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 materials

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

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

U.S. ATOMIC ENERGY COMMISSION

[Reprint from Federal Register] 30 F.R. 3462, March 16, 1965

ATOMIC ENERGY COMMISSION

USE OF BYPRODUCT MATERIAL AND SOURCE MATERIAL

Products Intended for Use by General Public (Consumer Products)

Criteria for the approval of products intended for use by the general public containing byproduct material and source material. This notice sets forth the essential terms of the Commission's policy with respect to approval of the use of byproduct material and source material in products intended for use by the general public (consumer products) without the imposition of regulatory controls on the consumer-user. This is accomplished by the exemption, on a case-by-case basis, of the possession and use of the approved items from the licensing requirements for byproduct and source material of the Atomic Energy Act of 1954, as amended, and of the Commission's regulations "Licensing of Byproduct Material", 10 CFR Part 30 and "Licensing of Source Material", 10 CFR Part 40.

1. At the present time it appears unlikely that the total contribution to the exposure of the general public to radiation from the use of radioactivity in consumer products will exceed small fractions of limits recommended for exposure to radiation from all sources. Information as to total quantities of radioactive materials being used in such products and the number of items being distributed will be obtained through record-keeping and reporting requirements applicable to the manufacture and distribution of such products. If radioactive materials are used in sufficient quantities in products reaching the public so as to raise any question of population exposure becoming a significant fraction of the permissible dose to the gonads, the Commission will, at that time, reconsider its policy on the use of radioactive materials in consumer products.

2. Approval of a proposed consumer product will depend upon both associated exposures of persons to radiation and the apparent usefulness of the product. In general, risks of exposure to radiation will be considered to be acceptable if it is shown that in handling, use and disposal of the product it is unlikely that individuals in the population will receive more than a small fraction, less than a few hundredths, of individual dose limits recommended by such groups as the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the Federal Radiation Council (FRC), and that the probability of individual doses approaching any of the specified limits is negligibly small. Otherwise, a decision will be more difficult and will require a careful weighing of all factors, including benefits that will accrue or be denied to the public as a result of the Commission's action. Factors that may be pertinent are listed in paragraphs 9 and 10, below.

3. It is considered that as a general rule products proposed for distribution will be useful to some degree. Normally the Commission will not attempt an extensive evaluation of the degree of benefit or usefulness of a product to the public. However, in cases where tangible benefits to the public are questionable and approval of such a product may result in widespread use of radioactive material, such as in common household items, the degree of usefulness and benefit that accrues to the public may be a deciding factor. In particular, the Commission considers that the use of radioactive material in toys, novelties, and adornments may be of marginal benefit.

4. Applications for approval of "off-the-shelf" items that are subject to mishandling especially by children will be approved only if they are found to combine an unusual degree of utility and safety.

5. The Commission has approved certain long standing uses of source material, most of which antedate the atomic energy program. These include:

(1) Use of uranium to color glass and glazes for certain decorative purposes;

(2) Thorium in various alloys and products (gas mantles, tungsten wire, welding rods, optical lenses, etc.) to impart desirable physical properties; and

(3) Uranium and thorium in photographic film and prints.

6. The Commission has also approved the use of tritium as a substitute luminous material for the long standing use of radium for this purpose on watch and clock dials and hands.

7. The Commission has approved additional uses of byproduct and source material in consumer products. These include the following:

(1) Tritium in automobile lock illuminators;

(2) Tritium in balances of precision;

(3) Uranium as shielding in shipping containers; and

(4) Uranium in fire detection units.

8. In approving uses of byproduct and source materials in consumer products, the Commission establishes limits on quantities or concentrations of radioactive materials and, if appropriate, on radiation emitted. In some cases other limitations, such as quality control and testing, considered important to health and safety are also specified.

PRINCIPAL CONSIDERATIONS WITH RESPECT TO EVALUATION OF PRODUCTS

9. In evaluating proposals for the use of radioactive materials in consumer products the principal considerations are:

(a) The potential external and internal exposure of individuals in the population to radiation from the handling, use and disposal of individual products;

(b) The potential total accumulative radiation dose to individuals in the population who may be exposed to radiation from a number of products;

(c) The long-term potential external and internal exposure of the general population from the uncontrolled disposal and dispersal into the environment of radioactive materials from products authorized by the Commission; and

(d) The benefit that will accrue to or be denied the public because of the utility of the product by approval or disapproval of a specific product.

10. The general criteria for approval of individual products are set forth in paragraph 2, above. Detailed evaluation of potential exposures would take into consideration the following factors together with other considerations which may appear pertinent in the particular case:

(a) The external radiation levels from the product.

(b) The proximity of the product to human tissue during use.

(c) The area of tissue exposed. A dose to the skin of the whole body would be considered more significant than a similar dose to a small portion of the skin of the body.

(d) Radiotoxicity of the radionuclides. The less toxic materials with a high permissible body burden, high concentration limit in air and water, would be considered more favorably than materials with a high radiotoxicity.

(e) The quantity of radioactive material per individual product. The smaller the quantity the more favorably would the product be considered.

(f) Form of material. Materials with a low solubility in body fluids will be considered more favorably than those with a high solubility.

(g) Containment of the material. Products which contain the material under very severe environmental conditions will be considered more favorably than those that will not contain the material under such conditions.

(h) Degree of access to product during normal handling and use. Products which are inaccessible to children and other persons during use will be considered more favorably than those that are accessible.

(Sec. 161, 68 Stat. 948; 42 U.S.C. 2201. Administrative Procedure Act, sec. 3, 60 Stat. 238; 5 U.S.C. 1002)

Dated at Washington, D.C., this 8th day of March 1965.

For the Atomic Energy Commission.

W. B. McCool,
Secretary.

[F.R. Doc. 65-2616; Filed, Mar. 15, 1965; 8:45 a.m.]

Exemptions pertaining to Byproduct Material

Type of Product/Material	Possession and Use Exempted by 10 CFR Section	Effective date of Regulation
Exempt Concentrations	30.14	1960
Timepieces (watches & clocks)	30.15(a)(1)	1961: H-3 1967: Pm-147
Automobile Lock Illuminators	30.15(a)(2)	1962: H-3 1965: Pm-147
Balances of Precision	30.15(a)(3)	1964
Automobile Shift Quadrants	30.15(a)(4)	1966
Marine Compasses and Navigational Instruments	30.15(a)(5)	1966
Thermostat Dials and Pointers	30.15(a)(6)	1966
Electron Tubes	30.15(a)(8)	1966
Ionizing Radiation Measuring Instruments	30.15(a)(9)	1970
Spark Gap Irradiators	30.15(a)(10)	1978
Synthetic Plastic Resins for Sand Consolidation in Oil Wells	30.16	1967
Exempt Quantities	30.18	1970
Self-Luminous Products (Class Exemption)	30.19	1969
Gas and Aerosol Detectors (Class Exemption)	30.20	1969
Radioactive Drug: C-14	30.21	1998

Exemptions pertaining to Source Material

Type of Product/Material	Possession and Use Exempted by 10 CFR Section	Effective date
Chemical mixtures, compounds, solutions or alloys containing less than 0.05% source material	40.13(a)	1961
Unrefined and Unprocessed Ore	40.13(b)	1961
Incandescent Gas Mantles	40.13(c)(1)(i)	1947
Vacuum Tubes	40.13(c)(1)(ii)	1947
Welding Rods	40.13(c)(1)(iii)	1961
Electric Lamps for Illuminating Purposes	40.13(c)(1)(iv)	1966
Germicidal Lamps, Sunlamps, and Lamps for Outdoor or Industrial Lighting	40.13(c)(1)(v)	1966
Rare Earth Metals and Compounds	40.13(c)(1)(vi)	1947
Personnel Neutron Dosimeters	40.13(c)(1)(vii)	1977
Glazed Ceramic Tableware	40.13(c.)(2)(i)	1947
Piezoelectric Ceramic	40.13(c)(2)(ii)	1970
Glassware	40.13(c)(2)(iii)	1947
Glass Enamel & Glass Enamel Frit	40.13(c)(2)(iv)	1964[1]
Photographic Film, Negatives & Prints	40.13(c)(3)	1947
Finished Tungsten or Magnesium-Thorium Alloy Products or Parts	40.13(c)(4)	1949[2]
Uranium Counterweights for Use in Aircraft, Rockets, Projectiles & Missiles	40.13(c)(5)	1960
Uranium as Shielding in Shipping Containers	40.13(c)(6)	1961
Thorium in Finished Optical Lenses	40.13(c)(7)	1963
Thorium in Finished Aircraft Engine Parts	40.13(c)(8)	1967
Uranium in Fire Detection Units	40.13(d)	1964

[1]The exemption for glass enamel frit was suspended in 1983 and amended in 1984 to exclude further distribution of the product.

