POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Baran

SUBJECT: SECY-19-0008: DENIAL OF PETITIONS FOR RULEMAKING REGARDING LINEAR NO-THRESHOLD MODEL AND STANDARDS FOR PROTECTION AGAINST RADIATION (PRM-20-28, PRM-20-29, AND PRM-20-30)

Approved X **Disapproved** ____ **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** ____ **Attached** X **None** ____

Jeffery M. Baran

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DATE

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No ____

Commissioner Baran's Comments on SECY-19-0008,
"Denial of Petitions for Rulemaking Regarding Linear No-Threshold Model and Standards for Protection Against Radiation"

In 2015, petitioners filed three petitions for rulemaking seeking to amend NRC's Part 20 regulations to discontinue the use of the linear no-threshold (LNT) model as the primary scientific basis for the agency's radiation protection standards.[1] In this paper, the NRC staff recommends denying these petitions.

Based on its review of the current state of the science, the staff found that "there is a lack of consensus in the scientific community regarding the level of risk associated with low doses of radiation and that there is substantial doubt within the scientific community regarding the validity of the hormesis concept."[2] As a result, the national and international authoritative scientific bodies with expertise in the science of radiation protection, including the National Academy of Sciences, National Council on Radiation Protection and Measurements, International Commission on Radiological Protection, and International Atomic Energy Agency, all support the continued use of the LNT model. Moreover, the U.S. Environmental Protection Agency, National Cancer Institute within the National Institutes of Health, and National Institute for Occupational Safety and Health within the Centers for Disease Control also recommend that NRC continue to base its radiation protection standards on the LNT model.

For these reasons, I agree with the staff that it is prudent to continue to rely on the LNT model for the purpose of setting radiation protection standards to ensure the health and safety of workers and members of the public. We should not weaken radiation dose limits for members of the public or eliminate the As Low As Reasonably Achievable (ALARA) principle from NRC's regulations without convincing scientific evidence that low doses of radiation are not harmful. Therefore, I approve the draft *Federal Register* notice and letters to the petitioners announcing the denial of the petitions, subject to the attached edits.

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[1] The LNT model holds that "ionizing radiation is always considered harmful and that there is no threshold below which any amount of radiation exposure to the human body is not harmful."
[2] The hormesis concept provides that "exposure of the human body to low and very low levels of ionizing radiation is beneficial to the human body."

JMB edits **[7590-01-P]**

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

[Docket No. PRM-20-28, PRM-20-29, and PRM-20-30;

NRC-2015-0057]

Linear No-Threshold Model and Standards for Protection Against Radiation

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying three petitions for rulemaking (PRMs), submitted by Dr. Carol S. Marcus, Mr. Mark L. Miller, CHP, and Dr. Mohan Doss, et al. (collectively, the petitioners) in correspondence dated February 9, 2015, February 13, 2015, and February 24, 2015, respectively. The petitioners request that the NRC amend its regulations based on what they assert is new science and evidence that contradicts the linear no-threshold (LNT) dose-effect model that serves as the basis for the NRC's radiation protection regulations. The NRC docketed these petitions on February 20, 2015, February 27, 2015, and March 16, 2015, and assigned them Docket Numbers PRM–20–28, PRM–20–29, and PRM–20–30, respectively. The NRC is denying the three petitions because they fail to present an adequate basis supporting the request to discontinue use of the LNT model. Given the current state of scientific knowledge, the NRC has determined that the LNT model continues to provide a ~~prudent~~ sound regulatory basis for minimizing the risk of unnecessary radiation exposure to both members of the public and occupational

workers. Therefore, the NRC will maintain the current dose limit requirements contained in its regulations.

DATES: The dockets for PRM–20–28, PRM–20–29, and PRM–20–30 are closed on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID NRC-2015-0057 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to https://www.regulations.gov and search for Docket ID: NRC-2015-0057. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, ~~select "ADAMS Public Documents" and then~~ select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. For the convenience of the reader, a list of materials referenced in this document are provided in Section V, "Availability of Documents."

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Vanessa Cox, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-8342; e-mail: Vanessa.Cox@nrc.gov; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I.The Petitions

Section 2.802 of title 10 of the *Code of Federal Regulations* (10 CFR), "Petition for rulemaking—requirements for filing," provides an opportunity for any interested person to petition the Commission to issue, amend, or rescind any regulation in 10 CFR chapter I. By correspondence dated February 9, 2015, February 13, 2015, and February 24, 2015, respectively, the NRC received three similar petitions from Dr. Carol S. Marcus, Mark L. Miller, CHP, and Mohan Doss, PhD, et al[1]. The NRC published a notice of docketing for the three petitions in the *Federal Register* on June 23, 2015 (80 FR 35870), and requested public comment. The public comment period was initially set to close on September 8, 2015, but was extended to November 19, 2015.[2]

The petitioners request that the NRC amend 10 CFR part 20, "Standards for Protection against Radiation," to discontinue use of the LNT model as the primary scientific basis for the agency's radiation protection standards. The petitioners' assertion is that the use of the LNT model is no longer valid based on various scientific studies. In particular, the petitioners advance the concept of radiation hormesis, which posits that

[1] Dr. Doss was the first of several signatories on the February 24, 2015, correspondence. The correspondence identified the signatories as members or associate members of Scientists for Accurate Radiation Information (SARI). There is no indication in the February 24, 2015, correspondence that SARI, as an organization, formally endorsed the petition from Dr. Doss, et al.

[2] 80 FR 50804-05; August 21, 2015.

low doses of ionizing radiation protect against the deleterious effects of high doses of radiation and result in beneficial effects to humans. Therefore, the petitioners request that the NRC amend its dose limits for radiation workers and members of the public as follows:

- Maintain worker doses "at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic";
- Remove the As Low As Is Reasonably Achievable (ALARA) principle entirely from the regulations, because they claim that~~as~~ "it makes no sense to decrease radiation doses that are not only harmless but may be hormetic";
- Raise the public dose limits to be the same as the worker doses, because they claim that~~as~~ "these low doses may be hormetic"; and
- "End differential doses to pregnant women, embryos and fetuses, and children under 18 years of age."

