# Regulatory Analysis for Final Rulemaking - Expanded Definition of Byproduct Material Established by Section 651(e) of the Energy Policy Act of 2005

**U.S. Nuclear Regulatory Commission**

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Enclosure

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**ACRONYMS**

| | |
|---|---|
| AEA | Atomic Energy Act of 1954 |
| AEC | U.S. Atomic Energy Commission |
| ARM | accelerator-produced radioactive material |
| CFR | Code of Federal Regulations |
| CRCPD | Conference of Radiation Control Program Directors, Inc. |
| DHS | U.S. Department of Homeland Security |
| DOE | U.S. Department of Energy |
| DOT | U.S. Department of Transportation |
| EPA | U.S. Environmental Protection Agency |
| EPAct | Energy Policy Act of 2005 |
| FR | Federal Register |
| IAEA | International Atomic Energy Agency |
| LLWPA | Low-Level Radioactive Waste Policy Act |
| NARM | naturally occurring and accelerator-produced radioactive material |
| NORM | naturally occurring radioactive material |
| NRC | U.S. Nuclear Regulatory Commission |
| OAS | Organization of Agreement States, Inc. |
| OSHA | Occupational Safety and Health Administration |
| PET | positron emission tomography |
| RCRA | Resource Conservation and Recovery Act |
| SS&D | sealed source and device |
| SSRs | Suggested State Regulations for the Control of Radiation |
| U.S.C. | United States Code |

## 1.0 Introduction

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to include certain radium sources, certain naturally occurring radioactive material, and accelerator-produced radioactive materials as required by Section 651(e) of the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. The EPAct expanded the definition of byproduct material in Section 11e. of the Atomic Energy Act of 1954 (AEA) to include certain "naturally occurring and accelerator-produced radioactive materials" (NARM), placing these byproduct materials under NRC authority. The EPAct also required the NRC to provide a regulatory framework for licensing and regulating this NARM.

The purpose of this regulatory analysis is to evaluate the costs and benefits associated with the rule. The rule (Reference 1) amends 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170 and 171. This document presents background material, rulemaking objectives, rulemaking alternatives, and analysis results for each alternative in terms of constant 2005 dollars. Public comments were requested for the proposed rule text and this regulatory analysis.

## 1.1 Background

Radioactive materials may be divided into two general groups: naturally occurring radioactive material (NORM), which would exist in nature even in the absence of human activity, and radioactive materials that are produced by the technological activities of humankind. The second group, which makes up the vast majority of radioactive material used in human activity, includes products of nuclear reactors and accelerator-produced radioactive material (ARM).

Collectively, "naturally occurring and accelerator-produced radioactive material," other than source material, is referred to as NARM. The significance of the distinction between source material and the products of nuclear fission reactors and NARM is that prior to the passage of the EPAct in 2005, the NRC had no regulatory authority over NARM. Since the passage of the AEA, the NRC and its predecessor agency, the Atomic Energy Commission (AEC), have regulated the acquisition, possession, use, transfer, and disposal of byproduct material, as well as source material and special nuclear material. Byproduct material was originally defined to include only materials made radioactive in the production or utilization of special nuclear material, i.e., radioactive material produced in a fission reactor, and later to also include tailings and waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

The regulation of NORM other than source material (and that in the tailings and waste produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content), and accelerator-produced radioactive material was left primarily to the individual States. Although efforts were made by several States to provide a uniform regulatory environment, there was no nationwide consistency to the regulation of NARM. Other federal agencies exercised limited external regulatory authority over activities involving NARM consistent with their primary missions, but again there was no overall, consistent external regulation as in the case of byproduct, source, and special nuclear material.

### 1.1.1 The Energy Policy Act of 2005

On August 8, 2005, the President signed into law the EPAct. Among other provisions, Section 651(e) of the EPAct expanded the definition of byproduct material, as defined in Section 11e. of the AEA. It also required the Commission to provide a regulatory framework for licensing and regulating byproduct material in accordance with this new, expanded definition.

Specifically, Section 651(e) of the EPAct expanded the definition of byproduct material to include certain naturally occurring and accelerator-produced radioactive materials as defined below, and hereafter referred to as NARM:

(1) any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of this paragraph for use for a commercial, medical, or research activity;

(2) any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of this paragraph for use for a commercial, medical, or research activity; and

(3) any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with the Administrator of the Environmental Protection Agency (EPA), the Secretary of Department of Energy (DOE), the Secretary of the Department of Homeland Security (DHS), and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security, and that is extracted or converted after extraction before, on, or after the date of enactment of this paragraph for use in a commercial, medical, or research activity.

The EPAct's expanded byproduct material definition introduces a new term, "discrete source," as applied to radium-226 and certain other sources of NORM. Section 651(e) also requires the NRC to define this term by rulemaking.

Finally, the EPAct clarifies that NARM, as included in the expanded byproduct material definition, shall not be considered low-level radioactive waste for disposal for the purposes of meeting the provisions of the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA).

### 1.1.2 Current Status of NRC Requirements

The AEA authorizes States to assume regulatory control over radioactive materials produced in or by a nuclear reactor, provided the State has an adequate, NRC-compatible program to protect the public health and safety and enters into an agreement with the NRC. As authorized by Section 274b. of the AEA and as of April 2006, 34 States have assumed responsibility for regulating certain activities related to radioactive material by entering into agreements with the NRC. The activities regulated by these "Agreement States" include the use of byproduct, source, and some uses of special nuclear material. Each Agreement State issues licenses to persons who use these materials in that State, except for DOE, Federal facilities, Federally recognized Indian tribes, and for certain activities. The NRC issues licenses to persons using these materials in Federal facilities, Federally recognized Indian tribes, and non-Agreement States.

Prior to enactment of the EPAct, the NRC did not have authority over NARM nor did it have regulations for such material. Although the NRC has not regulated NARM, all 34 Agreement States and certain non-Agreement States have regulatory programs for NARM. Nonetheless, the NRC's current regulations do require licensees to account for occupational dose contributed from NARM, as well as dose contributed from byproduct material, because the definition of occupational dose encompasses both licensed material and nonlicensed material. In addition, the NRC requires, in its radiological criteria for license termination, that licensees consider other sources including radium during decommissioning activities at sites contaminated with source material.

**Non-Agreement States**

Most non-Agreement States and territories have some type of program for NARM, but the regulatory structures vary greatly. A few non-Agreement States have no regulatory programs for NARM. Certain other non-Agreement States have established a *licensing structure* for regulating their NARM users. For these, the regulatory structure could:

- parallel the NRC regulations applicable to the current materials program, or
- parallel the Suggested State Regulations for the Control of Radiation (SSRs) developed by the Council of Radiation Control Program Directors, Inc. (CRCPD).

The remaining non-Agreement States or territories have elected to use *registration* as their regulatory structure for managing the NARM users. Some register facilities; others register both facilities and devices. Some use registration information to conduct inspections; others use registration to identify facility locations for security purposes. In general, there is limited regulatory oversight where registration is used in non-Agreement States. It was, in part, due to this lack of national consistency in NARM regulatory structure, that the EPAct placed these materials under the NRC jurisdiction.

**Agreement States**

For many years, the Agreement States have regulated NARM use in a fairly uniform and consistent manner. The Agreement States have accomplished this essentially by regulating NARM the same way that they regulate other radioactive material under NRC authority. In many respects, regulations applicable to NARM adopted by the Agreement States are compatible to the NRC regulations for the current materials program, or parallel to the CRCPD's SSRs.

For the most part, the regulatory structure used by Agreement States does not distinguish between NARM, as defined above, and other radioactive material. NARM users in Agreement States are expected to implement all aspects of standards for their radiation protection programs with respect to NARM, including those aspects relating to receipt, possession, use, storage, transfer, transportation, and disposal. This regulatory structure also subjects NARM users in the Agreement States to the same licensing, inspection, and enforcement policies as those using other radioactive materials. In addition, this regulatory structure allows for both specific and general licensing of various NARM products, the distribution of certain NARM items to persons exempt from regulation, and, in most cases, includes provisions to review and approve proposals for NARM sealed sources and devices.

Finally, the Agreement States have regulated a vast array of NARM produced for medical, industrial, research and development, commercial, and consumer purposes. In many Agreement States, this regulatory structure also captures some types of nondiscrete sources found in the oil, gas and mining industries; moreover, it also captures inadvertently produced activation products from the use of proton beams for medical radiation therapy. However, the regulation of these nondiscrete sources and activation products has greater variation from Agreement State to Agreement State.

### 1.1.3 Other Federal Agencies' Regulatory Authority Over NARM

Prior to the passage of the EPAct, NARM was regulated as a radioactive material, or as a hazardous substance, but was not regulated by the NRC. Although States had the primary responsibility for regulating the use of NARM, certain Federal regulations applied under some circumstances, including:

- transportation,
- environmental protection and waste disposal,
- workplace radiation exposure and safety,
- export controls,
- consumer products, and
- radioactive drug and medical device safety.

With passage of the EPAct, the NRC has primary responsibility for radiation safety and in regulating the use of these radioactive materials in cooperation with the States, with the exception of activities that are self-regulated by the DOE. Other Federal regulatory agencies have established programs in regulating certain aspects of activities involving NARM (Table 1-1).

**Table 1-1. Federal Agencies with Regulatory Responsibility for NARM**

| Agency | Responsibilities for NARM Regulation |
|---|---|
| Department of Transportation | Regulates interstate transport of radioactive material. In cooperation with DOT, NRC approves Type B packages through 10 CFR Part 71 regulations. |
| Environmental Protection Agency | Has established controls for certain radioactive material through several authorities, including the Clean Air Act, the Safe Drinking Water Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and the Comprehensive Environmental Response, Compensation, and Liability Act. |
| Occupational Safety and Health Administration of the Department of Labor | Oversight for occupational health and safety; has established regulations addressing the exposure to radioactive material in the workplace; in general, defers its authority to NRC with respect to AEA materials. |
| Department of Commerce | Has controlled the export of radioactive material. |
| Consumer Product Safety Commission | Regulations have addressed hazardous substances other than byproduct, source, and special nuclear materials currently regulated by the NRC. |
| Food and Drug Administration | Regulates all drugs (including drugs containing radioactive materials) by requiring good manufacturing practices to assure the purity, potency, and consistency of finished drugs with their labeling in establishing the safety and effectiveness of these drugs.<br><br>Regulates all medical devices (including medical devices containing radioactive materials) by requiring good manufacturing practices to assure medical devices are not adulterated or miss-branded and safe and effective when used in accordance with the labeling. |

Section 651(e)(3) of the EPAct provides that byproduct material, as defined by sections 11e.(3) or 11e.(4) of the AEA, may only be transferred to and disposed of in a disposal facility that is licensed by either the NRC, or a State that has entered into an agreement with the Commission under Section 274b. of the AEA, or at a disposal facility in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act.

### 1.1.4 Development of the Suggested State Regulations

Since enactment of the AEA in 1954, scientists have continued to develop new technologies to produce radionuclides, for example particle accelerators. At the beginning of the twentieth century, naturally occurring radioactive material, including radium-226, was routinely used in consumer products and in cancer treatment (Reference 2). With no Federal mandate to regulate these materials, most States established regulatory structures for both accelerator-produced radioactive materials and naturally occurring radioactive material, including radium-226.

In 1968, CRCPD was chartered as a nonprofit organization to provide a forum for enhancing communication among States and Federal agencies regarding radiation regulations and to promote a uniform radiation protection environment for all radioactive material. Throughout the years, CRCPD developed policies and guidance for its member States. In addition, CRCPD is responsible for the development of model regulations, known as the SSRs. CRCPD has formed many working groups to develop, for radioactive materials, a set of SSRs that are compatible in many respects to the NRC regulations. Under the SSRs' regulatory framework, NARM is a regulated radioactive material comparable to byproduct material. Nearly all of the Agreement States have based their regulations on this model for NARM.

For NARM regulation only, CRCPD also established "Licensing States" similar to the Agreement State Program under Section 274 of the AEA. Licensing States recognized by CRCPD pursuant to criteria found in Publication 94-8 "CRCPD Recognition of Licensing States for the Regulation and Control of NARM" are those States that have demonstrated an adequate and consistent regulatory control program for NARM. Licensing State designation assures comparable regulatory structures with respect to NARM, and other States may grant reciprocal recognition of their licenses or acceptance of their licensees' manufactured products.

### 1.1.5 Issuance of Waiver on August 31, 2005

Section 651(e) of the EPAct became effective upon signature by the President on August 8, 2005. Prior to enactment of the EPAct, the NRC did not have authority over NARM, and did not have regulations in place that would specifically apply to this material. Nonetheless, persons carrying on activities involving NARM could be, and States seeking to continue regulation of NARM would be, in technical violation of the AEA. Therefore, the NRC determined that it would be prudent to establish a mechanism to permit individuals currently engaged in activities involving NARM to continue with their activities. Although the Commission could have proceeded through issuing orders on a case-by-case basis to oversee activities involving NARM while establishing the regulatory framework for regulating this material, the Commission determined that this would be inefficient and resource intensive.

Section 651(e)(5) of the EPAct authorizes the Commission to issue a waiver of the requirements of Section 651(e) to any entity with respect to NARM for specified periods of time if the Commission determines that the waiver is in accordance with the protection of the public

health and safety and the promotion of the common defense and security. The Commission determined that such a waiver could be granted to entities that engaged in activities involving NARM. The Commission determined that there was no basis to conclude that these materials would not continue to be used in a manner that is protective of public health and safety while the waiver is in effect. The Commission also determined that it would be in the best interests of the public to allow continued use of NARM, especially for medical purposes, and to allow the States to continue to regulate NARM until the Commission could codify new regulations for these materials.

The Commission believed that granting the waiver would allow the States to continue with their regulatory programs, would allow persons engaged in activities involving NARM to continue their operations in a safe manner, and would allow continued access to medical radiopharmaceuticals. In addition, it would enable the Commission to work with the States to develop appropriate regulations for NARM and to formulate a sound transition plan for implementation of such regulations. It would also provide an opportunity for non-Agreement States to consider entering into an agreement with the NRC. The Commission determined that issuance of the waiver would be in accordance with the protection of public health and safety and the promotion of the common defense and security.

The Commission granted a waiver (70 FR 51581; August 31, 2005) from the requirements of Section 651(e) of the EPAct to: (1) all persons engaged in export from or import into the United States of byproduct material through August 7, 2006, unless terminated sooner if the Commission determined that an earlier termination was warranted and except with regard to the requirements of the Department of Commerce relating to export of such material; (2) all persons acquiring, delivering, receiving, possessing, owning, using, or transferring byproduct material through August 7, 2009, unless terminated sooner if the Commission determined that an earlier termination was warranted; and (3) all States that had entered into an agreement with the Commission under Section 274b of the AEA and States that had not entered into such an Agreement, through August 7, 2009, unless terminated sooner by the Commission.

### 1.1.6 Related Rulemakings

**Byproduct Material in Specifically Licensed Portable Gauges**

The NRC published a final rule amending its regulations governing the use of byproduct material in specifically licensed portable gauges (70 FR 2001; January 12, 2005). Specific licenses for portable gauges are governed by NRC regulations in 10 CFR Part 30. The final rule requires a portable gauge licensee to use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal whenever the portable gauges are not under the control and constant surveillance of the licensee. The primary intent of this rulemaking is to increase licensees' control of portable gauges to reduce the opportunity for unauthorized removal or theft.

