POLICY ISSUE
(Notation Vote)

November 18, 2004 SECY-04-0217

FOR: The Commissioners

FROM: Luis A. Reyes
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SUBJECT: DISTRIBUTION OF EXEMPT MATERIAL - DATABASE, DOSE LIMITS/CRITERIA, AND SECURITY ISSUES RELATED TO RISK-INFORMING 10 CFR PARTS 30, 31, AND 32

PURPOSE:

To request the Commission's approval that the information provided in this paper satisfies the Commission's current need and that the individual Issue Papers on the topics of the distribution of exempt material database, dose/limits criteria, and security that Staff Requirements Memorandum (SRM)-SECY-02-0196 directed staff to provide are no longer necessary.

BACKGROUND:

In 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," dated November 1, 2002, staff recommended regulatory changes as a result of a systematic assessment conducted by the staff on exemptions from licensing, for both byproduct and source material. Staff also provided options to make 10 CFR Parts 30, 31, and 32 less prescriptive and more risk-informed. In SRM-SECY 02-0196, dated November 17, 2003, the Commission approved in part and disapproved in part the recommendations and options that staff provided. In the SRM, the Commission also directed that staff prepare Issue Papers on several topics, including: (1) a database for the

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distribution of exempt material, (2) the criteria and dose limits for exempt material, and (3) the replacement of exempt material quantities with a fraction of the TECDOC-1344 'D' values ('D' values).

On September 1, 2004, the Commission's Materials Technical Assistants (TAs) requested clarification from the staff regarding the Issue Papers discussed in SRM-SECY-02-0196. The TAs commented that the Issue Papers on the database for the distribution of exempt material, and the criteria and dose limits for exempt material may no longer be required because the information that the above-referenced papers would have provided has been satisfied by other means. This paper provides information and a recommendation regarding staff activities applicable to the three Issue Papers requested by the Commission in SRM-SECY-02-0196.

DISCUSSION:

Distribution of exempt material database

Beginning in 1970, U.S. Nuclear Regulatory Commission (NRC) regulations have required that exempt distribution licensees submit a report of the radionuclides and total quantities distributed. Initially, the frequency was at least annually. Currently, these reports must be submitted at least every five years. The Commission agreed with staff in SRM-SECY-02-0196 that the reporting requirements should be returned to annual reporting. The purpose of the reporting, as stated in the 1965 Policy Statement on Consumer Products, is for NRC to monitor the usage and re-evaluate the regulations should population exposure, due to exempt product use, become a significant fraction of the permissible dose. The reported data provides the NRC with a means to determine if previous analysis of the effect of those distributed radionuclides on the public's health and safety should be reexamined.

Reports are scanned into ADAMS upon receipt from the licensee. Pre-ADAMS reports are available, mostly in hardcopy only. A considerable staff effort has been required on two occasions in the past to evaluate the distribution of exempt quantities and verify that past assumptions on use and disposal are still accurate. As discussed in SECY-02-0196, the staff plans to develop or re-establish a database to make this information more readily available for use in reviewing exempt-quantity thresholds or exempt material usage. Also, use of a database would allow staff to verify that the reporting requirements are met and meaningful data is being evaluated by the distributors as data is reported, rather than when a special evaluation occurs.

The resource savings that would be realized by the use of a database would more than compensate for the modest staff effort needed to start-up and maintain it, especially in consideration of the staff's plans to require annual reporting, in the near future as part of the implementation of SRM-SECY-02-0196. Staff understands that the Commission was concerned that the creation of this database would require significant resources, possibly similar to other recent large databases (e.g. the General License Tracking System (GLTS) and Web-Based Licensing). However, staff believes that the exempt material database could be

developed either as a small addition to the future Web-Based Licensing system, or as an internal, MS-Access database. In either case, the resource requirements would be minimal and could be included in ongoing work. The decision on whether or not information gathered on exempt material distribution will be incorporated in the Web-Based Licensing effort will be made

as part of Task 3 of the SafeSource software project. This decision is anticipated to occur in the first two quarters of FY 2006.