[2]An exemption for 3% thorium in thoriated tungsten was issued in 1949 which covered welding rods; it was replaced with the present product specific exemption for welding rods without a concentration limit in 1961.

Exemptions from licensing for byproduct material

Provisions of regulations pertaining to:

The product:	Exempt concentrations	Timepieces, hands, and dials	Automobile lock illuminators	Balances of precision	Automobile shift quadrants	Marine compasses	Thermostat dials and pointers	Electron tubes	Ion. rad. measuring instruments	Spark gap irradiators	Resins containing Sc-46	Exempt quantities	Self-luminous products	Gas and aerosol detectors	C-14 urea capsules
Manufactured or imported by specific licensee	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Distribution license by NRC only		✔	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔	✔
Specific final product		✔	✔	✔	✔	✔	✔		✔	✔	✔				✔
Certain nuclides specified		✔	✔	✔	✔	✔	✔	✔		✔	✔		✔		✔
Quantity limit/product		✔	✔	✔	✔	✔	✔	✔	✔	✔		✔			✔
Concentration or weight % limit	✔										✔				
External radiation level limit		if Pm-147	✔					✔				as packaged			
Various restrictions such as not in toys, adornments, food, beverage, etc.	✔											✔	✔		✔
Safety criteria: a. specific dose limits for use, distribution, etc.													✔	✔	
b. unlikely for change in integrity, containment, shielding													✔	✔	
Labeled with: a. manufacturer			✔	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	
b. product name											✔				
c. identity of radionuclide			✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
d. quantity per product												✔		✔	✔
e. specific legend												✔		✔	✔
f. safety instructions											✔	✔			

Exemptions from licensing for byproduct material	Exempt concentrations	Timepieces, hands, and dials	Automobile lock illuminators	Balances of precision	Automobile shift quadrants	Marine compasses	Thermostat dials and pointers	Electron tubes	Ion. rad. measuring instruments	Spark gap irradiators	Resins containing Sc-46	Exempt quantities	Self-luminous products	Gas and aerosol detectors	C-14 urea capsules
Provisions of regulations pertaining to:															
Specific licensee distributor:															
Testing of inspection lots with specified criteria		✔	✔	✔	✔	✔	✔	✔	✔	✔					
Visual inspection of every unit		✔	✔	✔	✔	✔	✔		✔	✔					
Approved quality control procedures	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔			✔	✔	
Records and reports of transfers	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔	
Applicant for a specific license supplies info:															
Description of product and intended uses	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Type, quantity, chemical, physical form of the material		✔	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔	✔
Changes expected during useful life													✔	✔	
Solubility in water & body fluids													✔	✔	
Design features for containment, shielding, safety under normal & severe handling, storage, use, disposa		✔	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔	
Maximum radiation level & method of measurement		✔	✔					✔					✔	✔	
Degree of access to human beings													✔	✔	
Total quantity expected to be distributed annually													✔	✔	
Expected useful life													✔	✔	

Exemptions from licensing for byproduct material

Provisions of regulations pertaining to:

Applicant for a specific license supplies info:	Exempt concentrations	Timepieces, hands, and dials	Automobile lock illuminators	Balances of precision	Automobile shift quadrants	Marine compasses	Thermostat dials and pointers	Electron tubes	Ion. rad. measuring instruments	Spark gap irradiators	Resins containing Sc-46	Exempt quantities	Self-luminous products	Gas and aerosol detectors	C-14 urea capsules
Method of labeling or sample labels			✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔	✔
Prototype test procedures and results		✔	✔	✔	✔	✔	✔	✔	✔	✔			✔	✔	
prototype tests and standard specified			✔												
Estimated external radiation dose & dose commitment													✔	✔	
Quality control procedures	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	✔
Demonstration of ALARA	✔														
User: actions restricted												only as instruction			✔
Licensed user: explicit exemption from Part 20		✔	✔	✔	✔	✔	✔	✔	✔	✔	✔		✔	✔	

Exemptions from licensing for source material

Provisions of regulations pertaining to:

The product:	Source material < 0.05 wt%	Unrefined and unprocessed ore	Incandescent gas mantles	Vacuum tubes	Welding rods	Electric lamps	Germicidal lamps, sunlamps, etc.	Rare earths ≤ 0.25% source material	Personnel neutron dosimeters	Glazed ceramic tableware	Piezoelectric ceramic	Glassware	Glass enamel or glass enamel frit	Photographic film, negatives, prints	Tungsten or mag-thorium alloys	Uranium in counterweights	Uranium in shipping containers	Thorium in optical lenses	Aircraft engine parts	Fire detection units
Manufactured or imported by specific licensee																✔				
Distribution license by NRC only																✔				
Specific final product			✔		✔	✔	✔		✔	✔				✔		✔				✔
Certain nuclides specified	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Quantity limit/product						✔	✔		✔											✔
Concentration or weight % limit	✔							✔		✔	✔	✔	✔		✔			✔	✔	
External radiation level limit																				
Various restrictions such as not in toys, adornments, food, beverage, etc.																				
Safety criteria: a. specific dose limits for use, distribution, etc.																				
b. unlikely for change in integrity, containment, shielding																				
Labeled with: a. manufacturer																✔				
b. product name																				
c. identity of radionuclide																✔	✔			
d. quantity per product																				
e. specific legend																✔	✔			
f. safety instructions																				

Exemptions from licensing for source material

Provisions of regulations pertaining to:

	Source material < 0.05 wt%	Unrefined and unprocessed ore	Incandescent gas mantles	Vacuum tubes	Welding rods	Electric lamps	Germicidal lamps, sunlamps, etc.	Rare earths ≤ 0.25% source material	Personnel neutron dosimeters	Glazed ceramic tableware	Piezoelectric ceramic	Glassware	Glass enamel or glass enamel frit	Photographic film, negatives, prints	Tungsten or mag-thorium alloys	Uranium in counterweights	Uranium in shipping containers	Thorium in optical lenses	Aircraft engine parts	Fire detection units
Specific licensee distributor:																				
Testing of inspection lots with specified criteria																				
Visual inspection of every unit																				
Approved quality control procedures																				
Records and reports of transfers																				
Applicant for a specific license supplies info:																				
Description of product and intended uses																				
Type, quantity, chemical, physical form of the material																				
Changes expected during useful life																				
Solubility in water & body fluids																				
Design features for containment, shielding, safety under normal & severe handling, storage, use, disposal																				
Maximum radiation level & method of measurement																				
Degree of access to human beings																				
Total quantity expected to be distributed annually																				
Expected useful life																				

Exemptions from licensing for source material

Provisions of regulations pertaining to:

Applicant for a specific license supplies info:	Source material < 0.05 wt%	Unrefined and unprocessed ore	Incandescent gas mantles	Vacuum tubes	Welding rods	Electric lamps	Germicidal lamps, sunlamps, etc.	Rare earths ≤ 0.25% source material	Personnel neutron dosimeters	Glazed ceramic tableware	Piezoelectric ceramic	Glassware	Glass enamel or glass enamel frit	Photographic film, negatives, prints	Tungsten or mag-thorium alloys	Uranium in counterweights	Uranium in shipping containers	Thorium in optical lenses	Aircraft engine parts	Fire detection units
Method of labeling or sample labels																				
Prototype test procedures and results																				
prototype tests and standard specified																				
Estimated external radiation dose & dose commitment																				
Quality control procedures																				
Demonstration of ALARA																				
User: actions restricted															✔	✔		✔		
Licensed User: explicit exemption from Part 20																				

Basis for Staff's Reevaluation of the Adequacy of Exemptions

The primary guidance for the Commission's decisions in establishing (or revising) exemptions from licensing is the 1965 Consumer Product Policy (published March 16, 1965; 30 FR 3462) (the policy). Despite the age of the policy, its content continues to be generally appropriate and consistent with the Commission's current approach to radiation protection and the basic framework for radiation protection recommended by the International Commission on Radiological Protection (ICRP). It incorporates some considerations related to the three basic principles of radiation protection: justification of practice, dose limits, and ALARA, although justification of practice and ALARA are not explicitly noted. The policy states that, "Approval of a proposed consumer product will depend upon both associated exposures of persons to radiation and the apparent usefulness of the product." 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. 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, National Council on Radiation Protection and Measurements (NCRP), and the Federal Radiation Council (FRC). The revised Part 20 (effective no later than January 1, 1994) established a public dose limit of 100 mrem/year (1 mSv/year)(§ 20.1301) from licensed activities. The recommended dose limit for the public was not explicitly stated in the policy, so it has not been made outdated by the use of specific dose criteria which are no longer applicable, although the value of this small fraction would be lower under current recommendations/limits.