**Export and Import of Radioactive Materials**

The NRC published a final rule amending its regulations relating to the export and import of radioactive materials for certain radionuclides listed in the Code of Conduct (70 FR 37985; July 1, 2005). General and specific licenses for export and import of nuclear equipment or material are governed by NRC regulations in 10 CFR Part 110. In an effort separate from this rulemaking, the NRC amended its regulations in 10 CFR Part 110 on export and import of

radioactive material to address discrete sources of radium-226 in a manner consistent with the Code of Conduct.

**National Source Tracking System**

The NRC published a final rule related to implementing a National Source Tracking System for certain sealed sources (71 FR 65686; November 8, 2006). The amendments require licensees to report certain transactions involving these sealed sources to the National Source Tracking System. These transactions include manufacture, transfer, receipt, disassembly, or disposal of nationally tracked sources. The amendments also require each licensee to provide its initial inventory of nationally tracked sources to the National Source Tracking System and annually reconcile the information in the system with the licensee's actual inventory. In addition, the amendments require manufacturers to assign a unique serial number to each nationally tracked source.

**Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material**

The NRC published a proposed rule related to exemptions from licensing, general licenses, and distribution of byproduct material (71 FR 275; January 4, 2006). Exemptions from licensing of byproduct material are governed by NRC regulations in 10 CFR Part 30. The NRC is proposing to amend its regulations governing the use of byproduct material to revise requirements for reporting transfers to persons exempt from licensing, simplify the licensing of smoke detector distribution, remove obsolete provisions, and clarify certain regulatory provisions. These changes would affect licensees who distribute byproduct material to exempt persons, users of some generally licensed devices, and some exempt persons.

## 1.2 Objectives of the Rule

The EPAct requires the NRC to provide a regulatory framework for licensing and regulating the naturally occurring and accelerator-produced radioactive materials that are included in the expanded byproduct material definition in Section 651(e) of the Act. The EPAct directed the NRC to develop regulations to establish a national program for NARM. These regulations are the subject of this rule. The NRC is amending its regulations to include certain radium sources, accelerator-produced radioactive materials, and certain naturally occurring radioactive material, as required by Section 651(e) of the Energy Policy Act of 2005.

The EPAct mandated that the NRC use model State regulations to the maximum extent practical in developing regulations for the expanded definition of byproduct material. CRCPD publishes SSRs as the model regulations for radioactive materials. Since SSRs are the model regulations that most CRCPD member States have adopted, or States have developed requirements that are similar to the SSRs, then the SSRs can provide the NRC a model for the basic regulatory framework for regulating the additional byproduct materials as defined by the EPAct.

This rule is not intended to impose unnecessary regulatory burden beyond what is necessary and sufficient for providing reasonable assurance that public health and safety is protected. This purpose is consistent with NRC's policy, as discussed in NUREG-1614, Vol. 3 entitled "U.S. Nuclear Regulatory Commission Strategic Plan, Fiscal Year 2004-2009," to assure that the nation's use of radioactive material is conducted in a manner that protects public health and safety and the environment. In addition, the EPAct directs the Commission to develop regulations that address threats to common defense and security. This final rule is designed to

provide maximum flexibility in its implementation and impose the minimum regulatory burden while achieving these and other objectives identified in the EPAct.

## 2.0 Identification of Alternative Approaches

NRC identified three alternatives for providing a regulatory framework to license and regulate NARM consistent with the expanded byproduct material definition in the EPAct. These alternatives were developed using input from a public process, and are the same as those considered in the Environmental Assessment for the rule (Reference 3).

The NRC took several initiatives to enhance stakeholder involvement and to improve efficiency during the rulemaking process. With assistance from OAS and CRCPD, the NRC was able to obtain participation of several State representatives in the development of the rule. Principals from OAS and CRCPD, representing interests for both Agreement States and non-Agreement States, participated in the steering committee, forming a partnership with the NRC in rulemaking decisions. In an effort to keep stakeholders informed, the NRC held a public roundtable meeting in early November 2005 and established the "Expanded Definition of Byproduct Material (NARM Rulemaking)" Web page via the rulemaking website, http://ruleforum.llnl.gov, for posting rulemaking-related documents. The NRC met with other Federal agencies to ensure coordination regarding this rulemaking. The NRC met with OSHA on August 30, 2005, and with FDA on November 17, 2005. At both meetings, the participants discussed the NRC's new role under the EPAct. In addition, the NRC conducted a public meeting with stakeholders in August 2006 to discuss the rule.

## 2.1 Comparison of Alternatives

NRC identified the following three alternatives for this regulatory analysis:

1. take no action, which provides a baseline to assess the other two alternatives;

2. revise regulations to maximize NRC regulatory authority and control allowed by the EPAct; and

3. revise regulations to apply a graded risk informed approach to exercising regulatory authority over NARM.

In defining the alternatives, the NRC staff reviewed the EPAct to differentiate between the actions specifically mandated by the EPAct and actions in the EPAct that have some flexibility in the degree of regulatory authority or control that may be applied in the rule. Alternative 3 represents the best balance with regard to this degree of flexibility by adopting a “graded approach,” and is the preferred alternative to implement the new regulations.

### 2.1.1 Actions Mandated by the EPAct

Section 651(e)(4)(B) of the EPAct requires the Commission to use model State standards, to the “maximum extent practicable,” in developing the regulations. The NARM regulations for most Agreement States are based on model regulations, known as Suggested State Regulations for the Control of Radiation, or SSRs. The SSRs for radioactive materials are compatible in many respects to the NRC regulations.

Section 651(e) of the EPAct mandates that NARM not be considered low-level radioactive waste for the purposes of the Low-Level Radioactive Waste Policy Amendments Act (42 U.S.C. 2021b) (LLRWPAA). This provision is consistent with current NRC policy, under which NARM would be classified as "radioactive waste" for disposal purposes and may be disposed of according to Federal and State hazardous waste laws. This provision is included in all of the alternatives.

### 2.1.2 Issues Where EPAct Allows Flexibility

During the process of developing a regulatory framework for licensing and regulating NARM, the staff identified several areas where the Act allows some degree of flexibility. As discussed below, the EPAct does not specifically address the type of license to be required for NARM licensed activities or whether incidentally irradiated material should be regulated. Furthermore, the EPAct delegated, to the NRC, the responsibility for defining the term "discrete source," as it applies to radium-226 and certain other NORM.

Section 651(e) of the EPAct requires the Commission to develop regulations to establish the regulatory requirements necessary to carry out this section of the Act. While the requirement to maintain consistency with current State regulations strongly suggests using a similar regulatory framework of specific and general licenses and exemptions, the EPAct does not mandate which license type (i.e., general or specific) would be required for NARM, nor does the Act specify whether allowances for exemptions from byproduct material regulations should be provided in the final regulations. Under the AEA, the Commission has authority to issue both general and specific licenses for the use of byproduct material and also to exempt byproduct material from regulatory control under the AEA. Because of the flexibility allowed by current regulations and Section 651(e) of the EPAct, it is reasonable to consider more than one alternative specifying different license types and exemption allowances, depending upon whether or not there exist model State regulations upon which the rule could be based.

Section 651(e) of the EPAct requires the Commission to include, as byproduct material, certain accelerator-produced radioactive material (ARM). This expanded byproduct material definition only includes material that is produced, extracted, or converted specifically for use in a commercial, medical, or research activity. The radioactive material intentionally produced by activation of the target is commonly referred to as "product ARM." The EPAct does not specifically address whether material that is incidentally irradiated during operation of an accelerator (referred to as "incidental ARM") should be regulated. Because of the flexibility allowed by the EPAct in this respect, it is reasonable to consider more than one alternative with differing regulatory approaches for incidental ARM.

Section 651(e)(4)(A)(ii) of the EPAct requires the Commission to define the term "discrete source" as applied to radium-226 and certain other NORM in the expanded definition of byproduct material. A discrete source would be defined to include a concentrated radioactive material that is distinct from the radiation present in nature. The flexibility allowed by this requirement relates to whether the radionuclide or radioactive material specifically has been concentrated on purpose for use for commercial, medical, or research activity. A broad "discrete source" definition could include any concentrated radium-226 or other NORM, regardless of whether it was concentrated specifically for commercial, medical, or research use or incidentally from a process that extracts or produces products, such as fertilizer, fly ash, or residue from the purification of water. A more limited "discrete source" definition would only include radioactive material in which the radionuclide was concentrated with the intent of using its properties, thereby excluding NRC jurisdiction over inadvertent movement or concentration

of NORM. Because of the flexibility in allowing the Commission to provide this definition, it is reasonable to consider more than one alternative, each with a different discrete source definition.

Section 651(e)(4)(D) of the EPAct requires the Commission to consider the impact on the availability of pharmaceuticals to physicians and patients in promulgating these regulations. This requirement does not prescribe how to consider the potential impact of the regulations on the medical community or patients; nor the approach to be taken to address potential impacts. This requirement allows flexibility in the regulatory framework that is applied to ARM products generated for medical activities, as well as the implementation aspects for the regulations. Although the EPAct allows flexibility in considering the regulation's potential impacts on the medical community or patient, and it is reasonable to consider more than one alternative with differing medical ARM product licensing requirements and implementation plans, there are no discernable differences between the environmental and economic impacts of the alternative approaches to addressing pharmaceutical availability. Therefore, both the preferred action and Alternative 2 would establish a similar set of regulations and an implementation process to minimize the regulatory impact on the availability of accelerator-produced radioactive drugs. The key points associated with this area of the final regulations are summarized later in this section, under the discussion of Alternative 3.

Based on the staff's review of the actions specifically mandated by the EPAct and areas where the EPAct allows flexibility in the degree of regulatory authority, the staff identified three alternatives: (1) to take no action; (2) to establish regulations that apply the greatest extent of regulatory authority and control allowed by the EPAct; and (3) to establish regulations that apply a graded, risk-informed approach to exercising the regulatory authority provided by the EPAct. The following provides a more detailed discussion of each alternative. Section 3.0 shows input assumptions used to analyze the alternatives, and Section 4.0 presents results and the economic basis for choosing Alternative 3 as the preferred alternative. Section 5 provides a summary of the decision rationale.

## 2.2 Alternative 1: The No-Action Alternative

The No-Action alternative is to maintain the status quo, with no costs incurred and no benefits realized. Under the No-Action alternative, the Commission would neither adopt the expanded definition of byproduct material provided in Section 651(e) of the EPAct, nor provide a regulatory framework for licensing and regulating NARM.

The staff understands that the No-Action alternative is not acceptable, as this rulemaking activity is Congressionally mandated. However, this alternative provides a baseline condition from which the other alternatives will be assessed (Reference 4).

## 2.3 Alternative 2: Revise Regulations to Maximize NRC's Regulatory Authority

This alternative would establish regulations to implement the requirements specifically required by the EPAct and the highest degree of regulatory authority and control included within the bounds allowed by the flexibility within the EPAct. In accordance with EPAct Section 651(e)(4)(B), the NARM regulatory framework would be based, to the maximum extent practicable, on the SSRs.

This alternative is to establish regulations and an implementation process that would minimize the regulatory impact on the availability of accelerator-produced radioactive drugs by taking the

following actions: (1) applying NRC's established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of PET drugs within a consortium; (3) "grandfathering" current users of accelerator-produced drugs; and (4) permitting individuals and other entities to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

Under this alternative, the revised regulations would require more specific licenses for the production, use, transfer, and distribution of NARM and products containing NARM. In areas where the SSRs do not specifically address material within the scope of the new byproduct material definition or where there are few model State regulations at the national consensus level upon which the NRC can base its regulations, this alternative would require specific licenses. Part N of the SSRs address NORM; however, this is generally applicable to diffuse sources of NORM, which have not been produced for the purpose of using the radioactive material within for commercial, medical, or research activities.

SSR requirements for ARM and discrete sources of radium are the same as for reactor-produced radioactive material as they are all covered under provisions for "radioactive material." Only a few provisions in the model State regulations are specific to discrete sources of radium and accelerator-produced radioactive material. Specific provisions concerning ARM radionuclides include: (1) a general license and associated requirements for cobalt-57 *in vitro* clinical or laboratory tests , (2) concentration ratios for strontium-82/rubidium-82 generators for medical use, (3) exempt quantity limits for certain accelerator-produced radionuclides. With respect to radium, the SSRs include: (1) an exemption for previously acquired timepieces containing up to 37 kilobecquerels (kBq) (1 microcurie (μCi)) of radium-226, (2) an exemption for other previously acquired self-luminous products containing up to 3.7 kBq (0.1 μCi) of radium-226, (3) a provision to allow a specifically licensed person to possess up to 185 kBq (5 μCi) of radium-226 in calibration and reference sources under a general license, and (4) an exemption for gas and aerosol detectors containing NARM, with a limit of 3.7 kBq (0.1 μCi) of radium-226 that may be incorporated into smoke detectors distributed for use under exemption from licensing. Under this alternative, these specific requirements would be included in the regulations.

However, the SSRs do not specifically address certain categories of products and discrete sources containing radium-226 which are in the public domain but may not be otherwise covered under a license. Therefore, under this alternative, the regulations would require specific licenses for discrete sources of radium-226 that may not be otherwise covered under a general license or an exemption in the SSRs. For NARM and products containing NARM that are addressed in the SSRs, such as those discussed above, this alternative would include a regulatory framework similar to the SSRs.

Section 651(e)(4)(A)(ii) of the EPAct requires the Commission to define the term "discrete source" as applied to radium-226 and other NORM in the expanded definition of byproduct material. Under this alternative, "discrete source" would be defined broadly to include any concentrated radium-226 or other NORM, regardless of whether it was intentionally concentrated or incidentally concentrated from a process that extracts or produces products not intended to be radioactive. This definition would not limit the NRC's jurisdiction to only include radionuclides that are concentrated and used purposefully for their properties. This broader definition would divert the staff's regulatory efforts away from those materials that pose the greatest health and security risk by including an array of NORM sources, including sources that were created through inadvertent movement or concentration of naturally occurring radioactive

material, such as that found in scaling on pipes from the fossil fuel industry, in fly ash from coal burning, or in fertilizers.

Under this alternative, any material rendered radioactive by a particle accelerator, including incidental radioactive materials, would be covered by the Commission's regulations from the time at which it is initially irradiated. Byproduct material would include product ARM and incidental ARM, including irradiated target material, accelerator internal structures, and facility building materials, regardless of the accelerator type or use.

In accordance with Section 651(e)(3), for disposal purposes, this newly defined byproduct material would be classified only as radioactive waste, and would not be considered to be low-level radioactive waste for the purposes of the LLRWPAA.

### 2.4 Alternative 3: Revise Regulations to Apply a Graded Regulatory Authority

The NRC proposed and is now finalizing an alternative that revises its regulations by applying a graded regulatory authority and control over NARM in order to focus the staff's regulatory efforts on those activities that pose the greatest risk to protection of the public health and safety and promotion of the common defense and security. Beyond implementing the requirements specifically mandated by the EPAct, this alternative addresses the flexibility within the EPAct by establishing regulations that are commensurate with the potential health and safety consequences applicable to each NARM-containing product type. As required by the EPAct, the NARM regulatory framework has been based, to the maximum extent practicable, on the SSRs.

