November 17, 2003

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS - SECY-02-0196 - 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

The Commission has approved in part and disapproved in part the staff's recommendation to develop a proposed rulemaking to address exemptions from licensing in 10 CFR Parts 30 and 40 and for risk-informing 10 CFR Parts 30, 31, and 32, subject to the comments noted below.

1. The Commission has approved the recommendation to revise the requirements in Part 32 for reporting material transfers from every five years and when applying for renewal or termination of the license to annual, but has disapproved the database at this time. (Option 1, item #1)

2. The Commission has approved the recommendation to revise § 30.18 to reflect the 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. The Commission has disapproved revising the quantities of the exemptions at this time until staff completes an evaluation of all major efforts underway that could have an impact on NRC's regulations for exemptions from licensing. (Option 1, item #2)

3. The Commission has disapproved, at this time, the recommendation to revise § 32.11 to require distributors of exempt concentrations to demonstrate products/materials meet safety criteria. (Option 1, item #3)

4. The Commission has approved the recommendation to eliminate or restrict to previously distributed products, exemptions that have never been or are no longer being used. (Option 1, item #4) The staff should verify that they really are obsolete. The proposed rulemaking should include a discussion of the research that was performed by the staff to confirm the determination of obsolescence.

5. The Commission has disapproved items #1 and #5 in Option 2. With respect to item #5, the staff should work with OGC to clarify the legal options available for this action.

6. The Commission has approved items #2, #3, #4, #7, #8, #9, #10, #11, and #12 in Option 2. The Commission has not approved item #6 in Option 2 at this time.

The staff should continue to collect information on the approved items listed above and develop a proposed rulemaking which should include all associated communications outside of the agency.

(EDO) (SECY Suspense: 5/20/05)

The staff should provide the Commission with a comprehensive plan for evaluating the latest scientific information and the recommendations of the international/national radiation protection organizations for possible incorporation into our regulatory activities, policies, and regulations. This plan should include evaluation of all major efforts scheduled to be completed in the next several years, and lead to staff recommendations on the need to revise NRC's regulatory program, e.g., recommendations on if and when the tables in Part 20 and the tables in Part 30 should be updated.

(EDO) (SECY Suspense: 4/2/04)

In the interim, staff should apply greater use of updated scientific methods and models in evaluating exemptions from the regulations for use of byproduct material. Specifically:

NUREG-1717 should not be updated in its entirety, but rather should be recognized as a historical document developed using the models and methodology available at a particular time. However, when exemption requests are assessed, the appropriate sections of the NUREG should be re-analyzed on a case-by-case basis using the most up-to-date information, methodology, and models, and realistic exposure scenarios. The staff should present to the Commission a plan of action for addressing any significant revision to the analysis in NUREG-1717 and making the new analysis publicly available.

The staff should continue to use the newer methodologies in ICRP Publications 66 and 68-72 on a case-by-case basis.

The Commission has disapproved the staff's recommendation to revise the policy position for labeling of products and/or point-of-sale packaging.

Given that this rulemaking involves very low-risk radioactive material from a public health and safety perspective, the staff should carefully evaluate the resources required for this rulemaking relative to other rulemakings involving higher-risk material or activities (e.g., rulemakings associated with the orders and additional security measures) and the need to evaluate if and when the tables in Parts 20 and 30 need to be updated. If necessary, the Commission would not object if this rulemaking had to be put on hold if resources were needed for these other activities.

The staff should provide the Commission with Issue Papers on the following topics.

Distribution of exempt material database - The proposed changes in Option 1 #1 discuss changing the reporting requirement from every 5 years to annually and "developing" or "re-establishing" a database to "better use the information supplied by licensees". The staff should determine the resource impacts of developing this database, the specific information it will track, and whether there will be any overlap with information which is tracked in other systems such as the GLTS, or the National High-

Risk Source Registry. Is there a reason why this information should not be combined with these other systems? What is currently done with the 5 year information we collect now? The SRM on SECY-01-0072 directed the staff to "compile additional available information about the products and quantities of source material distributed and used by exempt persons and general licensees..." Is this information going to be included in this database?

Dose limits/criteria - This issue involves the staff's proposals related to "safety criteria" and to doses that result from using exempt material. In several of the proposals the staff suggests changes to the safety criteria or the exempt quantity thresholds because of potentially unacceptable doses. For example in Option 1 #3 the staff proposes to revise the regulations to require distributors of exempt concentrations to demonstrate that products meet safety criteria similar to those for class exemptions. These safety criteria specify that the use of a product must not exceed certain dose limits. Another example is the staff's proposal to revise some of the exempt quantity limits in the table in section 30.71 (Option 1 #2) because the doses may be unacceptable. This raises the issue of what the staff considers an "unacceptable dose"? It is not clear at all in the paper but it appears as if the staff is using 1 mrem/yr as a criterion. The paper does discuss the fact that the staff did not rely on NUREG-1717 calculations, but what scenarios were, or will be used to determine that an exempt value is now unacceptable. 1 mrem/yr is not a reasonable criterion and it is not a reasonable use of staff resources to spend the time and energy to develop a proposed rulemaking without input from the Commission on the dose criteria that would be acceptable to use. The staff should more fully explain the scenarios and models being considered, the types and number of isotopes impacted, the typical use of these isotopes in exempt products, etc.

Security - The staff should step back and take a broader look at Part 30 from a security perspective. Are there sections of Part 30 that should be revised, not because of an immediate health and safety risk but from a security risk? The revised Code of Conduct on the Safety and Security of Sources is going to be adopted not only by the U.S., but internationally as well. The NRC will be basing several of its security measures for sealed sources, including import and export regulations, on the Category I and II quantities of radionuclides of concern listed in Appendix 1 to the Code. These quantities were based on the D values calculated in TECDOC-1344. The staff should look at the original basis for the exempt quantity values in Part 30 and consider how they can be revised for consistency with the TECDOC-1344 methodology. For example, 30.71 Schedule B could be revised so that the exempt quantities were based on $1/10^5$ or $1/10^6$ of the D values contained in TECDOC-1344. Adopting some fraction of the D-values values in this way could result in some dramatic changes for some of the values in Schedule B. Dramatic across the board changes like this could significantly impact facilities that deal with exempt quantities of material, however, the Commission does not have a sense of how disruptive a change like this would be or even how many facilities would be disrupted. The staff should provide a discussion of the pros and cons of replacing section 30.71 Schedule B with some fraction of the TECDOC-1344 D values. The staff should also consider and discuss other sections of Part 30 that could be updated to address security issues.

A recent Federal Register Notice announced the receipt of a petition for rulemaking (PRM-40-29)

to request the amendment of Part 40 regulations to exempt end users of a catalytic device containing thorium from NRC's licensing requirements. The staff should evaluate the potential to change the regulations as requested in the petition at the same time they change the regulations as proposed in this SECY paper.

The staff should consider appropriate changes to guidance documents to achieve greater consistency in the decisions regarding the use of radioactive devices for potentially "frivolous purposes." While not part of the rulemaking plan, the staff should proceed with developing appropriate guidance in this area. In addition, staff should engage with appropriate Customs Service and Commerce Department staff to inform them of the Commission's concerns with products involving the frivolous use of radioactive sources and seek to identify possible interagency efforts which can be adopted to minimize or eliminate entry of such products into the United States.

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR