RULEMAKING ISSUE
NOTATION VOTE

November 1, 2002 SECY-02–0196

FOR: The Commissioners

FROM: William D. Travers, Executive Director for Operations

SUBJECT: RECOMMENDATIONS STEMMING FROM THE SYSTEMATIC ASSESSMENT OF EXEMPTIONS FROM LICENSING IN 10 CFR PARTS 30 AND 40; AND A RULEMAKING PLAN FOR RISK-INFORMING 10 CFR PARTS 30, 31, AND 32

PURPOSES:

To inform the Commission of the recommendations for regulatory changes to 10 CFR Parts 30, 31, and 32 stemming from the systematic assessment of the exemptions.

To obtain Commission approval of a rulemaking plan for making 10 CFR Parts 30, 31, and 32 less prescriptive and more risk-informed.

To obtain Commission approval of a recommended policy position concerning labeling of products and/or point-of-sale packaging.

SUMMARY:

This paper provides the staff's recommendations for potential regulatory changes as a result of the systematic assessment of the exemptions from licensing for both byproduct and source material and provides a rulemaking plan for Commission consideration. The rulemaking plan focuses on issues related to the exemptions from licensing for byproduct material and provides options intended to make 10 CFR Parts 30, 31, and 32 less prescriptive and more risk-informed. The staff recommends an option that considers all issues identified by the staff for which a net benefit is projected. This paper also includes discussion supplemental to

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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, related to exemptions from licensing for source material in Part 40.

BACKGROUND:

Parts 30 and 40 provide for a set of exemptions for certain products and materials. In staff requirements memoranda (SRM’s) dated October 13, 1989, and July 28, 1990, the Commission directed the staff to develop plans for systematically assessing existing NRC exemptions of radioactive material from regulatory control. The importance of this reevaluation of exemptions relates to the following:

(1) The 1965 Consumer Product Policy Statement (published March 16, 1965; 30 FR 3462) (Attachment 1) 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 may result in a significant fraction of the permissible dose; a complete reevaluation by the Commission of the doses from consumer products was last done in the late 1970's;

(2) Most exemptions were written when the recommended dose limit for members of the public was 500 mrem/year (5 mSv/year) and without full consideration of the as low as reasonably achievable (ALARA) concept; and

(3) The major revision of 10 CFR Part 20 published May 21, 1991 (56 FR 23360), established a new public dose limit of 100 mrem/year (1 mSv/year) from licensed activities. The dose calculation methodology used to develop the current version of Part 20 significantly impacts some of the doses previously estimated to result from the use of radioactive materials under exemptions from licensing.

The staff presented overall plans for the systematic assessment of exemptions and initial recommendations in SECY-90-345, “Staff Action Plan for Implementation of Below Regulatory Concern Policy,” dated October 4, 1990. In accordance with the plans presented in that paper, the staff initiated a reassessment of the individual and collective doses associated with the exemptions from licensing in Parts 30 and 40, and an evaluation of certain generally licensed devices as possible candidates for exemption. The final report on the dose assessments (NUREG-1717, “Systematic Radiological Assessment of Exemptions for Source and Byproduct Material”) was published in June 2001. The plans in SECY-90-345 also included conducting cost/benefit analyses and developing recommendations for regulatory improvements in the area of exemptions. A list of the exemptions from licensing for byproduct and source material and their effective dates is provided in Attachment 2.

In addition, in an SRM dated March 7, 1997, the Commission directed the staff to consider the need to make 10 CFR Parts 30, 31, and 32 more “flexible and user friendly.” In response to that SRM, the staff presented discussions of possible approaches to regulatory improvements 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. That paper indicated that the staff planned to consider those issues in conjunction with making recommendations for rulemaking based on the results of ongoing risk assessments, in

particular, the systematic assessment of exemptions. Thus, the issues identified in that paper have also been considered in the development of the subject rulemaking plan.

A copy of this draft rulemaking plan was provided to Agreement States on February 15, 2002, for a 45-day period of review and comment. The comment period closed on April 1, 2002. Comments were received from six States.

DISCUSSION:

Although presenting very low risks of significant individual doses to members of the general public, exempt products[1] are a source of routine exposure to the public. A substantial portion of the population uses and enjoys benefits from exempt products, such as smoke detectors, but, at the same time, receives some radiation exposure from those products. Regulatory improvements in this area may have a significant impact on reducing cumulative exposures to the public.