This preferred alternative includes general licensing provisions for certain products and discrete sources containing radium-226 that are apparently in the public domain but may not be otherwise covered under a license and are not specifically addressed in the SSRs. This alternative also accommodates generally licensed devices meeting the restrictions of the general licenses that were previously approved by States under existing regulations. This alternative is to regulate NARM under most of the same requirements as reactor-produced radioactive material. Additionally, this alternative adds certain products and materials containing NARM to some of the current exemptions, thereby allowing these NARM-containing products to be used without any regulatory requirements imposed on the user. This alternative does not require any changes be made to the exempt concentrations for radionuclides included in the SSRs, and adopts appropriate values for exempt quantities for the newly defined byproduct material consistent with the SSRs. The preferred alternative also adopts an exemption for timepieces containing 37 kBq (1 µCi) or less of radium-226 and adopts the requirement to allow a specifically licensed person to possess up to 185 kBq (5 µCi) of radium-226 in calibration and reference sources under a general license.

Under this preferred alternative, "discrete source" is defined to include only radionuclides that were concentrated with the intent of using the radionuclides for commercial, medical, or research activities. *Discrete source* is defined in the final rule as "a radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so that its concentration within a material has been purposely increased for use in commercial, medical, or research activities." Under this definition, discrete sources of radium-226 or discrete sources of naturally occurring radioactive material, may have the same radiological characteristics (i.e., type of radiation, half-life, etc.) as the radionuclides found in nature, but the radionuclides will have been purposely concentrated for use of the radionuclides specifically. This definition limits NRC's jurisdiction, by excluding inadvertent movement or concentration of naturally occurring

radioactive material, such as that found in scaling on pipes from the fossil industry, in fly ash from coal burning, or in fertilizers. NRC's authority over source material would not be changed by this definition. This definition is revised from that proposed for clarification purposes. Under the revised definition, once a radioactive material, defined as a discrete source, becomes byproduct material, it continues to be byproduct material, even if no longer "discrete" in the usual sense. Contamination resulting from the use of discrete sources of radium-226, or other radionuclide identified under section 11e.(4) of the AEA, is still byproduct material.

Under this preferred alternative, the NRC will regulate the radioactive material (product and incidental ARM) produced by all accelerators that intentionally produce a radioactive material for its radiological properties (e.g., PET production facilities). The rationale for this approach is that this incidentally produced radioactive material is a direct result of producing the radioactive material for use for a commercial, medical, or research activity. In addition, it is necessary for the NRC to consider all radioactive material in its regulatory evaluation to ensure health and safety of the radioactive material production. This preferred alternative would not regulate incidental ARM that results from the operation of accelerators that only produce particle beams and do not intentionally produce radioactive materials for use for a commercial, medical, or research activity (e.g., electron microscopes and medical therapy linear accelerators). The reasons for not regulating this incidentally produced radioactive material are: (1) no radioactive material is produced for use for a commercial, medical, or research activity from such operation, and (2) the incidentally produced radioactive material resides within the accelerator or facility. For those accelerators that are used to produce both radioactive material and particle beams, the preferred alternative would establish regulations for the incidental ARM, as well as the product ARM, produced by the accelerator. The incidental ARM produced in such accelerators during the production of radioactive material for use for a commercial, medical, or research activity is indistinguishable from that produced when the same accelerator is operated to produce only particle beams, so both are covered by this final rule.

The regulatory framework and implementation process associated with radiopharmaceuticals under this preferred alternative would be the same as that described previously for Alternative 2. This preferred alternative would establish regulations and an implementation process that would minimize the regulatory impact on the availability of accelerator-produced radioactive drugs by taking the following actions: (1) applying its established regulatory framework to the commercial distribution of these drugs; (2) expanding the regulations to permit noncommercial distribution of PET drugs within a consortium; (3) "grandfathering" current users of accelerator-produced drugs; and (4) permitting individuals and other entities to continue to prepare and use radioactive drugs while they are applying for new licenses or amendments.

Under the preferred alternative, as required by Section 651(e)(3), NARM-containing byproduct material would be classified only as radioactive waste, and would not be considered to be low-level radioactive waste for the purposes of the LLRWPAA.

The next section describes the methodology to analyze benefits and costs of implementing the rule based on the assumptions in Alternatives 2 and 3.

## 3.0 Analysis of Values and Impacts

This chapter examines the values (benefits) and impacts (costs) expected to result from NRC's rule. The benefits and costs are analyzed for implementation of the rule under Alternative 2, Maximum Regulation, and Alternative 3, Graded Approach. Alternative 1 is described below as the "baseline" for the analysis.

Section 3.1 lists the affected attributes. Section 3.2 describes the methodology for calculating benefits and costs associated with each attribute. The analysis is done over a ten-year time period. General assumptions are presented, as are the specific assumptions for each alternative. Appendix A shows the input and results for Alternative 2. Appendix B shows the input and results for Alternative 3. Appendix C presents a list of references.

The results are shown in Section 4.0, in constant 2005 dollars. The results are presented for the one-time costs and the annual operating expense to implement the rule. The total cost of the rule over the 10-year implementation period is estimated using 7 percent and 3 percent real discount rates. Under the preferred Graded Approach, Alternative 3, the estimated total costs are $33 million and $39 million, discounted at 7 percent and 3 percent, respectively. Under the Maximum Regulation alternative, the estimated costs are about $90 million and $102 million at 7 percent and 3 percent real discount rates, respectively.

### 3.1 Identification of Affected Attributes

This section identifies characteristics in the public and private sectors that will be affected by the rule. These are called "attributes," using the list of potential attributes provided by NRC in Chapter 5 of its *Regulatory Analysis Technical Evaluation Handbook* (Reference 5). The affected attributes for the rule include the following:

1. ***Industry Implementation***. Under Alternatives 2 and 3, industry would incur one-time costs, both capital and labor, to implement the rule. These costs are associated with activities to prepare license amendments and applications, to make necessary capital improvements to facilities, to prepare new procedures for recordkeeping and reporting, and to develop safety programs among other activities.

2. ***Industry Operation***. Under Alternatives 2 and 3, industry would incur an increase in annual labor-related operating expense to implement the rule, such as conducting routine surveys, updating records and procedures, inspecting and testing equipment, training personnel, and other operating and maintenance activities.

3. ***NRC Implementation.*** NRC will incur one-time costs to prepare guidance documentation during this implementation time period, and will process license applications and amendments during the initial period of implementation.

4. ***NRC Operation***. NRC will incur an increase in annual operating expense due to staff time to review license amendments and applications, and to conduct inspections.

5. ***Other Government***. The identified alternatives may impose a small cost to Agreement State governments with respect to additional reporting requirements for products that contain radium-226. This cost is insignificant and is not included in the analysis.

6. ***Public Health (Routine)***. No costs are anticipated for this attribute. NRC anticipates a slight benefit since some additional byproduct material will fall within the NRC regulatory framework under the rule. The number of affected particle accelerators that fall within the regulatory framework is well known and under adequate control in Agreement States and many of the non-Agreement States. The number of affected persons who come in contact with discrete sources containing radium-226 is not known, and is a contributor to uncertainty in this analysis.

   NRC anticipates a small number of specific licenses will be issued to persons who repair, assemble and disassemble products containing radium-226, or who possess items or products containing radium-226 that exceed those specified in the rule under 10 CFR 31.12. There also is a general license category in 10 CFR 31.12 that includes notification requirements, should a discrete source containing radium-226 show any indication of damage such that it could result in a loss of radioactive material. 10 CFR 31.12 also specifies disposal requirements for products or items that contain radium-226. Specific licenses are expected for gauges containing radium-226. The public and occupational health concern includes the following types of sources: a) radium needles, thought primarily to be at hospitals and research centers as a sealed source but with a safety concern if the source has leaked; b) gauging devices that contain a radium-226 source that have a safety concern if the source is not secure; c) intact luminescent devices, such as those found in older aircraft gauges; d) collections of intact collectible antiquities that contain radium-226 and could pose a radon or a contamination hazard; and e) other luminous antique products such as watch hands and dials. NRC anticipates a slight benefit in public health due to improved radiological control of these discrete sources containing radium-226.

7. ***Occupational Health (Routine)***. No costs are anticipated for this attribute. NRC anticipates a slight benefit from the rule due to increased regulation of radioactive material used in medical applications and radium-226 in gauges.

   In January 2000, NRC released an evaluation of radiological occupational health risk for 40 different types of byproduct material licensed activities and devices ("*Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems*", see Reference 6). The risk results were derived for workers at licensee facilities and the maximally exposed member of the public, who in most cases was another worker at the facility but who was not directly involved in the licensed activity. The results were derived based on both "normal operations" and "accident" risk. In the relative risk rankings, field radiography, shielded room radiography, and three medical applications were ranked "high" in risk. The medical applications were therapeutic nuclear medicine, medical brachytherapy with manual afterloading, and medical teletherapy with a single source. The radiation safety practices are considered adequate at facilities that provide these medical procedures.

8. ***Public Health (Accidental)***. No costs are anticipated for this attribute. NRC anticipates a slight benefit due to increased regulation of byproduct material.

9. ***Occupational Health (Accidental)***. No costs are anticipated for this attribute. NRC anticipates a slight benefit due to increased regulation of byproduct material.

10. ***Regulatory Efficiency***. The alternatives to no action under consideration would result in a small benefit due to more consistent regulations among Agreement States and the NRC.

11. ***Environmental Considerations***. No costs are anticipated for this attribute. NRC anticipates a slight benefit due to increased regulation of byproduct material. Reference 3, the Environmental Assessment, contains more information.

12. ***Safeguards and Security Considerations***. The identified alternatives to no action are expected to provide a slight benefit in terms of prevention of radiological sabotage.

13. ***Improvements in Knowledge***. A benefit may occur for NRC as a result of the rulemaking. NRC may gain valuable information about previously unregulated entities, such as those possessing certain radium-226 sources.

14. ***Other Considerations***. Public confidence in NRC may be affected positively by the rule. The public may have more confidence in NRC's program for protection of human health and safety, and the environment, through the regulatory framework to ensure proper management and safe use of the newly defined byproduct material (discrete sources of radium-226 and product ARM in conjunction with the existing byproduct material (reactor-produced radioactive material). This is done while providing a general license for persons who have small numbers of discrete radium-226 sources and radium-226 used in collectible items or antiques.

The following attributes are not expected to be affected:

15. ***Offsite Property***. No impacts are anticipated to affect offsite property because no changes are anticipated in accident frequency. A slight reduction in property consequences is possible due to regulation, and remediation of sites with radium-226 contamination.

16. ***Onsite Property***. No impacts are anticipated to affect onsite property for the same reasons provided above for offsite property, with a slight benefit from site remediation efforts.

17. ***General Public***. No impacts are anticipated for the general public.

18. ***Antitrust Considerations***. There are no costs associated with this attribute because there are no antitrust considerations applicable to this rulemaking.

## 3.2 Analytical Methodology

This section describes the process used to evaluate values and impacts associated with the affected attributes discussed above for the alternative methods to implement the rule. The *values* (benefits) include any desirable changes in affected attributes. As described earlier, only slight benefits are expected due to improved public and occupational health. These benefits are not quantified because of the perceived small numbers of radium-226 sources in the general population, and the effectiveness of existing regulations in the Agreement States and many non-Agreement States to monitor radioactive material. The *impacts* (costs) include any undesirable changes in affected attributes, such as increased costs for different segments of industry to conduct their business in accordance with new regulations. These attributes have quantifiable values and impacts due to implementing the rule:

– Industry Implementation
– Industry Operation
– NRC Implementation
– NRC Operation

Costs are calculated for Alternative 2, Maximum Regulation, and Alternative 3, Graded Approach, to implement the rule. This requires input assumptions for the following:

- Number of existing and new licensees that may be affected by the rule;
- Industry costs to prepare and submit license amendments and license applications;
- NRC costs to review license amendments and license applications;
- Industry costs for recordkeeping and reporting to comply with new regulations; and
- Industry capital costs to comply with new regulations.

NRC collected the input assumptions using data and information obtained from the following sources: Public Meetings; Public Comments; NRC Workgroups and NRC Staff experience; Reports and documents (e.g., OMB burden statements); and Independent Research. Both Agreement and non-Agreement States participated in public meetings and in the NRC workgroup meetings. The number of affected entities for this rule was estimated using NRC information on existing licensees, NRC staff best professional judgement, and consultation with Agreement State and non-Agreement States.

### 3.2.1 General Assumptions

The general input assumptions for the analysis are discussed below.

- NRC wage rate: $87.00/hour. This is NRC's incremental labor rate which includes only the variable costs associated with implementation and operation costs of the rule; this labor rate is consistent with Section 5.2 of NUREG/CR-4627, Generic Cost Estimates (Reference 7).

- Industry wage rate: $87.00/hour.

- No incremental costs or benefits are expected to occur for this rule under the regulations in 10 CFR Parts 33, 50, 61, 62, 72, 150, 170 and 171, although there are rule text changes in these regulations resulting from the definition of byproduct material.

- NRC will have additional licensees due to the new definition of byproduct material. For Alternative 2, Maximum Regulation, NRC estimates an increase of 3985 licensees. About 3500 licensees are expected to have particle accelerators, 40 licensees in the industrial sector, 45 medical users, and 400 that have gauges or other items containing radium. Medical use licensees with accelerators are counted within these approximations. Fees collected by NRC for license applications and annual license fees are assumed to be a transfer payment and are not included in the analysis. For Alternative 3, the Graded Approach, NRC estimates an increase of 335 licensees. About 100 licensees are expected to have radium products, 45 are expected to be from the industrial sector, 60 from medical, 45 PET accelerators, and 85 independent accelerators. None from the industrial sector are expected to be in well-logging or radiography applications. Although flyash and pipescale could have been included in this analysis, these licensees were not included because of a lack of data.

- The time period for the analysis is 10 years. We estimate both first year, one-time implementation costs and an increase in annual operating expense to support implementation of the rule. The values for annual operating expense are identical for each of the 10 years in the analysis, and are based primarily on labor hours contained in current OMB submission statements for the affected regulations. The annuity formula used to discount the annual expense values is on page B.3 of Reference 5.

### 3.2.2 Specific Assumptions for Alternative 1

Under the No-Action alternative (Alternative 1), NRC would maintain the current requirements for byproduct material and NARM. Thus, relative to existing requirements, no values or impacts would result from Alternative 1. The costs (impacts) and benefits (values) to be derived from the other alternatives would not be realized.

### 3.2.3 Specific Assumptions for Alternative 2

The specific assumptions are shown below for Alternative 2, Maximum Regulation. The primary difference between Alternative 2 and Alternative 3, Graded Approach, is the number of licensees that fall under this regulatory framework. Alternative 2 assumes 3985 new licensees while Alternative 3 assumes 335.

The NRC also has made assumptions for the number of specific licenses for persons with products and materials containing radium-226. For these licensees, under Alternative 3, we have added 300 licensees for possession of radium products, that would be generally licensed, in addition to the 100 assumed in both Alternatives 2 and 3. Appendix A shows the line item assumptions for the implementation and annual operating expense for Alternative 2.

10 CFR Part 19, Notices, Instructions and Reports to Workers: Inspection and Investigations

- We assumed 3585 new licensees, all of which have one-time set-up costs to comply with 10 CFR 19.12 regarding radiation exposure reports and instructions to workers. This is 3350 more licensees than Alternative 3, the Graded Approach.
- All of the 3585 licensees would be affected by annual reporting requirements regarding notifications and reports to workers under 10 CFR 19.12, 19.13(a), and 19.13(b), and about 10 percent of the licensees would be affected by the requirements in 10 CFR 19.13(c) and 19.13(e).

