Rulemaking Plan
10 CFR Parts 30, 31, and 32

EXEMPTIONS FROM LICENSING AND DISTRIBUTION OF BYPRODUCT MATERIAL; LICENSING AND REPORTING REQUIREMENTS

REGULATORY ISSUES

The staff has been conducting a systematic reevaluation of the exemptions from licensing in Parts 30 and 40 of NRC's regulations (in Title 10 of the Code of Federal Regulations), which govern the use of byproduct and source materials. This reevaluation has been conducted, in part, because (1) the 1965 Consumer Product Policy Statement (published March 16, 1965; 30 FR 3462) (the policy) calls for monitoring the amounts of radioactive materials being distributed for use by the general public and reconsidering the policy if there is any indication that materials in products reaching the public are resulting in a significant fraction of the permissible dose; and (2) the dose methodology, based on the International Commission on Radiological Protection (ICRP) Publication 26 recommendations, adopted in revised Part 20 (56 FR 23360; May 21, 1991) could significantly change the doses previously estimated to result from the use of certain radioactive materials under exemptions from licensing. Another key point in the policy is that, generally, a product is acceptable for use by the general public if it is unlikely to result in doses exceeding a small fraction of limits recommended for exposure to radiation from all sources, and the probability of individual doses approaching any of the limits is negligibly small. At the time the policy was written, there was a limit for doses to the general public of 500 mrem/year (5 mSv/year) recommended by various groups, such as the ICRP. The revised Part 20 established a public dose limit of 100 mrem/year (1 mSv/year)(§ 20.1301).

A major part of the effort has been an assessment of potential and likely doses to workers and public under these exemptions. The assessment of doses associated with most of these exemptions can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Material," June 2001. For some exemptions, the difference between potential (possible under the conditions of the exemption) and likely doses is significant because the actual usage of the exemption is limited or non-existent, or quantities used in products are significantly lower than allowed under the exemption. NUREG-1717 also includes dose assessments for certain devices currently used under a general or specific license that had been identified as candidates for use under exemption (in SECY-90-175; Staff Requirements - October 3, 1989, following a Briefing on Study of Adequacy of Regulatory Oversight of Materials under a General License; May 14, 1990). In addition, the staff has reviewed the existing regulations governing the distribution of byproduct and source material to exempt persons and to general licensees (primarily in Part 32). The conclusions of these evaluations with respect to the regulation of source material will be addressed in a separate rulemaking for which a rule plan is before the Commission: SECY-01-0072, Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22 General License, April 25, 2001.

Note: in the remainder of this document, the terms “exempt product” and “exempt materials” are used as a convenience, even though according to the regulations, products or materials are not exempt from licensing requirements. An exemption from licensing requirements applies to “persons” to the extent that they receive, possess, use, transfer, etc. certain products or materials.

One conclusion of the staff’s review was that current reporting requirements imposed on distributors of exempt products and materials do not result in submission of sufficient, timely, and informative reports for the staff to determine what products and how much source material and byproduct material are distributed annually for exempt use. This issue was discussed (with respect to byproduct material) along with a few other specific issues concerning making the regulations more flexible, user-friendly, and performance-based in SECY-97-291, Revising Rules on Generally Licensed and Exempt Products and the Manufacturers/Distributors of These Products (10 CFR Parts 30, 31, and 32), December 15, 1997. The issues identified in that paper were considered in the development of this rulemaking plan.

The limitations of the information on the products/materials and quantities distributed for use under exemption impacted greatly the effort involved in developing the dose assessments in NUREG-1717 and contributed to the remaining uncertainties in the results. In the case of material transfer reports for byproduct material, annual reports were required prior to 1983. Since that time, reports have been required every five years and when filing an application for renewal or termination of a license. The breakdown of the information by year is not required. Experience shows that there have been more implementation problems under the current scheme than with annual reporting. For example, because of the long interval between reports, licensees frequently forget about the requirement, sometimes resulting in the need for a deficiency letter to be sent in order for an application for renewal or termination of license to be processed. Routine annual reporting, rather than consolidating and reporting 5 years of distribution information, is expected to be a minimal burden and more efficient, for both the NRC and the licensees, particularly given the current state of information technology.