II. Background

In 1991, the NRC issued the 10 CFR part 20 final rule, which established the current regulatory framework for the NRC's radiation protection regulations. All NRC licensees are subject to the NRC's radiation protection requirements set forth in 10 CFR part 20. These requirements are designed to protect both members of the public and occupational workers from harm that could be caused by a licensee's use of radioactive materials. In accordance with § 20.1101, "Radiation protection programs," each licensee

"shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities."[3]

The LNT model has been the underlying premise of much of the NRC's radiation protection regulations since the late 1950s.[4] The LNT model provides that ionizing radiation[5] is always considered harmful and that there is no threshold below which an amount of radiation exposure to the human body is not harmful. The LNT model further holds that biological damage caused by ionizing radiation (~~essentially,~~ the cancer risk and adverse hereditary effects) is directly proportional to the amount of radiation exposure to the human body (response linearity). Thus, the higher the amount of radiation exposure, or dose,[6] the higher the likelihood that the human receptor will suffer biological damage. The validity of the LNT model has been the subject of ~~much~~ dispute within the scientific community for decades.[7] The NRC's standards for protection against radiation, which are contained in 10 CFR part 20, are underpinned by the LNT model. These radiation protection standards provide requirements for--

- Dose limits for radiation workers and members of the public,
- Monitoring and labeling radioactive materials,
- Posting signs in and around radiation areas, and
- Reporting the theft or loss of radioactive material.

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[3] 10 CFR 20.1101(a).

[4] The Atomic Energy Act of 1954 assigned the Atomic Energy Commission (AEC) the functions of both encouraging the use of nuclear power and regulating its safety. The AEC was the predecessor agency to the NRC.

[5] The terms "ionizing radiation" and "radiation" are used interchangeably in this document.

[6] "The biological dose or dose equivalent, given in rems or sieverts (Sv), is a measure of the biological damage to living tissue as a result of radiation exposure." NRC Glossary, Definition of Dose, https://www.nrc.gov/reading-rm/basic-ref/glossary/dose.html.

[7] For example, in the October 2015 ACMUI teleconference, Dr. Zanzonico noted that "[w]e all recognize that the issue of the linear no-threshold model of radiation carcinogenesis versus a hormetic model versus an alternative model remains highly controversial and really engenders very strong emotions from folks on different sides of the question." ACMUI, Official Transcript of Proceedings (October 28, 2015), at 18-19.

The petitioners do not dispute that high doses of radiation exposure are harmful to the human body. Instead, ~~T~~their argument~~dispute~~ centers on low doses of radiation exposure, generally doses below 10 rem (100 mSv), the effects of which are difficult to quantify. In this regard, the petitioners contend that there is a threshold below which radiation exposure to the human body is not harmful. As described by the International Commission on Radiological Protection (ICRP) in its Publication No. 99, "Low-dose extrapolation of radiation-related cancer risk," the threshold theory posits that "there is some threshold dose below which there is either no radiation-related health detriment or a radiation-related health benefit that outweighs any detriment. If the threshold was a universal value for all individuals and all tissues, a consequence of the theory is that, at some point, a very low dose to any number of people would have no associated risk and could be ignored."[8]

The petitioners also advance a companion concept to the existence of a threshold, the radiation hormesis concept (hormesis), which provides that exposure of the human body to low and very low levels of ionizing radiation is beneficial to the human body.

III.Petitioners' Assertions

The petitioners~~'~~ request to amend NRC dose limits (dose limit for workers; dose limit for embryos, fetuses, and pregnant workers; and the public dose limits) as well as to remove the ALARA principle for the NRC's regulations. The requested amendments to the regulations were supported by several assertions made by the petitioners. The NRC

[8] ICRP, "Low-dose extrapolation of radiation-related cancer risk," Pub. No. 99 (2005), at 38.

reviewed each assertion separately, as outlined in this section~~. Each assertion is outlined~~ and followed by the NRC's response.

Petitioners' Assertion that LNT is Not Justified by Current Science

The petitioners assert that current science does not justify the use of the LNT model and that there is a threshold below which radiation exposure to the human body is not harmful.

NRC's Response

The NRC does not agree with the petitioners' assertion. Exposure to ionizing radiation is a known cancer risk factor for humans. The LNT model assumes that, in the long term, biological damage caused by ionizing radiation (i.e., cancer risk and adverse hereditary effects) is directly proportional to the dose. The NRC acknowledges the difficulties inherent in determining the amount of damage to the human body caused by low doses of radiation. The NRC, however, does not use the LNT model to assess the actual risk of low dose radiation. Instead, the NRC uses the LNT model as the basis for a regulatory framework that meets the "adequate protection" standard of the Atomic Energy Act of 1954, as amended (AEA). Furthermore, the LNT model is applied so that the framework can be effectively implemented by ~~an~~ the agency ~~that~~ as it regulates diverse categories of licensees, from commercial nuclear power plants to individual industrial radiographers and nuclear medical practices. The NRC's use of the LNT model as the basis for its radiation protection regulations is premised upon the findings and recommendations of national and international authoritative scientific bodies, such as the ICRP, that have expertise in the science of radiation protection.

