administration.

Preparation of Environmental Reports

Regulations in 10 CFR 51.45, "Environmental Report," describe requirements for the content of a petitioner's ER. Section B of this regulatory guide provides specific and detailed guidance but some of the topics discussed may apply only in part, or not at all. The petitioner should apply the guidelines appropriate to the product for which the licensing exemption is sought and identify any topic that is not relevant to that particular product.

In preparing the ER, petitioners should use descriptive or narrative text, as well as such aids as tables, charts, and graphs. They should treat each subject in sufficient depth and provide sufficient documentation to permit the NRC to evaluate independently the extent of the environmental impact. They should use tables, line drawings, and photographs wherever they contribute to the clarity of the report. Descriptive and narrative passages should be brief and concise. The number of significant figures stated in numerical data should reflect the accuracy of the data; petitioners should, wherever practical, indicate the degree of accuracy by plus or minus values.

Petitioners should reference pertinent published information relating to the product and to its distribution, use, and disposal or include it in appendices.

The petitioner may have prepared some of the information to be included in the ER during consideration of the safety and marketing aspects of the product. Where appropriate, this information (in the form of text, tables, or figures) should be incorporated in, or appended to, the ER to provide a complete document.

If the petitioner considers any information requested by this guide to be a trade secret or commercial or financial information submitted in confidence, he or she should submit the requested information as a separate document with a written request that the NRC withhold the information from public disclosure in accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding" (Ref. 5), on the grounds that it is proprietary.

Commission Action on Environmental Reports

The NRC places the petitioner's ER in the Commission's Public Document Room at Public File Area O1F21, One White Flint North, 11555 Rockville Pike, Rockville, MD. At the same time, the NRC issues a public announcement and publishes a summary notice in the *Federal Register*.

The NRC staff considers the petitioner's ER, relevant published information, and any comments received from interested persons in preparing either a draft environmental assessment (EA) or a draft environmental impact statement (EIS) concerning the proposed rulemaking action, if undertaken. The staff makes the decision to prepare an EA or an EIS in accordance with 10 CFR 51.25, "Determination to Prepare Environmental Impact Statement or Environmental Assessment; Eligibility for Categorical Exclusion." The NRC transmits its draft environmental document for comment to appropriate Federal agencies and State officials, and in particular, to the U.S. Environmental Protection Agency for information, in the case of a draft EIS. The agency also makes the draft environmental document available to the general public. Those who comment on either the petitioner's ER or the staff's draft environmental document are requested to do so within a specified time.

As described in detail in 10 CFR 51.70 through 10 CFR 51.73 and 10 CFR 51.85, 10 CFR 51.90, and 10 CFR 51.91, the staff considers the comments on a draft EIS and prepares a final EIS (FEIS).[1] This FEIS is then transmitted to the Environmental Protection Agency appropriate State agencies, and other stakeholders listed in 10 CFR 51.93. The NRC issues a public announcement and publishes a notice of availability in the *Federal Register*. The NRC also considers comments in developing a final EA and a finding of no significant environmental impact, which it announces in the *Federal Register* notice of final rulemaking and makes them available to the public.

Subsequent hearings, if required, on the environmental aspects involved in rulemaking on an exemption from licensing requirements are based on the petitioner's ER and the NRC's FEIS. The FEIS, or final EA, takes into account information from many sources, including the petitioner's ER and its supplements and the comments of the various governmental agencies, private organizations, and individuals.

The NRC staff intends its environmental document to provide a generic treatment of the product. This treatment is appropriate for a rulemaking procedure involving a licensing exemption that permits the distribution of products by any person who satisfies the conditions of the regulations. In this regard, in the absence of information to the contrary, the staff will view the petitioner's particular product as typical of all products likely to be distributed for use under the exemption. Accordingly, detailed and complete information on the petitioner's particular product and on the petitioner's planned distribution system is important to the NRC's consideration of the petition.

The NRC does not expect the petitioner's ER to address the impact of manufacturing the product. Accordingly, the ER need not discuss the possible creation of manufacturing jobs at the petitioner's plant and the possible radiation exposures to individuals who may perform those jobs. In most instances, the manufacturing impact will be negligible. In those few instances where it is not, the NRC will assess the manufacturing impact when considering issuance of the materials license that authorizes manufacture of the product.