10 CFR Part 20, Standards for Protection Against Radiation

- We assumed about 5 percent of a total of 3985 licensees, or 199 licensees, would have one-time set-up costs to comply with 10 CFR 20.1101 regarding development, documentation and implementation of a radiation safety program. The 3985 total includes all 3585 licensees with implementation costs for 10 CFR Part 19 and the 400 licensees for possession of radium products. A $10,000 one-time capital expense is assumed for each of the 199 licensees to construct new facilities or to renovate existing facilities to comply with this part. All 3985 licensees also would have one-time labor expense to comply with 10 CFR 20.1406 regarding design and operating procedures for minimization of contamination and 10 CFR 20.2102 regarding ALARA records retention.
- We assume about 15 percent of the 3985 licensees, or 598 licensees, would have an annual labor expense for other reporting and recordkeeping requirements primarily in 10 CFR 20.1906, 20.2102 and 20.2103.
- All 3985 licensees are assumed to be correctly filling-out the manifests, currently, for waste disposal, so there is no additional cost for this activity under Appendix G.

10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material

- We assume 3985 new licensees would have one-time labor costs for license application under 10 CFR 30.32.
- We assume 15 authorizations for production of PET drugs for non-commercial distribution to consortium members under 10 CFR 30.32(j) which is a one-time labor expense. We assume for the same 15 licensees an annual expense of 390 hours each for labeling of vials and syringes under 10 CFR 30.34(j); this assumption is the same as under Alternative 3.
- Only 5 new licensees, the same as under Alternative 3, are assumed to have one-time and annual labor expense to comply with financial assurance requirements for decommissioning under 10 CFR 30.35(a) and 30.35(b).
- Of the total 3985 new licensees, only 8 are assumed to have quantities of material that would require a one time expense to calculate whether an emergency plan was needed, and 3 would have to prepare an emergency plan for compliance with the emergency planning regulations in 10 CFR 30.32.

10 CFR Part 31, General Domestic Licenses for Byproduct Material

- We assume that 100 General Licenses in Alternative 2, the same as Alternative 3, would have an annual labor expense to comply with the regulations in 10 CFR 31.5.
- The provisions for a general license in 10 CFR 31.12 do not apply to Alternative 2. The general license for products containing radium-226 are only in Alternative 3.

10 CFR Part 32, Specific Licenses for Manufacture or Transfer

- No differences are modeled in Alternative 2 compared to Alternative 3. The specific assumptions for 10 CFR Part 32 are listed in Section 3.2.4.

10 CFR Part 35, Medical Use of Byproduct Material

- There will be one-time implementation costs under 10 CFR Part 35, but only minor incremental changes compared to the Alternative 3 assumptions. About one-half of the extra one-time implementation cost is due to an estimated 80 licensees with review and approval requirements from NRC for the protection of human subjects (under 10 CFR 35.6).
- The assumptions for annual operating expense burden are based on regulatory requirements in certain sections of 10 CFR Part 35. The specific assumptions for most of these line items are moderately higher than the assumptions used to represent Alternative 2.
- The most significant change in annual operating expense for Alternative 2 is an estimated 160 licensees that have an approximate 42 hour labor burden to record dosages of unsealed byproduct material for medical use, per 10 CFR 35.2063.

Additional Cost to NRC

- We assume 3985 new license applications with a one-time implementation effort of 40 hours staff time to process each new license. 3500 are for particle accelerators; 40 are in the industrial sector, 45 are medical users, and 400 are for gauges and other items containing radium-226. Medical uses and the non-commercial distribution of PET drugs to consortium members are included in these totals.
- We assume annual labor expense to process 150 new license amendments per year and 50 inspections per year for Alternative 2.

Waste and Decommissioning

- Of the 3500 particle accelerators, we assume that 150 of these facilities have large enough amounts of radioactive waste for modeling waste costs. The other 3350 accelerators are non-producing ARM with minimal radioactive waste. We assume the 45 particle accelerators producing significant waste under Alternative 3 produce on average two-thirds of the tonnage in the waste stream produced by the 150 accelerators in Alternative 2.

- No costs were assumed for waste disposal and decommissioning for the 40 industrial sector licensees and the 400 licensees with gauges and other items containing radium-226. This is the same assumption used for Alternative 3; additional information regarding the basis for this assumption is presented in the specific assumptions for Waste and Decommissioning for Alternative 3.

### 3.2.4 Specific Assumptions for Alternative 3

The specific assumptions are described below for Alternative 3, Graded Approach, which is the NRC preferred alternative. Appendix B shows the assumptions used for the number of licensees affected, assumed capital and labor implementation costs, and the labor hours associated with annual operating expense activities for each line item in the cost analysis.

10 CFR Part 19, Notices, Instructions and Reports to Workers: Inspection and Investigations

- We assume 235 licensees would have one-time set-up costs to comply with 10 CFR 19.12 regarding worker radiation exposure reporting. This includes 25 manufacturing and distribution licensees, of which 5 have accelerators and 20 are users; 20 are large medical licensees, of which 15 have accelerators and 5 are users; 40 are small medical users; 20 are industrial users; 45 are PET accelerators; and 85 are independent accelerators.
- All of the 235 licensees would be affected by annual reporting requirements regarding notifications and reports to workers under 10 CFR 19.12, 19.13(a), and 19.13(b), and about 10 percent of the licensees would be affected by the requirements in 10 CFR 19.13(c) and 19.13(e).

10 CFR Part 20, Standards for Protection Against Radiation

- We assume 5 percent of a total of 335 licensees would have one-time set-up costs to comply with 10 CFR 20.1101 regarding development, documentation and implementation of a radiation safety program. A $10,000 one-time capital expense is assumed for each licensee to construct new facilities or to renovate existing facilities to comply with this regulation. The 335 total includes the 235 new licensees described above and an additional 100 licensees with specific licensed gauges.
- All 335 licensees would have one-time labor expense to comply with 10 CFR 20.1406. The assumption is 20 hours per licensee.
- We assume all 335 licensees would have an annual labor expense for other reporting and recordkeeping requirements primarily in 10 CFR 20.1906, 20.2102 and 20.2103.

10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material

- We assume that all 335 licensees would have one-time labor costs for license application under 10 CFR 30.32.
- We assume 15 authorizations for production of PET drugs for non-commercial distribution to consortium members under 10 CFR 30.32(j) and a one-time labor expense and annual expense for these 15 licensees for labeling of vials and syringes under 10 CFR 30.34(j).
- A subset of the particle accelerator licensees, estimated at 5, also would have one-time labor expense to comply with financial assurance requirements for decommissioning under 10 CFR 30.35 (unsealed byproduct material with a half-life greater than 120 days and in quantities exceeding 100,000 times Appendix B to 10 CFR Part 30). The amount of decommissioning funding assurance is specified in 10 CFR 30.35(d) and is based on the possession limit of material at the licensed site. The range is from $113,000 to $1,125,000 unless the quantity upper bound is exceeded, in which case a decommissioning funding plan must be submitted per 10 CFR 30.35(e).
- Most of the annual burden hours is in the licensee's labeling requirements and procedures of use of instrumentation in 10 CFR 30.34(j)(2).

10 CFR Part 31, General Domestic Licenses for Byproduct Material

- We assume that 100 General Licenses would have an annual labor expense to comply with the regulations in 10 CFR 31.5.
- We assume 300 persons, who possess certain items containing radium-226, are eligible for a general license under the new section 10 CFR 31.12. Of these, we assume that 1 percent (3) would have annual labor expense to comply with notification and reporting conditions. This is a new labor burden, estimated at 4 hours per affected licensee.

10 CFR Part 32, Specific Licenses for Manufacture or Transfer

- The assumptions for part 32 are the same in Alternative 2 compared to Alternative 3. We assume that 22 new accelerator facilities, that manufacture and distribute radioactive drugs for medical purposes, would have a one-time labor expense of 2 hours each to prepare instrumentation procedures consistent with the requirements of 10 CFR 32.72(c). We assume the three licensees under 10 CFR 32.74 do not require implementation activities.
- We assume the 22 new accelerator facilities would have an annual labor burden of 390 hours each for labeling requirements under 10 CFR 32.72(a) and an equivalent annual labor burden associated with procedures for use of instrumentation under the requirements under 10 CFR 32.72(c).

10 CFR Part 35, Medical Use of Byproduct Material

- There will be one-time implementation costs under 10 CFR Part 35. Most of the one-time implementation cost is due to requirements under 10 CFR 35.6, 35.24 and 35.26.
- The most significant change in annual operating expense for Alternative 3 is an estimated 80 licensees that have an approximate 42 hour labor burden to record dosages of unsealed byproduct material for medical use, per 10 CFR 35.2063, and an estimated 200 licensees that have an approximate 13 hour labor burden to prepare written directives before the administration of I-131 sodium iodide or any therapeutic dosage of unsealed byproduct material, per 10 CFR 35.40(a).

Additional Cost to NRC

- We assume 335 new license applications with a one-time effort of 40 hours staff time to process each new license.
- We assume the one-time effort to develop a new guidance document in the first year of implementation, with 300 staff hours required to prepare the document.
- For annual operating costs, we assume that 75 license amendments and 25 additional inspections are required each year over the 10-year analysis. Each license amendment requires 20 staff hours and each inspection requires 24 hours staff time.

Waste and Decommissioning

- Of the particle accelerators, we assume that 45 of these facilities have material amounts of radioactive waste for estimation of waste processing costs. We assume these 45 accelerators have 0.25 tons per year of waste, with a disposal cost of $22 per ton and a transport cost to an authorized solid waste facility of $40 per ton. Few if any of the facilities are expected to be decommissioned during the 10-year analysis period. We

assume a $10,000 annual sinking fund expense for decommissioning these particle accelerators.

- No costs were assumed for waste disposal and decommissioning the 50 industrial sector licensees and 100 licensees with gauges and other items containing radium-226 or the small number of sites where there are people who have large collections of products containing radium-226. The gauges are believed to be owned by companies with larger numbers of gauges containing other radioactive material, and the waste and decommissioning related to radium-226 gauges is low compared to other obligations.

## 4.0 Results

This section presents results of values and impacts that are expected to be derived from the rule. The results are shown for each affected part in Title 10 of the Code of Federal Regulations and by the following four attributes as discussed in section 3.2:

– Industry Implementation
– Industry Operation
– NRC Implementation
– NRC Operation

The rule is expected to provide values in other attributes, such as Public Health, Occupational Health, and Safeguards and Security Considerations, but these values are not quantified because they are expected to be small and there is no verifiable input available at this time to support input assumptions. For health attributes, the benefits in terms of avoided radiological exposure are expected to be small. As a result, the quantifiable results in this analysis are entirely on the impacts (i.e., costs) expected from implementation of the rule as required by Section 651(e) of the EPAct. The costs are presented in constant 2005 dollars, for both implementation and annual operating expense. The impact of the rule over a 10-year analysis period is estimated using 7 percent and 3 percent real discount rates to show an overall effect in terms of constant 2005 dollars.

Alternative 3 is the Graded Regulatory approach, which is the preferred approach. Alternative 2 would revise the regulations to maximize NRC's regulatory authority. Alternative 1 is the "No-Action" alternative that provides a baseline against which the other two alternatives are assessed.

## 4.1 Summary of Results

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

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

| Regulatory Alternative | 10-Year Total 7% discount rate (2005$) | 10-Year Total 3% discount rate (2005$) |
|---|---|---|
| 1. No-Action | 0 | 0 |
| 2. Maximum Regulatory Authority | (90,108,228) | (101,774,070) |
| 3. Graded Regulatory Authority | (32,534,759) | (38,820,088) |

Note: Costs in all tables are represented by negative numbers.

Table 4-2 provides the estimated costs, by attribute, over the 10-year analysis period. The Industry Implementation and NRC implementation costs are all one-time capital and labor expense, in 2005 dollars, and are thus not discounted. The other two categories have annual expense, so the discounted expenses are different under 7 percent and 3 percent discount rates. Industry Operation costs are a large part of total estimated cost over the 10-year period.

**Table 4-2. Values and Impacts by Attribute**

| Attribute | Alternative 2 10-Year Total Cost (2005$) | | Alternative 3 10-Year Total Cost (2005$) | |
|---|---|---|---|---|
| | 7 percent discount | 3 percent discount | 7 percent discount | 3 percent discount |
| Industry Implementation | (24,257,346) | (24,257,346) | (2,245,864) | (2,245,864) |
| Industry Operation | (49,390,565) | (60,505,888) | (27,813,787) | (33,823,857) |
| NRC Implementation | (13,893,900) | (13,893,900) | (1,191,900) | (1,191,900) |
| NRC Operation | (2,566,417) | (3,116,936) | (1,283,208) | (1,558,468) |
| **Total** | (90,108,228) | (101,774,070) | (32,534,759) | (38,820,088) |

The Industry Implementation and NRC Implementation attributes represent projected costs that would be incurred by affected licensees and the NRC to install or implement changes as required in the rule, or to process new license applications. Alternative 2, Maximum Regulation, has substantially higher implementation costs than Alternative 3.

The Industry Operation attribute represents the additional annual operating expense projected to be incurred by the affected licensees as required by the regulations in the rule. For Alternative 2, the Industry Operation costs are about 60 percent of the total costs because the implementation costs are so high. For Alternative 3, where there are less implementation costs, the Industry Operation costs are about 85 percent of the total costs.

The NRC Operation attribute represents additional annual expense to process license amendments and to conduct inspections for the rule.

Table 4-3 shows the results for estimated implementation costs and annual operating expense to comply with the rule, by affected 10 CFR Part. For Alternative 3, the largest *one-time* cost to industry is to comply with 10 CFR Part 20 regulations, followed by the requirements in 10 CFR Part 30. The largest *annual cost* to industry for Alternative 3 is to comply with 10 CFR Part 32 regulations, followed by the requirements in 10 CFR Part 30 and 10 CFR Part 35.

An “impact per entity” for one-time costs to comply with the rule is about $6,700 for each of the estimated 335 licensees who are affected by the new regulations under 10 CFR Part 19, 20, 30, 32, and 35 for the preferred Alternative 3. In general, this cost would be applied to renovate an existing facility and expand the radiation safety program in order to comply with radiation protection safety functions that the licensee may not have fully implemented before the effective date of the rule.

**Table 4-3. Summary of One-Time Costs and Annual Labor Expense**

| 10 CFR Part | Alternative 2 | | Alternative 3 | |
|---|---|---|---|---|
| | One-time Cost ($) | Annual Cost ($) | One-time Cost ($) | Annual Cost ($) |
| 19 | (5,614,110) | (2,875,791) | (368,010) | (188,681) |
| 20 | (15,858,583) | (697,566) | (1,336,583) | (429,345) |
| 30 | (2,683,298) | (1,112,360) | (460,448) | (1,096,004) |
| 31 | 0 | (5,525) | 0 | (6,569) |
| 32 | (3,828) | (1,494,608) | (3,828) | (1,494,608) |
| 35 | (97,527) | (1,181,021) | (76,995) | (755,543) |
| NRC Operation | 0 | (365,400) | 0 | (182,700) |
| NRC Implementation | (13,893,900) | 0 | (1,191,900) | 0 |
| Waste and Decommissioning | 0 | (28,200) | 0 | (19,900) |
| **Total** | (38,151,246) | (7,760,470) | (3,437,764) | (4,173,349) |

Note: Costs are represented by negative numbers.

There is a margin of error in the operating expense assumptions when applied to the working experience of individual facilities. Most of the labor expense assumptions to derive the costs shown above were obtained from OMB submission statements that have information of burden for regulated recordkeeping and reporting activities. These burden statements that were used for the input assumptions have not, to date, included production accelerators or persons who possess or repair products that contain radium-226. The costs in this analysis are based on best available data to support the rulemaking.

