November 17, 2003

COMMISSION VOTING RECORD

DECISION ITEM: SECY-02-0196

TITLE: 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 (with Chairman Diaz and Commissioner McGaffigan agreeing in part and disagreeing in part and Commissioner Merrifield agreeing) responded to the subject paper as recorded in the Staff Requirements Memorandum (SRM) of November 17, 2003.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

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Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-02-0196

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DIAZ	X	X			X	10/19/03
COMR. McGAFFIGAN	X	X			X	10/31/03
COMR. MERRIFIELD	X				X	2/5/03

COMMENT RESOLUTION

In their vote sheets, Chairman Diaz and Commissioner McGaffigan approved in part and disapproved in part and Commissioner Merrifield approved the staff's recommendation. All provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on November 17, 2003.

Commissioner Comments on SECY-02-0196

Chairman Diaz

I approve, in part, and disapprove, in part, staff's recommendation to proceed with Option 2 in the rulemaking plan for revising the regulations for exemptions from licensing for byproduct material in 10 CFR Parts 30, 31, and 32. Specifically, I approve Item #4 of Option #1 and Items #2-4 and #7-12 of Option #2.

I disapprove Item #1 in Option #1. In SECY-02-0196 the staff indicates that insufficient information exists to bound the uncertainty of potential doses to workers and the public that could result from the distribution of exempt material and recommends that reports of distribution of byproduct material to exempt persons be made annually. However, no information is provided from either the existing five-year reports or the development of potential exposure scenarios to suggest that there is a significant health and safety issue that would be identified by requiring annual reports. Without further information to suggest significant exposures could potentially occur, there appears to be little basis for requiring annual reports.

I approve, in part, and disapprove, in part, Item #2 in Option #1. I approve staff revising §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. I disapprove staff 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. The discussion below under Item #3 of Option #1 and Item #6 of Option #2 provides more detail on this issue.

I approve, in part, and disapprove, in part, Item #1 in Option #2. I strongly believe that there should be consistent regulations for materials/products with equivalent risks. However, I believe that the Commission needs more information before it can adequately evaluate a policy on the applicability of the regulations in Part 20 to Part 30 exempt users, and specific licensees. Without any safety justification for this issue, I believe that resources should not be used to address this issue at this time.

I disapprove Item #5 in Option #2. The paper does not provide enough information to make a decision, at this time, either on the benefits of having the NRC exempt distribution license cover possession for importers so that there is no need for separate possession and use licenses or on the benefits of NRC issuing licenses for possession and use in Agreement States. In addition, since there is no health and safety issue identified for this item, I believe that there is no need to include this item in the rulemaking plan.

At this time, I also disapprove staff proceeding with Item #3 of Option #1 and Item #6 of Option #2, which would require development of safety criteria for certain exemptions. I have consistently emphasized that we should base our regulations, associated documents, and regulatory decisions on the most up-to-date scientific information, methodology, and models and realistic scenarios. Therefore, before the staff proceeds with either developing or revising the safety criteria associated with exempt materials, 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.

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:

> Staff should continue to use the newer methodologies in ICRP Publications 66 and 68-72 on a case-by-case basis to approve exemptions. This is consistent with my vote on exemptions from source material, which approved the issuance of case-specific exemptions, when justified.
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> I do not believe that NUREG-1717 should 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.
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> I continue to support the earlier position of the Commission that staff should not revise Part 20, at this time, to reflect ICRP Publications 60, 66, and 68-72 because of the efforts underway that could change the recommendations in those documents.

I also disapprove staff's recommended policy position for labeling of products and/or point-of-sale packaging, which staff acknowledges is "based on a consumer's right to know," rather than on the need to provide the consumer with health and safety information. I believe that providing the consumer with certain information, such as "a statement that the use and disposal of the product are exempt from regulations," would needlessly confuse and/or alarm the public. In general, we need to develop and implement consistent policies and regulations that are commensurate with the risk to public health and safety. Therefore, any policy decision on labeling should be based on the potential for an individual to receive a significant dose from the product.

Given that this rulemaking involves very low-risk radioactive material from a public health and safety perspective, 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, I would not object if this rulemaking had to be put on hold if resources were needed for these other activities.