Because the policy has not been revised since 1965, it does not address all factors that need to be considered at this time. One change that has occurred since adoption of the policy is the move away from the concept of radiation worker and the clear separation of occupational dose and public dose now in Part 20. Persons exposed while working at an unlicensed facility are considered to be receiving an occupational dose in accordance with the definition in § 20.1003; thus, these exposures do not need to be within the dose limits in § 20.1301(a) for individual members of the public. However, for consistency in protection of health and safety, an exemption from Part 20 should not be applicable in situations where a worker could receive (under routine conditions) more than 10 % of the occupational limit or 500 mrem/year (5 mSv/year) as there would be no required monitoring of exposures (consistency with § 20.1502). An exemption from licensing (where Parts 19 and 20 do not apply) should not result in untrained workers being likely to receive more than 100 mrem/year (1 mSv/year)(consistency with § 19.12). Exceptions to this may be appropriate based on cost/benefit considerations, because the cost of specific licensees providing training to a larger number of employees based on the 100 mrem/year (1 mSv/year) criterion is different from the total cost of licensing a practice.

Thus, the staff believes that the use of radioactive materials in situations where training or monitoring of workers would not be required, should meet the following conditions: Workers are not routinely expected to receive more than 100 mrem/year (1 mSv/year) from sources exposed to in the course of work (not including exposures received as members of the public). It is possible that even routine, non-accident conditions could occasionally result in an exposure greater than 100 mrem/year (1 mSv/year) (but not greater than 500 mrem/year (5 mSv/year)),

from sources exposed to in the course of work (not including exposures received as members of the public).

For low probability events (accidents), some probability of workers receiving greater than 500 mrem/year (5 mSv/year) is acceptable. Risk should be considered based on both the probability of an event and the maximum likely exposure. The policy includes consideration of potential accident doses and probabilities of occurrence, but does not provide specific guidance on what is acceptable. In looking at the results for the misuse and accident scenarios in the radiological assessment, the staff has considered that the safety criteria in the two class exemptions: §§ 30.19 and 30.20, self-luminous products and gas and aerosol detectors, respectively, are appropriate for judging the acceptability of risks from accidents and misuse for other exemptions as well. These safety criteria are contained in §§ 32.23 and 32.24 for self-luminous products and in §§ 32.27 and 32.28 for gas and aerosol detectors. (The dose criteria are, however, stated in terms of whole body and organ doses in lieu of total effective dose equivalent (TEDE) which is used in Part 20. Thus for consistency, the staff recommendations include revising §§ 32.24 and 32.28 and related sections to state the criteria in terms of TEDE.) Although these safety criteria are for exposures of the general public, the level of risk in the case of low probability events is also considered appropriate for workers at unlicensed facilities, where workers are not trained or monitored. For example, devices generally licensed under § 31.5 are required by § 32.51(a)(2)(iii) to meet the same 15 rem limit in § 32.24 for accidents such as fire and explosion.

Note that although 100 mrem/year (1 mSv/year) is the primary criterion, as it is for public dose, it is appropriate to look at occupational and public doses separately. Workers are enjoying the benefit of having a job, although they should be similarly protected as workers at specifically licensed facilities. For either a member of the public or an untrained worker, doses above 100 mrem/year (1 mSv/year) may be justifiable in some cases based on cost/benefit considerations, e.g., the patient release criterion of 500 mrem (5 mSv) (§ 35.75) and case-by-case determinations allowed by § 20.1301(c).

A goal of NRC regulations is that exposures to the public are unlikely to exceed 100 mrem/year (1 mSv/year) from all practices under NRC jurisdiction (with limited probability of individuals' doses sometimes exceeding this). Thus, there are lower dose limits for individual practices, particularly where the public may be exposed to multiple sources. One of the criteria in the consumer product policy, which addresses only exposures to the general public, is for each exempt practice to result in a small fraction of the public dose limit, because members of the public may be exposed to a number of consumer products. The intent is that resultant exposures of members of the general public from all exempt products are unlikely to be a significant fraction of the permissible dose as they may also be exposed to other sources such as effluent releases from licensees.

Widely distributed items would be expected to contribute to the exposures of large numbers of people and thus there should be a higher degree of assurance that routine doses from individual practices involving such items meet the small fraction of the public dose limit criterion.

While the policy does not refer to the concept of justification, it does include consideration of the degree of benefit or usefulness of a product to the public and indicates that the use of radioactive material in toys, novelties, and adornments may be of marginal benefit. There is an explicit

exclusion in the class exemption for self-luminous products (§ 30.19(c)) of products primarily for "frivolous" purposes and of toys and adornments. Nonetheless, the benefit of a particular product distributed for use under this exemption may be minimal, thus, it has the lowest practice-specific dose criterion of 1 mrem/year (10 μSv/year) from normal use and disposal (safety criteria in §§ 32.23 and 32.24). Applying the concept of justification also minimizes the number of products made available for use by the general public under the exemptions from licensing. This helps to ensure that exposures to the public are unlikely to exceed 100 mrem/year (1 mSv/year) from all practices under NRC control.

Looking at the scenarios in which the critical group (the group of people reasonably expected to receive the greatest exposure from a practice) is occupationally exposed, e.g., welding, it would be reasonable for routine doses to these workers to approach 100 mrem/year (1 mSv/year), if it is unlikely that they are occupationally exposed to other sources. Generally, there are few situations in which the same workers would be expected to be the critical group for multiple practices. However, waste collectors and workers at disposal facilities, i.e., landfills and incinerators, are potentially exposed to all categories of radioactive material allowed to be disposed of without regard to its radioactivity. In order for their cumulative dose from these materials/products to be acceptable, their dose from any individual practice should be quite small. The estimates in NUREG-1717 for disposal workers and for members of the general public from disposal do not suggest that the net effects of uncontrolled disposals are significant. Waste collectors have the highest potential exposures, up to a few mrem/year from a single practice but a small fraction of 1 mrem/year (10 μSv/year) from most.

The policy and this discussion focus on control of individual doses. NUREG-1717 also estimated collective doses. Given the uncertainty in the estimates and the fact that the collective doses are, for the most part, summing very small individual doses, the staff has considered the collective dose estimates only as general indicators of the magnitude of benefit to be achieved by actions that may reduce individual doses. In evaluating the results of the dose assessments in NUREG-1717, particular attention was paid to identifying potential regulatory improvements for exemptions for which either the potential individual doses or the estimated collective doses were relatively high in comparison to others. Both the reduction of maximum potential individual doses and associated impacts in terms of collective doses should be considered in the Regulatory Analyses for rulemakings in this area. Generally speaking, the control of individual doses tends to improve the cost/benefit balance for the practice, as it also reduces the average collective dose per product. The total collective dose also depends on the degree to which a product is used. The larger the number of a product used, the greater the collective dose, but also the greater the benefit, or at least perceived benefit, of a practice to society.

ISSUES IDENTIFIED IN REEVALUATION OF EXEMPTIONS OR INCLUDED IN SECY-97-291

A. Issues Related to Regulation of Both Byproduct and Source Material

1. Information on Impact of Regulatory Program on Public Health and Safety

Issue: Reporting requirements imposed on distributors of exempt products and materials do not result in submission of sufficient, timely, and informative reports for NRC to determine what products and how much byproduct material and source material is distributed annually for exempt use, limiting the agency's ability to evaluate the impact of these practices on public health and safety.