The greatest uncertainty in the cost estimates is with the input assumptions for waste and decommissioning activities, which fall within the Industry Operation attribute. The input data to represent these activities are based on independent research and staff experience for waste transportation and disposal. Reference 8, "Economic Risk of Contamination Cleanup Costs Resulting from Large Nonreactor Nuclear Material Licensee Operations," provides information about decontamination costs following several types of hypothetical accidents, including separately a waste warehouse fire and a tornado, at a large facility that manufactures a variety of radiological products. The upper bound of economic risk for this large facility was estimated to be $31,000/year in 1990 dollars. Reference 9, "Radiological Assessments for Clearance of Materials from Nuclear Facilities," has an estimate of total amount of steel scrap cleared from U.S. hospitals with rooms under radiological regulatory control. Decommissioning information for a variety of radioactive material sites is available for review at the following NRC website, www.nrc.gov/info-finder/decommissioning/complex. Among these sites, one had operated a Co-60 irradiator and was reporting decommissioning costs to date of about $25 million, with an additional $2 million to $3 million needed to complete decommissioning. Other smaller byproduct material sites have significantly lower estimated decommissioning costs.

## 5.0 Decision Rationale

The assessment of costs and benefits discussed above, quantitatively when possible and qualitatively otherwise, leads the NRC to the conclusion that the rulemaking would:

- Use the model State regulations to the maximum extent practicable to regulate certain radium sources, accelerator-produced radioactive materials, and certain naturally occurring radioactive material, as required by EPAct;

- Minimize the impact on the availability of radioactive drugs to physicians and patients while assuring the protection of public health and safety in the future; and

- Minimize the regulatory burden on regulated entities while protecting the public health and safety and the common defense and security.

Because the regulation is mandated by the U.S. Congress, adoption of the No-Action Alternative is not feasible. In order to meet the Congressional mandate to promulgate regulations, while minimizing burden on stakeholders, NRC developed Alternative 3, a Graded Approach for exercising regulatory authority over NARM. In so doing, NRC took advantage of opportunities in the EPAct to consider alternatives in developing its regulations. Alternative 2 would not allow such discretion, and the impacts associated with this Alternative would be much higher than NRC's preferred approach (Alternative 3). Because both Alternatives are believed to be equally protective of public health and safety and the common defense and security, NRC has determined that Alternative 3, providing regulatory discretion, is the most appropriate alternative.

## 6.0 Implementation

Specific provisions are included in this rule, and several actions are planned in conjunction with, or following, the issuance of this final rule covering the newly added byproduct material, including:

1. Issuance and publication of a Transition Plan for the orderly transition of regulatory authority for the newly added byproduct material;

2. Termination of the waiver issued by the NRC (70 FR 51581; August 31, 2005) for the States and users of the newly added byproduct material; and

3. Inclusion of specific provisions allowing users of the newly added byproduct material to continue with their activities for a period of time while coming into compliance with the newly issued regulations.

With respect to a Backfit Analysis, the alternatives examined in this regulatory analysis do not involve any provisions that would require backfits as defined in 10 CFR Part 50.109(a)(1). Consequently, a backfit analysis is not necessary.

### 6.1 Transition Plan

Section 651(e) of the EPAct requires the NRC, in issuing new regulations for the newly added byproduct material, to prepare and publish a transition plan for regulatory authority over the newly added byproduct material in Agreement and non-Agreement States. The transition plan must describe the conditions under which a State may exercise authority over the newly added byproduct material. The transition plan also must include a statement of the Commission that any agreement between the Commission and a State, under Section 274b. of the Atomic Energy Act of 1954, as amended, covering byproduct material and entered into before the date of publication of the transition plan, must be considered to include the newly added byproduct material, providing that the Governor of the Agreement State certifies to the Commission on the date of publication of the transition plan that: (1) the State has a program for licensing the newly covered byproduct material that is adequate to protect the public health and safety, as determined by the Commission; and (2) the State intends to continue to implement the regulatory responsibility of the State with respect to the newly defined byproduct material.

## 7.0 Implications for Other Federal Agencies

Promulgation of this rule would have no significant adverse effects on other Federal regulatory agencies.

## 8.0 Effect on Small Entities

This rule may have a minor economic impact on some small entities in non-Agreement States. A small number of businesses that may be impacted by the rule fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

Section 651(e) of the EPAct expanded the definition of byproduct material in Section 11e. of the AEA to include any discrete source of radium-226, any material made radioactive by use of a particle accelerator, and any discrete source of naturally occurring radioactive material that would pose a similar threat to the public health and safety or the common defense and security as a discrete source of radium-226 that is extracted or converted after extraction for use in a commercial, medical, or research activity. This rulemaking would amend the NRC regulations to include this newly defined byproduct material. This amendment would potentially affect large numbers of individuals, businesses, or licensees engaged in activities involving discrete radium-226 sources or accelerator-produced radioactive material used for commercial, medical, or research activities.

Many individuals, businesses, or licensees would qualify as small business entities as defined by 10 CFR 2.810. Because the NRC is using the existing regulatory framework to regulate these materials and is allowing sufficient time for individuals, businesses, and licensees to implement the requirements for this radioactive material, the impact on small entities is believed to be acceptable.

Based on the analysis provided in Section 3 of this Regulatory Analysis, the NRC believes that the selected alternative is protective of public health and safety and is not overly burdensome in order to accomplish the NRC's regulatory objective. The NRC also notes that several Agreement States have similar regulations already implemented either by rule, order, or license condition.

## APPENDIX A Input and Results for Alternative 2

This appendix provides details of the line-by-line input and results for Alternative 2, the Maximum Regulation. The following pages show input and results for 10 CFR Part 19, 20, 30, 31, 32, 35, NRC Costs, and Waste and Decommissioning.

## 10 CFR Part 19
## Alternative 2

| Section # | Total # Licensees | One Time | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 19.12 | 3585 | 100% | 3585 | 18 | 100% | 3585 | 0.2 | $ (5,614,110) | $ (62,379) |
| 19.13(a) | 3585 | 0% | 0 | 0 | 100% | 3585 | 0.2 | $ - | $ (62,379) |
| 19.13(b) | 3585 | 0% | 0 | 0 | 100% | 3585 | 8.4 | $ - | $ (2,620,542) |
| 19.13(c) | 3585 | 0% | 0 | 0 | 10% | 359 | 3.3 | $ - | $ (102,569) |
| 19.13(e) | 3585 | 0% | 0 | 0 | 10% | 359 | 0.9 | $ - | $ (27,922) |
| | | | | | | | **Total** | **$ (5,614,110)** | **$ (2,875,791)** |

Notes: as of 8-Feb-2006:

Annual hours of labor per licensee reduced by 80 percent compared to OMB Final Supporting Statement for 10 CFR Part 19 (OMB Clearance No. 3150-0044)

19.12 Requires licensees to provide radiation exposure reports to workers
19.13(a) Notification and report to individuals
19.13(b) Advise workers annually of dose
19.13(c) At request of worker formerly engaged in activities at the facility, exposure report for each year.
19.13(e) At request of worker terminating employment at the facility, exposure report for year and current quarter.

## 10 CFR Part 20
## Alternative 2

| Section # | Total # Licensees | One Time | | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Capital Cost per Licensee | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 20.1101 * | 3985 | 5% | 199 | $ (10,000) | 0 | 0% | 0 | 0 | $ (1,990,000) | $ - |
| 20.1406 | 3985 | 100% | 3985 | $ - | 20 | 0% | 0 | 0 | $ (6,933,900) | $ - |
| 20.1601(c) | 1 | 100% | 1 | $ - | 8 | 0% | 0 | 0 | $ (696) | $ - |
| 20.1906(d) | 1 | 100% | 1 | $ - | 1 | 0% | 0 | 0 | $ (87) | $ - |
| 20.1906(e) | 3985 | 0% | 0 | $ - | 0 | 15% | 598 | 1 | $ - | $ (52,026) |
| 20.2102(a)&(b) | 3985 | 100% | 3985 | $ - | 20 | 15% | 598 | 4 | $ (6,933,900) | $ (208,104) |
| 20.2103(a)&(b) | 3985 | 0% | 0 | $ - | 0 | 15% | 598 | 8 | $ - | $ (416,208) |
| 20.2107(a) | 25 | 0% | 0 | $ - | 0 | 100% | 25 | 5 | $ - | $ (10,875) |
| 20.2108(a) | 50 | 0% | 0 | $ - | 0 | 15% | 8 | 8 | $ - | $ (5,568) |
| 20.2201(a) | 1 | 0% | 0 | $ - | 0 | 100% | 1 | 3 | $ - | $ (261) |
| 20.2201(b) | 1 | 0% | 0 | $ - | 0 | 100% | 1 | 3 | $ - | $ (261) |
| 20.2201(d) | 1 | 0% | 0 | $ - | 0 | 100% | 1 | 3 | $ - | $ (261) |
| 20.2202(b) | 1 | 0% | 0 | $ - | 0 | 100% | 1 | 40 | $ - | $ (3,480) |
| 20.2203(a) | 1 | 0% | 0 | $ - | 0 | 100% | 1 | 6 | $ - | $ (522) |
| | | | | | | | | **Total** | **$ (15,858,583)** | **$ (697,566)** |

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is Draft OMB Supporting Statement for 10 CFR Part 20 (OMB Clearance No. 3150-0014)

* A $10,000 capital expense is assumed for each affected licensee to construct or renovate facilities.

20.1101 Requires licensees to develop, document and implement radiation protection programs, establish procedures, and perform program review.
20.1406 Requires applicants for licenses to describe how facility design and procedures for operation will minimize contamination of the facility and environment, facilitate eventual decommissioning, and minimize generation of radioactive waste.
20.1601(c) Allows licensees to apply to the Commission for approval of alternate methods for control of access to high radiation areas.
20.1906(e) Requires licensees to develop and maintain procedures regarding radioactive material shipment.
20.2102(a)&(b) (a) Requires licensees to maintain records of the radiation protection program, including ALARA; (b) requires licensees to retain records of radiation programs until the Commission terminates the license.
20.2103(a)&(b) (a) Requires licensees to maintain records showing the results of surveys and calibrations; (b) requires licensees to maintain records for 3 years, unless they form the basis of dose estimates in which case they must be maintained through license termination.
20.2107(a) Requires information on the identity and quality of the radionuclides released by licensee in effluents to unrestricted areas.
20.2108(a) Requires records of waste disposal to permit routine inspection for compliance, and inspection against constraints on the kinds and quantities of licensed material.
20.2201(a) Requires licensees to report any theft or loss of licensed material by telephone immediately or in writing within 30 days, dependent upon the potential risk to the health and safety of the public.
20.2201(b) Requires licensees to follow up telephone reports with written reports of the incident within 30 days of the telephone report.
20.2201(d) Requires additional information relevant to the loss of radioactive material, discovered after the written report, be submitted within 30 days of discovery.
20.2202(b) Requires that the licensee notify the NRC within 24 hours upon becoming aware of specific incidents involving licensed material.
20.2203(a) Contains the requirements for the content of the reports required by Paragraph 20.2203(a).

10 CFR Part 30
Alternative 2

| Section | Total # Licensees | One Time | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 30.9(b) | 1 | 0% | 0 | 0 | 100% | 1 | 1.0 | $ - | $ (87) |
| 30.32 | 3985 | 100% | 3985 | 7 | 5% | 199 | 1.0 | $ (2,426,865) | $ (17,335) |
| 30.32 (i) - EP | 3 | 100% | 3 | 10 | 100% | 3 | 10.0 | $ (2,610) | $ (2,610) |
| 30.32 (i) - Calculation | 5 | 100% | 5 | 1 | 0% | 0 | 0.0 | $ (435) | $ - |
| 30.32 (j) | 15 | 100% | 15 | 42.5 | 0% | 0 | 0.0 | $ (55,463) | $ - |
| 30.32 (g) | 20 | 100% | 20 | 3 | 0% | 0 | 0.0 | $ (5,220) | $ - |
| 30.34(e)(4) - Orders | 1 | 0% | 0 | 0 | 100% | 1 | 3.0 | $ - | $ (261) |
| 30.34(e)(4) - Sfguards | 5 | 0% | 0 | 0 | 100% | 5 | 0.5 | $ - | $ (218) |
| 30.34(h) | 5 | 0% | 0 | 0 | 1% | 2 | 0.5 | $ - | $ (87) |
| 30.34(j)(2)(i) | 15 | 100% | 15 | 2 | 100% | 15 | 390.0 | $ (2,610) | $ (508,950) |
| 30.34(j)(2)(ii) | 15 | 0% | 0 | 0 | 100% | 15 | 390.0 | $ - | $ (508,950) |
| 30.34(j)(4) | 15 | 0% | 0 | 0 | 20% | 3 | 0.5 | $ - | $ (131) |
| 30.35(a)&(b) - Certific | 5 | 100% | 5 | 100 | 100% | 5 | 10.0 | $ (43,500) | $ (4,350) |
| 30.35(a)&(b) - F Plan | 5 | 100% | 5 | 300 | 100% | 5 | 10.0 | $ (130,500) | $ (4,350) |
| 30.35(g) | 14 | 100% | 14 | 10 | 100% | 14 | 10.0 | $ (12,180) | $ (12,180) |
| 30.36(d) | 1 | 0% | 0 | 0 | 100% | 1 | 1.0 | $ - | $ (87) |
| 30.36(g) | 1 | 0% | 0 | 0 | 100% | 1 | 336.0 | $ - | $ (29,232) |
| 30.41(c)&(d) | 60 | 0% | 0 | 0 | 100% | 60 | 4.0 | $ - | $ (20,880) |
| 30.50(a),(b),&(c) | 2 | 0% | 0 | 0 | 100% | 2 | 4.0 | $ - | $ (696) |
| Appendix D | 25 | 100% | 25 | 1 | 50% | 13 | 1.0 | $ (2,175) | $ (1,088) |
| Appendix E | 20 | 100% | 20 | 1 | 50% | 10 | 1.0 | $ (1,740) | $ (870) |
| | | | | | | | **Total** | **$ (2,683,298)** | **$ (1,112,360)** |

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 30 (OMB Clearance No. 3150-0017).

| | |
|---|---|
| 30.9(b) | Requires applicant or licensee to notify the Commission of information which has significant implications for public health and safety or the common defense and security. |
| 30.32 | License application process for entities with gauges containing radium-226 products, accelerators and other NARM use. |
| 30.32 (i) - EP | Requires applicants that will posses amounts of materials requiring an emergency plan to either submit an evaluation demonstrating an emergency plan is not needed or to provide the emergency plan. |
| 30.32 (j) | License appliction process for authorization for production of PET drugs for non-commercial distribution to consortium members. |
| 30.34(e)(4) - Orders | The authority for Commission issuance of orders for the modification of licenses. |
| 30.34(e)(4) - Sfguards | Certain licensees are required to take compensatory actions against threats, requiring safeguards plans and other safeguard requirements. |
| 30.34(h) | Requires immediate notification to the appropriate NRC regional administrator, in writing, following the filing of bankruptcy petition. |
| 30.34(j)(2)(i) | Applicants must satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold radioactive drug to be transferred for commercial distribution. |
| 30.34(j)(2)(ii) | Requires licensee to have procedures for use of instrumentation used to measure radioactivity of radioactive drugs. |
| 30.34(j)(4) | Requires licensees, licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution, to provide certification information to NRC. |
| 30.35(a)&(b) - Certific | Specifies licensees required to submit a decommissioning funding plan or a certification of financial assurance for decommissioning. |
| 30.35(a)&(b) - F Plan | Specifies licensees required to submit a decommissioning funding plan or a certification of financial assurance for decommissioning. |
| 30.35(g) | Requires records retention, regarding decommissioning of the facility, until the license is terminated by the Commission. |
| 30.41(c)&(d) | Requires verification informaton, prior to transfer and receipt of byproduct material; and (d) specifies acceptable methods for verification. |
| 30.50(a),(b),&(c) | Notification of events or conditions that threaten the health and safety of individuals using or potentially exposed to licensed material. |
| Appendix D | Criteria for companies to pass the financial test when they furnish their own funds guarantee for decommissioning cost. |
| Appendix E | Criteria for nonprofit colleges, universities and hospitals to pass the financial test when they furnish their own funds guarantee for |

## 10 CFR Part 31
## Alternate 2

| Section # | Total # Licensees | One Time | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 31.5(c)(4) | 100 | 0% | 0 | 0.0 | 100% | 100 | 0.3 | $ - | $ (2,175) |
| 31.5(c)(8) | 5 | 0% | 0 | 0.0 | 100% | 5 | 0.6 | $ - | $ (261) |
| 31.5(c)(9) | 1 | 0% | 0 | 0.0 | 100% | 1 | 1.0 | $ - | $ (87) |
| 31.5(c)(11) | 100 | 0% | 0 | 0.0 | 100% | 100 | 0.3 | $ - | $ (2,958) |
| 31.5(c)(14) | 5 | 0% | 0 | 0.0 | 100% | 5 | 0.1 | $ - | $ (44) |
| 31.12 | 0 | 0% | 0 | 4.0 | 0% | 0 | 4.0 | $ - | $ - |
| | | | | | | | **Total** | **$ -** | **$ (5,525)** |

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 31 (OMB Clearance No. 3150-0016).