Commissioner McGaffigan

Before I begin to outline my vote I need to make a general statement about the structure and organization of this paper. I found this paper very difficult to read and to understand. This was in stark contrast with some recent excellent papers from the staff on arguably far more complex issues (e.g., SECY-03-0069 and SECY-03-0068). The paper contained numerous proposed changes and in many cases I found it difficult to understand the exact nature of what the staff was proposing to change. The Commission paper itself was very short and did not provide an adequate overview of the issues. Attachment 7 was more useful but it did not always describe

or organize the proposed changes the same way as Attachment 6 which added to the confusion. The staff should have done a much better job organizing and writing this paper. That being the case, I have approved or disapproved those actions for which I had enough information to make a decision, and I have requested that the staff provide additional information for the remaining issues.

I approve the staff moving forward with a proposed rulemaking paper for a subset of the actions that are recommend in Option 2. Attachment 7 of this SECY paper contains a list of actions recommended under each Option. Using this list as a reference I approve the staff to move forward with Option 1 actions #1(reporting requirements only - not the database), #2 (combining sources only - not revisions to 30.71), and #4 (obsolete requirements). I also approve under Option 2 actions #2 (SS&D requirements), #3 (broaden the class exemption for other types of detectors), #4 (electron tubes), #7 (immediate reporting requirements), #8 (new class exemption for generally licensed devices), #9 (smoke detectors), #10 (Prototype testing), #11 (QC sampling) and #12 (Prototype testing).

The staff should continue to collect information on these items and develop a proposed rulemaking including all of the associated communications outside of the agency. One point I would like to make here is that several of the proposed changes listed above are requirements that the staff wants to eliminate because they are obsolete, i.e., the product is no longer manufactured, imported or used. I agree with the staff that truly obsolete requirements should be removed. However, 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.

The rest of the actions listed in Options 1 and 2 that I have not specifically identified as approved above, are not ready to go to the proposed rulemaking stage. Many are vague and have policy issues associated with them. The staff should provide the Commission with more specific information concerning the proposals before a decision can be made to go forward with these actions. 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". As I stated above, I approve changing the reporting requirement to an annual requirement, but I am concerned with the development of yet another database. I would like to have a clear understanding of how the database will be used. What are the resource impacts of developing this database, what specific information will it track, will there 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 to me as if the staff is using 1 mrem/yr as a criterion. I am very concerned that the staff is proposing to lower any exempt quantity limits for which the potential dose dose exceeds 1 mrem/yr. The paper does discuss the fact that the staff did not rely on NUREG-1717 calculations, but what scenarios did they, or will they use to determine that an exempt value is now unacceptable. I do not think 1 mrem/yr is a reasonable criterion and I also do not think it is 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 - I personally believe 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? As I have said many times, 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. I realize that dramatic across the board changes like this could significantly impact facilities that deal with exempt quantities of material. However, I do 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.

I believe there are several policy issues contained in this paper. The first, concerning labeling, is specifically discussed by the staff. The paper asks the Commission to address the policy issue of requiring labeling for products containing exempt material. Most exempt products containing byproduct material currently require labeling while most exempt products containing source material do not. The staff recommends increasing the items that require labeling. I do not agree and believe that changing the labeling requirements at this point would be too resource intensive. The Commission has designated these quantities of source and byproduct material as exempt because they pose very little risk. The doses associated with the use of these products are so low that the products can be used and disposed of with no restrictions. Requiring labeling seems to be in direct conflict with the staff's goal of risk-informing all materials regulations and regulatory activities. The staff and the licensees could spend considerable resources developing and complying with this requirement and there would be no clear health and safety benefit. In

addition, the paper states that labeling should be done when practical. What is the definition of practical? How much will it cost to make these changes and at what cost is it no longer "practical"? I do not want NRC to be creating burdensome new requirements when there is not a health and safety benefit that would justify even minimal costs. In fact, it may actually be more risk-informed to remove the current labeling requirements for byproduct material and focus more on tracking where and to whom large amounts of exempt material is being distributed since that is where there is at least the possibility of some small health and safety issue. I disapprove this action.

I see a second policy issue that was raised in this paper. Option 2 #1 discusses the fact that it is unclear exactly how a specific licensee should treat exempt material when it is in their possession. Should they be required to dispose of exempt quantities of material as if it were licensable radioactive material? I do not think so. Again, this is exempt material for a reason, and simply because a facility already has a license does not make this exempt material any more risky. If this material requires special handling and disposal it should not be considered exempt. In addition, this situation only serves to punish those facilities with an NRC license. How would the staff justify adding a burden to a licensee when his neighbor, who has the same material but does not have a license, has no such burden? I can not support requiring a licensee to spend money to treat exempt materials differently especially when there is no health and safety risk. I disapprove this action.