The systematic reevaluation of exemptions identified only four exemptions involving byproduct material as having the potential for allowing doses to the public exceeding a small fraction of 100 mrem/year (1 mSv/year) under routine conditions (a few mrem/year). These exemptions include: (1) resins containing scandium-46 for sand consolidation in oil wells (§ 30.16), (2) exempt concentrations (§ 30.14), (3) ionizing radiation measuring instruments (§ 30.15(a)(9)), and (4) exempt quantities of byproduct material (§ 30.18). The staff considers the exemption for the resins to be obsolete and proposes to eliminate such obsolete provisions. (Only preliminary dose estimates were made for this exemption. These were not refined nor included in NUREG-1717, because of the fact that the exemption was no longer being used.) The evaluations for the exemptions for ionizing radiation measuring instruments and for exempt concentrations indicated the potential for doses that are inappropriate for exemption, possibly even exceeding the annual public dose limit of 100 mrem/year (1 mSv/year) under routine conditions. However, based on current trends in distribution for use under the exemptions, actual doses do not appear to be approaching 100 mrem/year (1 mSv/year). Only in the case of the exemption for small quantities of byproduct material is there a potential for actual doses greater than intended for some radionuclides, possibly approaching or exceeding 100 mrem/year (1 mSv/year) under routine use conditions. Because it is difficult to assess the actual number of exempt quantities likely to be used by any one individual, or the worst case

conditions under which exposure occurs, the actual doses to users under this exemption are highly uncertain. An additional issue related to this exemption (§ 30.18) concerns gauge manufacturers' distribution of gauging devices without sources, with instructions to the customer to obtain multiple exempt sources to place into the source holder, resulting in a gauge without regulatory control. This issue was discussed in SECY-98-261, Policy Concerning Bundling of Exempt Sources, November 5, 1998.

For the various licensed devices suggested for possible use under exemption and included in the dose evaluations of NUREG-1717, some of the devices would clearly result in doses so low that use under license would be considered an unnecessary regulatory burden and an unnecessary expenditure of user and NRC administrative resources. However, it is not clear that each type of device would necessarily qualify for exemption for all of the radionuclides and quantities considered. A new class exemption, covering a broad range of industrial products, could relieve these burdens, while maintaining health and safety. A class exemption covers a class or category of product (e.g., self-luminous products) rather than a specific product and uses safety criteria, rather than specific radionuclide quantity limits, to protect health and safety.

The regulatory requirements related to the distribution of byproduct material in products used by persons exempt from licensing generally appear to be overly burdensome given the small risk associated with some of these products. These requirements include applicant submission and NRC review and approval of prototype testing and quality control procedures. Additionally, certain requirements for distribution of both generally licensed and exempt products appear to be unnecessarily prescriptive, in some cases requiring the use of very specific procedures. This rulemaking plan includes proposals to reduce these burdens, as appropriate, while continuing to maintain public health and safety.

Additionally, there are a number of areas where the regulations are not clear, consistent with other provisions, or explicit. This leads to inefficiencies in the regulatory process and can lower public confidence. One example is the difficulty in interpreting the regulations in Part 30 containing exemptions (discussed in the next section) with respect to the responsibilities of specific licensees who possess exempt materials or products, in particular, exempt quantities of byproduct material (§ 30.18).

EXISTING REGULATORY FRAMEWORK

Part 30 sets out the basic requirements for licensing of byproduct material and includes a number of exemptions from licensing requirements. The exemptions are in §§ 30.14, 30.15, 30.16, 30.18, 30.19, 30.20, and 30.21. The two exemptions in §§ 30.19 and 30.20, self-luminous products and gas and aerosol detectors, respectively, are class exemptions, which cover a broad class of products. Under these provisions, new products can be approved for use through the licensing process, if the applicant demonstrates that the specific product meets certain safety criteria. This is in contrast to the other exemptions for which the level of safety is controlled through such limits as specification of radionuclides and quantities. Sections 30.14 and 30.18, exempt concentrations and exempt quantities, are broad materials exemptions, which allow the use of a large number of radionuclides. The specific radionuclide limits on the quantities and concentrations are contained in tables in §§ 30.71 and 30.70, respectively. The remainder of the exemptions from licensing are product specific, for which many assumptions can and have been made concerning how the product is distributed, used, and disposed.

Part 31 provides general licenses for the use of certain items containing byproduct material and the requirements associated with these general licenses.

Part 32 sets out requirements for the manufacture or initial transfer (distribution) of items containing byproduct material to persons exempt from licensing requirements and to persons using a general license. The requirements for distributors address such measures as: prototype testing, labeling, quality control, and, in some cases, specific sampling procedures. The requirements for distribution to general licensees include material transfer reports on a quarterly or annual basis. The requirements for distribution to exempt persons include material transfer reports on a five-year interval, and when applying for renewal or termination of a license.