The NRC issued the framework for its current 10 CFR part 20 radiation protection

regulations in 1991.[9] The NRC acknowledged the role of the national and international authoritative scientific bodies in the 1991 final rule, stating that "[t]he [U.S. Atomic Energy Commission] and the NRC have generally followed the basic radiation protection recommendations of the [ICRP] and its U.S. counterpart, the National Council on Radiation Protection and Measurements (NCRP), in formulating basic radiation protection standards." The 1991 final rule explained that the NRC based its radiation protection regulations upon three assumptions. The first assumption concerned the use of the LNT model, which was described as follows:

> The first assumption, the linear nonthreshold dose-effect relationship, implies that the potential health risk is proportional to the dose received and that there is an incremental health risk associated with even very small doses, even radiation doses much smaller than doses received from naturally occurring radiation sources. These health risks, such as cancer, are termed stochastic because they are statistical in nature; i.e., for a given level of dose, not every person exposed would exhibit the effect.[10]

The other two assumptions supporting the NRC's radiation protection requirements relate to stochastic and nonstochastic effects. Stochastic risks or effects from exposure to radiation are primarily the long-term potential for cancer induction and adverse hereditary effects, while deterministic or nonstochastic risks or effects are those that can be directly correlated with exposure to high or relatively high doses of radiation, such as the formation of cataracts.[11] The NRC's second assumption was that the

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[9] 56 FR 23360; May 21, 1991. Under current NRC regulations, each NRC licensee must ensure that its operations do not exceed, for each member of the public, a total effective dose limit of 0.1 rem (1 mSv) in a calendar year. § 20.1301(a)(1). For occupational workers, the primary annual dose limit, per licensee, is a total effective dose equivalent of 5 rems (50 mSv). § 20.1201(a)(1)(i).

[10] *Id*.

[11] The NRC defines the term "stochastic effects" as meaning "health effects 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 incidence are examples of stochastic effects." § 20.1003. The NRC defines the term "nonstochastic effects" as meaning "health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect)." *Id*.

severity of a stochastic effect is independent of, or not related to, the amount of radiation dose received.[12] The NRC's third assumption was that there is an "apparent threshold; i.e., a dose level below which the [nonstochastic] effect is unlikely to occur."[13] Therefore, the LNT model only applies to stochastic effects.

In the 1991 final rule notice, the NRC stated that these "assumptions are necessary because it is generally impossible to determine whether or not there are any increases in the incidence of disease at very low doses and low dose rates, particularly in the range of doses to members of the general public resulting from NRC-licensed activities."[14] The NRC further noted that there is "considerable uncertainty in the magnitude of the risk at low doses and low dose rates."[15] The NRC concluded:

> In the absence of convincing evidence that there is a dose threshold or that low levels of radiation are beneficial, the Commission believes that the assumptions regarding a linear nonthreshold dose-effect model for cancers and genetic effects and the existence of thresholds only for certain nonstochastic effects remain appropriate for formulating radiation protection standards and planning radiation protection programs.[16]

Thus, the NRC, as a regulator statutorily charged under the AEA[17] with protecting the public from radiological harm, determined in 1991 that it was prudent to assume the validity of the LNT model because of the considerable uncertainty with respect to the effect of low doses of radiation. The NRC's 1991 final rule was premised, to a large extent, upon the recommendations of ICRP Publication 26, "Recommendations of the International Commission on Radiological Protection" (1977), several of which, in turn,

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[12] 56 FR 23360.
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*, at 23360-61.
[17] 42 U.S.C. §§ 2011 et seq.

were premised upon the LNT model.[18] The 1991 final rule also referenced the government-wide "Federal Radiation Protection Guidance for Occupational Exposure," signed by President Reagan in 1987, which was similarly premised upon the ICRP Publication 26 recommendations.[19]

The NRC's position remains unchanged from 1991. ~~c~~Convincing evidence has not yet demonstrated the existence of a threshold below which there would be no stochastic effects from exposure to low radiation doses. As such, the NRC's view is that the LNT model continues to provide a sound basis for a conservative radiation protection framework that protects both the public and occupational workers.

Despite the various studies cited by the petitioners, uncertainty and lack of consensus persists in the scientific community about the health effects of low doses of radiation. For example, the Health Physics Society (HPS) has stated that "[h]ealth risks of radiation exposure can only be estimated with a reasonable degree of scientific certainty at radiation levels that are orders of magnitude greater than limits established by regulation for protection of the public."[20] The HPS has further stated "that radiation protection literature is filled with differing views as to the shape of the radiation dose-

[18] 56 FR at 23360. In its Publication 26, the ICRP states "[f]or radiation protection purposes it is necessary to make certain simplifying assumptions. One such basic assumption underlying the Commission's recommendations is that, regarding stochastic effects, there is, within the range of exposure conditions usually encountered in radiation work, a linear relationship without threshold between dose and the probability of an effect." ICRP Pub. No. 26.

[19] 56 FR at 23360. The "Federal Radiation Protection Guidance for Occupational Exposure" concerned the protection of workers from ionizing radiation and was published in the *Federal Register* on January 27, 1987 (52 FR 2822). The guidance was prepared by the Environmental Protection Agency, the NRC, and several other Federal agencies having an agency program or function that involved the use of radioactive material. The guidance stated "[w]e have considered these [ICRP] recommendations, among others, and believe that it is appropriate to adopt the general features of the ICRP approach in radiation protection guidance to Federal agencies for occupational exposure;" and "[b]ased on extensive but incomplete scientific evidence, it is prudent to assume that at low levels of exposure the risk of incurring either cancer or hereditary effects is linearly related to the dose received in the relevant tissue." 52 FR at 2824.

[20] Position Statement of the Health Physics Society (HPS), PS008-2, "Uncertainty in Risk Assessment," Adopted July 1993, Revised April 1995, February 2013.

response curve at low doses and dose rates."[21] According to HPS, "[s]ome data support a linear no-threshold model, whereas other data support models that predict lower estimates of risk and perhaps even a threshold below which no detectable radiation health risk exists."[22]

Although there are studies and other scholarly papers that support the petitioners' assertions, there are also studies and findings that support the continued use of the LNT model, including those by national and international authoritative scientific advisory bodies. Those authoritative scientific advisory bodies that have a specialty in the subject matter area of radiation protection include, domestically, the National Academy of Sciences (NAS)[23] and the NCRP,[24] both Federally chartered, and, internationally, the ICRP and the International Atomic Energy Agency (IAEA). All four of these bodies support the continued use of the LNT model. It has been the longstanding practice of the NRC to generally place significant weight on~~follow~~ the recommendations of these authoritative scientific advisory bodies.[25]

National Authoritative Scientific Advisory Bodies Favoring Continued Use of LNT

In 2006, the NAS published its Biological Effects of Ionizing Radiation (BEIR) VII report, "Health Risks from Exposure to Low Levels of Ionizing Radiation," the seventh in a series of reports that concern the health effects from low doses of radiation, and by

[21] HPS PS-008-2 at 2.