NUREG-1717 presents an assessment of the potential individual and collective doses with the exemptions from licensing in Parts 30 and 40. The dose assessments were, in general, based on reasonable assumptions concerning the doses possible under the conditions of the exemption. In some cases, the maximum allowable amounts of radionuclides in products or materials, as specified in the applicable regulations, provide the basis for the estimate. In many cases, however, the actual amounts of radionuclides present in the products or materials are known to be considerably less than the maximum allowable amounts, and the difference between the individual doses for the maximum allowable and actual amounts is noted. In many cases, there is some information about the doses possibly allowed by the regulations, as well as the doses likely to be actually resulting from the materials/products currently being distributed.

The results of the individual dose assessments in NUREG-1717 vary considerably in uncertainty and in conservatism. Assessments need to be more conservative when there is a lack of information concerning the scenarios under which people are exposed. Generally, the assessments for source material are the most uncertain, because there is no regulatory requirement in place through which the Commission obtains information on the specifics of the products or materials or on the quantity distributed. In a few cases, fairly complete information was obtained from industry representatives; these are, of course, estimates of distribution only at one point in time. Product exemptions are based on evaluations of products for which the use is foreseen and scenarios in the life cycle are generally known; exemptions for materials are more difficult to analyze, as all potential uses of a material cannot be foreseen. In evaluating the results of the dose assessments, the staff has considered the assumptions used in the development of each dose assessment, the degree of conservatism, and the likelihood of the various scenarios.

[1]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.

The dose methodology reflected in the revised Part 20, and used in NUREG-1717, presents a significant change in calculated internal doses for some radionuclides. Of the radionuclides commonly distributed for use under exemptions for byproduct and source material, the most significant increase in estimated doses is for inhalation of thorium. However, the International Committee on Radiation Protection (ICRP) recommendations on dose calculation methodology have continued to change. The Commission has allowed the use of more recent ICRP methodology on a case-by-case basis. The dose methodology used in NUREG-1717 overestimates doses from what would more realistically be estimated under newer dose calculation methodology for inhalation of thorium. The staff has considered the impact of newer dose calculation methodologies on a few key dose estimates in NUREG-1717 in developing the recommendations in this paper.

As part of any rulemaking, the modeling and assumptions in NUREG-1717 will be specifically reviewed. Sensitivity of dose calculations to the exposure assumptions and internal dosimetry models will be identified as appropriate. In cases where decisions might be based on collective dose involving the exposure of very large populations to very low doses, staff recommendations will note cautions on the use of collective dose by national and international scientific organizations. Commission policy guidance will be sought.

The doses likely to result from exempt products depend not only on constraints within the exemption itself, such as radionuclide quantity limits, but also on requirements placed on the distributor, such as following approved quality control procedures or providing information to the user on safe use of a product. Thus, the staff has included in its review, the existing regulations governing the distribution of these products and materials to exempt persons. Attachments 3 and 4 tabulate and summarize both the existing provisions of the exemptions and the associated requirements for distribution to exempt persons. There are two aspects to the staff's evaluations: the adequacy or appropriateness of the exemptions and whether the level of control, as established by requirements placed on the manufacturer or distributor, is commensurate with the level of associated risk for each exemption.

Attachment 5 presents the basis of the staff's evaluation of the adequacy and appropriateness of the exemptions from licensing. This aspect of the evaluation relates to the performance goal of maintaining safety and is based primarily on a key point in the 1965 Consumer Product Policy (the Policy) that, generally, a product is acceptable for use by the general public if it is unlikely to result in doses exceeding a small fraction (a few hundredths) of limits recommended for exposure to radiation from all sources, and the probability of individual doses approaching any of the limits is negligibly small. The basic radiation protection principles of justification of practice[2] and ALARA were also considered. Attachment 5 discusses considerations concerning acceptable doses for those occupationally exposed at unlicensed facilities, which are not addressed by the Policy. Although the staff recognizes some limitations in the guidance provided by the Policy, the staff believes that there is a clear regulatory basis for making appropriate changes to the regulations.