RULEMAKING OPTIONS

This plan identifies a number of specific regulatory issues, many of which are interrelated. These issues are categorized into three options for rulemaking (in addition to an option to maintain the status quo), which can be correlated, in part, with the NMSS performance goals. Option 1 focuses primarily on rulemaking to achieve the performance goal of maintaining safety. Option 2 would add to Option 1 by also including issues addressing the performance goals of reducing unnecessary regulatory burden and increasing efficiency, effectiveness, and realism. Option 3 would add other issues for which further effort would be necessary to determine the merits of implementation and may require additional technical basis development. Option 4 would maintain the status quo.

The options for rulemaking considered in this plan are intended to represent general approaches as to how the staff would make improvements to the basic regulatory framework governing the use of byproduct material. If the Commission approves this rulemaking plan, it would be expected that, during the rulemaking process, the development of supporting documents and comments from stakeholders could present additional information or considerations that may impact the staff's recommendations concerning some of the individual issues, or may identify additional issues. The identification and categorization of issues involved application of the risk-informed regulation screening considerations (discussed in SECY-01-0218, Update of the Risk-Informed Regulation Implementation Plan, December 5, 2001). The first four of these considerations are related to the NMSS performance goals. The primary relevant performance goals that the resolution of an issue would meet is indicated for each issue. The fifth and sixth considerations relate to the availability of appropriate information on which to base risk-informed regulation, the costs of startup and implementation, and whether a net benefit is expected. These considerations were important in categorizing the issues amongst the options. In particular, the resolution of issues included in Option 2 are projected, based on available information, to result in a net benefit. Option 3 identifies issues for which sufficient information is not currently available to make this determination. Thus, addressing those issues would create a delay in the rulemaking. With respect to the seventh consideration, the staff is not aware of factors, such as legislative, judicial, or adverse stakeholder reaction which would preclude making any of the potential changes identified under the various options; however, relaxing any regulation in the area of releases from regulatory control has potential for adverse impacts on public confidence. Consideration has also been given to whether a particular issue can be addressed through approaches other than rulemaking.

OPTION 1: Address only those issues important to maintaining safety. These are issues for which a net benefit from addressing in rulemaking is clearly expected and for which there are sufficient underlying bases to support the proposed changes. These issues are also ones that clearly require rulemaking to address, and which cannot appropriately be addressed through changes in licensing or inspection practice. Proposed issues under this option include:

1. Revise requirements in Part 32 for reporting material transfers from every five years and when applying for renewal or termination of license to annual. This is important to the NRC's ability to carry out its policy to monitor the amounts of radioactive materials being distributed for use by the general public and evaluate the net impact to the public of the various exemptions. In addition to this rule change, the staff would create a database to better use the information supplied by licensees on the amounts being distributed. This would also enable the NRC to inform the public on products distributed and the resulting doses. [§§ 32.12, 32.16, 32.20, 32.25(c), and 32.29(c)] [MS, PC, EER][1]

2. Revise § 30.18 to reflect NRC's position to preclude combining two or more exempt quantities, thereby preventing the basic safety properties relied on in the issuance of the exemption from being circumvented. [Previously identified in the Rulemaking Activity Plan as RM #526.] Also, the risks associated with some of the specific quantities of radionuclides (in § 30.71) that present a significant external dose, may exceed acceptable levels given that there is no limit on the total quantity that can be used under the exemption. Revise some quantities or other conditions of the exemption to reduce risk level. [MS]

3. Revise § 32.11 to require distributors of exempt concentrations (§§ 30.14 and 30.70) to demonstrate products/materials meet safety criteria (similar to those for class exemptions: §§ 32.23, 32.24, 32.27, and 32.28). [MS]

4. Eliminate, or restrict to previously distributed products, exemptions that have never been or are no longer being used. [§§ 30.15(a)(2)-(6) and (10), 30.16] One of these (§ 30.16) could allow significant doses if used. Also, delete extraneous associated distributor requirements. [§§ 32.17, and 32.40] This would simplify the regulations and eliminate the need to consider potential doses to the public from these products in any future evaluation of the net impact to the public from exempt products. [MS, EER]

Advantages

- Safety concerns arising from the dose assessments made in NUREG-1717 would be resolved.
- The NRC would have more complete and up-to-date data for evaluating impacts to the public and persons using byproduct material under exemptions from licensing, which would form a better basis for any future changes to Parts 30 and 32 in this area.

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[1] MS - Maintain safety, protection of the environment, and the common defense and security
RUB - Reduce unnecessary regulatory burden on stakeholders
EER - Make the NRC activities and decisions more effective, efficient, and realistic
PC - Increase public confidence

- The NRC would also be better able to inform the public on products distributed and the resulting doses, thus improving public confidence.
- Rulemaking would involve fewer resources than required for Options 2 or 3.