Possible Solution: The usefulness of information collected through reports of byproduct material in products and materials being distributed to exempt persons could be improved by changing the period of reporting to every calendar year rather than 5 years (and when filing an application for renewal or termination of the license). Specific licensing and annual reporting of commercial distribution of source material to exempt persons should be required (as planned under SECY-01-0072). In addition, the staff could improve the handling of the information once received by re-establishing a computer database.

Discussion: This change would provide product distribution information that is more useful for evaluating potential individual doses to the public from multiple sources and collective doses to the public from exempt products and materials than under the existing regulations. Because the date of reporting for each licensee is different and the information is not necessarily reported by year (in the case of source material, there is no reporting), it is difficult to estimate the amount or types of products/materials containing byproduct material distributed each year or to see any trends in the market. Also, the information is not very current. Reporting annually would eliminate these difficulties and would not significantly change the reporting burden for these licensees. In fact, it would be more straightforward and easier for licensees to report on a routine annual basis. (Prior to 1983, annual reports were required; experience shows that there have been more implementation and enforcement problems under the current scheme than there had been with annual reporting.) Also, providing a standard format or a form and allowing electronic submission could make the reporting process more efficient and could improve the quality of the information. As a result, the NRC could better evaluate the doses to the public from exempt products and materials, as well as inform the public concerning such exposures. These changes would also provide a better basis for considering any future rulemaking in this area and in allocating NRC resources.

2. Obsolete Provisions

Issue: Some regulations could be removed, because they are obsolete, i. e., no products/materials are being distributed for use under certain exemptions. In some cases, there appears to be no inventory in use under the exemption. Among these, the exemptions for resins containing scandium and for ceramic tableware could result in significant doses if used.

Possible Solution: Delete exemptions for products that are no longer being used or manufactured, or restrict further distribution while allowing for the continued possession and use

of previously distributed items. Candidate exemptions in Part 30 are those for: automobile lock illuminators, balances of precision, automobile shift quadrants, marine compasses, thermostat dials, spark gap irradiators, and resins containing Sc-46 for sand consolidation in oil wells. Specific requirements for manufacturers and distributors of products that are no longer being manufactured or distributed could also be deleted. These include § 32.17 for manufacture or distribution of resins containing scandium-46 and the prototype test procedures for automobile lock illuminators in § 32.40. Additional obsolete exemptions in Part 40 are: glazed ceramic tableware; photographic film, negatives, and prints; and fire detection units.

Discussion: For those exemptions where significant doses are possible, this action would provide assurance that health and safety is adequately protected from possible future distribution. This change would also simplify the regulations by eliminating extraneous text. It would eliminate the need to reassess the potential exposure of the public from these products for possible future distributions of the products. Also, these products would no longer need to be considered when assessing the total potential doses to the public from multiple sources. Five of these are self-luminous products; thus, distribution for use under § 30.19 could be evaluated and authorized, if a renewed interest arose.

3. ALARA

Issue: Section 20.1101 requires each specific licensee to implement an ALARA program. Does the scope of that requirement include the consideration by a distributor of doses to the public which result from the licensee's distribution of products used under the exemptions? Should applicants for licenses to distribute exempt products be required to demonstrate ALARA in design of their products? Should licensees who distribute exempt products implement ALARA in the design of products on a continuing basis?

Possible Solutions: Clearly state the NRC's position and implement that position in the NRC regulatory program (clarification of ALARA requirement in Part 20). Require all applicants for a license to distribute exempt products to demonstrate ALARA in the design of products. Require licensees distributing exempt products to implement ALARA in the design of products on a continuing basis.

Discussion: It is appropriate to apply the ALARA process to the design of products for which the user is exempt from licensing requirements. However, most products being distributed for use under an exemption 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 from requiring a demonstration of ALARA for all of these products in the licensing process may not be justified. It should, however, be clarified in guidance and/or inspection procedures that the specific licensee’s ALARA program should consider new developments in technology as they may impact ALARA in the design of products.

4. Application of Part 20 to the Use of "Exempt" Materials and Products by Specific Licensees

Issue: The regulations are not clear concerning specific licensees' responsibilities under Part 20 for materials/products which are clearly exempt from Part 20 when possessed/used by non-licensees. For example, must the specific licensee control disposal of the “exempt” materials/products in the same manner that it controls disposal of radioactive material listed in its license? 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.

Possible Solution: Develop a position based on a re-examination of the individual exemptions and reasonable intent. Identify those products or materials, if any, for which there should be some controls when used by specific licensees and clarify licensees’ responsibilities in the regulations. Rulemaking would be needed to implement this position as the interpretation is not consistent across all exemptions.

Discussion: The need for controls concerns whether or not certain categories of licensees may be able to circumvent the regulations that should apply. Manufacturers/distributors may need to dispose of “exempt” products/materials as radioactive waste if large amounts of material are handled, e.g., they may have large numbers of defective products to dispose of; thus, it may not be appropriate to allow uncontrolled disposal. The exempt quantities provision needs to be carefully crafted.

5. Labels and Instructions

Issue: In some cases, labeling or the inclusion of instructions may be required in order to provide information to the user (and possibly others) on the radioactive material contained and how the product can be safely used, with the assumption that this knowledge may impact doses received. However, there is also a policy question as to whether the user has a "right to know" that a product contains radioactive material. This latter rationale was the reason for many of the existing labeling requirements, such as those for smoke detectors.

Possible Solution: Determine policy and apply consistently in the regulations. If the Commission adopted a policy of providing information to the purchaser on a right-to-know basis, some exceptions may be appropriate. Possible reasons for exceptions might be: (1) the practicality of labeling either the finished product or packaging or (2) low concentrations of radioactive material are present inadvertently rather than purposefully, such as with exempt concentrations. A specific example, where both of these apply, might be irradiated gemstones, which result in very low doses from induced radioactivity not purposely present, and for which, requiring information to be provided to the consumer could be more difficult than for many products.

Discussion: The staff does not believe that removing any existing requirements in this area, even if unnecessary for providing information on safe use, would be appropriate, as this could have a negative impact on public confidence. When there is information that could be instrumental to the user reducing his/her dose, this information should clearly be required to be

provided by the distributor. With respect to adding new requirements of this type based on "right to know," it is difficult to predict if the overall effect on public confidence would be positive or negative. Initially, people finding out a product they have previously used contains radioactivity may tend to have negative effects. However, over the long term, making better information available to the public should have a positive effect. The staff recommends that requirements should be added for the labeling of point-of-sale packaging for all products, and in some cases the product itself, to the extent practical, to inform consumers about radioactive material content and that the purchaser is exempt from any regulatory requirements. This would be an additional, though limited, expense to distributors, without a tangible benefit to society. Note, however, some industries have voluntarily developed consumer information about radioactive content of their products, their regulatory status as exempt from regulatory requirements, and/or safe handling instructions. Also, labeling of products can sometimes have the added benefit that when properly labeled products containing radioactive material are received at landfills, smelters, etc., the product can be more readily identified as exempt from regulation, thus reducing costs of responding to alarms.

6. "Frivolous" Products

Issue: One of the basic principles of radiation protection is justification of practice. This principle leads to restrictions on products for frivolous purposes. While the consumer product policy does not refer specifically to the concept of justification, it does include consideration of the degree of benefit or usefulness of a product to the public and indicates that the use of radioactive material in toys, novelties, and adornments may be of marginal benefit. Also, there is an explicit exclusion in the class exemption for self-luminous products (§ 30.19(c)) of products primarily for "frivolous" purposes and of toys and adornments. Decisions on individual products to be used under this exemption are made in licensing actions and sometimes involve making difficult judgments.

Possible Solution: Provide a more consistent basis for regulatory and 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.

Discussion: This issue 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, this should be addressed in guidance rather than through changes to the regulations. The NRC's policy to exclude the use of radioactive material in "frivolous" products comes not only from the basic radiation protection principle of "justification of practice," but also an intent to minimize the number of widely distributed products, so as to better ensure that public doses are appropriately limited given exposure to multiple sources.

7. International Issues

Issue: There are products that are exempt from regulatory control in other countries, but not in the U.S. These are sometimes found being sold in the U.S. This primarily results from the differing judgments made concerning justification of practice by various regulatory authorities, e.g., the United Kingdom has authorized the distribution of key rings containing tritium.

