April 21, 1999

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-99-077 - TO REQUEST COMMISSION APPROVAL TO GRANT EXEMPTIONS FROM PORTIONS OF 10 CFR PART 20

The Commission has approved the staff's proposal to grant OSRAM, Inc. an exemption from all sections of 10 CFR Part 20 that refer to quantities in Appendix B to Part 20 and instead require OSRAM, Inc. to use equivalent quantities calculated using the new internal dosimetry models as described in ICRP Publication 68. The Commission has also approved the staff granting exemptions on a case-by-case basis, based on the precedent set by the decision in this case. Should a significant number of exemption requests be received, the staff should provide this information to the Commission for consideration of a rulemaking effort to revise the affected portions of Part 20.

Generically, the staff should consider this issue in the development of future rulemakings related to the adoption of Industry Standards so as not to unnecessarily tie the agency and its licensees to industry methodologies that are static and quickly dated. Methodologies developed to show compliance with industry standards are dynamic in nature and continually evolving; therefore, rather than incorporating methodologies and protocols into the regulations themselves, the staff should instead incorporate the standards through reference in guidance documents which can be updated as needed to reflect the current state of the art. The final measure of the licensee's program should be compliance with the dose limits, not with a set of values that were meant to ease the calculational burden of the licensees.

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

K-18

March 12, 1999

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: TO REQUEST COMMISSION APPROVAL TO GRANT EXEMPTIONS FROM PORTIONS OF 10 CFR PART 20

PURPOSE:

To request Commission approval to grant OSRAM, Inc., a nuclear materials licensee, exemptions from certain provisions of those sections of 10 CFR Part 20 that specify requirements for protection against intakes of radioactive materials. These provisions will be replaced by equivalent provisions to be specified in the amended license.

BACKGROUND:

OSRAM, Inc., a Region I licensee, manufactures electric light bulb filament wire and welding rods using a powdered mixture of thorium oxide and tungsten. The thorium tungsten powder is subjected to a variety of manufacturing operations, some of which generate airborne thorium dust. Inhalation of that dust poses an internal radiation hazard, and Nuclear Regulatory Commission (NRC) regulations require the licensee to implement certain protective measures to minimize that hazard. These measures include taking a variety of air samples, using respirators in certain work areas, posting airborne radioactivity warning signs outside the work areas, and putting the potentially exposed workers on a routine bioassay program to assess their intakes and verify the effectiveness of the protection program. These measures are especially difficult in the case of thorium, because thorium is extremely difficult to measure quantitatively in air and in bioassay samples with a sensitivity adequate to show compliance with the regulations.

Many of the protective measures noted above are triggered when the air concentrations in the workplace reach specified fractions of the air concentrations tabulated in 10 CFR Part 20, Appendix B. OSRAM has submitted a request to amend its license to permit use of values other than those tabulated in Part 20 as the basis for triggering protective measures. and for assessing the internal dose to its workers. The exemption request is based upon international radiological protection recommendations published by the International Commission on Radiological Protection (ICRP) since the time Part 20 was published. OSRAM maintains that the assessment of the thorium hazard based upon 10 CFR Part 20, Appendix B has required it to implement monitoring and protection programs at levels that are out of proportion to what it believes to be the true level of hazard, and that do not significantly add to worker protection. OSRAM believes that granting the exemption would enable it to reduce the size of its internal exposure protection program while, at the same time, providing a level of protection proportional to the actual hazard.

The staff agrees that OSRAM should be granted the requested license amendment, and this paper presents a brief description of the circumstances that led to the position adopted by the licensee. Although Management Directive 9.26 grants the Office Director, NMSS, the authority to grant such a license amendment, NMSS wishes to inform the Commission of this action, and to request Commission approval, because it involves a significant departure from current regulatory practices.

DISCUSSION:

A. REGULATORY REQUIREMENTS

The basic limits on radiation exposures, as well as the minimum radiation protection practices required of any NRC licensee, are specified in 10 CFR Part 20, "Standards for Protection Against Radiation." Part 20 underwent a major revision in the 1980s, and the revised regulation was published as a proposed rule in December 1985. The final rule was published in the Federal Register on May 21, 1991, and became mandatory for all licensees in January 1994.