Disadvantages

- There would be some increase in necessary licensee burden.
- If the exempt quantities provision is modified to preclude combining of sources, but a new class exemption for devices is not added, some products would be required to be used under a general or specific license. This may result in an increase in unnecessary regulatory burdens to users.
- Resolution of many other issues related to Parts 30 and 32 (e.g., clarifications of regulations, NUREG-1717 data, etc.) would not be addressed.
- Increase in public confidence would likely be less than that resulting under Options 2 or 3.

OPTION 2: In addition to addressing the issues in Option 1, also include resolution of a number of issues related primarily to the performance goals of reducing unnecessary regulatory burden and increasing regulatory efficiency, effectiveness, and realism. These are issues identified for which a net benefit from addressing in rulemaking is clearly expected and for which there are sufficient underlying bases to support the proposed changes. Most of these issues would require rulemaking to resolve, and cannot appropriately be addressed through changes in licensing or inspection practice. Issues for which resolution in rulemaking would not clearly result in a net benefit would not be addressed through rulemaking at this time.

Based on cost/benefit information developed to date and staff judgment, the additional issues to address under this option in rulemaking are:

1. Most exemptions from licensing in Part 30 also exempt users from Part 20. (The inclusion of such an exemption only concerns specific licensees possessing exempt products.) However, §§ 30.14, 30.18, or 30.21 do not include an exemption from Part 20. Thus, specific licensees are told to dispose of exempt quantities (§ 30.18) as if they were licensed material. Identify those products or materials, if any, that should have some controls when used by specific licensees and clarify licensees' responsibilities in the regulations. [EER]

2. Section 32.210 provides only for voluntary registration for specifically licensed products, yet registration of many specifically and generally licensed and exempt products is required as a matter of licensing practice and fees are assessed based on whether or not a "sealed source and/or device review" is required. Although there are regulatory provisions that form the basis of this process, which products the registration process is to be used for are indicated in guidance only. Make registration requirement explicit in the regulations, so that it is easier for potential applicants to determine the applicable requirements and associated fees. [PC, EER]

3. Broaden the class exemption for gas and aerosol detectors (§ 30.20), to include other potential applications. For example, drug detectors were rejected for distribution under

this exemption because they were not "designed to protect life or property from fires and airborne hazards." [EER, RUB]

4. Reduce the quantities of radionuclides allowed in electron tubes (§ 30.15(a)(8)) to be closer to the much lower quantities actually used, based on the as low as reasonably achievable (ALARA) principle. The additional assurance of extremely low doses may also help to justify removing some requirements on distributors, such as prototype testing or using approved quality control procedures. [MS, RUB]

5. Make the NRC exempt distribution license cover possession for importers so that there is no need for separate possession and use licenses, particularly if no on-site testing is required. For manufacturers, explore the possibility of an option for NRC licensing possession and use in Agreement States, in addition to distribution, at the discretion of the individual State. [EER, RUB]

6. In the class exemptions for self-luminous products and gas and aerosol detectors, the safety criteria in §§ 32.24 and 32.28 are stated in terms of whole body and organ doses in lieu of total effective dose equivalent (TEDE) which is used in Part 20; for consistency, revise §§ 32.24 and 32.28 and related sections to state the criteria in terms of TEDE. [EER, PC]

7. Some generally licensed devices contain quantities of radionuclides meeting the criterion in § 20.2201(a) for immediate notification if lost or stolen. There is an inconsistency in the risk basis of allowing a device to be generally licensed when the loss or theft of which would justify immediate notification. If the risk does not justify immediate vs. 30-day notification, exempt some or all § 31.5 (and § 31.7) general licensees from § 20.2201(a)(i), leaving only a 30-day notification requirement. [RUB. EER]

8. Establish a new class exemption for the types of industrial products covered by the general license in § 31.5 that contain relatively low quantities of radionuclides, e. g., gauges using small beta sources. This includes two products for which case studies were conducted. (Plans for the case studies were published November 7, 2000; 65 FR 66782.) These studies on static eliminators using Po-210 and certain gas chromatographs generally support such an exemption. The class exemption would have associated safety criteria (with lower dose limits than those for § 31.5) and could allow for the use under exemption of a broad range of products with the safety decision for individual products made through the licensing process. [RUB, EER]

9. For residential smoke detectors, add a product-specific exemption to simplify licensing, from that currently used in connection with the class exemption for gas and aerosol detectors (§ 30.20), based on extensive licensing experience with product. [RUB, EER]

10. In keeping with the move to less prescriptive, more performance-based regulations, remove from the regulations, any prescriptive requirements applicable to exempt and general license distributors for prototype testing, sampling procedures, and quality control (QC) procedures and provide examples of acceptable practices in guidance.