Possible Solution: Increase controls on the import and sale of products that are exempt from regulatory control in other countries, but not in the U.S.

Discussion: 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. Some aspects of the staff's enforcement efforts in this area are discussed in SECY-02-0013, "Issues Concerning Self-Luminous Tritium Consumer Products," January 17, 2002.

8. Exempt Distributors in Agreement States

Issue: A distributor of exempt byproduct material in an Agreement State must have two licenses, a distribution license from NRC and a possession and use license from the State. When the requirement for an NRC distribution license for source material is added (as planned in SECY-01-0072), the same thing will be true for distributors of source material. There may be some inefficiency connected with this. Also, some States have questioned their need to license distributors who are also NRC licensees.

Possible Solution: Expand the NRC exempt distribution license to also cover possession for importers, so that there is no need for a separate possession and use license, particularly when no on-site testing is required. In the case of manufacturers, explore the possibility of allowing for the option of NRC licensing possession and use in Agreement States, in addition to distribution, at the discretion of the individual State.

Discussion: If there is no in-plant safety concern in the case of importers, the distribution license should cover possession. For manufacturers, the responsibility for licensing the facility is within the authority of the State; however, some efficiency may be gained from a distributor being subject to licensing by NRC only. This would be negotiated with the Agreement States.

9. Should the Requirement for SS&D Registry Be Made Explicit?

Issue: 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 an administrative practice, and fees are assessed based on whether or not a "sealed source and/or device review" is required. The products in each of these categories for which this is applicable are indicated in guidance. Also, there is no provision comparable to § 32.210 in Part 40 related to the Sealed Source and Device Registry. Administrative practice has resulted in the inclusion of a small number of devices and sources containing source material in the registry.

Possible Solution: Make registration requirement explicit in the regulations governing byproduct material, so that it is easier for potential applicants to determine the applicable requirements and associated fees. Add a provision to Part 40 similar to § 32.210.

Discussion: The regulations include requirements for information to be submitted by applicants and for determinations to be made by the NRC staff, which form the basis of the sealed source and device review and resultant registration. However, as a matter of licensing practice, applicants/licensees must obtain sealed source and device registration certificates for most, but

not all, sources and devices. The regulations should be explicit concerning this process, so that it is easier for potential applicants to determine the applicable requirements and associated fees. The rulemaking process will include providing an explanation of the rationale for using a registration process as a licensing mechanism and will likely involve some reexamination of the basis for determination of which products should be included in the Sealed Source and Device Registry. Not only will the regulations be more explicit and understandable, but there will be better assurance that there is a sound basis for the inclusion of devices and sources in the registration process.

B. Other Issues Related to the Regulation of Byproduct Material

1. Prescriptive Requirements for Distributors of Generally Licensed Devices and Exempt Products

Issue: The requirements for manufacturers of exempt and generally licensed products are in some cases very prescriptive, particularly in the areas of prototype testing, sampling, and quality control. The regulations could be made less prescriptive and continue to contain general requirements and may provide standards by which performance may be judged rather than specifying details of procedures that must be followed. Regulatory guidance would be provided on acceptable approaches to meeting the requirements. It may also be possible to allow licensees to submit assurance programs that verify product integrity in lieu of specific quality control procedures. In the case of generally licensed products, regulations that are possible candidates for modification include:

> Prototype test procedures (§§ 32.53(d)(4), 32.57(d)(2), 32.101, 32.102, and 32.103)
>
> Specified sampling or testing procedures (§§ 32.15(a)(2) and (3) and (c)(2), 32.55(a) through (d), 32.59, 32.62(a) through (e), and 32.110)

The only such prescriptive requirement pertaining to manufacturers of an exempt product is § 32.40, which is also obsolete; see item A. 2. above.

Possible Solution: Revise these paragraphs to make the requirements for distributors less prescriptive. The revision of the following guidance document would include example acceptable approaches: NUREG-1556, Vol. 16, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees."

Discussion: Less prescriptive, more flexible regulations would be more performance-based. The licensee would be free to propose alternative methods to those presented in guidance to satisfy the requirement in the regulation. The requirements would continue to provide adequate assurance that the products being distributed meet performance standards. Note, some of these requirements may instead be candidates for elimination under the following issue.

2. Make the Requirements for Distributors of Exempt Products More Risk-informed

Issue: The level of control on the distribution of the various exempt products and materials is not commensurate with the associated risk, particularly in the areas of prototype testing, sampling

procedures, and quality control. Some existing requirements may be unnecessary given the risk associated with the particular product. There are currently no requirements in the case of distributors of source material. Each requirement should be reviewed based on the risk presented by the individual product.

Existing requirements for distributors of byproduct material to exempt persons include:

Prototype test procedures (§§ 32.14(b)(4), 32.22(a)(2)(xi), 32.26(b)(11), and (12)),

Sampling procedures (§§ 32.15(a)(2) and (3), and 32.110)

Submittal of quality control procedures (§§ 32.14(b)(5), 32.22(a)(2)(xv), 32.25(a), 32.26(b)(15)).

The staff does not believe that any similar requirements for submitting such procedures for generally licensed devices are candidates for revocation based on risk, as the safety of these devices relies on the design to a greater degree than exempt products.

Possible Solution: Eliminate individual requirements if not justified, based on risk. If appropriate, add requirements for some products containing source material.

Discussion: Unnecessary regulatory burden on distributors of byproduct material would be reduced. Adequacy of prototype testing and quality control for products containing source material have not yet been evaluated. A consistent approach should be applied in also determining whether any of the source material products should have such requirements.

3. Exempt Quantities - § 30.18

Issue (1): The NRC issued the exemption in § 30.18 based, in part, on the safety properties inherent to a single exempt quantity; however, later an NRC position had endorsed gauge manufacturers' distribution of gauging devices with a source holder, but without sources. The customer was then instructed by the manufacturer/distributor to obtain and insert multiple "exempt" sources into the source holder and enjoy the use of a gauge without regulatory control. The NRC subsequently withdrew its approval of such distribution of gauging devices and by letter so advised the gauge manufacturers. There appears to be a need for clarifying the regulations concerning NRC's position on combining exempt quantities.

Possible Solution (1): Clarify the regulations concerning NRC's position to preclude combining multiple exempt quantities so as to prevent circumvention of the basic safety properties relied on in the issuance of the exemption in § 30.18.

Discussion (1): Although a letter was sent to distributors to stop this practice (Generic Letter 99-01), the regulations should be clarified to preclude combining or bundling exempt sources. The radiological assessment shows there is a potential safety hazard if multiple exempt sources (for some radionuclides) are combined and used in a device. Both of the objectives of risk-informing the regulations and protecting the health and safety of the public can be achieved with the proposed solution.

Issue (2): Recommended dose calculational methodology has changed since the establishment of this exemption; thus, the various nuclide quantity limits present significantly different potential doses. Also contributing to the range of potential doses associated with the individual radionuclide limits is the approach to controlling external vs. internal doses, whereby radionuclides that present an external hazard tend to present higher potential doses than those that present primarily an internal hazard.

Possible Solution (2): Update the tables in § 30.71 to reflect the dose limits in Part 20 and the most up-to-date data on radionuclide uptake and metabolism as a basis for setting limits to control internal doses. Also, use a somewhat more restrictive approach to controlling external doses. Alternatively, identify the specific radionuclide limits with the highest potential doses and selectively reduce those limits to maintain the appropriate level of risk.

Discussion (2): This would maintain the overall intended level of risk, while equalizing the level presented by the individual quantity limits for the various radionuclides and reducing the maximum potential individual doses. However, this would involve significant effort and a relatively small number of the radionuclides are actually distributed for use under this provision. Thus, there may not be a net benefit from a complete revision of the table in § 30.71. In addition, the Commission recently approved not moving forward with rulemaking to reflect current ICRP recommendations at this time. (SRM dated April 12, 2002, on SECY-01-0148) The alternative approach would do much of the same with respect to the radionuclides presenting the highest potential dose, mostly involving external dose.

4. Exempt Concentrations - § 30.14

Issue (1): Lack of assurance that the allowed concentrations and other conditions for issuance of the specific license authorizing distribution of materials for possession under § 30.14 will not result in individual members of the public receiving doses greater than a small fraction of 100 mrem/year (1 millisievert/year); even doses in excess of 100 mrem (1 millisievert) in a year are possible, although not occurring under present practices.