[22] *Id.*

[23] The NAS "is a private, non-profit society of distinguished scholars. Established by an Act of Congress … the NAS is charged with providing independent, objective advice to the nation on matters related to science and technology. Scientists are elected by their peers to membership in the NAS for outstanding contributions to research." http://www.nasonline.org/about-nas/mission/.

[24] The NCRP is a private, non-profit corporation whose mission is "to formulate and widely disseminate information, guidance and recommendations on radiation protection and measurements which represent the consensus of leading scientific thinking." http://ncrponline.org/about/mission/.

[25] *E.g.*, 56 FR at 23360.

extension, the appropriateness of the LNT model.[26] The report was prepared by the Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation that was established by NAS for the purpose of advising "the U.S. government on the relationship between exposure to ionizing radiation and human health."[27] The BEIR VII report focused on health effects from low doses of radiation (below 10 rem or 100 mSv)[28] and updated the findings of the previous report of low dose radiation, the 1990 BEIR V.

The BEIR VII committee analyzed epidemiologic data and biological data, including a study of the survivors of the Hiroshima and Nagasaki atomic bomb attacks and studies of cancer in children. The BEIR VII committee found "that the preponderance of information indicates that there will be some risk, even at low doses" and "that there is no compelling evidence to indicate a dose threshold below which the risk of tumor induction is zero."[29] The BEIR VII committee further found "[w]hen the complete body of research on this question is considered, a consensus view emerges. This view says that the health risks of ionizing radiation, although small at low doses, are a function of dose."[30] The BEIR VII committee concluded that "current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-

[26] NAS, "Health Risks from Exposure to Low Levels of Ionizing Radiation, BEIR VII -- Phase 2" (2006) (NAS BEIR VII). The BEIR VII report may be viewed online at https://www.nap.edu/catalog/11340/health-risks-from-exposure-to-low-levels-of-ionizing-radiation. The NRC was one of several Federal agencies that provided funding to NAS for the BEIR VII study.

[27] *Id*., at vii.

[28] In its report, the BEIR VII committee "defined low dose as doses in the range of near zero up to about 100 mSv (0.1 Sv) of low-[linear energy transfer] radiation." NAS BEIR VII at 2. The NCRP has considered a "very low dose" to be a dose below 1 rem or 10 mSv. NCRP, "Implications of Recent Epidemiologic Studies for the Linear Nonthreshold Model and Radiation Protection," Commentary 27 (April 24, 2018), at 66.

[29] NAS BEIR VII at 10.

[30] *Id*.

response relationship between exposure to ionizing radiation and the development of cancer in humans."[31]

Following the publication of BEIR V, the NCRP updated its radiation protection recommendations in its 1993 report, NCRP Report No. 116, "Limitation of Exposure to Ionizing Radiation." Although the NCRP acknowledged that it could not exclude the possibility of no health risk from low doses, the NCRP expressed its reliance on the LNT model as the basis for several of its recommendations,

> Based on the hypothesis that genetic effects and some cancers may result from damage to a single cell, the Council assumes that, *for radiation-protection purposes, the risk of stochastic effects is proportional to dose without threshold, throughout the range of dose and dose rates of importance in routine radiation protection*. Furthermore, the probability of response (risk) is assumed, for radiation protection purposes, to accumulate linearly with dose.[32]

In 2001, the NCRP published Report No. 136, "Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation," which reported the work of the NCRP's Scientific Committee 1-6. Scientific Committee 1-6 was charged with reassessing "the weight of scientific evidence for and against the linear-nonthreshold dose-response model, without reference to policy implications."[33] The NCRP Report No. 136 explained that the existence of the LNT model for low radiation doses must be extrapolated from data showing adverse health effects from high radiation doses and that there were differing sets of data that both showed evidence for and against the LNT model. Nevertheless, the NCRP noted "that radiation imparts its energy to living matter through a stochastic process, such that a single ionizing track has a finite probability of

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[31] *Id.*, at 323.

[32] NCRP, "Limitation of Exposure to Ionizing Radiation," Report No. 116 (1993), at 10 (emphasis in the original).

[33] NCRP, "Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation," Report No. 136 (2001), at 1.

depositing enough energy in traversing a cell to damage a critical molecular target within the cell, such as DNA."[34] After a comprehensive review of many studies, the NCRP concluded that "[a]lthough other dose-response relationships for the mutagenic and carcinogenic effects of low-level radiation cannot be excluded, no alternate dose-response relationship appears to be more plausible than the linear-nonthreshold model on the basis of present scientific knowledge."[35]

In a May 2017 article published in the "International Journal of Radiation Biology," the NCRP's president, Dr. John D. Boice, Jr., supports the continued use of the LNT model. Dr. Boice states that "[t]he LNT model, at least at the current time, has been useful in radiation protection, e.g. a safety culture exists that encompasses the principle of 'as low as reasonably achievable' (ALARA) considering financial and societal issues," and in this context, notes that "worker exposures have dropped dramatically over the years."[36] Given that epidemiological studies may not demonstrate the validity of the LNT model for low doses (below 100 mSv), Dr. Boice further states that the use of the LNT model combined with the technical and professional judgment of a competent regulator provides "a prudent basis for the practical purposes of radiological protection."[37] In his conclusion, Dr. Boice emphasized that the LNT model is not an appropriate mechanism to assess radiological risk but is the most appropriate model currently available for a

[34] *Id*., at 208.