[§§ 32.14(d)(2), 32.15(a)(2) and (3), 32.40, 32.53(d)(4), 32.55(b)-(d), 32.57(d)(2), 32.59, 32.62(a)-(e), 32.101, 32.102, 32.103, 32.110] [RUB, EER]

11. Make the Part 32 requirements for QC and sampling procedures for exempt products more risk-informed by eliminating some of the individual requirements. [§§ 32.14(b)(5), 32.25(a), 32.26(b)(15)] [RUB, EER]

12. Make the Part 32 requirements for prototype tests for exempt products more risk-informed by eliminating some of the individual requirements. [§§ 32.14(b)(4), 32.22(a)(2), 32.26(b)(11) and (12)] [RUB, EER]

Advantages

- Safety concerns arising from the dose assessments made in NUREG-1717 would be resolved, as in Option 1.
- Significant improvements in efficiency and effectiveness would be made.
- Unnecessary regulatory burden on distributors and some users of byproduct material would be reduced.
- The NRC would have more complete and up-to-date data for evaluating impacts to the public and persons using byproduct material under exemptions from licensing, which would form a better basis for any future changes to Parts 30 and 32 in this area.
- The NRC would also be better able to inform the public on products distributed and the resulting doses, thus improving public confidence.
- Licensees' responsibilities with respect to exempt products and materials would be clarified.
- Requirements would be clarified for applicants for exempt and general license distribution licenses with respect to product registration and fees.

Disadvantages

- There would be some increase in necessary licensee burden.
- Comparing Option 2 to Option 3, Part 30 exemptions for exempt concentrations and exempt quantities of byproduct material would continue to be inconsistent with the current Part 20, as well as the latest dose calculation methodologies, because they were based on methodologies on which previous versions of Part 20 were based.
- Resolution of some issues related to Parts 30 and 32 (identified below) would not be achieved.
- Rulemaking would involve somewhat greater resources than Option 1.

OPTION 3: Address all issues identified. Issues to be considered in addition to those discussed in Options 1 and 2 are:

1. Consider revising Part 32 to explicitly require distributors to demonstrate ALARA in design of exempt products; in practice, such a demonstration is not included when applying the broad ALARA provisions of Part 20. [MS]

2. Add a specific provision in the regulations in Parts 30 and/or 32 to define when a distributor of items containing byproduct material may make changes to the product without prior NRC approval (broadly similar to §§ 50.59 and 72.48). [RUB, EER]

3. For exempt concentrations (§ 30.14), revise § 32.11 to specify information to be submitted by an applicant when seeking an exemption from the criterion of "not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being." Set out the NRC's criteria for granting the requested exemption. [EER]

4. Update the tables in § 30.70, exempt concentrations, and § 30.71, exempt quantities, to present a more consistent level of risk and to reflect the dose calculation methodology contained in the latest recommendations of the ICRP. [EER, PC]

5. Provide a more consistent basis in the regulations for licensing decisions concerning the acceptability to NRC of consumer products for which minimal societal benefit is envisioned or specifically in interpreting the restriction against products for "frivolous purposes" in § 30.19. [MS, PC, EER]

6. Increase controls on the import and sale of products that are exempt from regulatory control in other countries, but not in the U.S. [MS, PC]

As the staff is not recommending this option, the following discusses the primary considerations for not including each of these issues in the recommended option for rulemaking.

With respect to Issue 1 of Option 3, although it is appropriate to apply the ALARA process to the design of products for which the user is exempt from licensing requirements, most products being distributed have been manufactured for many years. During that time, the industry has made technological improvements in products and their manufacture that have reduced doses. Therefore, further reduction in doses for most products may be difficult. Although such improvements are to be encouraged, the staff believes that the burden of requiring demonstration of ALARA in the licensing process for all of these products may not be justified. It should, however, be clarified in guidance and/or inspection procedures that the specific licensee's ALARA program should include consideration of new developments in technology as they may impact ALARA in the design of products.