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that

[1] 10 CFR 51.70, "Draft Environmental Impact Statement—General"; 10 CFR 51.71, "Draft Environmental Impact Statement—Contents"; 10 CFR 51.72, "Supplement to Draft Environmental Impact Statement"; 10 CFR 51.73, "Request for Comments on Draft Environmental Impact Statement"; 10 CFR 51.85, "Draft Environmental Impact Statement—Rulemaking"; 10 CFR 51.90, "Final Environmental Impact Statement—General"; 10 CFR 51.91, "Final Environmental Impact Statement—Contents."

the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required.

This regulatory guide contains information collection requirements covered by 10 CFR Part 51 that the Office of Management and Budget (OMB) approved under OMB control number 3150-0021. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. STANDARD FORMAT AND CONTENT OF AN ENVIRONMENTAL REPORT TO SUPPORT A RULEMAKING PETITION SEEKING AN EXEMPTION FOR A RADIONUCLIDE-CONTAINING PRODUCT

Summary

The summary should support a conclusion that adoption of the requested rule change would be consistent with the national environmental goals under the National Environment Policy Act. In preparing the summary and much of the remainder of the report, the petitioner should assume the requested rule change to be in effect and assess the impacts accordingly. Because the rule change would permit any person who satisfied the specific licensing requirements to distribute products for use under the exemption, the scope of the report should go beyond the petitioner's own particular product. For most types of products, the report should show that the petitioner's particular product and means of distribution should be viewed as "typical examples" of models and distribution systems that can reasonably be expected to develop if the requested rule change is made.

The summary should include the following information:

a a concise description of the specific product, including specific design features, intended use, and methods of use, operation, distribution, and disposal or recycling;

b a brief comparison of alternative product designs (both radioactive and nonradioactive) of alternative methods of use, distribution, and disposal, and of alternative actions as extracted from the material prepared for Chapter 6 of this guide; and

c a brief listing of significant environmental impacts associated with the product as extracted from the benefit-cost analysis in Chapter 7 of this guide, including both adverse and beneficial environmental and socioeconomic impacts that would occur if the Commission takes the action proposed by the petitioner.

Chapter 1. Introduction

1.1 The Petition for Rulemaking

The petitioner should give the substance or text of the proposed rule change in this section. He or she should elaborate on the purpose to be served by the rule change requested in the petition, provide pros and cons for the change, and indicate why he or she believes the change should be made.

1.2 The Petitioner

1.2.1 Description

The petitioner should identify himself or herself by name and address and should describe his or her business and the types of products he or she manufactures. He or she should also estimate the number of persons (i.e., competitors) who can reasonably be expected to request regulatory approval to distribute products similar to the petitioner's if the rule change is accomplished.

1.2.2 Relationship to (Specific Name of Product)

The petitioner should provide a clear statement of his or her interest in the distribution of such a product. Also, state whether the petitioner will manufacture, subcontract the manufacture, purchase, or import the product and whether the manufacturer or importer will distribute the product directly or through others.

Chapter 2. Description and Use of *(Specific Name of Product)* That Contains *(Names of Radionuclides)*

This section should describe the product how it works; what it will be used for; how it will be used, distributed, installed, serviced, and repaired; and the method of its disposal. In the absence of information to the contrary, the NRC may consider this information to be "typical" for all such products, whether distributed by the petitioner or by competitors.

2.1 Description

2.1.1 General Construction

The petitioner should use the following guidelines to describe how the product is constructed, emphasizing particularly how the radioactive material is incorporated.

- Identify all radioactive materials contained in the product.

- Describe and draw the product and include all designs. Indicate the maximum and average amount of radioactive material used and its chemical and physical form. Show how the radioactive material is incorporated into the product. Include drawings. Specify the composition, dimensions, density, thickness, and location of any substrates, coatings, or sandwich material. Indicate the measured radiation dose rates at the surface and at specified distances from the product. Also, indicate the measured radiation dose rates at the surface and at specified distances from separable components, such as pieces that could be replaced or repaired or parts that could be disassembled. Give the results of any tests (e.g., wipe, leak-rate, leach-rate, combustion, vibration, abrasion) that show the degree of integrity of the containment and shielding of the radioactive material in the product under expected conditions of use. Also, describe the test procedures and radiation-measuring instruments.