Possible Solution (1): Add a requirement that the applicant for the specific license authorizing the introduction of the byproduct material in exempt concentrations must, in addition to present requirements in § 32.11, provide reasonable assurance by means of appropriate scenarios, measurement data and calculations that the dose to an average member of the critical group of the public will not exceed certain safety criteria. In this case, this might include a routine dose limit of 1 mrem/year (10 μSv/year), as the byproduct material usually serves no purpose in the product/material, but arises as a result of a production process. The new rule could also set out conditions for granting of exceptions to this dose limit.

Discussion (1): Although based on current trends in distribution, actual doses do not appear to be approaching 100 mrem/year (1 mSv/year), and are generally much lower, the evaluation 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. Better assurance is needed to prevent inappropriate exposures under this exemption.

Issue (2): The exempt concentrations in § 30.70 are based on out-of-date technical data. These concentrations are generally based on the same scientific information on radionuclide uptake and metabolism and dose limits that served as a basis for concentration tables in Part 20 as published by the AEC in 1960. The revised Part 20, effective no later than January 1, 1994, is based on more recent information on radionuclide uptake and metabolism and revised dose limits. Many entries in the concentration tables in the revised Part 20 differ from those in the earlier tables of 1960. Accordingly, there is no longer consistency between the exempt concentrations in § 30.70 and the revised Part 20. This lack of consistency between § 30.70 and the current Part 20 raises a question about the adequacy of the technical basis for the exempt concentrations in § 30.70. Also, newer dosimetry (ICRP 72) would result in somewhat different dose estimates.

Possible Solution (2): Update the concentration tables in § 30.70 to reflect the radionuclide uptake and metabolism models on which Part 20 limits are based or use current technical data and ICRP recommendations as a basis.

Discussion (2): There are complex issues related to the exempt concentration provisions and a number of approaches that may be taken to address these issues. Until these are explored in more detail, it is difficult to determine whether there would be a net benefit from a complete revision of the tables in § 30.70 (as well as § 30.71, Exempt Quantities) to reflect a more consistent level of risk, based on the latest dosimetric methodologies. Doing so would leave these tables of nuclides inconsistent with Part 20. In addition, the Commission recently approved not moving forward with rulemaking to reflect current ICRP recommendations at this time. (SRM dated April 12, 2002, on SECY-01-0148)

Issue (3): Section 32.11(c) requires, among other things, that the applicant for specific license provide reasonable assurance that "...the product or material is 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." Under general authority provided in § 30.11, exemptions to this provision have been granted by the NRC for irradiated gemstones. The regulations could be more specific concerning the information and showing to be made by an applicant in requesting exemptions to this prohibition.

Possible Solution (3): Consider amending § 32.11 and revising NUREG-1556, Vol. 8, “Consolidated Guidance about Materials Licenses, Program-Specific Guidance about Exempt Distribution Licenses” to: (a) advise the license applicant of the information to be submitted when seeking an exemption to the above requirement, and (b) set out the NRC’s criteria for granting the requested exemption. Another alternative would be to remove or revise this restriction. It is primarily for the purpose of not interfering with the responsibilities of the FDA, although it is also consistent with the Commission’s Consumer Product Policy indicating that toys, novelties, and adornments are considered of marginal benefit.

Discussion (3): Such information with respect to gemstones specifically is already contained in NUREG-1556, Vol. 8, “Consolidated Guidance about Materials Licenses, Program-Specific Guidance about Exempt Distribution Licenses.” The only other practice for which this had been considered is the use of explosives detection devices at airports that involves neutron irradiation of cargo and baggage using Cf-252. This system was developed in the 1980's but is not

currently licensed by the NRC. Additional guidance could be developed, if needed. Developing a generic provision for addition to the regulations may not be cost-beneficial.

5. Class Exemptions for Self-luminous Products and Gas and Aerosol Detectors

Issue: In §§ 32.24 and 32.28, safety criteria are stated in terms of whole body and organ doses consistent with ICRP 2 recommendations rather than Total Effective Dose Equivalent (TEDE) as used in Part 20, and more recent recommendations on dose calculational methodology.

Possible Solution: Revise §§ 32.24 and 32.28 and related sections to remove the specific organ dose criteria and state the criteria in terms of TEDE.

Discussion: Although this use of whole body and organ dose limits has been effective in controlling doses to the public, the use of TEDE limits would be consistent with the NRC's basic radiation protection standards in Part 20 and its consideration of dose to individual members of the public (see § 20.1301). Note: Part 20 specifically defines TEDE to include deep dose equvalent for external doses; however, the Commission has interpreted Part 20 to include discretion for the use of effective dose equivalent for estimating external doses. The use of TEDE dose criteria, which reflect overall risk, without separate organ limits, are considered adequate to protect public health and safety for this application. The use of TEDE in §§ 32.24 and 32.28 and related sections would facilitate comparison of these limits with the limits in Part 20. Such consistency may contribute positively to public confidence. This would also result in a small increase in efficiency, effectiveness, and realism.

6. Establish a New Class Exemption for Certain Industrial Products

Issue: Specific or general licenses now used for products such as H-3 and Ni-63 chromatography units, gauges using small beta sources, and internal calibration sources provide overregulation and unnecessary expenditure of user and NRC resources.

Possible Solution: Establish a new class exemption, with associated safety criteria for these and similar products. This might include x-ray fluorescence analyzers and static eliminators. As the potential doses cover a wide range, these products cannot easily be exempted across the board for any product in one of these categories. Licensing requirements for distribution of devices for use under the new exemption may be comparable to those now imposed on specifically licensed distributors of devices used under the general license in § 31.5 and the specifically licensed distributors of gas and aerosol detectors used under § 30.20. The applicant for a distribution license would be required to provide reasonable assurance that doses to users would be unlikely to exceed a small fraction of Part 20 dose limits for members of the public. If the new class exemption is limited to industrial uses, where the critical group is projected to be workers, and designed to avoid residential use, a somewhat higher dose limit might be included. Alternatively, the new rule could set out conditions for granting exceptions to the routine use dose limit. In either case, the licensing requirements would need to account for disposal and recycle concerns.

Discussion: For each of the various categories of 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 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. This would put the burden of demonstrating that a particular product meets the safety criteria on the applicant distributor (with NRC review and approval). Such a class exemption would also allow for the development of new products for use under exemption without the necessity for rulemaking.

7. Manufacturer's Modification of Product without Prior NRC Approval

Issue: As stated in NUREG-1556, Vol. 8, "...If any of the information provided in the original application (for license to distribute products to exempt persons) is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. ..." This is also the case for generally licensed products and some specific licensee programs and facilities. This requirement delays changes in products and their production and in licensees' programs and facilities. Some of the changes may be safety improvements or may maintain the existing level of safety but be cost saving. This issue was identified in SECY-97-291.

Possible Solution: Provide, within limits, flexibility for the licensed manufacturer/distributor to make changes in the product and its production. Section 50.59 provides for reactor licensees to make certain changes in the facility and procedures described in the final safety analysis report without prior NRC approval. By rule change or by administrative practice, a comparable provision for change could be afforded manufacturers of products. The Commission could consider revising Parts 30 and/or 32 to allow some byproduct material licensees to make changes to facilities, programs, or product designs without NRC prior approval, if they can determine that there will be no reduction in safety.

Discussion: Based on the history of a 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. Thus, the staff is not recommending such a change in the regulations at this time. However, eliminating some unnecessary impediments to a licensee making changes that do not adversely affect safety has been addressed in licensing practice since this issue was identified. Also, due to changes made to the fee structure, fees for amendment of licenses are no longer a deterrent to licensees proposing changes. This issue can and should continue to be addressed as appropriate in the licensing and sealed source and device registration process.

8. Class Exemption for Gas and Aerosol Detectors - Unnecessary Limitations

Issue: Products similar to those allowed, but not quite fitting the "class" cannot be approved under this exemption. 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."

Possible Solution: Broaden the class exemption for gas and aerosol detectors (§ 30.20), to include other potential applications.

Discussion: This would allow other potential applications under an existing framework, which has safety criteria that adequately protect public health and safety.

