

NUCLEAR REGULATORY COMMISSION**10 CFR Part 51****[Docket No. PRM-51-11]****Sally Shaw; Denial of Petition for Rulemaking**

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM) submitted by Sally Shaw on June 23, 2006. The petition, docketed as PRM-51-11, requests that the NRC prepare a rulemaking to reconcile NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants" (May 1996) (GEIS), for nuclear power plant operating license renewal applications with the National Academy of Sciences' (NAS), "Health Risks from Exposure to Low Levels of Ionizing Radiation: Biological Effects of Ionizing Radiation (BEIR) VII, Phase 2" Seventh Ed., 2005 report. The petitioner believes that this action is necessary because the BEIR VII report represents new and significant information on radiation standards and risk factors that must be reflected in NRC's GEIS. Although the NRC recognizes that the petition highlighted that BEIR VII contains a more refined risk assessment based on additional medical data and a better dosimetry system, the NRC is denying PRM-51-11 because it does not provide significant information or arguments that were not previously considered by the Commission.

ADDRESSES: Publicly available documents related to these petitions and the NRC's letter of denial to the petitioner may be viewed electronically on public computers in the NRC's Public Document Room (PDR), 01 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From

this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR reference staff at (800) 387-4209, (301) 415-4737 or by e-mail to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: David T. Diec, telephone (301) 415-2834, e-mail dtd@nrc.gov, or Andrew Luu, telephone (301) 415-1078, e-mail anl@nrc.gov, Office of Nuclear Reactor Regulation, Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

The Petition

On November 20, 2006 (71 FR 67072), the NRC published a notice of receipt of a petition for rulemaking filed by Sally Shaw (the petitioner). The petitioner requested that the NRC reconcile the GEIS with the NAS BEIR VII report, which was released in 2005. The GEIS incorporates data from BEIR V, an earlier NAS report that was released in 1990. The NRC regulation, Part 10 of the Code of Federal Regulations Section 51.95(c), requires that the NRC prepare a supplemental environmental impact statement (SEIS) to the GEIS. The findings of the GEIS are set forth in Table B-1 of Appendix B to Subpart A of 10 CFR Part 51 (Table B-1). A copy of the petition can be found in ADAMS under accession number ML061770056.

Specifically, the petitioner requests that the NRC consider the NAS BEIR VII report as new and significant information and update the radiological impacts and conclusions set forth in the GEIS, including early fatalities, latent fatalities, and any injury projections based on this information. The petitioner asserts that BEIR VII represents the "current science," and states that BEIR VII, unlike BEIR V, "estimates risks for cancer incidence rates as well as mortality and also provides detailed risk figures according to age of exposure for males and females, by

cancer type.” According to the petitioner, BEIR VII shows that the cancer mortality risks for women and children are much higher than for men. Further, the petitioner asserts that the GEIS’ radiological impact analysis is calculated based on an “arbitrary and false” threshold dose model, implying that dose received below the threshold would not be of “regulatory concern.” In this regard, the petitioner refers to BEIR VII, which concludes that there is no evidence of a “threshold dose phenomenon.”

The petitioner also asserts that the GEIS reports radiation risks to nuclear workers of one rem per year based on BEIR V. The petitioner requests that these radiation risks be recalculated using BEIR VII and the latest science in medical journals, which include exposure to internal radiation sources (alpha and beta emitters, via inhalation or ingestion). Finally, the petitioner asserts that the radiological impact analysis contained in the GEIS assumes that non-stochastic effects will not occur if the dose equivalent from internal and external sources combined is less than 50 rem per year and, as such, must be recalculated in light of BEIR VII.