2.1.2 Radionuclides

The petitioner should describe in detail the radioactive material used, including all radionuclides (parents, daughters, and contaminants) present and their nuclear properties and abundances. Give pertinent chemical, biological, and physical data. Also, indicate the availability and cost of the material.

2.2 Operations

The petitioner should discuss how the product functions, giving particular emphasis to its unique features and the function of the radioactive material. Describe typical operating conditions and environments (e.g., temperature and gas or air flows), as well as typical labels and instructions as they relate to the safety and operation of the product.

2.3 Uses

The petitioner should discuss the use for which the product is designed, along with possible uses unintended by the manufacturer but that the product may experience after distribution. Emphasize how the radioactive material facilitates such uses.

2.4 Methods of Use

The petitioner should describe how, where (e.g., geographic locations, facilities, homes), and by whom the product will be used. Specify the expected useful life of the product under the various use conditions. Include descriptions and numbers of persons, other than actual users, who might be affected by using the product.

2.5 Distribution

2.5.1 Packaging

For each package design that will contain the product, the petitioner should give the number and arrangement of the following:

a units per package,
b packages per box, and
c boxes per carton.

The petitioner should also discuss the geometry and composition of construction materials for boxes, packages, and cartons. Describe labeling, markings, and instructions, both outside and inside the container. Indicate the radiation dose rates at specified distances from packages, boxes, and cartons.

2.5.2 Distribution

The petitioner should characterize the sites (such as warehouses, freight terminals, and large or small retail stores) where the product will be temporarily located during distribution. Estimate the number of units, packages, boxes, cartons, or shipments that will pass through each site; the length of time they will remain there; the methods for handling and storing them at each site; and all important environmental factors (e.g., temperature ranges in freight terminals and the probability and consequences of accidents or fires).

2.5.3 Transport

The petitioner should provide a list of the modes of transport (e.g., long-haul or local-delivery truck, rail, mail) that will be used to transfer the product from its place of manufacture to the sites described above and, ultimately, to the user. For each mode, give the size of a shipment (number of cartons), number and frequency of shipments, likely routes of shipments, and average distance and environment. For each mode of transport, provide the radiation dose rate at a specified distance from the shipping vehicle.

2.6 Installation, Maintenance, and Repair

The petitioner should describe the intended installation, maintenance, and repair activities relating to the radiation safety features of the product. Also, indicate methods precluded by design and methods that are possible and likely to be performed but not specifically planned or recommended. Include the frequency of the installation, maintenance, and repair activities; the time required; and the general operations to be performed. Emphasize any operations during which persons will come into contact with the radioactive material or during which the shielding of the radioactive material might be significantly reduced or the radioactive material released.

2.7 Disposal

The petitioner should describe likely methods of disposal of the product and the predicted percentages for each method. These methods may include disposal as domestic, commercial, or industrial solid or liquid waste. Identify any efforts made to encourage the return of the product to the manufacturer for controlled disposal as radioactive waste.

Define any disposal procedures during which persons will come into contact with the product and any conditions under which the radioactive material may be released from the product.

Chapter 3. Market for *(Name of Product)* That Contains *(Names of Radionuclides)*

The petitioner should demonstrate that the product is needed, describe the need, and indicate how the need is presently being filled. Also, provide estimates of the demand for the product and indicate how the demand will be met.

3.1 Need

This section should describe the need for the general and specific product.

3.1.1 For (General Name of Product)

The petitioner should identify the need for the product to be provided by the petitioner and for similar products. Describe how the need is presently being met and how it would be met in the future without the product.

3.1.2 For (Name of Specific Product)

The petitioner should describe how the specific product will fill the need for products of this type. Identify and discuss those aspects of the product that will fill the need differently from existing or planned products (e.g., new, better, worse) of the same general type.