9. Electron Tubes - § 30.15(a)(8)

Issue: Quantities actually used in electron tubes distributed for use under § 30.15(a)(8) are much lower than allowed, on the order of 1000 times less.

Possible Solution: Reduce the quantities of radionuclides allowed in electron tubes to be closer to quantities actually used.

Discussion: This change would be based on the as low as reasonably achievable (ALARA) principle. Also, 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.

10. General Licensees and Part 20

Issue: General licensees under §§ 31.5 and 31.7 are exempt from Part 20 except for §§ 20.2201 and 20.2202. Some generally licensed devices contain quantities of radionuclides meeting the criterion in § 20.2201(a) for immediate notification if lost or stolen. There seems 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. It has, however, been suggested that, for certain radionuclides at least, the quantities of materials requiring immediate notification are lower than necessary given the associated risk.

Possible Solution: 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.

Discussion: Although reevaluating the risk basis of the criteria in § 20.2201 overall may be useful at some point, it is not urgent, nor should it fall within the scope of the current rulemaking as it would extend the scope of this action too much. The situation for general licensees and specific licensees is sufficiently different, that it would not be unreasonable for specific licensees to be expected to call the Operations Center immediately concerning thefts or losses and general licensees within 30 days for the same quantities of radionuclides. Generally licensed devices are designed to be safely used by persons untrained in radiological protection, who would not be expected to have the same level of familiarity with the regulations as specific licensee personnel. None of the generally licensed devices present an imminent danger to health and safety; most are required to meet the safety criterion of no person likely to receive a dose in excess of 15 rem (whole body) under accident conditions; others generally present a lower risk. Also, generally licensed devices do not contain the types and quantities of radioactive material that are considered to be of concern for possible terrorist use in a radiological dispersion device. Further consideration will be made concerning the risks presented by less timely notification of loss or theft of generally licensed devices. As generally licensed devices meeting the requirement for registration are considered a potential problem for contamination if smelted, this aspect will also be evaluated.

11. Residential Smoke Detectors Distributed under Class Exemption

Issue: Residential smoke detectors represent a well established practice with consistency in the design of products and with extensive licensing experience, but are licensed under a class exemption requiring product-specific evaluation against safety criteria.

Possible Solution: 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 the product.

Discussion: Experience with the product provides a basis for reducing burden. Specific radionuclide quantity limits consistent with current practice would provide the primary safety basis.

C. Other Issues Related to the Regulation of Source Material

1. Welding Rods - § 40.13(c)(1)(iii)

Issue: NUREG-1717 shows calculated individual doses of up to 800 mrem/year (8 mSv/year) for a dedicated grinder of welding rods and 500 mrem/year (5 mSv/year) for welders using alternating current (AC) and no local exhaust ventilation. Using ICRP-68+ dose conversion factors, these dose estimates would be roughly 100 mrem/year (1 mSv/year) and 80 mrem/year (0.8 mSv/year), respectively, rounding to one significant digit as was done in NUREG–1717. Using dose conversion factors for actual measured particle sizes, or to those applicable to an activity median aerodynamic diameter (AMAD) of 5 μm as now recommended by ICRP for calculating occupational doses, would reduce these dose estimates further. Also, welders in the U.S. rarely, if ever, use thoriated-tungsten for AC welding. Pure tungsten or tungsten with a small percentage of zirconia is typically used for AC welding, particularly for aluminum. The thoriated-tungsten begins to melt when using AC, and as a result, the weld is not a good weld. Doses to welders using direct current (DC) are roughly a factor of 25 lower than doses to welders who use AC. According to NUREG-1717, exposure could be reduced by a factor of roughly 10 if local exhaust ventilation is used. The most significant concern would be the few distributors whose primary job is to grind electrodes to customers' specifications. They may be secondary distributors and not licensed. This activity occurs only at a handful of places in the U.S., and most likely, local exhaust ventilation is used. They may also use automated systems, where inhalation of grinding dusts are significantly less. Therefore, the dose to dedicated grinders is expected to be less than 100 mrem/year (1 mSv/year). According to one manufacturer, approximately 10,000,000 thoriated-tungsten welding electrodes are distributed annually in the U.S. According to a major distributor, approximately 20% of those sold are pre-ground.

Possible Solution(s): (1) Require distribution by a specific licensee who would be required to package welding rods with instructions on the hazards associated with use and the precautions to be taken to adequately control those hazards, such as, for example, using local exhaust ventilation. (2) Given that there are now reasonable alternatives, using rare-earths, consider restricting further distribution of any thoriated welding rods for use under an exemption.

Discussion: The staff will give consideration to both these options; however, it appears that the first will be the most cost beneficial. Doses to the general public are likely to be very small. It is considered unlikely that welders, who are occupationally exposed, are likely to be operating under the worst conditions throughout the year. Thus, it is unlikely for them to be exposed to doses of 100 mrem/year (1 mSv/year) or more. The highest potential dose is to the dedicated grinder. Because of inherent conservatism in the dose estimates and the likelihood that some precautions, such as local exhaust or respiratory protection, or automated systems, are likely to be used at least part of the time, even the pregrinding of welding rods by distributors is unlikely to routinely expose workers to doses approaching or exceeding 100 mrem/year (1 mSv/year). If thorium does not in fact present unique benefits over alternative types of welding rods and the costs of changing over are limited, the trend toward replacing the use of thorium with rare-earth alternatives will continue, but without the possible disruptions caused by an NRC prohibition.

2. Glassware containing Not More than 10% Source Material - § 40.13(c)(2)(iii)

Issue: Uranium has been used in the production of fluorescent and iridescent glass. The use of source material to achieve a particular appearance presents a question of whether this benefit is sufficient justification for the doses. There are also products being distributed that are potentially used by children, i.e., small tea sets, marbles. NUREG-1717 estimates doses to individuals of up to 2 mrem/yr (0.02 mSv/year) for users of the glassware (assuming uranium at the exemption limit of 10% by weight). NUREG-1717 estimates a potential for 10,000 person-rem (100 person-Sv) to result over 20 years from the display of such glassware in public places, such as museums, of 100,000 pieces. Note: A particular color of yellow-green glass made with 2% uranium dioxide is identified by collectors as “Vaseline Glass.” Information on the internet about Vaseline Glass Collectors, Inc., a non-profit club organized in 1998, indicates that Vaseline Glass was primarily made from Victorian times up to just before WWII, but some is still being made today by at least five manufacturers. At least one manufacturer has been recently selling sets of dinnerware made of Vaseline glass. This website also indicates that Vaseline glass is typically 2% uranium. There is a possibility that additional types of glassware containing source material are being imported or manufactured.

Possible Solutions: Treat in the same way as glass enamel frit was treated in 1983-4. Prohibit further manufacture/distribution but retain the exemption for previously distributed items. Alternatively, require that the “point-of-sale” packaging inform the purchaser of the radioactive component of the product, giving the user the ability to choose whether or not to use a radioactive product. Also, limiting the exemption to decorative pieces, specifically restricting use in products likely to be used by children, or lowering the concentration limit, would limit individual doses, though potential collective doses would still be significant.

Discussion: The concept of justification of practice would tend to lead to a decision to ban further distribution of these glass products. However, as this is an existing industry, and individual doses are a small fraction of the recommended dose limit for the public, the impact on current distributors and on users who want this product should probably be considered. The estimated collective dose may be significant; however, it is calculated based on millions of individual viewers each of whom receives an estimated dose of 3×10^{-4} mrem (3×10^{-6} mSv). Also, the assumed 100,000 pieces on display in public places is one half of one year’s assumed annual distribution. It would seem unlikely that one half of all items produced would end up on display for an average of 20 years after its initial use in homes. As the value of and interest in

previously distributed items may increase as a result of a discontinuation of distribution, it may be some time before the number of items on display in public places is significantly reduced from the present number. Note also, although the estimated collective dose is high, it is made up of extremely small individual doses. Requiring distributors to be specifically licensed and report types and quantities distributed as planned in SECY-01-0072 would provide a better picture of the industry as the basis of considering a possible ban in the future.