[35] *Id*., at 7. *See also id*., at 48-49 (The NCRP also stated "[t]herefore, if radiation-induced cancer results directly from the induction of mutations involved in the oncogenic pathway, the data reported do not support the existence of a threshold."); and *id*., at 77 (The NCRP also noted that "the majority of studies report linear dose-response relationships in the lower dose range with the coefficient being quite similar to the alpha coefficient of the in vitro linear-quadratic dose-response curves.").

[36] J. Boice, Jr., "The linear nonthreshold (LNT) model as used in radiation protection: an NCRP update," *International Journal of Radiation Biology*, Vol. 93, No. 10 (2017), at 1080 (Boice).

[37] *Id*.

system of radiological protection when coupled with the appropriate regulatory and technical judgment.[38]

In a study funded by the NRC, the NCRP reevaluated the LNT model based on new studies completed since the publication of NCRP Report No. 136 in June 2001. In April 2018, the NCRP released Commentary 27, "Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection," which provides a detailed assessment of currently available epidemiological evidence and concludes that "the LNT model (with the steepness of the dose-response slope perhaps reduced by a DDREF [dose and dose rate effectiveness factor] factor) should continue to be utilized for radiation protection purposes."[39] The Commentary explains that "[w]hile the LNT model is an assumption that likely cannot be scientifically validated by radiobiologic or epidemiologic evidence in the low-dose range, the preponderance of epidemiologic data is consistent with the LNT assumption, although there are a few notable exceptions."[40] The Commentary concludes that the "current judgment by national and international scientific committees is that no alternative dose-response relationship appears more pragmatic or prudent for radiation protection purposes than the LNT model on the basis of available data, recognizing that the risk [for doses] <100 mGy [<10 rad] is uncertain but small."[41]

International Authoritative Scientific Advisory Bodies Favoring Continued Use of LNT

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[38] *Id*., at 1089.

[39] NCRP, "Implications of Recent Epidemiologic Studies for the Linear Nonthreshold Model and Radiation Protection," Commentary 27 (April 24, 2018), at 139. The acronym "DDREF" refers to the dose and dose-rate effectiveness factor, and is used to extrapolate the risk of cancer induction from high doses received acutely, and thus measurable, to those low doses, which cannot be measured and are the focus of the LNT model. *Id*., at 20 22-23, and 34.

[40] *Id*., at 140.

[41] *Id*.

The ICRP, in its Publication No. 99, "Low-dose Extrapolation of Radiation-related Cancer Risk," stated that "we are uncertain about the likelihood of a dose threshold, and that, in addition, if there should be a dose threshold, we are uncertain about what dose level it would be."[42] The ICRP further stated that "the mechanistic and experimental data discussed in this monograph tend to give weight to a non-threshold model, as do the solid tumour data in the Japanese atomic bomb study."[43] The ICRP concluded that the "LNT theory remains the most prudent risk model for the practical purposes of radiological protection."[44] The ICRP reaffirmed this conclusion in its Publication No. 103, "The 2007 Recommendations of the International Commission on Radiological Protection" (2007).[45] In Publication No. 103, the ICRP acknowledged that the LNT model was not "universally accepted as a biological truth" and that the possibility of a low-dose threshold could not be ruled out, but "because we do not actually know what level of risk is associated with very-low-dose exposure, [the LNT model] is considered to be a prudent judgement for public policy aimed at avoiding unnecessary risk from exposure."[46] While a 2005 joint French Academy of Sciences and National Academy of Medicine review expressed "doubts on the validity of using LNT for evaluating the carcinogenic risk of low doses," this review noted that "[t]he LNT concept can be a useful pragmatic tool for assessing rules in radioprotection for doses above 10 mSv [1 rem]."[47]

The IAEA, in its 1997 nuclear safety review (published in August 1998), stated that "some researchers have interpreted experimental results and epidemiological

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[42] ICRP, "Low-dose Extrapolation of Radiation-related Cancer Risk," Pub. No. 99 (2005), at 108.
[43] *Id*.
[44] *Id*., at 113.
[45] ICRP, "The 2007 Recommendations of the International Commission on Radiological Protection," Pub. No. 103 (2007), at 36 and 38, 65-67.
[46] *Id*., at A178 and A180.
[47] Academy of Sciences and National Academy of Medicine (France), "Dose-Effect Relationships and Estimation of the Carcinogenic Effects of Low Doses of Ionizing Radiation" (2005), at 5.

findings as providing evidence that low doses of radiation are much more harmful than the LNT hypothesis implies. A number of mechanisms have been proposed by which this might occur, a recent example being the phenomenon of genomic instability."[48] The IAEA report concluded that "[f]rom the evidence available at the present time, however, the LNT hypothesis continues to seem the most radiobiologically defensible basis for radiation protection recommendations. It is also a workable hypothesis that can underpin systems of regulation which, when applied reasonably, provide sound and sensible management of the risks from radiation."[49] The current IAEA radiation safety standards, *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*, published in 2014, relies upon the LNT model, stating that the LNT model "is the working hypothesis on which the IAEA's safety standards are based. It is not proven — indeed it is probably not provable — for low doses and dose rates, but it is considered the most radiobiologically defensible assumption on which to base safety standards."[50]

Comments of Federal Agencies

In addition to the findings of the national and international authoritative scientific advisory bodies, three Federal agencies provided comments on the petitions and supported the continued use of the LNT model as the basis for the NRC's radiation protection program. The three agencies are the National Cancer Institute (NCI), National Institutes of Health, Department of Health and Human Services; National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and

[48] IAEA, "Measures to Strengthen International Co-Operation in Nuclear, Radiation and Waste Safety, Nuclear Safety Review for the Year 1997" (August 1998), Attachment at 32.
[49] *Id*.
[50] IAEA, "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3" (2014), at 401.

Prevention, Department of Health and Human Services; and the Radiation Protection Division, Office of Air and Radiation, Environmental Protection Agency (EPA). Furthermore, the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI)[51] recommends that the NRC continue to rely upon the LNT model.