NRC Evaluation

The petitioner’s request is that the NRC reconcile the GEIS with the NAS BEIR VII, 2005 report. The NRC’s regulations for implementing its responsibilities under the National Environmental Policy Act (NEPA) are contained in 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.” The renewal of a nuclear power plant operating license is identified as a major Federal action significantly affecting the quality of the human environment, and thus an SEIS (in conjunction with the GEIS) is required before the NRC determines whether to approve or disapprove the license renewal application. The NRC’s requirements for renewal of operating licenses for nuclear power plants are contained in 10 CFR Part 54. The GEIS assesses environmental impacts that could be associated with nuclear power plant license renewal and establishes generic findings for each type of environmental impact covering as many plants as possible. The GEIS reflects the

NRC's findings regarding those environmental impacts associated with license renewal that are well understood.

GEIS

The GEIS assesses the various environmental impacts associated with license renewal in terms of significance and assigns one of three significance levels to a given impact—small, moderate, or large. A small impact means that the environmental effects are not detectable or are so minor that they will neither destabilize nor noticeably alter any important attribute of the resource. For the purpose of assessing radiological impacts, the NRC has concluded that those impacts that do not exceed permissible levels in the NRC's regulations are considered small. A moderate impact means that the environmental effects are sufficient to alter noticeably but not to destabilize important attributes of the resource. A large impact means that the environmental effects are clearly noticeable and are sufficient to destabilize important attributes of the resource.

In addition to determining the significance of environmental impacts associated with license renewal, the NRC determines if its analysis can be applied to all plants and whether additional mitigation measures would be warranted. The GEIS sets forth two categories: Category 1 and Category 2. Category 1 means that the GEIS analysis has shown that the environmental impacts associated with the issue have been determined to apply either to all plants or, for some environmental issues, to plants having a specific type of cooling system or other specified plant or site characteristics; a single significance level (i.e., small, moderate, or large) has been assigned to the impacts; mitigation of adverse impacts associated with the issue has been considered in the analysis; and it has been determined that additional plant-specific mitigation measures are not likely to be sufficiently beneficial to warrant implementation. Category 2 means that the GEIS analysis does not meet the criteria of Category 1, and thus, on that particular environmental issue, additional plant-specific review is required. The GEIS findings are set forth in Table B-1 of Appendix B to Subpart A of 10 CFR Part 51.

For each license renewal application, the NRC will prepare a draft SEIS to analyze those plant-specific (Category 2) issues. The SEIS is not required to cover any Category 1 issues. The draft SEIS is made available for public comment. After consideration of any public comments, the NRC will prepare and issue a final SEIS under 10 CFR 51.91 and 51.93. The final SEIS and the GEIS serve as the requisite NEPA analysis for any given license renewal application.

The GEIS analysis, as shown in Table B-1, concluded that both public and occupational radiation exposures during any plant refurbishment or plant operation through the license renewal term are of a small significance level and meet all Category 1 criteria. This conclusion is based on a given licensee's adherence to, and if necessary, NRC enforcement of, the dose limits as required in 10 CFR Part 20, "Standards for Protection Against Radiation" and in Appendix I to 10 CFR Part 50, "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low As Is Reasonably Achievable' (ALARA) for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents." Regulations at 10 CFR Part 20 require that a licensee limit the annual dose to a member of the public to no more than 0.1 rem (1mSv) total effective dose equivalent (TEDE). In addition, 40 CFR Part 190, "Environmental Radiation Protection Standards For Nuclear Power Operations," further restricts the allowable annual dose to a member of the public to a lower value of 0.025 rem (0.25 mSv) and to maintain doses to members of the public that are ALARA. Finally, 10 CFR 50.34a requires a nuclear power plant to maintain control over radioactive gaseous and liquid effluents produced during normal operations to dose levels contained in Appendix I to 10 CFR Part 50, which are in the range of 0.003 rem (0.03 mSv) to 0.005 rem (0.05 mSv).

BEIR Reports

The risk estimates of human health effects from radiation were first evaluated by scientific committees starting in the 1950s. Since 1972, the National Academy of Sciences has

published a series of reports on the biological effects of ionizing radiation (the BEIR reports), including the BEIR V report in 1990 and the BEIR VII report in 2005. The BEIR V and BEIR VII reports concentrated primarily on providing a comprehensive review of all biological and biophysical data regarding the health effects attributable to exposures to low doses of ionizing radiation, ranging between 0 to 10 rem (0-100 mSv). Although the BEIR VII committee examined several sources of epidemiological data (i.e., medical and occupational exposures), the single most important source of epidemiological data is the cohort of 120,000 Japanese atomic bomb survivors from the cities of Hiroshima and Nagasaki.