3. Gas Mantles containing Thorium- § 40.13(c)(1)(i)

Issue: NUREG-1717 shows a calculated individual dose rate of 7 mrem/yr (0.07 mSv/year) for campers from gas mantles. This dose rate could be reduced if there were simple handling instructions that were followed. Final NUREG-1717 added an assessment of gas lanterns used indoors at vacation facilities and in permanent residences. The highest individual effective dose equivalent calculated and reported in NUREG-1717 is 200 mrem/year (2 mSv/year). This dose is to an individual exposed to the continued use of mantles in four lamps in a permanent residence (assumed to be the only source of light). As indicated in NUREG-1717, it is unknown how many people actually use gas lanterns containing thoriated mantles as their primary source of lighting.

Possible Solutions: Require that distributors of thorium gas mantles be specifically licensed and that the distributors label the mantle's packaging with handling instructions for minimizing inhalation and ingestion of thorium. At least one distributor has voluntarily provided safety instructions. Alternatively, prohibit further distribution of any gas mantles containing thorium.

Discussion: For the critical routes of exposure, the primary contributors to dose are radon and its progeny; the dose estimates for these scenarios are not likely to be reduced greatly by applying current dose methodology. Also, potential doses associated with the use of thorium gas mantles in residential lighting would not be reduced significantly by providing handling instructions. As the mantles used in residential lighting are unique designs, different from the soft mantles used in camping, it might be practical to limit further distribution to mantles used in camping lanterns and provided with handling instructions. However, domestic manufacture using thorium ceased some time ago, and no recent import has been identified. The only known distributor is distributing hard mantles used in decorative lighting and in much smaller quantities than had been estimated in NUREG-1717. Although there may still be some soft mantles being imported, the practice has severely declined in recent years. Thus, the impact of a complete prohibition on future distribution for use under the exemption may be minimal.

4. Optical Lenses containing up to 30% by Weight Thorium - § 40.13(c)(7)

Issue: Although routine exposures would not be expected to exceed 20 mrem/year (200 μSv/year) to television cameramen, 1 mrem/year (10 μSv/year) to typical users of 35-mm cameras, and 2 mrem/year (20 μSv/year) to more avid photographers, one factor in this is the assumption that concentrations do not exceed 10% by weight thorium. Up to 30% by weight thorium is allowed in the exemption. Also, there are thorium-coated lenses for which the regulatory status is unclear and for which a radiological assessment was not included in NUREG-1717.

Possible Solutions: Revise the exemption to allow only 10% by weight thorium. Additionally, consider clarifying regulatory status of thorium-coated lenses by specifically excluding them from the exemption or explicitly exempting them.

Discussion: Revising the concentration limit would be in keeping with ALARA and would provide better assurance that doses do not exceed a small fraction of the dose limit. However, little is known about the concentration in currently distributed lenses. It is possible that there is no current distribution of the types of lenses considered in NUREG-1717. Thus, the cost/benefit for reducing the concentration limit is not clear at this time. More information concerning the use of thorium-coated lenses is being collected by the staff. More information and analysis may lead to the conclusion that thorium-coated lenses are acceptable for use without a license. Also, reasonable controls, possibly other than a concentration limit for averaging over the lens, may be developed that could ensure the protection of health and safety of the public without significantly affecting the existing industries that use these lenses. If enough information is obtained to conclude that this is the case, an explicit provision for these lenses will be included in the Part 40 proposed rule. For efficiency and effectiveness and to ensure the protection of public health and safety, it is important to clarify the regulatory status of these lenses.

5. Depleted Uranium in Aircraft Counterweights - § 40.13(c)(5)

Issue: Although NUREG-1717 did not estimate significant potential doses from this exemption; PRM-40-28 and comments made by the petitioner on draft NUREG-1717 suggest that there is a significant problem with this exemption in that there is little or no control over proper transfer or disposal when the counterweights are no longer in service. A Regulatory Issue Summary (RIS) 2001-13 was issued on July 20, 2001, to clarify disposal options. A key point was that the counterweights should not be transferred to scrap dealers or recyclers who are likely to physically, chemically, or metallurgically process the counterweights as such processing would violate the restrictions of the exemption.

Possible Solution: Replace this exemption with a general license. The primary requirement would be that products be appropriately handled and disposed of when removed from service. In order to ensure this occurs, some tracking or inventorying may be required. Another option may be to revise the general license in § 40.25 to accommodate most depleted uranium products.

Discussion: The intent of these possible solutions would be to more completely control the disposition of these materials. However, how to do so without causing significant increases in the costs of disposal needs to be studied further.

6. Finished Tungsten- or Magnesium-Thorium Alloy Products or Parts - § 40.13(c)(4) and Aircraft Engine Parts containing Nickel-Thoria Alloy - § 40.13(c)(8)

Issue: The exemption in § 40.13(c)(4) includes restrictions on the ultimate disposal of the products or parts. This is inappropriate for an exemption, as it is very difficult to enforce such restrictions, and there are limited ways of informing users. The exemption states, in part, that it "shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part..." The term "processing" precludes parts containing tungsten or magnesium-thorium alloy from being sent to scrap facilities as an option for disposition. In contrast, § 40.13(c)(8) does not contain such a restriction. Since the alloys

regulated in both sections are similar and used almost exclusively in aircraft engine parts, it may be more appropriate to regulate them in a consistent fashion.

Possible Solution: Replace these exemptions with a general license, possibly combined with airplane counterweights. These products are used almost exclusively in aircraft, and many of the users would be the same.

Discussion: The intent of the possible solution would be to more completely control the disposition of these materials. However, how to do so without causing significant increases in the costs of disposal needs to be studied further.

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.

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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 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.
- 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

Agreement State Comments on Draft Rulemaking Plan

Summary:

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.

Discussion:

Regarding the comments on exempt distribution under § 150.15(a)(6), in a clarifying revision to that paragraph published April 16, 1969 (34 FR 6517), the reasons for NRC's retaining this authority were summarized as follows: "[T]he Commission was seeking to maintain surveillance over the safety of products containing radioactive materials, without the imposition of regulatory controls, and to be able to assess the effect of the attendant uncontrolled addition of these radioactive materials to the environment." This general intent, as well as the more specific related goals of the Consumer Product Policy, could not be well attained with multiple entities regulating such distribution.

In response to Colorado's comment on a standing compatibility committee, if such a committee is established, as recommended by the National Materials Program, the compatibility categorization of the proposed rule would be reviewed by that committee.

Concerning NYDOL's comments on the issue of making the regulations explicit on the use of the Sealed Source and Device Registry, the staff agrees that the rulemaking process should include an explanation of the rationale for using a registration process as a licensing mechanism and basis for determinations on which products should be included in the Registry. The staff does not agree that there is a problem with legislative authority in using this tool in the licensing process or that this issue warrants a separate rulemaking.

With respect to the possible inconsistency in the risk basis of generally licensed devices meeting the criteria for immediate notification when lost or stolen (i. e., allowing a device to be generally licensed when its loss or theft may justify immediate notification), comments

suggested that the NRC needed to revisit either the appropriateness of some of the devices' generally licensed status or the appropriateness of the risk levels associated with the criteria for immediately reporting thefts or losses under § 20.2201(a)(i). The staff has not identified a problem with the safety criteria associated with generally licensed devices. Although the criteria in § 20.2201 may require immediate notification for quantities of some radionuclides that present too low a level of risk, the staff believes that a reevaluation of these criteria should not fall within the scope of the subject rulemaking. Also, the situation for general licensees and specific licensees is sufficiently different, particularly in the area of training, that it would be reasonable for specific licensees to be required to call the Operations Center immediately concerning thefts or losses, and general licensees within 30 days, for the same quantities of radionuclides. As generally licensed devices meeting the requirement for registration are considered a potential problem for contamination if smelted, this aspect will also be evaluated. In addition, generally licensed devices are not expected to contain the types and quantities of radioactive material that would be of concern for possible terrorist use in a radiological dispersion device. However, the staff will consider any conclusions developed with respect to that issue and the need for improved control of sources, when developing the subject proposed rule.

Clarifications have been made to the draft rulemaking plan in response to Agreement State comments. In addition, Attachment 6, which was not reviewed by the Agreement States, provides supplemental discussion of some of the issues. Such clarifications may reduce State concerns (e. g., allowing an option for NRC licensing of possession and use by manufacturers in Agreement States may have implied that the NRC might reduce States' authority to do so; however, the staff only suggests that a possible option might be made available for this to happen if the individual State agrees). The Agreement State comments will also be considered during the development of the proposed rule.