Dose limits/criteria

In SRM-SECY-02-0196, the Commission directed staff not to move forward with revising the exempt concentrations of 10 CFR 30.70 or the exempt-quantity thresholds of 10 CFR 30.71, at this time. A specific Issue Paper on this topic would have included a general discussion of how the staff would approach the issue in the future. Staff plans to reconsider whether to revise the exempt-quantity thresholds in the future, after several national and international activities are completed. These activities are discussed in SECY-04-0055, "Plan for Evaluating Scientific Information and Radiation Protection Recommendations," and approved by the Commission in SRM-SECY-04-0055, dated May 13, 2004. Before formalizing plans to revise the exempt concentrations and exempt-quantity thresholds, the staff will work with the Agreement States to obtain their input. After obtaining Agreement State input, staff will submit its recommendations to the Commission for its review and approval.

Security

The Commission suggested the staff might compare the current exempt-quantity thresholds listed in 10 CFR 30.71, Schedule B (Schedule B), with the 'D' values used to determine the thresholds for security considerations of certain radionuclides, and provide a discussion of the pros and cons for replacing the Schedule B values with a small fraction of the 'D' values. Staff believes, however, that such an approach would not serve the underlying basis for exemption, namely that the exempt activity poses only a negligible cancer risk should a member of the public be exposed to gamma radiation emitted by the source or should the activity become airborne. The 'D' values, on the other hand, are based on a different health end-point, namely death from one of the acute radiation syndromes. Using a specified fraction of the 'D' values as a basis for determining exempt quantities would not necessarily provide the intended level of protection against the risk of cancer from exempt sources or, conversely, may be excessively conservative in the case of some radionuclides.

The basis for the quantities of byproduct material authorized for exempt distribution was derived from or based on one of two radiological criteria. First, since inhalation was considered the most likely means of exposure, the quantity was calculated that would result in the maximum permissible concentration (MPC) in air for members of the public (International Commission on Radiological Protection, Publication 2 (ICRP 2)). Second, for each gamma-emitting radionuclide, the quantity that would produce a radiation level of 1 milliroentgen (mR)/hour at a distance of 10 cm (3.9 in.) from a point source was calculated. Then, the smaller of the two quantities was adopted as the quantity in Schedule B.

The radioactive material restrictions described above made it unlikely that any individual would inhale (or ingest), or otherwise be exposed, to more than a very small fraction of any radioactive material being used. Therefore, it was considered highly improbable that any member of the

public would receive more than a small fraction of the recommended limits for the public at the time the exemption was developed. Staff believes these criteria continue to be a reasonable basis for determining exempt quantities; however, the exposure scenarios need to be

re-evaluated for adequacy and the exempt quantities may need to be recalculated using current dosimetric models and quantities after several national and international activities are completed, as discussed above.

CONCLUSIONS:

Staff will continue with the development of a database for the distribution of exempt material reports. This database will likely be either an addition to the Web-based licensing system, or an MS-Access database. Staff agrees with the Commission TAs that a specific Issue Paper on this topic would not be useful because creating such a database does not require a significant allocation of resources.

The staff will consult with the Commission as a continuation of the rulemaking process before formalizing plans to revise the exempt-quantity thresholds. This will include obtaining Agreement State input prior to informing the Commission. Staff agrees with the Commission TAs that a specific Issue Paper on exempt quantity dose limits/criteria would not be useful at this time since no changes are currently being proposed by staff.

Risk-informing the exempt-quantity thresholds will involve reviewing many criteria. These include the adoption of new radiation protection standards, and the likely exposure scenarios for normal and accidental use of these materials, which can result in quite different relative risks for the various radionuclides than the risk resulting from the malicious use scenarios considered in the security arena. These criteria will be considered by the staff in coordination with the various stakeholders and the Agreement States.

RECOMMENDATION:

The staff recommends that the Commission approve the staff's submission of this paper in lieu of the individual Issue Papers on the topics of the distribution of exempt material database, dose/limits criteria, and security, as directed by SRM-SECY-02-0196.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections.

/RA/

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