With respect to Issue 2 of Option 3, based on the history of the recent revision to § 50.59 and the broad range of products and facilities involved in the use of byproduct material, it may be a resource intensive effort to develop an appropriate provision(s) for Parts 30 and/or 32. Eliminating unnecessary impediments to a licensee making changes that do not adversely affect safety has been addressed in licensing practice since this issue was identified and can continue to be addressed as appropriate in this way. Also, another deterrent to licensees proposing changes that was in place at the time this issue was identified in SECY-97-291, fees for amendment of licenses, has been removed because of changes made to the fee structure.

On Issue 3 of Option 3, such information with respect to gemstones specifically is contained in guidance. The other known possible reason for such an exemption concerns an airport explosive detector system that had been developed in the 1980's but is not currently licensed by

the NRC. It involves neutron irradiation of cargo and baggage and its use would result in very low levels of activation products in any foods, cosmetics, jewelry, and clothing transported in baggage. Additional guidance could be developed, if needed.

There are multiple issues related to the exempt quantities and the exempt concentration provisions and a number of approaches that may be taken to address these issues. Until these are explored in more detail (in resolving Issues 2 and 3 listed under Option 1), it is difficult to determine whether there would be a net benefit from a complete revision of the tables in §§ 30.70 and 30.71 to reflect a more consistent level of risk, based on the latest dosimetric methodologies (Issue 4 of Option 3). Doing so would leave these tables of nuclides inconsistent with Part 20. A relatively small number of the radionuclides in the tables are actually distributed for use. The most significant difference in risk relates to the approach taken in establishing the values based on internal vs. external risk. In addition, the Commission recently approved not moving forward with revising regulations based on current ICRP recommendations at this time. (SRM dated April 12, 2002, on SECY-01-0148, Processes for Revision of 10 CFR Part 20 Regarding Adoption of ICRP Recommendations on Occupational Dose Limits and Dosimetric Models and Parameters, August 2, 2001)

Issue 5 of Option 3 presents a difficult challenge given the subjective nature of the judgments underlying such decisions. To the extent that greater consistency may be achieved in these decisions, it is expected that this should be addressed in policy or guidance rather than through changes to the regulations. The NRC's policy to exclude the use of radioactive material in "frivolous" products comes from the basic radiation protection principle of "justification of practice," as well as the desire to minimize the number of widely distributed products, so as to better ensure that public doses are appropriately limited given exposure to multiple sources. It is primarily differences in such judgments that lead to inconsistency in the products approved for use by the general public in various countries, resulting in the problem identified in Issue 6 of Option 3. It is difficult to completely control the import of unapproved products, although the number of such products obtained by the public is much lower than is the case for approved products. The staff has not identified any regulatory change that would address this difficulty.

Advantages

- Safety concerns based on the dose assessments made in NUREG-1717 would be resolved.
- Significant improvements in efficiency and effectiveness would be made.
- Unnecessary regulatory burden on distributors and some users of byproduct material would be reduced.
- The NRC would have more complete and up-to-date data for evaluating impacts to the public and persons using byproduct material under exemptions from licensing, which would form a better basis for any future changes to Parts 30 and 32 in this area.
- The NRC would also be better able to inform the public on products distributed and the resulting doses, thus improving public confidence.
- Licensees' responsibilities with respect to exempt products and materials would be clarified.
- Requirements would be clarified for applicants for exempt and general license distribution licenses with respect to product registration and fees.

Disadvantages

- There would be some increase in necessary licensee burden.
- The greatest resource expenditure would be required in rulemaking process, because additional technical basis development and cost/benefit analyses are needed.
- Some of the resulting changes may not provide a clear net benefit.
- Some aspects would be contrary to recent Commission direction.

OPTION 4: Maintain the status quo.

This option would leave the provisions of Parts 30, 31, and 32 as they are.

Advantages

- No resources would be required to conduct rulemaking.

Disadvantages

- Safety concerns based on the dose assessments made in NUREG-1717 would not be resolved.
- The information available on byproduct material distributed to the public would not be improved.
- Unnecessary burdens on users and licensees would not be reduced.
- The efficiency and effectiveness of current processes would not be improved.
- Public confidence could be negatively affected by not making regulatory changes based on NUREG-1717 and not conducting rulemaking to address some issues for which plans for resolution were already included in publicly available documents.
- There would continue to be inconsistencies and difficulties of interpretation in the regulations.

RECOMMENDED APPROACH

OPTION 2:

Implementation of Option 2 is expected to improve the regulatory program in a number of ways. It would result in: greater assurance that doses from the use of exempt materials and products containing byproduct material do not exceed a fraction of 100 mrem/year (1 mSv/year); more risk-informed, performance-based regulation of the distribution and use of byproduct material; and reduction of unnecessary regulatory burden associated with specific licensing. Further, knowledge of the types and amounts of byproduct material distributed for use under exemptions from licensing would be improved, which would provide a better basis for future rulemaking in the area of exemptions and allow the NRC to better inform the public about the products being distributed, thus improving public confidence.