I also disapprove Option2- #5 which discusses NRC taking over issuing possession licenses to Agreement States licensees which also require an NRC distribution license. Based on my reading of the regulations and our authority in the Atomic Energy Act this could require renegotiation of the §274b agreement with each State. Under the existing agreements, with specifically stated exceptions only, NRC has discontinued its authority over source material, byproduct material, and less-than-formula amounts of special nuclear material with the State. The staff should work with OGC to clarify the legal options available for this action.

I would also like to state that I am uncomfortable with using NUREG-1717 as the basis for regulatory actions. This document is overly conservative, as the staff discussed in this paper and in SECY-03-0068. In using NUREG-1717 in the future the staff should always re-verify the dose calculations using reasonable scenarios. The fact that we have to do this makes NUREG-1717 an almost useless document. However, I also agree with Commissioner Merrifield's vote that it would be too costly to completely redo this NUREG on which the staff and its contractors labored for about a decade. The staff should present the Commission with their plan for making the public aware that this NUREG is flawed and that the doses calculated in it are often unrealistic overestimates.

In closing, I would like to mention a recent Federal Register Notice which I found interesting. The FRN was issued to notice 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. From the limited information contained in the FRN, this request seems reasonable and I would hope that the staff could change the regulations as requested in the petition at the same time they change the regulations as proposed in this SECY paper.

Commissioner Merrifield

I approve the three staff recommendations provided in SECY-02-0196 concerning rulemaking associated with exemptions to 10 CFR Parts 30, 32, and 40 as modified in the following paragraphs. To be specific, I approve (1) the staff proceeding with Option 2 of the subject rulemaking plan with two modifications described below, (2) the staff's use of a policy decision concerning the labeling of products, and (3) the staff coordinating this rulemaking with the rulemaking activity provided in SECY-01-0072. I also have some additional comments and staff direction that goes beyond the activities proposed by the staff in this SECY paper.

I approve all of the items in option 2 (which includes all of the items in option 1) as written. In addition, I would modify one item from option 3 and move it to option 2. Specifically, the tables in § 30.70 (exempt concentrations) and § 30.71 (exempt quantities) should at least be updated to be more consistent with the methodology in Part 20. I also have no objections, if the staff believes it is appropriate, for the staff modifying these tables to reflect the dose calculation methodology contained in the latest revisions to the ICRP. There are two components to my vote on this addition and I will address each in turn.

First, the last significant revision to 10 CFR Part 20 admittedly did not include modifications to all the Commission's regulations affected by the methodology introduced in Part 20. The regulations most significantly affected by the changes to Part 20 were appropriately modified. But other regulations (such as Part 30) were not specifically updated, at that time, because there was a marginal change in the benefits associated with the new methodology compared to the costs of rulemaking solely for the purpose of adopting the new Part 20 methodology. The decision was that when these regulations were significantly revised for other reasons then that would be the appropriate time to also modify them to reflect the changes in Part 20. As the staff correctly notes in this SECY paper, it is still a marginal activity to modify Part 30 solely to achieve consistency with Part 20. However, this is a significant change to Part 30 and we should use this opportunity to make it consistent with Part 20.

Second, the staff appears to have misconstrued the Commission guidance concerning using the latest version of ICRP methodology. The paper states several times that the Commission has directed the staff not to use the latest ICRP methodology. Previously, the Commission had been asked if the staff should precede with modifying Part 20 in another significant revision to conform to the latest versions of ICRP 60. The Commission decided that it was not appropriate, at this time, to revise Part 20 because proposals have been made to make additional significant changes to the ICRP standards. However, this Commission decision was not meant to preclude the staff from proposing the use of the most up-to-date methodologies or data (i.e., radionuclide uptake and metabolism data) for specific applications, where appropriate. The Commission is not restricting the staff from using the best science to address a specific application, but the Commission also does not believe this is the appropriate time to conduct another major revision to Part 20.

There is another item in option 3 concerning the use of radioactive products for "frivolous purposes" that requires further action by the staff. I agree with the staff that this may not be an appropriate issue to address in rulemaking, and I further agree with the staff that appropriate changes to guidance documents should be considered to achieve greater consistency in the decisions regarding the use of radioactive devices for potentially "frivolous purposes." I recognize that this is not part of the rulemaking plan, but the staff should proceed with developing appropriate guidance in this area. The paper is not clear in specifying if anything will be done with the additional items discussed under option 3, and I wanted to make it clear that I believe that development of additional guidance in this area is appropriate. 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.