31.5(c)(4) General licensee must maintain records showing that tests for leakage of radioactive materials, proper operation of on-off mechanism, and/or other specified tests have been performed.

31.5(c)(8) General licensees may transfer or dispose of devices containing byproduct material only by approved methods.

31.5(c)(9) General licensees wishing to transfer a devise to another general licensee may do so under certain conditions.

31.5(c)(11) General licensees must respond to written requests from NRC within certain time constraints.

31.5(c)(14) General licensees must notify NRC within 30 days of changes of address for the location of use of devices.

## 10 CFR Part 32
## Alternative 2

| Section | Total # Licensees | One Time | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 32.72(a)(4) | 22 | 0% | 0 | 0 | 100% | 22 | 390 | $ - | $ (746,460) |
| 32.72(b)(5) | 22 | 0% | 0 | 0 | 100% | 22 | 0.5 | $ - | $ (957) |
| 32.72(c) | 22 | 100% | 22 | 2 | 100% | 22 | 390 | $ (3,828) | $ (746,460) |
| 32.74(a)(2)(viii) | 3 | 0% | 0 | 0 | 100% | 3 | 2.8 | $ - | $ (731) |
| | | | | | | | **Total** | **$ (3,828)** | **$ (1,494,608)** |

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 32 (OMB Clearance No. 3150-0001).

32.72(a)(4) Applicants must satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold radioactive drug to be transferred for commercial distribution.

32.72(b)(5) Requires licensees, licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution, to provide information on authorized nuclear pharmacist status to NRC.

32.72(c) Requires licensee to have procedures for use of instrumentation used to measure radioactivity of radioactive drugs.

32.74(a)(2)(viii) Requires labeling instructions for handling and storing radioactive sources or devices, from the radiation safety standpoint.

10 CFR Part 35
Alternative 2

| Section | Total # Licensees | One Time | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 35.6 | 80 | 100% | 80 | 4.0 | 25% | 20 | 4.0 | $ (27,840) | $ (6,960) |
| 35.14 | 195 | 100% | 195 | 0.5 | 15% | 28 | 0.5 | $ (8,483) | $ (1,218) |
| 35.19 | 2 | 0% | 0 | 0.0 | 100% | 2 | 1.0 | $ - | $ (174) |
| 35.24 (a) | 410 | 100% | 410 | 0.5 | 2% | 8 | 2.5 | $ (17,835) | $ (1,740) |
| 35.24 (b) | 62 | 100% | 62 | 0.5 | 10% | 6 | 0.5 | $ (2,697) | $ (261) |
| 35.24 (f) | 21 | 100% | 21 | 0.5 | 0% | 0 | 0.0 | $ (914) | $ - |
| 35.26 | 410 | 100% | 410 | 0.5 | 2% | 8 | 0.5 | $ (17,835) | $ (348) |
| 35.27 | 120 | 100% | 120 | 1.0 | 1% | 1 | 1.0 | $ (10,440) | $ (87) |
| 35.40 (a) | 240 | 0% | 0 | 0.0 | 100% | 240 | 13.0 | $ - | $ (271,440) |
| 35.40 (a)(1) | 21 | 0% | 0 | 0.0 | 100% | 21 | 1.8 | $ - | $ (3,197) |
| 35.40 (c)(1) | 105 | 0% | 0 | 0.0 | 100% | 105 | 2.5 | $ - | $ (22,838) |
| 35.41 | 240 | 100% | 240 | 0.5 | 1% | 2 | 0.5 | $ (10,440) | $ (87) |
| 35.2060 | 49 | 0% | 0 | 0.0 | 100% | 49 | 5.1 | $ - | $ (21,741) |
| 35.61 | 120 | 0% | 0 | 0.0 | 100% | 120 | 0.0 | $ - | $ (313) |
| 35.2063 | 160 | 0% | 0 | 0.0 | 100% | 160 | 42.5 | $ - | $ (591,878) |
| 35.2067(a) | 176 | 0% | 0 | 0.0 | 100% | 176 | 0.2 | $ - | $ (2,756) |
| 35.2067(b) | 176 | 0% | 0 | 0.0 | 100% | 176 | 0.1 | $ - | $ (1,837) |
| 35.2070 | 55 | 0% | 0 | 0.0 | 100% | 55 | 1.1 | $ - | $ (5,264) |
| 35.80(a)(1) | 4 | 0% | 0 | 0.0 | 100% | 4 | 20.0 | $ - | $ (6,960) |
| 35.2080 (a) | 5 | 0% | 0 | 0.0 | 100% | 5 | 0.6 | $ - | $ (261) |
| 35.2080 (b) | 5 | 0% | 0 | 0.0 | 100% | 5 | 26.0 | $ - | $ (11,310) |
| 35.2092 | 120 | 0% | 0 | 0.0 | 100% | 120 | 1.0 | $ - | $ (10,858) |
| 35.2204 | 9 | 0% | 0 | 0.0 | 100% | 9 | 20.8 | $ - | $ (16,286) |
| 35.310 | 70 | 0% | 0 | 0.0 | 100% | 70 | 1.0 | $ - | $ (6,090) |
| 35.2310 | 58 | 0% | 0 | 0.0 | 100% | 58 | 0.1 | $ - | $ (505) |
| 35.315(b) | 1 | 0% | 0 | 0.0 | 100% | 1 | 1.0 | $ - | $ (87) |
| 35.315(a) | 70 | 0% | 0 | 0.0 | 100% | 70 | 1.8 | $ - | $ (10,962) |
| 35.2404 | 150 | 0% | 0 | 0.0 | 100% | 150 | 1.2 | $ - | $ (15,921) |
| 35.2406 | 150 | 0% | 0 | 0.0 | 100% | 150 | 3.0 | $ - | $ (39,150) |
| 35.410 | 39 | 0% | 0 | 0.0 | 100% | 39 | 1.0 | $ - | $ (3,393) |
| 35.415(c) | 7 | 0% | 0 | 0.0 | 100% | 7 | 1.0 | $ - | $ (609) |
| 35.415(a)(1) | 28 | 0% | 0 | 0.0 | 100% | 28 | 0.5 | $ - | $ (1,218) |
| 35.2432 | 40 | 0% | 0 | 0.0 | 100% | 40 | 3.0 | $ - | $ (10,440) |
| 35.2024 (a) | 410 | 0% | 0 | 0.0 | 100% | 410 | 1.3 | $ - | $ (44,588) |
| 35.2024 (b) | 62 | 0% | 0 | 0.0 | 100% | 62 | 0.1 | $ - | $ (539) |
| 35.2026 | 410 | 0% | 0 | 0.0 | 100% | 410 | 0.3 | $ - | $ (8,918) |
| 35.2040 | 210 | 0% | 0 | 0.0 | 100% | 210 | 2.6 | $ - | $ (47,502) |
| 35.2041 | 240 | 100% | 240 | 0.1 | 1% | 2 | 0.1 | $ (1,044) | $ (9) |
| 35.2061 | 120 | 0% | 0 | 0.0 | 100% | 120 | 0.4 | $ - | $ (3,915) |
| 35.2075 (a) | 56 | 0% | 0 | 0.0 | 100% | 56 | 1.5 | $ - | $ (7,308) |
| 35.2075 (b) | 4 | 0% | 0 | 0.0 | 100% | 4 | 0.4 | $ - | $ (139) |
| 35.3045(c) | 2 | 0% | 0 | 0.0 | 100% | 2 | 0.5 | $ - | $ (87) |
| 35.3045(d) | 2 | 0% | 0 | 0.0 | 100% | 2 | 8.0 | $ - | $ (1,392) |
| 35.3045(e) | 2 | 0% | 0 | 0.0 | 100% | 2 | 2.0 | $ - | $ (348) |
| 35.3045(g) | 2 | 0% | 0 | 0.0 | 100% | 2 | 0.5 | $ - | $ (87) |
| 35.3047(c) | 0 | 0% | 0 | 0.0 | 0% | 0 | 0.0 | $ - | $ - |
| 35.3047(d) | 0 | 0% | 0 | 0.0 | 0% | 0 | 0.0 | $ - | $ - |
| 35.3047(e) | 0 | 0% | 0 | 0.0 | 0% | 0 | 0.0 | $ - | $ - |
| 35.3047(f) | 0 | 0% | 0 | 0.0 | 0% | 0 | 0.0 | $ - | $ - |
| 35.3067 | 0 | 0% | 0 | 0.0 | 0% | 0 | 0.0 | $ - | $ - |
| | | | | | | | **Total** | **$ (97,527)** | **$ (1,181,021)** |

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 35 (OMB Clearance No. 3150-0010).
Section descriptions on following page.

# 10 CFR Part 35
# Alternative 2 (continued)

| | |
|---|---|
| 35.6 | Licensee must receive review and approval for compliance with the requirements for the protection of human subjects. |
| 35.14 | Licensees must provide training and experience documentation after the licensee permits an individual to work as an authorized user (AU), as an authorized nuclear pharmacist (ANP), or as an authorized medical physicist (AMP). |
| 35.19 | Allows NRC to grant exemptions to take into account special circumstances. |
| 35.24 (a) | Licensee management must approve license submittals and radiation protection program changes. |
| 35.24 (b) | Licensee management must approve Radiation Safety Officer who accepts all responsibility of the post. |
| 35.24 (f) | Licensees, who work with two or more types of uses of byproduct material, must establish a Radiation Safety Committee. |
| 35.26 | Allows a licensee to make certain changes in their radiation safety program. |
| 35.27 | Licensees must instruct each supervised individual, who contacts byproduct material for medical use, in the radiation protection procedures. |
| 35.40 (a)(1) | Complete record documentation of the administration of byproduct material or radiation from byproduct material. |
| 35.40 (c)(1) | Permits a written revision to an existing written directive. |
| 35.41 | Licensees must develop, implement and maintain written procedures to verify human research subject's identity. |
| 35.2060 | Licensees must possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject; licensee must keep these records for three years. |
| 35.61 | Licensees must perform and retain calibration information of survey instruments. |
| 35.2063 | Licensees must determine and record the activity of each dosage before medical use, and retain records for three years. |
| 35.2067(a) | Licensees, in possession of any sealed source or brachytherapy source, must test the source for leakage, take inventory at certain intervals, and retain relevant leak test and inventory records. |
| 35.2067(b) | Licensees must retain records of the semi-annual physical inventory for three years. |
| 35.69(b) | Labeling requirements for each syringe and vial that contains unsealed byproduct material. |
| 35.2070 | Licensees must survey ambient radiation exposure rate each day for all areas where unsealed byproduct material was prepared for use or administered; records retention of these surveys is 3 years. |
| 35.80(a)(1) | Licensees that provide mobile service must obtain a letter signed by the management of each client to permit the use of byproduct material at the client's address. |
| 35.2080 (a) | Licensees that provide mobile medical services must to retain letter for three years. |
| 35.2080 (b) | Licensees must maintain a record of each survey (all areas of use before leaving a client's address) for three years. |
| 35.2092 | Licensees must retain records of the disposal of licensed materials for three years. |
| 35.2204 | Licensees must maintain records of molybdenum-99 concentration tests for three years. |
| 35.310 | Licensees must provide safety instruction to personnel caring for patients or human research subjects that have received therapy with unsealed byproduct material, and cannot be released. |
| 35.2310 | Licensees must maintain records of safety instruction training, in caring for patients and human research subjects, for three years. |
| 35.315(b) | Licensee must notify the Radiation Safety Officer and the authorized user as soon as possible if a patient or human research subject who cannot be released has a medical emergency or dies. |
| 35.315(a) | Licensee must post information indicating where and how long visitors may stay in the patient's room. |
| 35.2404 | Licensees must maintain a record of patient or human research subject surveys for three years. |
| 35.2406 | Licensees must maintain records of brachytherapy source accountability for three years. |
| 35.410 | Licensees must provide safety instruction to personnel caring for patients or human research subjects that are receiving brachytherapy and cannot be released. |
| 35.415(c) | Licensee must promptly notify the Radiation Safety Officer and the authorized user as soon as possible if a patient or human research subject who cannot be released has a medical emergency or dies. |
| 35.415(a)(1) | Licensee must post information indicating where and how long visitors may stay in the patient's room. |
| 35.2432 | Licensees must maintain a record of calibrations of brachytherapy sources for three years. |
| 35.2630 | Licensees must have a calibrated domisetry system available for use and calibrated at specified intervals; the records retention for each calibration, intercomparison, and comparison is for the duration of the license. |
| 35.2024 (a) | Licensees must retain a record of actions, taken by the licensee's management, for five years. |
| 35.2024 (b) | Licensees must retain Radiation Safety Officer documentation for the duration of the license. |
| 35.2026 | Licensees must retain a record of each radiation protection program change for five years. |
| 35.2040 | Licensees must retain a copy of each written directive for three years. |
| 35.2041 | Licensees must retain a copy of procedures for administrations requiring a written directive for the duration of the license. |
| 35.2061 | Licensees must calibrate the survey instruments used to show compliance with 10 CFR Part 20 before first use, annually, and following a repair affecting calibration; records retention is for three years. |
| 35.2075 (a) | Licensees must retain a record documenting the basis for releasing individuals, containing radiopharmaceuticals or implants, into situations where they could expose members of the general public. |
| 35.2075 (b) | Licensees must retain a record of the instructions provided to a breast-feeding female (if exposed to a radiation dose) showing necessary information was given for the protection of the infant or child. |
| 35.3045(c) | Licensees must notify NRC by telephone no later than the next calendar day after discovery of a medical event. |
| 35.3045(d) | Licensees must submit a written report within 15 days of the discovery of a medical event. |
| 35.3045(e) | Licensees must notify the referring physician and the individual who is the subject of the medical event no later than 24 hours after its discovery. |
| 35.3045(g) | Licensees must provide an annotated copy of the medical event report with identifying information no later than 15 days after the discovery of an event. |
| 35.3047(c) | Licensee must notify by telephone the NRC Operation Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child. |
| 35.3047(d) | Licensee must submit a written report to the appropriate NRC Regional Office no later than 15 days after the discovery of a dose to an embryo/fetus or nursing child. |
| 35.3047(e) | Licensee must notify the referring physician and also notify the pregnant individual or mother no later than 24 hours after discovery of an event. |
| 35.3047(f) | Licensee must provide an annotated copy of the report to NRC and the referring physician, no later than 15 days after the discovery of dose to an embryo/fetus or a nursing child. |
| 35.3067 | Licensees must report detection of a leaking source within 5 days after a leakage test reveals removable contamination. |

NRC Costs
Alternative 2

| NRC | Units | Staff time per | One Time | Annual |
|---|---|---|---|---|
| New licenses applications | 3985 | 40 hours | $ (13,867,800) | |
| New license amendments annually | 150 | 20 hours | | $ (261,000) |
| Inspections of licensee facilities | 50 / year | 24 hours | | $ (104,400) |
| | | | $ - | $ (365,400) |

| NRC | | 2005 | 2006 |
|---|---|---|---|
| Guidance | 300 hours | | $ (26,100) |
| New licenses applications | | | $ (13,867,800) |
| Total one-time implementation | | | $ (13,893,900) |

Waste and Decommissioning
Alternative 2

| Waste | | One-time | Annual |
|---|---|---|---|
| | | 0 | $ (28,200) |
| Number accelerators | 150 | | |
| Waste/yr/fac (tons) | 0.1 | | |
| Disposal cost/ton ($) | 22 | | |
| Transport cost/ton ($) | 40 | | |
| **Decommissioning** | | | |
| | | | $ (15,000) |

## APPENDIX B Input and Results for Alternative 3

This appendix provides details of the line-by-line input and results for Alternative 3, the Graded Approach. The following pages show input and results for 10 CFR Part 19, 20, 30, 31, 32, 35, NRC Costs, and Waste and Decommissioning.