Three major changes have occurred after the BEIR V report was published. First, an additional 12 years of follow-up medical data are available. Second, cancer incidence data for the cohort are available (for BEIR V, only mortality data were available). The impact of these two developments has reduced the uncertainty in the assessment of cancer risk among the atomic bomb survivors. Third, the dosimetry system used to assign radiation exposure to the atomic bomb survivors was replaced with an improved dosimetry system. These changes have improved our understanding of the health risks associated with radiation exposure. The overall risk estimates of the BEIR V and BEIR VII reports, however, remain statistically insignificant. In this regard, the BEIR VII report states: "in general the magnitude of estimated risks for total cancer mortality or leukemia has not changed greatly from estimates in past reports such as BEIR V and recent reports of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the International Commission on Radiological Protection (ICRP). New data and analyses have reduced sampling uncertainty, but uncertainties related to estimating risk for exposure at low doses and dose rates and transporting risks from Japanese A-bomb survivors to the U.S. population remain large. Uncertainties in estimating risks of site-specific cancers are especially large."

The NRC staff completed a review of the BEIR VII report and documented its findings in the Commission paper SECY-05-0202, "Staff Review of the National Academies Study of the

Health Risks from Exposure to Low Levels of Ionizing Radiation (BEIR VII),” dated October 29, 2005 (ADAMS accession number ML052640532). In this paper, the NRC staff concluded that the findings presented in the BEIR VII report agree with the NRC’s current understanding of the health risks from exposure to ionizing radiation. The BEIR VII report’s major conclusion is that current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose response relationship between exposure to ionizing radiation and the development of cancer in humans. This conclusion is consistent with the system of radiological protection that the NRC used to develop its regulations and the GEIS. Therefore, the NRC’s regulations and the GEIS continue to be adequately protective of public health and safety and the environment. Consequently, none of the findings in the BEIR VII report represent new and significant information when compared to the findings of the BEIR V report and thus, there is no need to amend NRC regulations or the GEIS. The NRC has determined that a specific rulemaking to amend 10 CFR Part 51 and by extension, the GEIS, is not warranted.

Public Comments

The NRC received a total of 74 public comments relating to this petition. Of the 74 comments, 69 supported granting the petition. No comments opposed the petition and five comments were not applicable to this petition. The letters in support of the petition were essentially identical and contained one or more of the following four assertions:

- A. Protect the most vulnerable populations in the regulatory standards.
 - B. Recognize that “allowable” levels are not safe.
 - C. Consider radiation damage from inhaling or ingesting radionuclides; and
 - D. Recognize that there is no safe dose.
- A. Protect the most vulnerable populations in the regulatory standards.

Although some epidemiological studies have shown that children, individuals in poor health, and the elderly are more radiosensitive to radiation at high doses and high dose rates, no adverse health effects have been observed in these populations at the doses associated with NRC's radiation protection regulations and standards. The NRC, in NUREG 1850, "Frequently Asked Questions on License Renewal of Nuclear Power Reactors," provides information on a number of studies that have been performed to examine the health effects around nuclear power facilities. These studies report that there is no conclusive evidence which shows a statistical correlation between the low level radiation dose received by members of the public living near a nuclear power plant and their cancer incidence.