The staff recommends Option 2 over Option 1 because it would include addressing a number of problems of regulatory interpretation that lead to confusion and inefficiency in the licensing process and a number of possible revisions which could reduce unnecessary regulatory burden without affecting health and safety. The staff believes that the additional items in Option 2

would not result in the expenditure of major additional staff resources and that the resultant net benefits are worth the additional effort.

The staff recommends Option 2 over Option 3 primarily because it would likely result in a better cost/benefit balance, limiting the resources that will be needed to complete the rulemaking action. Option 3 would provide no clear additional advantages over Option 2. The staff does not have readily available information to specifically identify the impacts of the potential additional regulatory changes that would be included under Option 3. Option 2 would allow the staff to proceed to resolve the more important regulatory issues without significant delay. Additional information needs would be more limited than under Option 3. Those information needs for carrying out Option 2 relate primarily to the risk-informed decisionmaking involved in the individual decisions concerning the need to review prototype tests, and QC and sampling procedures for each product (Issues 11 and 12 listed under Option 2).

THE OFFICE OF THE GENERAL COUNSEL (OGC) LEGAL ANALYSIS

The Office of the General Counsel (OGC) has reviewed the NRC staff's plan for a rulemaking to amend 10 CFR Parts 30, 31, and 32. The purpose of the rulemaking would be to revise Parts 30, 31, and 32 relating to the exemptions from licensing in Part 30 and the requirements for exempt distribution in Part 32. The intent of the rulemaking would also be to make the regulations more flexible, user-friendly, and performance-based for requirements for distributors of generally licensed devices as discussed in SECY-97-291, "Revising Rules on Generally Licensed and Exempt Products and the Manufacturers/Distributors of These Products (10 CFR Parts 30, 31, and 32," December 15, 1997). The staff has developed options, ranging from Option 4, which maintains the status quo, to Option 3, which would address all the issues identified in Options 1 and 2 and six others. The staff recommends Option 2 which, described above, should address the issues identified for which a net benefit is clearly expected and for which there are sufficient underlying bases to support the proposed changes. These issues relate primarily to the performance goals of maintaining safety, reducing unnecessary regulatory burden, and increasing efficiency, effectiveness, and realism.

Because there are no categorical exclusions in 10 CFR 51.22(c) that are applicable to this overall action, the development of a proposed rule would require the preparation of an environmental assessment (EA) to determine if there would be any significant impacts to the public health and safety or the environment. In addition, a proposed rule would require a regulatory analysis to examine the costs and benefits of the options considered by the NRC staff; and pursuant to the Regulatory Flexibility Act, whether the rule, if adopted, would have a significant impact on a substantial number of small entities.

The rulemaking plan adequately describes implementation issues associated with the Agreement States.

Because a proposed rule would revise information collection requirements in Part 32, the NRC staff must prepare an Office of Management and Budget (OMB) package. In addition, as required by the Small Business Regulatory Enforcement Fairness Act, the NRC staff will confirm with OMB before issuing a final rule that this action does not constitute a "major rule."

We do not believe a proposed rule would require a backfit analysis, because this action does not constitute a backfit pursuant to the regulations in 10 CFR Parts 50, 72, and 76.

In conclusion, OGC has determined that at this time, there are no known bases for legal objection to proceeding with Option 2 as proposed in this rulemaking plan.

BACKFIT CONSIDERATIONS

None of the affected licensees are subject to the backfit requirements of §§ 50.109, 72.62. or 76.76.

AGREEMENT STATE IMPLEMENTATION ISSUES

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the NRC on June 30, 1997, and published in the *Federal Register* on September 3, 1997 (62 FR 46517), distribution of products to exempt persons is classified as compatibility Category "NRC." The applicable requirements in Part 32, with the exception of §§ 32.11 and 32.12 (requirements for distributors of exempt concentrations), and 32.17 (requirements for distributors of Sc-46 resins), are compatibility Category NRC. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act or provisions of Title 10 of the Code of Federal Regulations, Chapter I. The exemptions from licensing in Part 30 and the requirements in Part 32 pertaining to distribution of byproduct material to general licensees are compatibility Category B, as is §§ 31.10 and 32.17. Category B means the provisions affect a program element with significant direct transboundary implications. The State program element should be essentially identical to that of NRC. Section 32.11, except for paragraph (c), and § 32.12 are compatibility Category C. Category C means that the provisions affect a program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications, or gaps in the national program.