3.2 The (Name) Industry

The petitioner should characterize the likely manufacturers and distributors of the product (e.g., manufacturers of timepieces, medical devices, firearms). Discuss their normal manufacturing business transactions, products manufactured, and inter- and intra-industry practices (for example, purchase components such as small sealed sources of radioactive material and assemble the components to make the final product).

3.3 Demand

This section should provide estimates of historical demand for the product—both the general type and the specific product. It should also project estimates of demand for the short term (1 to 10 years) and the long term (10, 20, 30, 40, and 50 years). Provide bases for the estimates.

3.3.1 For (General Name of Product)

The petitioner should discuss the past, present, and future short- and long-term demands for the general type of product.

3.3.2 For (Specific Name of Product)

The petitioner should estimate the demand (present and future) for the specific product, relate it to the demand for the general type of product, as described in Section 3.3.1, and show how the demands will interact.

3.4 Supply

This section should show how the demands given in Section 3.3 have been, are being, and will be met. Identify and quantify past, present, and future sources and means of satisfying the demands for the general type of product.

Chapter 4. Environmental Effects of Normal Distribution, Use, and Disposal of *(Name of Product)*

The distribution, use, and disposal of the product will inevitably affect the environment. Effects are considered adverse if the environmental change provides an added stress that lessens a desirable characteristic of an important biotic population or natural resource (e.g., safety, health, abundance, and productivity); if the change provides an added stress that tends to lower the quality of renewable resources or to impair the recycling of depletable resources; or if the change provides an added stress that reduces the diversity and variety of individual choice, the standard of living, or the extent of sharing life's amenities. Effects are considered beneficial if they enhance the characteristics just enumerated. This section should discuss both adverse and beneficial effects.

The petitioner should use the information presented in Chapters 2 and 3 to describe the environments and populations that will be affected by the distribution, use, and disposal of the product. Include the effects of transportation and storage as they relate to wholesale and retail marketing.

The petitioner should quantify and systematically present any impacts arising from interactions of the product with the environment and the population. In the discussion of each impact, the petitioner should make clear whether the supporting evidence is based on theoretical, laboratory, or field studies and indicate the source of each impact and the population or resource affected. Distinguish the impacts on water, land, air, and biota and define any changes to the ecological system that may be caused by these impacts.

Identify and quantify radiological, economic, technological, social, ecological, aesthetic, and other impacts. Address the impacts of both a single product and multiple products. The numbers used for multiple products should be consistent with the demand estimated in Chapter 3.

4.1 Environments and Populations Affected

This section is intended to provide the scenarios that determine the impacts discussed in Sections 4.2 to 4.4. For each stage in the life span of the product (as described in Sections 2.3 to 2.7), provide the following descriptions:

a geographic locations;
b site and environments;
c persons involved directly with the stage and their actions; and
d bystanders or persons not involved directly with, but affected by, the stage and their actions.

The above should be discussed under the following topics:

4.1.1 During Distribution

4.1.2 During Use

4.1.3 During Installation, Maintenance, and Repair

4.1.4 Due to Disposal

4.2 Radiological Impacts

This section should contain detailed, quantified estimates of the radiation doses (both external doses and dose commitments) to individuals and to the population. Include any radiological consideration affecting the use of land, air, water, or other resources. Base these estimates on the scenarios given in Section 4.1.

The petitioner should consider the radiological effects of distribution, use, and disposal of the product on people and important biota. Provide estimates of the radiological impact on man, both to individuals and to population groups, through various exposure pathways. Identify the various pathways for external and internal exposure and describe them in textual and flowchart format.

4.2.1 On People

In each of the following sections, the petitioner should estimate radiation doses to all exposed persons.

4.2.1.1 During Distribution

4.2.1.2 During Use

4.2.1.3 During Installation, Maintenance, and Repair

4.2.1.4 Due to Disposal

4.2.2 On Terrestrial and Aquatic Ecology

In each of the following sections, the petitioner should estimate radiation doses to, and contamination of, terrestrial and aquatic flora and fauna.