It should be noted that the Policy and the additional considerations discussed in Attachment 5 are not intended to be applicable to establishing criteria for controlling release of solid

[2]Justification of practice concerns whether the expected benefits to society from a practice exceed the overall societal cost.

materials from a licensed use.[3] The basic framework for radiation protection would apply in either case; however, there are somewhat different aspects to be considered for decisions on exemptions from licensing. In most cases, the exemptions from licensing are based on evaluations of products for which the ultimate use is foreseen. Dose assessments and cost/benefit considerations are based on such assumptions. In most of these products/materials, the radioactive material serves a purpose in the product. In the case of exempt concentrations, there are unavoidable trace amounts of radioactive material present as a result of the production process.

In evaluating the existing regulations governing the distribution of products and materials to exempt persons and whether the level of control, as established by requirements placed on the manufacturer or distributor, is commensurate with the level of associated risk for each exemption, the staff is considering not only maintaining safety, but also the other NRC performance goals of increasing public confidence; making activities and decisions more effective, efficient, and realistic; and reducing unnecessary regulatory burden.

After identifying issues for consideration, the staff applied 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 concern whether each of the NRC performance goals will be advanced. Resolution of each of the issues would advance one or more of the performance goals. The fifth and sixth screening 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 used in developing the recommendations as to whether the individual issues should be addressed in rulemaking. The seventh screening consideration relates to other factors, such as legislative, judicial, or adverse stakeholder reaction. The staff is not aware of factors which would preclude making any of the potential changes identified; however, relaxing any regulation in the area of releases from regulatory control has potential for adverse impacts on public confidence. The staff has also considered whether a particular issue can be addressed through approaches other than rulemaking.

Based on current information, it is not expected that the issues discussed in this paper would increase security concerns related to the possible terrorist use of a radiological dispersion device. However, the staff will consider any conclusions developed with respect to that issue, when developing the two planned rulemakings (i.e., the subject rulemaking for Parts 30, 31, and 32, and the Part 40 rulemaking effort).

Cost/benefit information is under development for 11 of the individual exemptions, as well as for five broader issues related to exemptions and, in some cases, generally licensed products. The cost/benefit information provides preliminary support for the recommendations in this paper. The cost/benefit information will be refined and incorporated into the Regulatory Analyses for the two planned rulemakings. Attachment 6 presents a detailed discussion of the

[3]In a separate effort, the NRC is considering whether to develop criteria for controlling release of solid materials (SECY-02-0133, "Control of Solid Materials: Options and Recommendations for Proceeding," dated July 15, 2002). Such an effort would deal with disposition of materials previously used at a licensed facility that no longer serve a purpose and that have very low, or no, radioactivity.

issues identified for consideration in these rulemakings and potential approaches to resolution. Included for Commission information is discussion of a few issues that the staff identified for consideration during the reevaluation of exemptions, but for which resolution through rulemaking is not recommended at this time, as they do not pass screening considerations 5 and/or 6.

Conclusions Concerning Adequacy and Appropriateness of Exemptions

For the most part, actual doses likely to be occurring are not unacceptable for exempt products/materials; however, the regulations do not in all cases contain adequate constraints to ensure that doses to members of the public do not exceed a small fraction of the public dose limit or that occupational doses are unlikely to exceed 100 mrem/year (1 mSv/year) routinely. Exemptions were selected as candidates for revision, in part, based on the goal of maintaining safety and the dose assessments in NUREG-1717. In some cases where the dose estimates are uncertain and are also important to the particular decisionmaking, the staff would seek more complete information to support rulemaking in order to reduce uncertainties in the estimates. The projected revisions are intended to improve this assurance and to reduce unnecessary doses based on the radiation protection principles of justification of practice and ALARA. Revisions to byproduct material exemptions important to maintaining safety would be included under any of the options for rulemaking considered in the subject rulemaking plan.

The Jurisdictional Working Group established as a result of SECY-99-259, “Exemption in 10 CFR Part 40 for Materials less than 0.05 Percent Source Material - Options and Other Issues Concerning the Control of Source Material,” November 1, 1999, is considering broad jurisdictional issues related to the exemption in § 40.13(a), as well as exemptions in § 40.13(b) for unrefined and unprocessed ore and in § 40.13(c)(1)(vi) for rare earth metals and compounds, mixtures, and products. As a result, these three exemptions are not addressed in this paper.