The revised requirements for distributors of byproduct material to exempt persons would continue to be Category NRC. Changes to the exemptions from licensing and to the requirements for distribution to general licensees would be Category B. Consideration will be given to changing the provisions: §§ 32.11, 32.12, and 32.17 to Category NRC (however, § 32.17 would likely be deleted).

No significant problems are anticipated that could affect Agreement State implementation of the contemplated rulemaking options.

SUPPORTING DOCUMENTS

This rulemaking would require a regulatory analysis to demonstrate a benefit to the public by providing a greater assurance of health and safety, reducing unnecessary burden on licensees, increasing efficiency, effectiveness, and realism, and increasing public confidence. The information provided in the Regulatory Analysis for each change concerning the impact on small entities would be sufficient to support a Regulatory Flexibility Analysis or a certification that the proposed rule would not have a significant economic impact on a substantial number of small entities. A backfit analysis is not needed. An Office of Management and Budget (OMB)

clearance package would be needed because the rulemaking would revise recordkeeping and reporting requirements. An environmental assessment would be necessary to demonstrate that there are no significant impacts to the environment and public health and safety.

Consideration should be given to revising NUREG-1556, Vol. 8, “Consolidated Guidance About Materials Licenses; Program-Specific Guidance About Exempt Distribution Licenses,” NUREG-1556, Vol. 16, “Consolidated Guidance About Materials Licenses; Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses,” NUREG-1556, Vol. 3, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration,” and NUREG-1550, “Standard Review Plan for Applications for Sealed Source and Device Evaluations.” These are currently planned to be reviewed and revised on a three-year cycle, and this rulemaking would be considered in determining the schedule and priority of these revisions.

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the staff believes that this action is not a "major rule."

VOLUNTARY CONSENSUS STANDARDS

In accordance with the National Technology Transfer and Advancement Act of 1995, voluntary consensus standards are to be used, if appropriate. This rulemaking would not constitute the establishment of a standard that contains generally applicable requirements. There are no technical standards of consensus bodies that would be applicable to this rulemaking. However, to the extent that any exist in such limited areas as quality control procedures applicable to specific industries affected, they are and will continue to be considered.

RESOURCES

The resource estimate to complete this rulemaking under Option 2 is approximately:

	FTE	Contract Support
Proposed rule	2.2	$125k
Final rule	1.2	$50k

A number of the issues identified under Option 2 have the potential for reducing annual operating costs, in addition to reducing unnecessary regulatory burden to licensees. Resources for Option 1 are estimated to be about 2 full-time equivalents (FTEs) and $125,000 for contract support spread across 2 fiscal years. Resources for Option 3 are estimated to be about 6.5 FTEs and $250,000 for contract support spread across 3 fiscal years. Finally, Option 4 would result in the expenditure of no resources toward rulemaking.

LEAD OFFICE STAFF AND STAFF FROM SUPPORTING OFFICES

Staff Level Working Group	Concurring Official
Lead Office	
NMSS/IMNS/RGB - Catherine R. Mattsen Gary Comfort Betty Ann Torres	Martin J. Virgilio
NMSS/IMNS/MSIB - Susan Greene /Anthony Kirkwood	
NMSS/RTG - Jim Smith	
NMSS/RGN IV - Jack Whitten	
Supporting Offices	
OGC - Marjorie Rothschild /Susan Chidakel	Stuart Treby
STP - Steve Salomon	Paul Lohaus
OE - Sally Merchant	Frank Congel
RES - Sheryl Burrows	Ashok Thadani

PUBLIC PARTICIPATION

There is no need for enhanced public participation for this rulemaking at this time. This rulemaking plan and any subsequently published proposed rule would be placed in the NRC's rulemaking website. This website allows users to submit comments electronically as well as to review comments submitted by others. Should public interest increase in the future regarding this rulemaking, the staff will consider the need to provide enhanced public participation by holding public meetings in locales determined at that time to provide the greatest efficiency in allowing public participation. If this were done, the schedule for completion would need to be extended.

EDO OR COMMISSION ISSUANCE

This rulemaking would be issued by the Commission.

SCHEDULE

Establish expanded working group (Add Agreement States, CFO, ADM, OCIO)	1 month after approval of rulemaking plan
Proposed rule to EDO	18 months after approval of rulemaking plan
OMB clearance package submitted to OMB	no later than the date the proposed rule is forwarded to the Federal Register for publication
Public Comment Period	90 days because of the complexity of the issues
Final rule to EDO	9 months following expiration of public comment period