4.2.2.1 During Distribution

4.2.2.2 During Use

4.2.2.3 During Installation, Maintenance, and Repair

4.2.2.4 Due to Disposal

4.2.3 On Land, Air, and Water Use

In each of the following sections, estimate the contamination of land, air, water, and other resources or restrictions placed on their use.

4.2.3.1 During Distribution

4.2.3.2 During Use

4.2.3.3 During Installation, Maintenance, and Repair

4.2.3.4 Due to Disposal

4.3 Nonradiological Impacts

This section should contain detailed estimates of any nonradiological impacts on people, terrestrial and aquatic ecology, and the use of land, air, water, and other resources for the stages in the life span and disposal of the product. It should include evaluations of any toxic substances and alterations of existing environments or resources.

The structure of this section should be the same as that of Section 4.2.

4.4 Impacts on the Community

The petitioner should describe and estimate the expected magnitude of impacts of the product, both beneficial and adverse.

4.4.1 Economic

In each of the sections indicated below, the petitioner should discuss the following issues:

a employment—for example, new jobs, transfer of jobs from one location (or country) to another, job improvement, effects of product on job market;

b secondary effects, such as crime reduction and energy conservation;

c tax revenues, if applicable;

d service revenues to transporters, users, repairers, nonusers (general economic benefit or cost);

e use of resources; and

f improved service—costs that the product eliminates by providing a better service and costs that the product imposes.

The above subjects should be discussed in the following sections:

4.4.1.1 During Distribution

4.4.1.2 During Use

4.4.1.3 During Installation, Maintenance, and Repair

4.4.1.4 Due to Disposal

4.4.2 Social

In each of the sections listed below, discuss the following subjects:

a community services—the need for more or fewer services, such as housing, schools, hospitals, police and fire protection, recreation areas, and other institutions;

b national goals and security—energy conservation, new technologies, improved (or reduced) national security, balance of payments, more or less efficient use of resources; and

c concern about introducing radionuclides into the environment.

The above subjects should be discussed in the following sections:

4.4.2.1 During Distribution

4.4.2.2 During Use

4.4.2.3 During Installation, Maintenance, and Repair

4.4.2.4 Due to Disposal

4.5 Resources Committed

The petitioner should discuss any irreversible commitments of resources involved in manufacturing the product and in its distribution, use, repair, and disposal. The discussion should include direct commitments, as well as irreversible environmental losses and the use of natural resources.

In this discussion, the petitioner should consider lost resources from the viewpoint of both relative impacts and long-term net effects. As an example of a relative impact assessment, the commitment of a given resource to the manufacture, distribution, use, and disposal of the product should be given as the percentage of the total available resource committed and should be discussed in terms of the resources that would be committed to provide an equivalent service by an alternative means.

Chapter 5. Environmental Effects of Postulated Accidents or Misuse

The petitioner should postulate, describe, and indicate the probability of occurrence of all credible accidents or misuses of the product. Describe the effects of each and assess the associated impacts. Describe each accident or misuse and assess it in the same manner as the normal events discussed in Chapter 4. Accidents may involve events such as fire, explosion, submersion (flooding), mechanical failure, abrasion, wind, and shredding.

5.1 Radiological Impacts of Accidents

In each of the following sections, the petitioner should describe and assess accidents or misuses in which exposure to or release of the radioactive material is a significant factor. State the exposure conditions and modes of release (to air from rupture or fire, to water, to land) and the quantity of radioactive material released.

5.1.1 During Distribution

5.1.2 During Use

5.1.3 During Installation, Maintenance, and Repair

5.1.4 During Disposal

5.2 Nonradiological Impacts of Accidents

Each of the following sections should describe and assess accidents or misuses in which exposure to or release of the radioactive material is not a significant factor but in which significant personal injury or property loss may occur. Give special attention to the potential chemical effects of such occurrences.

5.2.1 During Distribution

5.2.2 During Use

5.2.3 During Installation, Maintenance, and Repair

5.2.4 During Disposal

Chapter 6. Alternatives

This section should identify and discuss feasible alternatives related to (1) the design, distribution, use, and disposal of the product and (2) the licensing requirements for the product. Clearly state the reasons for rejecting the alternatives.