The dose from radioactive gaseous and liquid effluents is based on the "maximum exposed individual" and calculated to each of the four age groups (0-1, 1-11, 11-17, and 17 years and older). The methodology and guidance for calculating these doses and the associated dose conversion factors for each age group, are contained in Regulatory Guide 1.109, "Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR Part 50, Appendix I." Nuclear power reactors implement this methodology and guidance in individual plant radiation protection programs and operating procedures. The NRC has concluded that the current NRC radiation protection standards continue to ensure adequate protection of the public. This position is further reiterated in the Commission Paper SECY-05-0202. In this paper, the NRC staff reviewed and evaluated NRC's radiation safety regulations and standards against the findings of the BEIR VII report. The NRC staff concluded "that the findings presented in the National Academies BEIR VII report contribute to our understanding of the health risks from exposure to ionizing radiation. The major conclusion is that current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose response relationship between exposure to ionizing radiation and the development of cancer in humans." The BEIR VII report's conclusion is consistent with the system of radiological protection that the NRC used to develop its regulations and the GEIS.

Therefore, the NRC concludes that the current regulations continue to be adequately protective of the public health and safety and the environment. Consequently, none of the findings in the BEIR VII report warrant initiating any immediate change to NRC regulations or the GEIS.

B. Recognize that “allowable” levels are not safe.

Commenter states that these levels are based on obsolete “standard man,” concept that applies to a healthy, white male in the prime of his life, and ignore the more vulnerable fetus, growing infant, children, and women who, according to the BEIR VII report, are 37-50 percent more vulnerable than men to the harmful effects of ionizing radiation. Although some epidemiological studies have shown that children, individuals in poor health, and the elderly are more radiosensitive to radiation at high doses and high dose rates, no adverse health effects have been observed in these populations at the doses associated with NRC’s radiation protection regulations and standards. The amount of radioactive material released from nuclear power facilities is well measured, closely monitored, and known to be very small. As shown by the studies referenced in NUREG-1850, the radiation dose received by members of the public from the normal operation of a nuclear power plant are so low that no cancers have been observed.

The BEIR VII committee’s preferred estimate of lifetime attributable risk for solid cancer incidence and mortality (Tables 12-13) suggest that females are more sensitive than males to radiation exposure at 10 rem, a level that is 100 times the NRC’s radiation protection standards specified in 10 CFR Part 20. The BEIR VII committee’s preferred estimate of lifetime attributable risk for leukemia cancer incidence and mortality (Tables 12-13), moreover, suggest that males are more sensitive than females. The BEIR VII committee uses the 95 percent confidence intervals associated with estimated lifetime cancer risk for males and females that suggest that the apparent gender difference may not be statistically significant. Consequently, the BEIR VII report combined the two risk estimates and cited an average value which was also

done by the BEIR V committee. A potential gender difference was not discussed in the BEIR VII report.

The NRC radiation protection regulation, 10 CFR 20.1208, requires each licensee to ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). These radiation protection standards continue to ensure adequate protection of the public health and safety and the environment.

The petitioner has also requested that the NRC review an article entitled “Healthy from the Start: Building a Better Basis for Environmental Health Standards-Starting with Radiation,” published by the Institute for Energy and Environmental Research (IEER), February 2007. This article was not published in a scientific peer-reviewed journal and the article’s conclusions do not appear to have been subjected to an independent peer review process. The authors of this article have stated that there are cause-and-effect relationships in the statistical associations between cancer rates and nuclear power reactor operations. Although it is true that cancer rates vary among locations, it is difficult to ascribe the cause of a cluster of cancers to a specific environmental agent, such as radiation from a nuclear power plant. Statistical association alone does not demonstrate causation. Also, well-established scientific methods must be used to demonstrate that these causal effects are appeared to be associated over time.

Discussions regarding infants, children, and women are addressed in section A of this document.

C. Consider radiation damage from inhaling or ingesting radionuclides.

The issue of radiation risks, as discussed in the GEIS (i.e., Appendix E, section E 4.1.1), used a reference value of 1 rem to calculate the estimated number of excess cancer fatalities, based on the BEIR V report. As discussed in the section titled, “BEIR Reports,” while the changes between the reports has increased our understanding of radiation risk, none of the

findings of the BEIR VII report represent new and significant information when compared to the findings of the BEIR V report. Thus, there is no need to amend NRC regulations or the GEIS.

