December 15, 1997

FOR: The Commissioners

FROM: L. Joseph Callan,
Executive Director for Operations /s/

SUBJECT: REVISING RULES ON GENERALLY LICENSED AND EXEMPT PRODUCTS AND THE MANUFACTURERS/DISTRIBUTORS OF THESE PRODUCTS (10 CFR PARTS 30, 31, AND 32)

PURPOSE:

To inform the Commission of the staff's plans related to the regulation of exempt and generally licensed products and the manufacturers/distributors of these products.

BACKGROUND:

In approving a rulemaking plan to amend the prototype testing requirements for hands, dials, and pointers containing tritium (Attachment 1; SRM dated March 7, 1997), the Commission directed the staff to consider the need to revise 10 CFR Parts 31, "General Domestic Licenses for Byproduct Material" and 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," and corresponding sections of Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," to make the rules for the manufacture and distribution of generally licensed and exempt products or materials more flexible and user-friendly, while still maintaining an adequate level of safety. The Commission also directed the staff to proceed quickly with the future regulatory improvements mentioned in the last two sentences of Section N of the Rulemaking Plan, as available resources permit, and to expand this effort to include generally licensed products and materials as well. The last two sentences of Section N in the Rulemaking Plan were:

> Further improvements in the licensing of distribution of exempt products/materials could be considered in the future as part of the ongoing program to reevaluate the exemptions. In addition to considering rulemaking, the staff may review the licensing practices implementing Part 32 with respect to exempt distribution, such as providing for a more generic product approval for distribution under 10 CFR 30.19.

DISCUSSION:

Current Activities

The staff has two separate ongoing programs to evaluate the risks associated with (1) exempt products and materials and (2) generally and specifically licensed products, which are expected to result in recommendations for rulemaking. In addition, the staff has a third project that is designed to improve the current review process for applications for possession, use and distribution of licensed materials.

A. Systematic Assessment of Exemptions

The staff has been in the process of reevaluating the exemptions from licensing requirements beginning with the assessment of radiation doses to individuals from exempt products and materials containing either byproduct or source material (exempt under Part 30 and Part 40, "Domestic Licensing of Source Material," respectively). This assessment includes evaluation of doses to individuals (e.g., users, store clerks, warehouse personnel, transportation workers) under normal as well as accident conditions. Several generally licensed products that may be candidates for reclassification as exempt products are also included in this assessment. A draft of a NUREG/CR report, entitled "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," was distributed in August 1997 to NRC staff for comment. The final report is expected to be issued in the first half of 1998. After the report is final, the staff will evaluate the adequacy of each of the current exemptions from licensing and the appropriateness of the associated requirements on the manufacturers/distributors for each exemption.

It is clear, however, from review of the regulations, that the requirements in this area are not consistent with respect to the level of control exercised by the NRC versus the potential impacts on public health and safety from the various exemptions. The requirements in Part 32 applicable to the distribution of byproduct material to exempt persons may be more burdensome than is necessary to adequately protect public health and safety. Some of the requirements for the approval of quality control programs, prototype testing, or sampling could be eliminated for products with extremely low risks. In contrast, there are essentially no requirements in Part 40 specifically to control the distribution of source material to exempt persons. Therefore, some requirements may need to be added so that the Commission can be cognizant of the types and quantities of source material being distributed to the public and ultimately to the environment and can ensure that the products distributed are as allowed by the exemptions. After the completion of the assessments, the staff will develop a plan to (1) ensure that the total exposure of the public from the many exempt products and materials are unlikely to exceed a fraction of the public dose limit and (2) modify the regulations so that the controls placed on the distributors of exempt products and materials are commensurate with the potential risks involved. This plan will be submitted to the Commission for consideration.

B. Program to Improve Control and Accountability of Generally and Specifically Licensed Devices

As part of its response to the December 31, 1996, SRM, "Improving NRC's Control Over, and Licensees' Accountability For, Generally and Specifically Licensed Devices," the staff has developed recommendations that include a comprehensive risk assessment of licensees' activities under the current licensing and inspection programs. These are discussed in SECY-97-273, November 26, 1997. The risk assessment would evaluate the risk associated with licensees' activities by determining and relating the probabilities of the occurrences and consequences of incidents involving radioactive material.

The results of the risk assessment would be used to develop restructured licensing and inspection programs for materials licensees. The designs of the restructured programs would be based on the risks associated with possession and use of the radioactive materials. The risk assessment was initiated in June 1997 and is projected to be complete in the fall of 1998. The staff will provide the Commission with the results of the risk assessment and a schedule for implementation of a restructured licensing and inspection program. The schedule will include the staff's plans for rulemaking to implement restructured licensing and inspection programs.

C. Improving Licensing Practices

As part of its response to the April 14, 1997, SRM, "Briefing on BPR Project on Redesigned Materials Licensing Process," the staff provided the status of the development and implementation of the Licensing and Inspection Online System (LIONS) and consolidated guidance for applicants and reviewers of license applications. LIONS and guidance consolidation, as well as the ongoing development of additional guidance, are designed to make the licensing process more flexible and user friendly for persons that possess, use, and distribute byproduct material. This includes distributors of products to general licensees and persons exempt from licensing.