NCI provided detailed comments during the 2015 public comment period for the petitions.[52] In response to the petitioners' assertions that several epidemiologic studies showed that individuals exposed to higher doses of radiation were less likely or no more likely to develop cancer than those who received lower doses of radiation, NCI, in its comments, noted the limitations of such studies. NCI explained that "because epidemiologic studies are observational and not controlled experiments, differences in risks in exposed and unexposed may reflect differences in life style factors such as smoking and may not necessarily result from radiation exposure."[53] In addition, NCI stated in its comments:

> the petitions are selective in citing studies that appear to support hormesis (or a threshold) and omitting mention of the many studies that provide evidence of a dose-response at low doses. In some cases, analyses published many years ago are cited, when more recent analyses based on current follow-up of the same populations, often with improved dose estimates, do not support their claims.[54]

[51] The ACMUI is an official advisory body to the NRC established in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2. The ACMUI advises the NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy.

[52] NCI, A. Berrington de González, et al, "Contribution to Nuclear Regulatory Commission (NRC) comments on petitions on linear no-threshold model and standards for protection against radiation" (November 19, 2015) (NCI 2015). The specific component of NCI that provided the comments was the Radiation Epidemiology Branch, Division of Cancer Epidemiology and Genetics.

[53] *Id*. at 1. *See also* Boice at 1089 ("All models are wrong, but some are useful for radiation protection. LNT is an assumption. It is unlikely to be scientifically validated in the low-dose domain, and not by epidemiology").

[54] NCI 2015, at 1.

In this regard, NCI, in its comments, provided several examples of such studies and the more recent follow-up analyses that did not support the petitioners' assertions but provided "evidence of a dose-response at low doses,"[55] especially among children.

NIOSH also provided detailed comments during the 2015 public comment period.[56] NIOSH, in its comments, noted that the "lines of evidence given by the petitioners are not new and are fundamentally the same as those rejected by the BEIR VII committee."[57] NIOSH's comments are based, in part, upon a large study of nuclear workers, completed in 2015, which found that even tiny doses slightly boost the risk of leukemia (the study has been informally referred to as the international nuclear workers or "INWORKS" study).[58] This study included within its cohort over 308,000 nuclear industry workers from the United States, the United Kingdom, and France.[59] The INWORKS study's authors stated that "[i]n summary, this study provides strong evidence of an association between protracted low dose radiation exposure and leukemia mortality."[60]

NIOSH, in its comments, further stated that its researchers and others

> conducted meta-analyses of cancer risk from low-dose exposures in a variety of populations receiving protracted exposure to external ionizing radiation [Jacob et al. 2009; Daniels and Schubauer-Berigan 2011]. These meta-analyses concluded that there is a small but significant excess risk of solid cancer and leukemia, respectively, at occupational doses received during a typical working lifetime [Walsh 2011].[61]

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[55] *Id*., at 2.

[56] NIOSH, S. Toye, "Comments of the National Institute for Occupational Safety and Health on the Nuclear Regulatory Commission Notice of Docketing and Request for Comment on Linear No-Threshold Model and Standards for Protection Against Radiation," September 11, 2015 (NIOSH 2015).

[57] *Id*., at 2.

[58] K. Leuraud et al., "Ionising Radiation and Risk of Death from Leukaemia and Lymphoma in Radiation-monitored Workers (INWORKS): An International Cohort Study, Lancet Haematology, Vol. 2" (June 2015).

[59] *Id.*, at 278.

[60] *Id.*, at 280.

[61] NIOSH 2015, at 2.

The NIOSH researchers and others also published two studies describing cancer risk among nuclear workers at four Department of Energy sites and the Portsmouth Naval Shipyard. According to the NIOSH comments, a pooled cohort study included nearly 120,000 nuclear workers from these five sites (these workers were also included in the larger INWORKS study). The authors of the pooled cohort study found that the "excess relative risk (ERR) was significantly associated with occupational radiation dose for all non-smoking related cancers combined."[62] NIOSH stated that "[t]hese findings suggest that the risk of these cancers rises by 0.7% and 2.0% (respectively) for every 10 millisieverts (mSv; 1 rem) increase in dose."[63] NIOSH, in its comments, stated that the LNT model presents "a reasonable framework for protecting workers from excess risks associated with occupational exposure to ionizing radiation"[64] and concluded with a recommendation that the NRC retain the current radiation protection standards.[65]

Similarly, in its comments, EPA recommended that the NRC deny the petitions. EPA stated the following:

> Within limitations imposed by statistical power, the available (and extensive) epidemiological data are broadly consistent with a linear dose-response for radiation cancer risk at moderate and low doses. Biophysical calculations and experiments demonstrate that a single track of ionizing radiation passing through a cell produces complex damage sites in DNA, unique to radiation, the repair of which is error-prone. Thus, no threshold for radiation-induced mutations is expected, and, indeed, none has been observed.[66]

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[62] *Id*., at 2-3.

[63] *Id*., at 3. The NRC's general public and occupational dose limits are 1 mSv (0.1 rem) and 0.05 Sv (5 rem), respectively. See § 20.1201(a)(1) (occupational dose limit) and § 20.1301(a)(1) (public dose limit).

[64] NIOSH 2015, at 3.

[65] *Id*., at 6.

[66] EPA, J. Edwards, "Comments on Linear No-Threshold Model and Standards for Protection Against Radiation" (October 7, 2015), at 1.