In response to the March 9, 2000, SRM on SECY-99-259, the staff submitted a rulemaking plan for Part 40 to the Commission in SECY-01-0072. The recommendations in that rulemaking plan included: (1) establishing requirements for distribution of source material to exempt persons; and (2) revising some of the existing exemptions based on the results of NUREG-1717. Source material exemptions identified as candidates for revision based on the goal of maintaining safety are discussed in Section C of Attachment 6. These types of details were not included in the rulemaking plan in SECY-01-0072, as the final dose assessments in NUREG-1717 were not yet available. These are, however, issues that the staff expects to include, if the Commission directs the staff to go forward with the Part 40 rulemaking.

General Conclusions Concerning the Level of Control on Distribution

The level of control of byproduct material in products used by persons exempt from licensing is generally greater than is necessary, given the small risk associated with these products. Some requirements for distribution of exempt products, as well as those for generally licensed devices, are more prescriptive than necessary (See detail in the subject rulemaking plan Attachment 7). The staff recommends that these regulations be made less prescriptive and that certain distributor requirements be further evaluated on the basis of risks associated with the individual exemptions and adjusted accordingly. Also, a new class exemption for industrial devices would relieve the users of the reporting, recordkeeping, testing, and disposal

requirements associated with the use of the devices under license. For this exemption, the potential exposures of the public would be controlled by establishing safety criteria in the regulations similar to those for other class exemptions. Such an exemption allows for the use under exemption of a broad range of products with the safety decision for individual products made through the licensing process. The Phase II report (August 2001) of the Byproduct Material Review suggested that it may not be an effective use of resources to engage in rulemaking to revise the status of devices between specific licensing, general licensing, and exempt status. However, the staff believes that by using a single class exemption, rather than a number of new product-specific exemptions (Issue B. 6. in Attachment 6), and combining the effort with other recommended regulatory changes in one rulemaking, these changes can be made more efficiently. Thus, adding the single class exemption would be cost-beneficial.

As discussed in the rulemaking plan in SECY-01-0072, the staff believes the level of control for distribution of source material warrants improvement and plans to do so as part of that rulemaking effort.

RULEMAKING PLAN FOR PARTS 30, 31, AND 32:

Based on its evaluation, the staff has developed a rulemaking plan concerning the regulation of byproduct material. The rulemaking plan categorizes the various issues identified by the staff into three options for rulemaking (in addition to an option to maintain the status quo), which can be correlated, in part, with the NRC performance goals. The staff's identification and categorization of issues also involved application of the risk-informed regulation screening considerations (discussed in SECY-01-0218).

The options identified in the plan are intended to represent general approaches as to how the basic regulatory framework governing the use of byproduct material could be improved. If the Commission approves the rulemaking plan, the staff expects that the development of supporting documents and comments from stakeholders could present additional information or considerations that may lead the staff to develop a draft rule that varies somewhat from the specifics presented in the rulemaking plan.

The four options are summarized as follows:

OPTION 1: Address only those issues important to maintaining safety. These are issues for which a net benefit from 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.

OPTION 2: In addition to addressing the issues in Option 1, also include resolution of 12 more issues related primarily to the performance goals of reducing unnecessary regulatory burden and increasing regulatory efficiency, effectiveness, and realism. A net benefit is also clearly expected from addressing these issues in rulemaking. There are sufficient underlying bases to support these additional changes. Resolution of most of these issues would require rulemaking, and could not appropriately be attained through changes in licensing or inspection practice. The specific issues identified for inclusion in this option pass the screening considerations for risk-informing regulatory activities based on currently available information on costs and benefits.

OPTION 3: Address in rulemaking all issues identified. This option would also include addressing some issues for which resolution in rulemaking does not appear to be practical or may not result in a net benefit (i.e., they failed screening considerations numbers 5 and/or 6).

OPTION 4: Maintain the status quo; leave the provisions of Parts 30, 31, and 32 as they are. Option 2 in the rulemaking plan is recommended. This option is to address all the issues identified for which a net benefit is clearly expected and for which there are sufficient underlying bases to support the proposed changes.

An Option 2 rulemaking would, among other things: (1) return the period of material transfer reporting to an annual basis; (2) revise the exempt quantities and exempt concentrations provisions; (3) eliminate obsolete exemptions; (4) establish two new exemptions; (5) make the requirements for distributors less prescriptive, more performance-based, and more risk-informed; and (6) address some areas where the regulations are not explicit or clear.