6.1 Alternatives Related to (specific name of product)

The petitioner should describe the alternatives to the specific product and to its design, distribution, use, and disposal and compare them to those proposed in Chapter 2. The discussion should show which alternative is best and give the bases for the decision (e.g., environmental, technical, economic).

6.1.1 Alternative Radionuclides

The petitioner should discuss all feasible alternative radionuclides and indicate why they are not being used.

6.1.2 Other Products or Designs

In this section, the petitioner should discuss feasible alternative designs of the specific product, the advantages and disadvantages of those designs, and the reasons why they are not used. Discuss all alternative products, both radioactive and nonradioactive, that could be used in place of the proposed product and compare them with the product. The petitioner should consider both his or her own products and those manufactured by other companies.

6.1.3 Other Means of Distribution, Use, and Disposal

The petitioner should discuss feasible alternatives to the proposed methods of packaging, labeling, transport, routing, storage, sales, intended use, unintended use, return for disposal, disposal, installation, maintenance, and repair. Compare these alternatives with the proposed methods.

6.2 Alternatives Related to Licensing Requirements for (Name of Product)

The petitioner should indicate what the effects (e.g., administrative, economic, psychological) of a different licensing action would be if applied to the product (i.e., the effects of an action other than an exemption from licensing and regulatory requirements).

6.2.1 General License

This alternative to a license exemption normally would require issuance of a general license that would (1) authorize the receipt, possession, use, export, ownership, and acquisition of the radioactive

material in the product, and (2) control the use, transfer, and disposal of the radioactive material in the product. The petitioner should discuss the administrative and other effects of such a license. For example, detailed records of product purchases and transfers would probably be required to facilitate verification that the distributor and the purchaser have complied with the use, transfer, and disposal requirements of the general license.

6.2.2 Specific License

This alternative normally would require each purchaser or user of the product to obtain a specific license. An application would have to be filed and a specific license issued to a named person (user) before the receipt of the radioactive material contained in the product. Possession, use, transfer, and disposal of the radioactive material would be controlled under the terms and conditions of the specific license. The petitioner should discuss these and other implications of obtaining a specific license.

Chapter 7. Summary of Potential Benefits and Possible Costs

In this section, the petitioner should provide a summary of the potential benefits and costs associated with the distribution, use, and disposal of the product. List the significant benefits and costs identified in previous sections, summarize them briefly, and quantify them in the text.

A table (see example in Table 7.1) should summarize and quantify the impacts. Emphasize the environmental and societal benefits and costs but consider private (producer-consumer) benefits and cost, as well. Some benefits could become costs, and vice versa, depending on the particular way in which the impact is imposed. Identify such factors and determine the probability that they will be costs or benefits. If significant changes in the numbers of products distributed annually are expected, make multiple entries (e.g., short-term, long-term) for many of the impacts.

Table 7.1 Summary of Potential Benefits (and Costs) due to the Introduction of the (Specific Name of Product)

IMPACT	MEANS OF DESCRIBING IMPACT
Radiological	
Potential radiation doses to individuals under:	
Normal conditions	mSv/year (millirem/year)
Accident conditions	mSv/year (millirem/year)
Potential radiation doses to population	person-sievert (person-rem/year)
Introduction of radioactive materials into the environment	kBq/year (μCi/year)
Potential contamination of the environment (e.g., disposal sites)	kBq/m^3 ($\mu Ci/m^3$)or kBq/m^2 ($\mu Ci/m^2$) and total volumes or areas
Socioeconomic	

IMPACT	MEANS OF DESCRIBING IMPACT
Provision of new or better product	Summarize implications of product availability, (e.g., improved safety).
Savings from new or better product	Money, energy, etc. per year
Uses of resources	Summarize; provide estimates of relative efficiency of resource use and magnitude of use.
Employment	Summarize and quantify jobs made available, lost, or upgraded.
Stimulation of competition within industry	Summarize effect of proposed product.
National security	Summarize potential contributions of product.
Balance of payments	Summarize potential effects of product; include import and export estimates.
Effects on existing products	Summarize effects on use of existing products.
Technological	
Introduction of new or improved product	Summarize implications.
Other	Identify and discuss any other important technological factors.
Ecological and other	Summarize any important effects or impacts on air, land, water, and biota.