## 10 CFR Part 19
## Alternative 3

| Section # | Total # Licensees | One Time | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 19.12 | 235 | 100% | 235 | 18 | 100% | 235 | 0.2 | $ (368,010) | $ (4,089) |
| 19.13(a) | 235 | 0% | 0 | 0 | 100% | 235 | 0.2 | $ - | $ (4,089) |
| 19.13(b) | 235 | 0% | 0 | 0 | 100% | 235 | 8.4 | $ - | $ (171,779) |
| 19.13(c) | 235 | 0% | 0 | 0 | 10% | 24 | 3.3 | $ - | $ (6,857) |
| 19.13(e) | 235 | 0% | 0 | 0 | 10% | 24 | 0.9 | $ - | $ (1,867) |
| | | | | | | | **Total** | **$ (368,010)** | **$ (188,681)** |

Notes: as of 8-Feb-2006:

Annual hours of labor per licensee reduced by 80 percent compared to OMB Final Supporting Statement for 10 CFR Part 19 (OMB Clearance No. 3150-0044)

19.12 Requires licensees to provide radiation exposure reports to workers
19.13(a) Notification and report to individuals
19.13(b) Advise workers annually of dose
19.13(c) At request of worker formerly engaged in activities at the facility, exposure report for each year.
19.13(e) At request of worker terminating employment at the facility, exposure report for year and current quarter.

## 10 CFR Part 20
## Alternative 3

| Section # | Total # Licensees | One Time | | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Capital Cost per Licensee | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 20.1101 * | 335 | 5% | 17 | $ (10,000) | 0 | 0% | 0 | 0 | $ (170,000) | $ - |
| 20.1406 | 335 | 100% | 335 | $ - | 20 | 0% | 0 | 0 | $ (582,900) | $ - |
| 20.1601(c) | 1 | 100% | 1 | $ - | 8 | 0% | 0 | 0 | $ (696) | $ - |
| 20.1906(d) | 1 | 100% | 1 | $ - | 1 | 0% | 0 | 0 | $ (87) | $ - |
| 20.1906(e) | 335 | 0% | 0 | $ - | 0 | 100% | 335 | 1 | $ - | $ (29,145) |
| 20.2102(a)&(b) | 335 | 100% | 335 | $ - | 20 | 100% | 335 | 4 | $ (582,900) | $ (116,580) |
| 20.2103(a)&(b) | 335 | 0% | 0 | $ - | 0 | 100% | 335 | 8 | $ - | $ (233,160) |
| 20.2107(a) | 25 | 0% | 0 | $ - | 0 | 100% | 25 | 5 | $ - | $ (10,875) |
| 20.2108(a) | 50 | 0% | 0 | $ - | 0 | 100% | 50 | 8 | $ - | $ (34,800) |
| 20.2201(a) | 1 | 0% | 0 | $ - | 0 | 100% | 1 | 3 | $ - | $ (261) |
| 20.2201(b) | 1 | 0% | 0 | $ - | 0 | 100% | 1 | 3 | $ - | $ (261) |
| 20.2201(d) | 1 | 0% | 0 | $ - | 0 | 100% | 1 | 3 | $ - | $ (261) |
| 20.2202(b) | 1 | 0% | 0 | $ - | 0 | 100% | 1 | 40 | $ - | $ (3,480) |
| 20.2203(a) | 1 | 0% | 0 | $ - | 0 | 100% | 1 | 6 | $ - | $ (522) |
| | | | | | | | | **Total** | **$ (1,336,583)** | **$ (429,345)** |

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is Draft OMB Supporting Statement for 10 CFR Part 20 (OMB Clearance No. 3150-0014)

* A $10,000 capital expense is assumed for each affected licensee to construct or renovate facilities.

20.1101 Requires licensees to develop, document and implement radiation protection programs, establish procedures, and perform program review.
20.1406 Requires applicants for licenses to describe how facility design and procedures for operation will minimize contamination of the facility and environment, facilitate eventual decommissioning, and minimize generation of radioactive waste.
20.1601(c) Allows licensees to apply to the Commission for approval of alternate methods for control of access to high radiation areas.
20.1906(e) Requires licensees to develop and maintain procedures regarding radioactive material shipment.
20.2102(a)&(b) (a) Requires licensees to maintain records of the radiation protection program, including ALARA; (b) requires licensees to retain records of radiation programs until the Commission terminates the license.
20.2103(a)&(b) (a) Requires licensees to maintain records showing the results of surveys and calibrations; (b) requires licensees to maintain records for 3 years, unless they form the basis of dose estimates in which case they must be maintained through license termination.
20.2107(a) Requires information on the identity and quality of the radionuclides released by licensee in effluents to unrestricted areas.
20.2108(a) Requires records of waste disposal to permit routine inspection for compliance, and inspection against constraints on the kinds and quantities of licensed material.
20.2201(a) Requires licensees to report any theft or loss of licensed material by telephone immediately or in writing within 30 days, dependent upon the potential risk to the health and safety of the public.
20.2201(b) Requires licensees to follow up telephone reports with written reports of the incident within 30 days of the telephone report.
20.2201(d) Requires additional information relevant to the loss of radioactive material, discovered after the written report, be submitted within 30 days of discovery.
20.2202(b) Requires that the licensee notify the NRC within 24 hours upon becoming aware of specific incidents involving licensed material.
20.2203(a) Contains the requirements for the content of the reports required by Paragraph 20.2203(a).

10 CFR Part 30
Alternative 3

| Section | Total # Licensees | One Time | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 30.9(b) | 1 | 0% | 0 | 0 | 100% | 1 | 1.0 | $ - | $ (87) |
| 30.32 | 335 | 100% | 335 | 7 | 5% | 16.75 | 1.0 | $ (204,015) | $ (1,457) |
| 30.32 (i) - EP | 3 | 100% | 3 | 10 | 0% | 0 | 10.0 | $ (2,610) | $ - |
| 30.32 (i) - Calculation | 5 | 100% | 5 | 1 | 0% | 0 | 0.0 | $ (435) | $ - |
| 30.32 (g) | 20 | 100% | 20 | 3 | 0% | 0 | 0.0 | $ (5,220) | $ - |
| 30.32 (j) | 15 | 100% | 15 | 42.5 | 0% | 0 | 0.0 | $ (55,463) | $ - |
| 30.34(e)(4) - Orders | 1 | 0% | 0 | 0 | 100% | 1 | 3.0 | $ - | $ (261) |
| 30.34(e)(4) - Sfguards | 5 | 0% | 0 | 0 | 100% | 5 | 0.5 | $ - | $ (218) |
| 30.34(h) | 1 | 0% | 0 | 0 | 1% | 2 | 0.5 | $ - | $ (87) |
| 30.34(j)(2)(i) | 15 | 0% | 0 | 2 | 100% | 15 | 390.0 | $ - | $ (508,950) |
| 30.34(j)(2)(ii) | 15 | 100% | 15 | 2 | 100% | 15 | 390.0 | $ (2,610) | $ (508,950) |
| 30.34(j)(4) | 15 | 0% | 0 | 0 | 20% | 3 | 0.5 | $ - | $ (131) |
| 30.35(a)&(b) - Certific | 5 | 100% | 5 | 100 | 100% | 5 | 10.0 | $ (43,500) | $ (4,350) |
| 30.35(a)&(b) - F Plan | 5 | 100% | 5 | 300 | 100% | 5 | 10.0 | $ (130,500) | $ (4,350) |
| 30.35(g) | 14 | 100% | 14 | 10 | 100% | 14 | 10.0 | $ (12,180) | $ (12,180) |
| 30.36(d) | 1 | 0% | 0 | 0 | 100% | 1 | 1.0 | $ - | $ (87) |
| 30.36(g) | 1 | 0% | 0 | 0 | 100% | 1 | 360.0 | $ - | $ (31,320) |
| 30.41(c)&(d) | 60 | 0% | 0 | 0 | 100% | 60 | 4.0 | $ - | $ (20,880) |
| 30.50(a),(b),&(c) | 2 | 0% | 0 | 0 | 100% | 2 | 4.0 | $ - | $ (696) |
| Appendix D | 25 | 100% | 25 | 1 | 50% | 13 | 1.0 | $ (2,175) | $ (1,131) |
| Appendix E | 20 | 100% | 20 | 1 | 50% | 10 | 1.0 | $ (1,740) | $ (870) |
| | | | | | | | **Total** | **$ (460,448)** | **$ (1,096,004)** |

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 30 (OMB Clearance No. 3150-0017).

| | |
|---|---|
| 30.9(b) | Requires applicant or licensee to notify the Commission of information which has significant implications for public health and safety or the common defense and security. |
| 30.32 | License application process for entities with gauges containing radium-226 products, accelerators and other NARM use. |
| 30.32(i) -EP | Requires applicants that will posses amounts of materials requiring an emergency plan to to provide the emergency plan. |
| 30.32(i) - Calc | Requires applicants with certain materials to calculate dose to the public to determine if an emergency plan is needed. |
| 30.32 (j) | License appliction process for authorization for production of PET drugs for non-commercial distribution to consortium members. |
| 30.34(e)(4) - Orders | The authority for Commission issuance of orders for the modification of licenses. |
| 30.34(e)(4) - Sfguards | Certain licensees are required to take compensatory actions against threats, requiring safeguards plans and other safeguard requirements. |
| 30.34(h) | Requires immediate notification to the appropriate NRC regional administrator, in writing, following the filing of bankruptcy petition. |
| 30.34(j)(2)(i) | Applicants must satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold radioactive drug to be transferred for commercial distribution. |
| 30.34(j)(2)(ii) | Requires licensee to have procedures for use of instrumentation used to measure radioactivity of radioactive drugs. |
| 30.34(j)(4) | Requires licensees, licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution, to provide certification information to NRC. |
| 30.35(a)&(b) - Certific | Specifies licensees required to submit a decommissioning funding plan or a certification of financial assurance for decommissioning. |
| 30.35(a)&(b) - F Plan | Specifies licensees required to submit a decommissioning funding plan or a certification of financial assurance for decommissioning. |
| 30.35(g) | Requires records retention, regarding decommissioning of the facility, until the license is terminated by the Commission. |
| 30.41(c)&(d) | Requires verification informaton, prior to transfer and receipt of byproduct material; and (d) specifies acceptable methods for verification. |
| 30.50(a),(b),&(c) | Notification of events or conditions that threaten the health and safety of individuals using or potentially exposed to licensed material. |
| Appendix D | Criteria for companies to pass the financial test when they furnish their own funds guarantee for decommissioning cost. |
| Appendix E | Criteria for nonprofit colleges, universities and hospitals to pass the financial test when they furnish their own funds guarantee for |

## 10 CFR Part 31
## Alternative 3

| Section # | Total # Licensees | One Time | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 31.5(c)(4) | 100 | 0% | 0 | 0.0 | 100% | 100 | 0.3 | $ - | $ (2,175) |
| 31.5(c)(8) | 5 | 0% | 0 | 0.0 | 100% | 5 | 0.6 | $ - | $ (261) |
| 31.5(c)(9) | 1 | 0% | 0 | 0.0 | 100% | 1 | 1.0 | $ - | $ (87) |
| 31.5(c)(11) | 100 | 0% | 0 | 0.0 | 100% | 100 | 0.3 | $ - | $ (2,958) |
| 31.5(c)(14) | 5 | 0% | 0 | 0.0 | 100% | 5 | 0.1 | $ - | $ (44) |
| 31.12 | 300 | 0% | 0 | 0.0 | 1% | 3 | 4.0 | $ - | $ (1,044) |
| | | | | | | | **Total** | **$ -** | **$ (6,569)** |

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 31 (OMB Clearance No. 3150-0016).

| | |
|---|---|
| 31.5(c)(4) | General licensee must maintain records showing that tests for leakage of radioactive materials, proper operation of on-off mechanism, and/or other specified tests have been performed. |
| 31.5(c)(8) | General licensees may transfer or dispose of devices containing byproduct material only by approved methods. |
| 31.5(c)(9) | General licensees wishing to transfer a devise to another general licensee may do so under certain conditions. |
| 31.5(c)(11) | General licensees must respond to written requests from NRC within certain time constraints. |
| 31.5(c)(14) | General licensees must notify NRC within 30 days of changes of address for the location of use of devices. |
| 31.12 | New section of regulations specifying general license conditions for products containing Radium-226. |

## 10 CFR Part 32
## Alternative 3

| Section | Total # Licensees | One Time | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 32.72(a)(4) | 22 | 0% | 0 | 0 | 100% | 22 | 390 | $ - | $ (746,460) |
| 32.72(b)(5) | 22 | 0% | 0 | 0 | 100% | 22 | 0.5 | $ - | $ (957) |
| 32.72(c) | 22 | 100% | 22 | 2 | 100% | 22 | 390 | $ (3,828) | $ (746,460) |
| 32.74(a)(2)(viii) | 3 | 0% | 0 | 0 | 100% | 3 | 2.8 | $ - | $ (731) |
| | | | | | | | **Total** | **$ (3,828)** | **$ (1,494,608)** |

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 32 (OMB Clearance No. 3150-0001).

| | |
|---|---|
| 32.72(a)(4) | Applicants must satisfy labeling requirements for each transport radiation shield and each syringe, vial, or other container used to hold radioactive drug to be transferred for commercial distribution. |
| 32.72(b)(5) | Requires licensees, licensed as a pharmacy by a State Board of Pharmacy or are operating as a nuclear pharmacy within a Federal medical institution, to provide information on authorized nuclear pharmacist status to NRC. |
| 32.72(c) | Requires licensee to have procedures for use of instrumentation used to measure radioactivity of radioactive drugs. |
| 32.74(a)(2)(viii) | Requires labeling instructions for handling and storing radioactive sources or devices, from the radiation safety standpoint. |