EPA, in its comments, referenced four epidemiological studies conducted after BEIR VII, including the INWORKS study, two studies of "residents along the Techa River in Russia who were exposed to radionuclides from the Mayak Plutonium Production Plant," and a study of children who had received computed tomography (CT) scans.[67] The EPA stated that "[t]hese studies have shown increased risks of leukemia and other cancers at doses and dose rates below those which LNT skeptics have maintained are harmless – or even beneficial."[68] EPA, in its comments, referenced the findings of the various domestic and international bodies, including the NAS and concluded,

> [g]iven the continuing wide consensus on the use of LNT for regulatory purposes as well as the increasing scientific confirmation of the LNT model, it would be unacceptable to the EPA to ignore the recommendations of the NAS and other authoritative sources on this issue.[69]

EPA concluded that it could not endorse basing radiation protection on the petitioners' proposals, which it characterized as "poorly supported and highly speculative."[70]

The ACMUI advises the NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy. The ACMUI is a committee authorized under the FACA, which regulates the formation and operation of advisory committees by Federal agencies. The ACMUI membership includes health care professionals from various disciplines, who comment on changes to NRC regulations and guidance; evaluate certain non-routine uses of radioactive material; provide technical assistance in licensing, inspection, and enforcement cases; and bring key issues to the attention of the Commission for appropriate action. Subsequent to the filing and docketing of the petitions, the ACMUI formed a

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[67] *Id.*
[68] *Id.*
[69] *Id.*, at 2.
[70] *Id.*

subcommittee to review and comment on the petitions. The ACMUI held a public teleconference meeting on October 28, 2015, to vote on the subcommittee's draft report.[71] The draft subcommittee report was approved by the ACMUI and issued as final on that same date. [72] The ACMUI report stated that determining the "'correct' dose-response model for radiation carcinogenesis remains an unsettled scientific question."[73] Although the report acknowledged that there "is a large, and growing, body of scientific literature as well as mechanistic considerations" that question the accuracy of the LNT model, the ACMUI determined that "very large-scale epidemiological studies with long-term follow-up would be needed to actually quantify any such risks or benefits" and that "such studies may be logistically and financially prohibitive."[74] According to the ACMUI report, "a mathematical extrapolation model remains the only practical approach to estimating the presumed excess cancer risk from low-dose radiation." Therefore, the "dose-response data derived from epidemiological studies of human cohorts, such as the [1945 Hiroshima and Nagasaki atomic bombing] survivors exposed to high-dose radiation, are largely consistent with an LNT model."[75] In making its recommendation, the ACMUI stated that it "recommends that, for the time being and subject to reconsideration as additional scientific evidence becomes available, the NRC continue to base the formulation of radiation protection standards on the LNT model."[76]

Conclusion

[71] The meeting notice for the October 28, 2015, meeting was published in the *Federal Register* on September 8, 2015 (80 FR 53896).
[72] ACMUI, "Final Report on the Hormesis/Linear No-Threshold Petitions" (October 28, 2015), at 1.
[73] *Id.*
[74] *Id.*, at 1-2.
[75] *Id.*, at 2.
[76] *Id.*, at 1.

Based upon the current state of science, the NRC concludes that the actual level of risk associated with low doses of radiation remains uncertain and some studies, such as the INWORKS study, show there is at least some risk from low doses of radiation. Moreover, the current state of science does not provide compelling evidence of a threshold, as highlighted by the fact that no national or international authoritative scientific advisory bodies have concluded that such evidence exists. Therefore, based upon the stated positions of the aforementioned advisory bodies; the comments and recommendations of NCI, NIOSH, and the EPA; ~~and in accordance with~~ the October 28, 2015, recommendation of the ACMUI; and~~as well as~~ its own professional and technical judgment, the NRC has determined that the LNT model continues to provide a ~~prudent~~ sound regulatory basis for minimizing the risk of unnecessary radiation exposure to both members of the public and occupational workers. Consequently, the NRC will retain the dose limits for occupational workers and members of the public in 10 CFR part 20 radiation protection regulations.

Petitioners' Assertion that Hormesis Disproves the LNT Model

The petitioners advance the concept of hormesis, "in which low levels of potentially stressful agents, such as toxins, other chemicals, ionizing radiation, etc., protect against the deleterious effects that high levels of these stressors produce and result in beneficial effects (e.g. lower cancer rates)."[77] Thus, the petitioners assert that low doses of radiation are beneficial to humans in that such doses may enhance the immune response or DNA repair processes. The petitioners request that the NRC amend its regulations to raise the dose limit for members of the public to be the same as the occupational dose limit.[78]

NRC's Response

There is scientific uncertainty and no compelling evidence as to whether the hormesis concept is valid for application to radiation protection requirements. None of the national and international authoritative scientific advisory bodies described above support the hormesis concept as a regulatory model for radiation protection. Of note, the BEIR VII report produced by NAS included a strong conclusion against applying the hormesis concept to radiation protection:

> Although examples of apparent stimulatory or protective effects can be found in cellular and animal biology, the preponderance of available experimental information does not support the contention that low levels of ionizing radiation have a beneficial effect. The mechanism of any such possible effect remains obscure. At this time, the assumption that any stimulatory hormetic effects from low doses of ionizing radiation will have a significant health benefit to humans that exceeds potential detrimental effects from radiation exposure at the same dose is unwarranted.[79]

[77] Marcus petition (PRM-20-28), at 1-2.
[78] *Id.*, at 7 ("Why deprive the public of the benefits of low dose radiation?").
[79] NAS BEIR VII, at 315.

Similarly, the NCRP has found that there is not strong support for the hormesis concept in the scientific literature.[80] ~~Moreover, hormesis is not compatible with the continued use of the LNT model; as described earlier in this document, t~~The NRC has determined that it is prudent to continue to rely upon the LNT model as a basis for the NRC's radiation protection regulations. Consequently, the NRC will retain the dose limits for occupational workers and members of the public in 10 CFR part 20 radiation protection regulations.

Petitioners' Assertion that the NRC has a Conflict of Interest

The petitioners suggest a conflict of interest, because the NRC is one of the Federal agencies that funded the development of the BEIR VII report by the NAS and has funded, and is funding, research by the NCRP.

NRC's Response

Sections 31.a and 161.c of the AEA authorize the NRC to enter into arrangements with organizations such as the NAS and the NCRP. Specifically, section 31.a of the AEA authorizes the NRC to enter into arrangements, with either public or private institutions or persons, for research and development and to expand theoretical and practical knowledge in the various fields specified in section 31.a, including radiological health and safety.[81] Additionally, section 161.c authorizes the NRC to "make such studies and investigations, obtain such information … as the Commission may deem necessary or proper to assist it in exercising any authority

[80] NCRP Report No. 136, at 196; *see also* NCI 2015, at 3 ("there is little data to suggest a threshold in dose, or possible hormetic (beneficial) effects of low-dose radiation exposure").