Additional Considerations in Response to the Commission Directive

In response to the SRM of March 7th, the staff has evaluated the regulations in Parts 30, 31, and 32 applicable to generally licensed products, products exempt from licensing, and the distributors of these products specifically for possible ways the regulations could be made more flexible and user-friendly. These regulations were promulgated at different times in a piecemeal manner and may not be as risk-informed, flexible, or user-friendly as they could be. Furthermore, the regulations may contain requirements that are now obsolete. Thus, the staff agrees with the Commission that opportunities exist for some current regulations to be improved to become more flexible and user-friendly. Regulatory improvements that could be made fall into two categories: those that would require the completion of the risk analyses before being undertaken and those that are not dependent on the results of the risk analyses. Because of the broad nature of the programs described above, many of these kinds of improvements would have been considered by the staff following completion of the risk analyses in any case. Attachment 2 presents brief discussions of possible approaches to regulatory improvement that could be considered without the results of the risk analyses. However, for reasons provided in the next section, the staff believes it is better to wait until the risk analyses are complete before proceeding with these actions.

Staff Plans

Although the staff could proceed now to more fully evaluate potential approaches to making certain regulations more flexible and user-friendly and then develop plans for further rulemaking to address risk-informed changes after the risk assessments are completed, the staff plans to complete the risk assessments before developing plans for any rulemaking in these areas. With this approach, all of the issues related to each of these broad areas (exemptions and general licenses) can be considered at one time. This will make deciding what issues should be dealt with in a single rulemaking action and prioritizing various actions more efficient. It would be confusing and inefficient to make revisions to regulations that may be eliminated when implementing the results of the risk assessments. This would be the case for items 3 and 5 in Attachment 2. Because of the broad nature of the evaluations that are underway, additional inconsistencies or inefficiencies may result if rulemaking in these areas are begun before the completion of the risk evaluations with subsequent development of plans for rulemaking. Because of these potential problems and because of resource limitations, the staff believes it is better to wait until the risk analyses are complete before initiating any rulemaking.

RESOURCES:

Resources are available to complete the risk analyses and to develop further plans for rulemaking in these areas. Total resource impacts for each program cannot be estimated at this time. Much of what is involved in completing these programs has been anticipated previously. The additional effort in the area of making the regulations more flexible could add approximately 2 FTE to the overall resource needs. However, the total required resources will be less if all rulemaking issues in each area (exemptions and general licenses) are considered in an integrated manner after the risk analyses are completed. The staff will provide task-specific resource estimates when more specific plans for rulemaking are developed. Since resources are not included in the FY 1998 and FY 1999 budgets to revise Parts 30, 31, and 32 to make them more flexible and user-friendly, staff will also provide an assessment of impacts to other budgeted activities if resources were reprogrammed to accommodate these actions.

COORDINATION:

The Office of the General Counsel has no legal objection to this plan. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed the paper for information technology and information management implications and concurs in it. However, the potential regulatory improvements discussed involve changes in information collection requirements that must be submitted to the Office of Management and Budget at the same time a rule is forwarded to the Federal Register for publication.

L. Joseph Callan
Executive Director for Operations

Contact: Catherine R. Mattsen, DRA/RES
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Attachments: 1. SRM dated March 7, 1997

2. Potential Approaches to Regulatory Changes

ATTACHMENT 1

March 7, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-97-028 - RULEMAKING PLAN FOR REVISION OF PROTOTYPE TESTING REQUIREMENTS FOR HANDS, DIALS, AND POINTERS USING TRITIUM: RESPONSE TO PRM-32-4 TO PUT TIMEPIECES WITH GASEOUS TRITIUM LIGHT SOURCES ON THE SAME REGULATORY BASIS AS TIMEPIECES WITH LUMINOUS TRITIUM PAINT

This is to advise you that the Commission has not objected to implementation of the proposed Rulemaking Plan. The staff should ensure that the proposed regulatory guide on prototype testing procedures for various types of timepieces is made available for use by applicants no later than the effective date of the final rule change to 10 CFR 32.14.

The staff should consider the need to revise 10 CFR Parts 31 and 32, and corresponding sections of 10 CFR Part 30, to make the rules for manufacture and distribution of generally-licensed and exempt products or materials more flexible and user-friendly, while still maintaining an adequate level of safety. The staff should proceed quickly with the future regulatory improvements mentioned in the last two sentences of Section N in the Rulemaking Plan, as available resources permit, and to expand this effort to include generally-licensed products and materials as well.