10 CFR Part 35
Alternative 3

| Section | Total # Licensees | One Time | | | Annual | | | Total One Time Cost | Total Annual Cost |
|---|---|---|---|---|---|---|---|---|---|
| | | % licensees affected | # of Licensees | Hours of labor per Licensee | % licensees affected | # of Licensees | Hours of labor per Licensee | | |
| 35.6 | 40 | 100% | 40 | 4.0 | 25% | 10 | 4.0 | $ (13,920) | $ (3,480) |
| 35.14 | 180 | 100% | 180 | 0.5 | 15% | 28 | 0.5 | $ (7,830) | $ (1,218) |
| 35.19 | 1 | 0% | 0 | 1.0 | 100% | 1 | 1.0 | $ - | $ (87) |
| 35.24 (a) | 370 | 100% | 370 | 0.5 | 2% | 6 | 2.5 | $ (16,095) | $ (1,305) |
| 35.24 (b) | 60 | 100% | 60 | 0.5 | 10% | 6 | 0.5 | $ (2,610) | $ (261) |
| 35.24 (f) | 20 | 100% | 20 | 0.5 | 0% | 0 | 0.0 | $ (870) | $ - |
| 35.26 | 370 | 100% | 370 | 0.5 | 2% | 6 | 0.5 | $ (16,095) | $ (261) |
| 35.27 | 115 | 100% | 115 | 1.0 | 1% | 1 | 1.0 | $ (10,005) | $ (87) |
| 35.40 (a) | 200 | 0% | 0 | 0.0 | 100% | 200 | 13.0 | $ - | $ (226,200) |
| 35.40 (a)(1) | 20 | 0% | 0 | 0.0 | 100% | 20 | 0.7 | $ - | $ (1,218) |
| 35.40 (c)(1) | 100 | 0% | 0 | 0.0 | 100% | 100 | 1.0 | $ - | $ (8,700) |
| 35.41 | 200 | 100% | 200 | 0.5 | 1% | 2 | 0.5 | $ (8,700) | $ (87) |
| 35.2060 | 25 | 0% | 0 | 0.0 | 100% | 25 | 5.1 | $ - | $ (11,093) |
| 35.61 | 60 | 0% | 0 | 0.0 | 100% | 60 | 3.0 | $ - | $ (15,660) |
| 35.2063 | 80 | 0% | 0 | 0.0 | 100% | 80 | 42.5 | $ - | $ (295,939) |
| 35.2067(a) | 88 | 0% | 0 | 0.0 | 100% | 88 | 0.2 | $ - | $ (1,378) |
| 35.2067(b) | 88 | 0% | 0 | 0.0 | 100% | 88 | 0.1 | $ - | $ (919) |
| 35.2070 | 28 | 0% | 0 | 0.0 | 100% | 28 | 1.1 | $ - | $ (2,680) |
| 35.80(a)(1) | 2 | 0% | 0 | 0.0 | 100% | 2 | 20.0 | $ - | $ (3,480) |
| 35.2080 (a) | 2 | 0% | 0 | 0.0 | 100% | 2 | 0.6 | $ - | $ (104) |
| 35.2080 (b) | 2 | 0% | 0 | 0.0 | 100% | 2 | 26.0 | $ - | $ (4,524) |
| 35.2092 | 60 | 0% | 0 | 0.0 | 100% | 60 | 1.0 | $ - | $ (5,429) |
| 35.2204 | 9 | 0% | 0 | 0.0 | 100% | 9 | 20.8 | $ - | $ (16,286) |
| 35.310 | 35 | 0% | 0 | 0.0 | 100% | 35 | 1.0 | $ - | $ (3,045) |
| 35.2310 | 29 | 0% | 0 | 0.0 | 100% | 29 | 0.1 | $ - | $ (252) |
| 35.315(b) | 1 | 0% | 0 | 0.0 | 100% | 1 | 1.0 | $ - | $ (87) |
| 35.315(a) | 35 | 0% | 0 | 0.0 | 100% | 35 | 1.8 | $ - | $ (5,481) |
| 35.2404 | 100 | 0% | 0 | 0.0 | 100% | 100 | 1.2 | $ - | $ (10,614) |
| 35.2406 | 100 | 0% | 0 | 0.0 | 100% | 100 | 3.0 | $ - | $ (26,100) |
| 35.410 | 20 | 0% | 0 | 0.0 | 100% | 20 | 1.0 | $ - | $ (1,740) |
| 35.415(c) | 4 | 0% | 0 | 0.0 | 100% | 4 | 1.0 | $ - | $ (348) |
| 35.415(a)(1) | 14 | 0% | 0 | 0.0 | 100% | 14 | 0.5 | $ - | $ (609) |
| 35.2432 | 20 | 0% | 0 | 0.0 | 100% | 20 | 3.0 | $ - | $ (5,220) |
| 35.2024 (a) | 370 | 0% | 0 | 0.0 | 100% | 370 | 1.3 | $ - | $ (40,238) |
| 35.2024 (b) | 60 | 0% | 0 | 0.0 | 100% | 60 | 0.1 | $ - | $ (522) |
| 35.2026 | 370 | 0% | 0 | 0.0 | 100% | 370 | 0.3 | $ - | $ (8,048) |
| 35.2040 | 200 | 0% | 0 | 0.0 | 100% | 200 | 2.6 | $ - | $ (45,240) |
| 35.2041 | 200 | 100% | 200 | 0.1 | 1% | 2 | 0.1 | $ (870) | $ (9) |
| 35.2061 | 60 | 0% | 0 | 0.0 | 100% | 60 | 0.4 | $ - | $ (1,958) |
| 35.2075 (a) | 28 | 0% | 0 | 0.0 | 100% | 28 | 1.5 | $ - | $ (3,654) |
| 35.2075 (b) | 2 | 0% | 0 | 0.0 | 100% | 2 | 0.4 | $ - | $ (70) |
| 35.3045(c) | 2 | 0% | 0 | 0.0 | 100% | 2 | 0.5 | $ - | $ (87) |
| 35.3045(d) | 2 | 0% | 0 | 0.0 | 100% | 2 | 8.0 | $ - | $ (1,392) |
| 35.3045(e) | 2 | 0% | 0 | 0.0 | 100% | 2 | 2.0 | $ - | $ (348) |
| 35.3045(g) | 2 | 0% | 0 | 0.0 | 100% | 2 | 0.5 | $ - | $ (87) |
| 35.3047(c) | 0 | 0% | 0 | 0.0 | 0% | 0 | 0.0 | $ - | $ - |
| 35.3047(d) | 0 | 0% | 0 | 0.0 | 0% | 0 | 0.0 | $ - | $ - |
| 35.3047(e) | 0 | 0% | 0 | 0.0 | 0% | 0 | 0.0 | $ - | $ - |
| 35.3047(f) | 0 | 0% | 0 | 0.0 | 0% | 0 | 0.0 | $ - | $ - |
| 35.3067 | 0 | 0% | 0 | 0.0 | 0% | 0 | 0.0 | $ - | $ - |
| | | | | | | | **Total** | **$ (76,995)** | **$ (755,543)** |

Notes: as of 8-Feb-2006:

Source of hours of labor per licensee is OMB Final Supporting Statement for 10 CFR Part 35 (OMB Clearance No. 3150-0010).
Section descriptions on following page.

## 10 CFR Part 35
## Alternative 3 (continued)

| | |
|---|---|
| 35.6 | Licensee must receive review and approval for compliance with the requirements for the protection of human subjects. |
| 35.14 | Licensees must provide training and experience documentation after the licensee permits an individual to work as an authorized user (AU), as an authorized nuclear pharmacist (ANP), or as an authorized medical physicist (AMP). |
| 35.19 | Allows NRC to grant exemptions to take into account special circumstances. |
| 35.24 (a) | Licensee management must approve license submittals and radiation protection program changes. |
| 35.24 (b) | Licensee management must approve Radiation Safety Officer who accepts all responsibility of the post. |
| 35.24 (f) | Licensees, who work with two or more types of uses of byproduct material, must establish a Radiation Safety Committee. |
| 35.26 | Allows a licensee to make certain changes in their radiation safety program. |
| 35.27 | Licensees must instruct each supervised individual, who contacts byproduct material for medical use, in the radiation protection procedures. |
| 35.40 (a)(1) | Complete record documentation of the administration of byproduct material or radiation from byproduct material. |
| 35.40 (c)(1) | Permits a written revision to an existing written directive. |
| 35.41 | Licensees must develop, implement and maintain written procedures to verify human research subject's identity. |
| 35.2060 | Licensees must possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject; licensee must keep these records for three years. |
| 35.61 | Licensees must perform and retain calibration information of survey instruments. |
| 35.2063 | Licensees must determine and record the activity of each dosage before medical use, and retain records for three years. |
| 35.2067(a) | Licensees, in possession of any sealed source or brachytherapy source, must test the source for leakage, take inventory at certain intervals, and retain relevant leak test and inventory records. |
| 35.2067(b) | Licensees must retain records of the semi-annual physical inventory for three years. |
| 35.69(b) | Labeling requirements for each syringe and vial that contains unsealed byproduct material. |
| 35.2070 | Licensees must survey ambient radiation exposure rate each day for all areas where unsealed byproduct material was prepared for use or administered; records retention of these surveys is 3 years. |
| 35.80(a)(1) | Licensees that provide mobile service must obtain a letter signed by the management of each client to permit the use of byproduct material at the client's address. |
| 35.2080 (a) | Licensees that provide mobile medical services must to retain letter for three years. |
| 35.2080 (b) | Licensees must maintain a record of each survey (all areas of use before leaving a client's address) for three years. |
| 35.2092 | Licensees must retain records of the disposal of licensed materials for three years. |
| 35.2204 | Licensees must maintain records of molybdenum-99 concentration tests for three years. |
| 35.310 | Licensees must provide safety instruction to personnel caring for patients or human research subjects that have received therapy with unsealed byproduct material, and cannot be released. |
| 35.2310 | Licensees must maintain records of safety instruction training, in caring for patients and human research subjects, for three years. |
| 35.315(b) | Licensee must notify the Radiation Safety Officer and the authorized user as soon as possible if a patient or human research subject who cannot be released has a medical emergency or dies. |
| 35.315(a) | Licensee must post information indicating where and how long visitors may stay in the patient's room. |
| 35.2404 | Licensees must maintain a record of patient or human research subject surveys for three years. |
| 35.2406 | Licensees must maintain records of brachytherapy source accountability for three years. |
| 35.410 | Licensees must provide safety instruction to personnel caring for patients or human research subjects that are receiving brachytherapy and cannot be released. |
| 35.415(c) | Licensee must promptly notify the Radiation Safety Officer and the authorized user as soon as possible if a patient or human research subject who cannot be released has a medical emergency or dies. |
| 35.415(a)(1) | Licensee must post information indicating where and how long visitors may stay in the patient's room. |
| 35.2432 | Licensees must maintain a record of calibrations of brachytherapy sources for three years. |
| 35.2630 | Licensees must have a calibrated domisetry system available for use and calibrated at specified intervals; the records retention for each calibration, intercomparison, and comparison is for the duration of the license. |
| 35.2024 (a) | Licensees must retain a record of actions, taken by the licensee's management, for five years. |
| 35.2024 (b) | Licensees must retain Radiation Safety Officer documentation for the duration of the license. |
| 35.2026 | Licensees must retain a record of each radiation protection program change for five years. |
| 35.2040 | Licensees must retain a copy of each written directive for three years. |
| 35.2041 | Licensees must retain a copy of procedures for administrations requiring a written directive for the duration of the license. |
| 35.2061 | Licensees must calibrate the survey instruments used to show compliance with 10 CFR Part 20 before first use, annually, and following a repair affecting calibration; records retention is for three years. |
| 35.2075 (a) | Licensees must retain a record documenting the basis for releasing individuals, containing radiopharmaceuticals or implants, into situations where they could expose members of the general public. |
| 35.2075 (b) | Licensees must retain a record of the instructions provided to a breast-feeding female (if exposed to a radiation dose) showing necessary information was given for the protection of the infant or child. |
| 35.3045(c) | Licensees must notify NRC by telephone no later than the next calendar day after discovery of a medical event. |
| 35.3045(d) | Licensees must submit a written report within 15 days of the discovery of a medical event. |
| 35.3045(e) | Licensees must notify the referring physician and the individual who is the subject of the medical event no later than 24 hours after its discovery. |
| 35.3045(g) | Licensees must provide an annotated copy of the medical event report with identifying information no later than 15 days after the discovery of an event. |
| 35.3047(c) | Licensee must notify by telephone the NRC Operation Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child. |
| 35.3047(d) | Licensee must submit a written report to the appropriate NRC Regional Office no later than 15 days after the discovery of a dose to an embryo/fetus or nursing child. |
| 35.3047(e) | Licensee must notify the referring physician and also notify the pregnant individual or mother no later than 24 hours after discovery of an event. |
| 35.3047(f) | Licensee must provide an annotated copy of the report to NRC and the referring physician, no later than 15 days after the discovery of dose to an embryo/fetus or a nursing child. |
| 35.3067 | Licensees must report detection of a leaking source within 5 days after a leakage test reveals removable contamination. |

RC Costs
Alternative 3

| NRC | Units | Staff time per | One Time | Annual |
|---|---|---|---|---|
| New licenses applications | 335 | 40 hours | $ (1,165,800) | |
| New license amendments annually | 75 | 20 hours | | $ (130,500) |
| Inspections of licensee facilities | 25 / year | 24 hours | | $ (52,200) |
| | | | $ - | $ (182,700) |

| NRC | | 2005 | 2006 |
|---|---|---|---|
| Guidance | 300 hours | | $ (26,100) |
| New licenses applications | | | $ (1,165,800) |
| Total one-time implementation | | | $ (1,191,900) |

Waste and Decommissioning
Alternative 3

| Waste | | One-time | Annual |
|---|---|---|---|
| | | 0 | $ (19,900) |
| Number accelerators | 45 | | |
| Waste/yr/fac (tons) | 0.25 | | |
| Disposal cost/ton ($) | 22 | | |
| Transport cost/ton ($) | 40 | | |
| **Decommissioning** | | | |
| | | | $ (10,000) |

## APPENDIX C

## References


1. Proposed Rule: Requirements for Expanded Definition of Byproduct Material (RIN: 3150-AH84).
2. "The First Nuclear Industry," *Scientific American*, v247, November 1982, pages 180-193.
3. Environmental Assessment for Final Rulemaking - Expanded Definition of Byproduct Material Established by Section 651(e) of the Energy Policy Act of 2005.
4. Nuclear Regulatory Commission (U.S.), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Revision 4, September 2004.
5. Nuclear Regulatory Commission (U.S.), "Regulatory Analysis Technical Evaluation Handbook, Final Report," NUREG/BR-0184, January 1997.
6. Nuclear Regulatory Commission (U.S.), "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems," NUREG/CR-6642, Volume 1, January 2000.
7. Nuclear Regulatory Commission (U.S.), "Generic Cost Estimates," NUREG/CR-4627, Revision 1 & 2, January 1992.
8. Nuclear Regulatory Commission (U.S.), "Economic Risk of Contamination Cleanup Costs Resulting from Large Nonreactor Nuclear Material Licensee Operations," NUREG/CR-5381, March 1990.
9. Nuclear Regulatory Commission (U.S.), "Radiological Assessments for Clearance of Materials from Nuclear Facilities," NUREG-1640, Volume 2, October 2004.