C. IMPLEMENTATION

The purpose of this section is to provide information to potential petitioners regarding the NRC's plans for using this draft regulatory guide. The NRC does not intend or approve any imposition or backfit in connection with its issuance.

The NRC has issued this draft guide to encourage public participation in its development. The NRC will consider all public comments received in development of the final guidance document. In some cases, petitioners may propose an alternative or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for petitions for rulemaking.

REGULATORY ANALYSIS

Statement of the Problem

The cited regulations and the addresses for submitting requests have changed since the issuance of Regulatory Guide 6.7. Thus the guidance is confusing and does not direct persons interested in making such petitions to the NRC to the appropriate relevant regulations, nor to the correct addresses.

Therefore, a revision of this regulatory guidance is necessary to update the guide to include correct regulatory references and addresses.

Objective

The objective of this regulatory action is to update the guidance to petitioners for rulemaking to establish an exemption from licensing for the use of radioactive material in a product. The purpose of this guide is to provide assistance to petitioners in their development of ERs.

Alternative Approaches

The NRC staff considered the following alternative approaches:

Do not revise Regulatory Guide 6.7.
Revise Regulatory Guide 6.7.

Alternative 1: Do Not Revise Regulatory Guide 6.7

Under this alternative, the NRC would not revise the subject regulatory guide nor issue additional guidance, and the current guidance would be retained. If the NRC does not take action, there would not be any changes in costs or benefit to the public, licensees, or the NRC. However, the "no-action" alternative would not address identified concerns with the current version of the regulatory guide. The NRC would continue to review each ER on a case-by-case basis. This alternative provides a baseline condition from which any alternatives will be assessed.

Alternative 2: Revise Regulatory Guide 6.7

Under this alternative, the NRC would revise Regulatory Guide 6.7, taking into consideration the changes to the regulations and other factors that have changed since issuance of the original guide.

The benefit of this action is that it would enhance future petitioners' ability to support requests for rulemaking to provide for the use, under exemption, of newly developed products. This is of particular benefit in the case of consumer products (i.e., products to be used by the general public), as such products can only reasonably be manufactured and distributed if users are exempt from regulatory requirements. If new uses for radioactive materials are to be developed that do not fit under current exemptions from licensing, it may benefit society for the regulatory program to accommodate such uses, provided that they do not compromise public health and safety. The NRC, however, needs adequate information on which to base any such rulemaking to properly ensure public health and safety and protection of the environment.

The impact to the NRC would be the costs associated with preparing and issuing the revision of the regulatory guide. The impact to the public would be the voluntary costs associated with reviewing and providing comments to the NRC during the public comment period. The value to the NRC staff and petitioners would be the benefits associated with enhanced efficiency and effectiveness in using a common guidance document as the technical basis for considering such a petition for rulemaking.

Conclusion

Based on this regulatory analysis, the NRC staff recommends the revision of Regulatory Guide 6.7. The staff concludes that the proposed action will enhance a petitioner's ability to supply adequate information to support a petition for rulemaking to add an exemption from licensing to the Commission's regulations. Ultimately, society may benefit when a product is developed for use under an exemption from licensing.

REFERENCES[2]

1. National Environmental Policy Act of 1969, 42 U.S.C. 4321, et seq.[3]

2. Executive Order 11514, "Protection and Enhancement of Environmental Quality," *Federal Register*, Vol. 35, p. 4247, Washington, DC, March 5, 1970.

3. Council on Environmental Quality's Guidelines of August 1, 1973, *Federal Register*, Vol. 38, p. 20550, Washington, DC, August 1, 1973.

4. 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," U.S. Nuclear Regulatory Commission, Washington, DC.

5. 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," U.S. Nuclear Regulatory Commission, Washington, DC.

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[2] Publicly available NRC published documents listed herein are available electronically through the Electronic Reading room on the NRC's public Web site at: http://www.nrc.gov/reading-rm/doc-collections/. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail PDR.Resource@nrc.gov.

[3] Copies of the non-NRC documents included in these references may be obtained directly from the publishing organization.

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