As a separate matter, I note that the staff provided additional information to supplement SECY-01-0072, a paper pending action by the Commission. The additional information is contained in Attachment 6 (Issues Identified in Reevaluation of Exemptions or Included in SECY-97-291) Section C (Other Issues Related to the Regulation of Source Material). I have already voted on SECY-01-0072 and reviewed this additional information to determine if I should consider modifications to my previous vote. Based on this review, my previous vote stands as written with no modifications. I agree that to avoid confusion, rulemaking for both SECY-01-0072 and SECY-02-0196 should occur at the same time.

Finally, I have a separate issue not directly associated with the rulemaking effort but directly associated with both SECY-01-0072 and SECY-02-0196. NUREG-1717, Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials, was specifically written to support these rulemaking efforts. The purpose of NUREG-1717 was to provide an assessment of potential radiation doses associated with the current exemptions from licensing for the majority of Part 30 byproduct and Parts 40 and 70 source material requirements. As the staff readily admits, the results of the individual dose assessments in NUREG-1717 vary considerably in uncertainty and conservatism. The purpose of the NUREG was to focus staff resources on the potentially more significant areas for changes in our exemption processes and regulations. This NUREG is not intended to state that there are definite problems in any particular area, it simply identifies areas that need to be investigated in more detail to determine if additional regulatory action is appropriate. As indicated in SECY-02-0196, the staff intends to review in more detail the modeling and assumptions used in NUREG-1717 as part of the rulemaking effort. Development of NUREG-1717 involved significant staff resources, and I want to publically acknowledge that the staff did a very credible effort in preparing this useful document.

However, my concern is that NUREG-1717 is a stand alone document. It contains a fairly conservative analysis that concludes that for some activities there is potentially significant exposures to workers. The staff fully intends to investigate these areas in more detail. Some of these investigations may conclude that the analysis in NUREG-1717 is overly conservative and that the exposures to the workers are much less than as presented in NUREG-1717. My concern is what plan does the staff have to document the new analysis and how is this new analysis to be connected to NUREG-1717? Staff should not interpret my concern as a desire to rewrite NUREG-1717. NUREG-1717 stands as a finished product which served to appropriately focus staff resources. But we have a public record in a very visible NUREG that states for some scenarios workers may be subject to significant exposure to radioactivity and perhaps somewhere deep in a safety evaluation we will conclude that the NUREG analysis was too conservative. How do we make sure that the public is aware of both analysis? Should the staff publish a supplement (or a series of supplements) to NUREG-1717 addressing only those areas of significant change?

Let me give a specific example, the zirconium sand industry. NUREG-1717 concludes that there could be significant exposures to certain workers in the zirconium sand industry under certain scenarios. Representatives of the zirconium sand industry have made credible presentations to the staff that actual exposures to their workers are much less than the

predicted values in NUREG-1717. Although I have not seen a written analysis by the staff, I have the firm impression that staff, at least in principal, agrees with the analysis of the industry representatives. The industry representatives have a very real concern that an official U.S. government document states they may be exposing their workers to too much radiation and there is nothing officially on the record changing that U.S. government position. The NRC may eventually conclude that rulemaking associated with the zirconium sand industry exemption is not necessary and there may be nothing publically available which documents the NRC conclusion. The industry believes that this publication places them at legal risk, and I can see their point of view. Realistically, this is a speculation by industry of potential legal action, and if the industry facts are correct, they have a high probability of prevailing in court, but at considerable expense. The question is what additional action should be taken by the NRC? I have reviewed the disclaimer on the NRC public website concerning NUREG-1717 and the zirconium sand analysis and note that it is only available if someone uses our website to access NUREG-1717. I am not sure that this disclaimer goes far enough. NUREG-1717 is published in hard copy format and is sold through the government printing office. Will people who obtain the publication in this manner also be informed of the disclaimer? Did the staff take any other action to address the concerns of the zirconium sand industry?

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 publically available. If the staff believes that what they did for the zirconium sand industry was sufficient (i.e., a disclaimer on the website), the staff should present their reasoning to the Commission and make it part of the plan. Again, I am not asking the staff to revise NUREG-1717, but I am asking the staff to devise a method to publically acknowledge when our thinking about NUREG-1717 results has significantly changed.