Implementation of Option 2 is expected to improve the regulatory program in a number of ways. Option 2 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). In addition, 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: (1) provide clarification for areas of the regulations subject to misinterpretation, which lead to confusion and inefficiency in the licensing process; and (2) 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 over Option 1 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.

Agreement State Comments on Draft Rulemaking Plan:

The States of Colorado, Ohio, Kansas, Washington, New York (Department of Labor), and Illinois commented on the draft Rulemaking Plan. Washington and Illinois specifically provided support for the recommended Option 2 and expressed particular support for addressing some of the specific issues. The comments were generally supportive with concerns about a few specific issues: (1) not fully applying recent ICRP methodology in regulations; (2) the use of the Sealed Source and Device Registry; (3) the possible exemption of general licensees from immediately reporting thefts or losses under § 20.2201(a)(i); (4) the possible NRC licensing of manufacturers for possession and use in Agreement States; and (5) not specifically requiring demonstration of ALARA in designs of products. Colorado, Ohio, and Illinois questioned NRC's continuing to retain authority to license exempt distribution under § 150.15(a)(6). Colorado suggested the use of a standing compatibility committee for this rulemaking. Kansas suggested that addressing all the issues as in Option 3 would provide the most comprehensive protection of the public from unnecessary exposure to radiation, but expressed concern about

reducing distributor and general licensee requirements. New York's Department of Labor (NYDOL) maintains that making the requirement for registration in the Sealed Source and Device Registry explicit in the regulations should involve justification as a new requirement and that doing so should be addressed in a separate rulemaking. NYDOL also suggests that there are questions of legislative authority for the registration requirement that need to be answered. A brief discussion of these comments is provided in Attachment 8.

POLICY ISSUE ON LABELING:

The reevaluation of distributor requirements also identified a policy issue on which the staff requests direction from the Commission for use in developing the two planned proposed rules (i.e., the subject rulemaking for Parts 30, 31, and 32, and the Part 40 rulemaking). The issue concerns whether the regulations should require labeling of products and/or point-of-sale packaging based on a consumer's right to know, beyond any need to supply safety information. The regulations are not consistent with respect to requiring labeling to inform consumers of the presence of radioactive material in exempt products. This issue is discussed in more detail under Item 5 of Section A of Attachment 6. The staff recommends that, in most cases, information should be provided to consumers about the radioactive material content of a product, including a statement that the use and disposal are exempt from regulation. This would primarily affect labeling for timepieces distributed for use under § 30.15(a)(1) and a few of the source material products (e.g., glassware containing uranium). Most products containing byproduct material (or their packaging) are currently required to be labeled. Some revision to the specific required content of labels may also be considered for these products. It is expected that, over the long term at least, making better information available to the public should have a positive effect on public confidence.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objection. The rulemaking plan suggests changes in information collection requirements that must be submitted to the Office of Management and Budget prior to publication of the proposed rule.

RESOURCES:

To complete and implement the subject rulemaking using the recommended approach in the plan, 3.4 full-time equivalent positions will be required. Additional contract support will be used to conduct the rulemaking on Parts 30, 31, and 32 (approximately $175k). These resources are included in the current budget. The estimated resources for revisions to Part 40 are addressed in SECY-01-0072.

RECOMMENDATIONS:

The staff recommends that the Commission:

1. Approve the staff's recommendation to proceed with Option 2 of the subject rulemaking plan to revise certain requirements governing the use of byproduct material;

2. Approve the staff's use in rulemaking of the policy position concerning labeling of products and/or point-of-sale packaging that, in most cases, information should be provided to consumers about the radioactive material content of products and the fact that the purchaser is exempt from any regulatory requirements; and

3. Note that, to ensure consistency, the staff will coordinate the work on the subject rulemaking and the proposed rule concerning source material that is the subject of SECY-01-0072.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:
1. Consumer Product Policy
2. Tables of Exemptions from Licensing
3. Tabulation of Requirements for Byproduct Material Exemptions
4. Tabulation of Requirements for Source Material Exemptions
5. Basis for Staff's Reevaluation of the Adequacy of Exemptions
6. Issues Identified in Reevaluation of Exemptions and in SECY-97-291
7. Rulemaking Plan: 10 CFR Parts 30, 31, and 32
8. Agreement State Comments on Draft Rulemaking Plan

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3. Note that, to ensure consistency, the staff will coordinate the work on the subject rulemaking and the proposed rule concerning source material that is the subject of SECY-01-0072.

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