Human health effects associated with ionizing radiation, which the GEIS classifies as a Category 1 issue, are divided into two broad categories, non-stochastic and stochastic. The non-stochastic health effects are those in which the severity varies in direct relationship with the radiation dose and for which, according to scientific reports from ICRP, UNSCEAR, as well as the BEIR committee, a dose threshold is known to exist. Radiation-induced cataract formation is an example of a non-stochastic effect. The stochastic health effects are those that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidences are examples of stochastic effects. For the mitigation of stochastic health effects, the NRC endorses the linear, no-threshold dose response model as a basis for its radiation protection standards. This model indicates that any increase in radiation dose, no matter how small, results in an incremental increase in the risk of adverse health effects.

NRC regulations and standards, such as the annual dose limits contained in 10 CFR Part 20 for members of the public and for occupational workers, account for stochastic and non-stochastic health effects of radioactive material inhaled or ingested into the human body. For members of the public, the annual dose limit from exposure to radiation from an NRC licensed facility is 0.1 rem. For occupational workers, there are specific dose limits to address the stochastic and non-stochastic health effects. The total effective dose equivalent limit which addresses the stochastic health effects is limited to an annual dose of 5 rem. To address the non-stochastic health effects, the annual dose limit to any individual organ or tissue and the skin, other than the lens of the eye, is 50 rem; the annual dose limit to the lens of the eye is 15 rem. The dose unit is specified as TEDE in rem. The TEDE dose is the sum of the deep-dose equivalent (i.e., external exposures) and the committed effective dose equivalent (i.e., internal exposures received from inhaling or ingesting of radioactive material which includes alpha, beta,

gamma, and neutron emitters). The current dose regulations and standards contain adequate radiation safety limits based on radiation exposures from all types of radioactive material and therefore, continue to ensure adequate protection of the public and occupational workers.

Further, Appendix I to 10 CFR Part 50 provides numerical ALARA dose criteria for the discharge of radioactive gaseous and liquid effluents from nuclear power plants. These dose objectives are incorporated into each nuclear power plant's license conditions. The NRC collects and assesses data regarding licensees' adherence to regulations based on site visits, audits and inspection records, and the annual radiological effluent release reports required to be submitted to the NRC and concludes that nuclear power plants continue to maintain their radioactive effluents to the ALARA dose criteria.

D. Recognize that there is no safe dose.

The BEIR VII report's major conclusion is that current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose response relationship between exposure to ionizing radiation and the development of cancer in humans. The BEIR VII committee did not attempt to equate radiation exposure and safety, nor did it offer any judgment or opinion on what constitutes a safe level of radiation exposure. It concludes that establishing limits on public exposure to ionizing radiation is the responsibility of Federal agencies like the U.S. Environmental Protection Agency and the NRC. The linear, no-threshold dose response relationship between exposure to ionizing radiation and the development of cancer in humans is consistent with the system of radiological protection that the NRC uses as a basis to develop its regulations. Therefore, the NRC's regulations continue to ensure adequate protection of the public health and safety and the environment.

Reasons for Denial

The Commission is denying the petition for rulemaking submitted by Sally Shaw. The specific issues contained in the petition are already adequately addressed in the NRC's radiation protection regulations and standards.

Although this petition is being denied, the Commission notes that the current GEIS that referenced the BEIR V, 1999 report, is undergoing planned revision and will consider recent radiological studies, including the BEIR VII, 2005 report. The summary of findings as a result of the planned update will be codified through an ongoing and routine rulemaking to 10 CFR Part 51, Subpart A, Appendix B, Table B1 - Summary of Findings on NEPA Issues for License Renewal of Nuclear Power Plants.

The Commission has concluded that nuclear plants that are in compliance with NRC radiation protection regulations and standards remain protective of public health and safety and the environment. The radiological health and environmental impacts contained in the GEIS, which are based on regulatory compliance, remain valid.

For these reasons, the Commission denies PRM-51-11.

Dated at Rockville, Maryland, this 10th day of December 2007.

For the Nuclear Regulatory Commission.

/RA/

Annette L. Vietti-Cook,
Secretary of the Commission