(EDO) (SECY Suspense:9/30/97)

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

SECY NOTE: THIS SRM AND SECY-97-028 WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

ATTACHMENT 2

Potential Approaches to Making the Regulations More Flexible or User-Friendly
Not Dependent on Outcomes of the Risk Assessments for Exempt and Generally Licensed Products
and the Manufacturers of the Products
(10 CFR Parts 30, 31, and 32)

(Applies to Products Distributed to General Licensees)

1. **Issue:** Consideration could be given to incorporation of provisions into Part 30 for specific licensees for byproduct material, including manufacturers of generally and specifically licensed products (but excluding manufacturers of exempt products), that would permit licensees to modify their facilities, programs, or product designs without prior approval from NRC provided that the modifications would not decrease the safety of the products or operations. Changes would be reported to NRC after the fact.
Rationale: This would provide flexibility to licensees in their operations and product design and, in some cases, improve safety. Currently, licensees must apply to NRC for prior approval (and pay substantial fees) before making changes even if they appear to improve safety; this is a deterrent to making improvements in facilities and products. However, consideration would need to be given to potential safety impacts if licensees make misjudgments concerning the effects of changes on safety.

(Applies to Products Distributed to Persons Exempt from Licensing)

2. **Issue:** The reporting of byproduct material in products and materials being distributed to the public (exempt persons) may be improved by changing the period of reporting transfers to every calendar year from 5 years and when filing an application for renewal or termination of the license. (The licensing and reporting of commercial distribution of source material to exempt persons also needs to be considered.) In addition, the staff could improve the handling of the information in-house, re-establishing a computer database.

Rationale: 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 practices 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 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 is considered more straightforward and easier 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 this more efficient and could improve the quality of the information. The NRC could better evaluate the doses to the public from exempt products and materials, as well as inform the public concerning such exposures. This change would also provide a better basis for considering any future rulemaking in this area.

(Applies to Products Distributed to General Licensees and Persons Exempt from Licensing)

3. Issue: The requirements for manufacturers of exempt and generally licensed products may be made less prescriptive, particularly in the areas of prototype testing, sampling, and quality control. The regulations would continue to contain the requirements and would 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 or deletion include:

   - Prototype test procedures (32.53(d)(4), 32.57(d)(2), 32.101, 32.102, and 32.103)
   - Sampling procedures (32.55(b) through (d), 32.59, 32.62(b) through (e), and 32.110)
   - Submittal of quality control procedures (32.51(a)(2), 32.53(b)(5), and 32.57(b)(5)).

   The only such prescriptive requirement pertaining to manufacturers of an exempt product that remains after responding to PRM-32-4 is 32.40, which is also obsolete; see item 4 below. Requirements to submit specific quality control procedures are in 32.22(a)(2)(xv) and 32.26(b)(15).

   Rationale: This would make regulations more flexible by making them performance-based. The licensee would be free to propose alternative methods to those presented in guidance to satisfy the requirement in the regulation. These changes could be made without the results of the risk analysis, because the requirements would continue to provide adequate assurance that the products being distributed meet the performance standards.

4. **Issue:** Some regulations are obsolete and could be removed. Consideration could be given to deleting exemptions and general licenses for products that are no longer being used or manufactured, or restricting further distribution while allowing for the continued possession and use of previously distributed items. Candidate exemptions in Part 30 include those for automobile lock illuminators, balances of precision, automobile shift quadrants, thermostat dials, and resins containing Sc-46. (There are additional obsolete exemptions in Part 40.) Ice detection devices containing strontium 90 are generally licensed under 31.10; this section may also be obsolete as it appears that this product is no longer being used. If this is verified, this section could be deleted.

   Specific requirements for manufacturers and distributors of products that are no longer being manufactured or distributed could also be deleted. For exempt products, the prototype test procedures for automobile lock illuminators in 32.40 could be deleted. The requirements on manufacturers of ice detection devices containing Sr-90 (32.61, 32.62, and 32.103) may be deleted, if it is determined that these products are not being manufactured under equivalent Agreement State regulations.

   Rationale: This change would simplify the regulations by eliminating extraneous text. It would eliminate the need to reassess the potential exposure of the public from these products for 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.

5. **Issue:** Regulatory text might be restructured to make it simpler to understand and less repetitious. One possible approach could be to consolidate like requirements into single sections. There are several sections in the regulations addressing essentially the same requirements for manufacturers and distributors of various exempt products. This is also the case for requirements applicable to various categories of general licensees and those applicable to most or all manufacturers/distributors of generally licensed devices. Specific types of requirements that could be consolidated include: information to be submitted on descriptions of products and records maintenance and reporting requirements. Another possible change would be to move certain criteria such as acceptable radiation levels from the exemption sections in Part 30 to the requirements applicable to distributors in Part 32.

   Rationale: Such changes may somewhat simplify the regulations by being more concise and less repetitious. Criteria important to the licensed manufacturer/distributor would be in the same place as other requirements for manufacturers/distributors. However, these would be non-substantive changes with limited effect; thus resources for a separate rulemaking may not be justified. Rather, this goal of making the regulations easier to understand could be considered in the process of developing other regulatory changes.