



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

December 10, 1999

DOCKET: 40-7102

LICENSEE: Shieldalloy Metallurgical Corporation (SMC)  
Newfield, NJ

SUBJECT: SAFETY EVALUATION REPORT: APPLICATION DATED  
SEPTEMBER 9, 1999

BACKGROUND

By letter dated September 9, 1999, SMC requested an amendment to its Source Material license SMB-743 to allow the use of Derived Air Concentration (DAC) and Annual Limit on Intake (ALI) values for uranium and thorium calculated using the new internal dosimetry models as described in ICRP 68. This is currently considered an exemption request from the requirements of 10 CFR Part 20. However, the Commission by Staff Requirement Memorandum (SRM) dated April 21, 1999, authorized the staff to grant such requests on a case-by-case basis.

DISCUSSION

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 1980's, 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, (56 FR 23391) 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 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), 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 two 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 ( $^{232}\text{Th}$ ), the 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  $^{232}\text{Th}$  than would be warranted based on the revised models. This is SMC's primary concern, and it has requested a DAC value for thorium of  $1.9 \text{ E-}11 \text{ } \mu\text{Ci}$  per milliliter and for uranium of  $8.4 \text{ E-}11 \text{ } \mu\text{Ci}$  per milliliter and an ALI value for thorium of  $0.047 \text{ } \mu\text{Ci}$  and for uranium of  $0.2 \text{ } \mu\text{Ci}$ . The staff has calculated the DAC and ALI for thorium and uranium using the new dose model and has determined that SMC's proposed DAC and ALI will limit worker doses to less than NRC's regulatory limit of 5 rems. Therefore SMC's request is acceptable, because it gives SMC workers using thorium and uranium equivalent radiological protection as required by 10 CFR Part 20.

Accordingly, the staff recommends that Condition 12 be revised as follows:

Condition 12 Notwithstanding the Derived Air Concentration (DAC) and Annual Limit on Intake (ALI) listed in Appendix B to 10 CFR 20, the licensee may use adjusted DAC values for thorium of  $1.9 \text{ E-}11$  microcuries ( $\mu\text{Ci}$ ) per milliliter and for uranium of  $8.4 \text{ E-}11 \text{ } \mu\text{Ci}$  per milliliter and adjusted ALI values for thorium of  $0.047 \text{ } \mu\text{Ci}$  and for uranium of  $0.2 \text{ } \mu\text{Ci}$ .

While the licensee does not currently use respiratory protection equipment to limit intakes pursuant to 10 CFR 20.1702, and accordingly is not required to have a bioassay program in accordance with 10 CFR 20.1703, the staff recommends and the Licensee has agreed to a new Condition 17 to require bioassays if in the future plant operations require respiratory protection equipment to limit intakes. This will eliminate the need for a future license amendment. The new Condition 17 would read as follows:

Condition 17 If the licensee uses respiratory protection equipment to limit intakes pursuant to 10 CFR 20.1702, the licensee shall perform bioassays to evaluate actual intakes at intervals not to exceed twelve months. Whenever an individual will no longer use respiratory protection equipment, the licensee shall perform a bioassay to evaluate the actual intake during the period of respirator use.

David R. Smith

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Enclosed are copies of the amended Materials License SMB-743 and the Safety Evaluation Report, which includes the Categorical Exclusion.

If you have any questions regarding this matter, please contact Ms. Julie Olivier of my staff at (301) 415-7292 or by e-mail at JAO@nrc.gov.

Sincerely,

Michael F. Weber, Deputy Director  
Division of Fuel Cycle Safety  
and Safeguards, NMSS

Docket 40-7102  
License SMB-743  
Amendment 3

Enclosures: 1. Materials License SMB-743  
2. Safety Evaluation Report

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**ENVIRONMENTAL REVIEW**

These changes are considered procedural in nature. The staff has determined that the proposed changes do not adversely affect public health and safety or the environment and are categorically excluded from the requirement to prepare a site-specific environmental assessment. Therefore, in accordance with 10 CFR 51.22(c)(11), neither an environmental assessment nor an environmental impact statement is warranted for this action.

**CONCLUSION**

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. The NRC supports these types of dose estimates, and authorizes the staff to grant exemptions on a case-by-case basis. In view of this situation, the staff recommends approving the licensee's request to use the new models.

The Region I inspection staff has no objection to this proposed action.

**PRINCIPAL CONTRIBUTORS:**

Julie Olivier

Mike Lamastra