One of the major changes incorporated in the revised Part 20 was the manner in which internal exposure to radioactive materials is regulated. Before the revision, NRC regulated internal exposures by limiting the amounts of radioactive materials that may be taken into the body over specified time periods. The revised Part 20 eliminated regulation based on intakes and, instead, regulated on the basis of the dose that resulted from those intakes. The internal dose from intake of radioactive material is referred to in Part 20 as the committed effective dose equivalent (CEDE). The change to regulation of dose instead of intake was prompted in part by similar changes in the recommendations provided by national and international bodies, and also by the desire to end the traditional treatment of internal and external doses as two distinct and separate entities. A consequence of the

dose-based rule is that compliance would not necessarily be constrained by use of a specific set of parameters to calculate the dose. Part 20, in fact, allows certain adjustments to be made to the model parameters if specific information is available, such as adjustments when the particle size of airborne radioactive material is known, rather than using a default particle size. However, Part 20 also specifies certain protection requirements in the rule in terms of the quantities tabulated in Appendix B, the Annual Limit on Intake (ALI) and the Derived Air Concentration (DAC), rather than in terms of dose. Thus requirements such as posting of airborne radioactivity areas, monitoring for intakes of radioactive materials, establishment of bioassay programs, and use of respirators are explicitly tied to the measurable quantities, rather than to a dose. This approach was taken in order to assure that these criteria would be easy to implement, and not impose an undue calculation burden on a licensee. The quantities tabulated in Appendix B to Part 20 are based on a specific internal dose model, namely that described in ICRP Publications 26 and 30.

B. INTERNAL DOSIMETRY MODELS

The dose resulting from the intake of radioactive materials is not a measurable quantity, but must be calculated using an internal dose model. The model consists of a set of interlinked, complex, mathematical equations that describe the behavior of the radioactive material from the time it is taken into the body by a specified intake route, such as inhalation or ingestion, until it decays in the body or is excreted. The model also calculates the doses to the various organs and tissues resulting from the presence of the radioactive material in the body.

The models used in Part 20 to regulate internal dose are those described in ICRP Publications 26 and 30, adopted by ICRP in 1977 and 1978, respectively. Much of the basic structure of these models was developed in 1966, although some of its components and parameters were altered somewhat between 1966, and their formal adoption by ICRP in 1978. In the same year that the Commission approved the final Part 20 rule, ICRP published a major revision of its radiation protection recommendations (ICRP 60). In the several years following this revision, ICRP published a series of reports in which it described the components of an extensively updated and revised internal dosimetry model. These reports include ICRP Publications 60 (1990), 66 (1993), 67 (1993), 68 (1994), 69 (1994), 71 (1995), 72 (1995), and 78 (1997). Because of the way Part 20 was written, NRC licensees are not permitted to use the revised and updated internal dosimetry models.

Although the dose per unit intake calculated using the new models does not differ by more than a factor of about 2 from the values in Part 20 for most radionuclides, the differences are substantial for some, particularly for the isotopes of thorium, uranium, and some of the transuranic radionuclides. For example, for inhalation of insoluble thorium-232 (^{232}Th), the isotope present at OSRAM, the committed effective dose equivalent (CEDE) per unit intake calculated using the revised ICRP lung model is a factor of about 15 times lower than that in Part 20. Because protective measures are based on hazard, and since hazard is proportional to dose, Part 20 requires significantly more protective measures, when using ^{232}Th, than would be warranted based on the revised models. This is OSRAM's primary concern, and the staff believes that this is a reasonable basis for approval of the exemption.

RECOMMENDATION:

It is generally agreed among the national and international scientific community that the newer models provide more accurate dose estimates than the models used in Part 20. In view of this situation, the staff recommends approving the licensee's request to use the new models. Licensees requesting to use the newer models would still be bound to the same dose limits in Part 20, but they would presumably be making more accurate estimates of the doses resulting from intakes of radioactive materials than they can using the current Part 20 model. The staff recommends that the proposed action exempt the licensee from all sections of Part 20 that refer to quantities in Appendix B to Part 20, and instead require the licensee to use equivalent quantities calculated using the new internal dosimetry models, as described in ICRP Publication 68. Proper implementation of these new models will be ensured through both licensing and inspection of the licensee's operation.

The staff also recommends approving any future exemption requests from materials licensees on this modeling issue on a case-by-case basis, based on the precedent set by the Commission's decision in this OSRAM case. It is possible that several requests, possibly 5 to 10, for similar exemptions may be submitted to NRC, if the Commission agrees with the staff in approving OSRAM's request. However, should such amendment requests start to be received in significant numbers, the staff would provide this information to the Commission for consideration of a rulemaking effort to revise those sections of Part 20 that have precipitated the requests. The staff believes that rulemaking is not warranted at this time, because of the relatively small number of requests expected to be received.

COORDINATION:

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

RESOURCES:

Granting exemptions as proposed in this paper is not expected to require significant resources aside from coordination with Headquarters staff and writing the amended license. Because new models will be used by those licensees that are granted the proposed exemption, NRC's technical staff will be required to update their knowledge of these models and their ability to use them to verify the licensee's proper implementation of the models. This is not considered a special resource need, because such an activity is a normal and expected part of the technical staff's responsibility to stay current with developments in their fields of expertise.

William D. Travers
Executive Director for Operations

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