[81] 42 U.S.C. § 2051(a).

provided in [the AEA]."[82]

~~The petitioners merely allege a conflict of interest.~~ The NRC did not influence or direct the findings of either the NAS or the NCRP, and the NRC is not aware of any irregularities in the methods invoked by NAS or NCRP technical experts who analyzed the data and prepared the respective reports. The petitioners did not present any evidence to the contrary. Moreover, ~~and most importantly,~~ the petitioners did not demonstrate that the findings of either the BEIR VII report or any of the various NCRP reports that were funded in part by the NRC are either technically or scientifically unsound. The NRC will continue to review and consider recommendations on radiation protection regulations provided by national and international authoritative scientific advisory bodies.

Petitioners' Assertion that the Cost of Compliance with LNT-Based Regulations Is Enormous

The petitioners assert that the cost of complying with LNT-based regulations is "enormous" and "incalculable."

[82] 42 U.S.C. § 2201(c).

NRC's Response

In 1991, the NRC issued the 10 CFR part 20 final rule, which established the current regulatory framework for the NRC's radiation protection regulations. In issuing that final rule, the Commission concluded that the rule "provides for a substantial increase in the overall protection of the public health and safety and that the direct and indirect costs of its implementation are justified in terms of the quantitative and qualitative benefits associated with the rule."[83] Although the NRC acknowledges the costs involved in complying with its regulations, the NRC continues to conclude that its regulatory provisions that rely on LNT, such as the ALARA concept, remain both beneficial, in terms of the health and safety benefits they provide to both members of the public and occupational workers, and are cost-justified.[84] The petitioners have not provided any new information that would cause the NRC to revisit its findings with respect to cost that it made in 1991.

~~Moreover~~Irrespective of cost, ~~in the 1991 final rule,~~ the Commission further noted that ~~if~~ it ~~had determined that the rule was not cost-justified, the Commission~~ would have still issued the 1991 final rule "because the changes made to part 20 also amount to a redefinition of the level of adequate protection."[85] "Adequate protection" is the NRC's fundamental safety standard and is derived from various provisions of the AEA.[86] An

[83] 56 FR at 23389.

[84] The NRC regulations define ALARA as "making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken." § 20.1003. Those individuals and entities that hold NRC licenses are required, "to the extent practical," to incorporate ALARA into their procedures and engineering controls in accordance with § 20.1101(b). The NRC's Regulatory Guide (RG) 8.10, "Operating Philosophy for Maintaining Occupational and Public Radiation Exposures As Low As Is Reasonably Achievable," Rev. 2 (August 2016), provides guidance to NRC licensees on complying with the ALARA requirement. Other NRC regulatory guides provide additional ALARA guidance to licensees in specific categories, e.g., RG 8.8 (power reactor licensees) and RG 8.18 (medical licensees).

[85] 56 FR at 23389.

[86] *E.g.*, Section 182a. of the AEA, with respect to reactor applications, requires the Commission to find that "the utilization or production of special nuclear material will be in accord with the common defense

"adequate protection" finding means that the Commission or the NRC staff, if appropriate, has determined that a given requirement is the minimum necessary for public health and safety. Applicable case law holds that "adequate protection" findings are made without regard to cost. In this regard, the United States Court of Appeals, District of Columbia Circuit stated that—

> Section 182(a) of the Act commands the NRC to ensure that any use or production of nuclear materials "provide[s] adequate protection to the health or safety of the public." 42 U.S.C. § 2232(a). In setting or enforcing the standard of "adequate protection" that this section requires, the Commission may not consider the economic costs of safety measures. The Commission must determine, regardless of costs, the precautionary measures necessary to provide adequate protection to the public; the Commission then must impose those measures, again regardless of costs, on all holders of or applicants for operating licenses.[87]

The NRC is mandated under the AEA to impose requirements that it determines to be necessary for adequate protection of public health and safety regardless of cost. As set forth earlier in this document, the consensus of the various international and domestic authoritative scientific advisory bodies, as well as the NCI, NIOSH, and EPA, is that the LNT model should remain the basis for radiological protection regulations. Based upon these external organizations' recommendations, the recommendation of the ACMUI, and the professional and technical judgment of the NRC, those regulations that are based upon the LNT model ~~will~~ remain ~~and continue to be~~ necessary for adequate protection. Therefore, the NRC will continue to use the LNT model as the basis for its current radiation protection regulations in 10 CFR part 20.

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and security and will provide adequate protection to the health and safety of the public." 42 U.S.C. § 2232(a).

[87] *Union of Concerned Scientists v. NRC*, 824 F.2d 108, 114 (D.C. Cir. 1987).

IV.Public Comments on the Petition

On June 23, 2015, the NRC published in the *Federal Register* a notice of docketing of the three petitions, and requested public comment with the comment period ending on September 8, 2015.[88] On August 21, 2015, the NRC extended the comment period to November 19, 2015, to allow more time for members of the public to develop and submit their comments.[89] The NRC received over 3,200 comment submissions, with 635 of those comment submissions being unique, including comments from certified health physicists, nuclear medical professionals, other scientific professionals, scientific associations, Federal agencies, and concerned citizens.

In determining the appropriate ~~disposition of~~response to the petitions, the NRC carefully reviewed the public comments. To simplify the analysis, the NRC grouped all comment letters into two main groups: those that opposed the petitions and those that supported them. A description of the comments in both groups and the NRC's responses are provided as follows.

Comments Opposed to the Petitions

Comments: There were 535 unique comment submissions that opposed the petitioners' recommendation to discontinue use of the LNT model as a basis for the NRC's radiation protection regulations. Some of these commenters stated that the petitioners did not provide sufficient evidence to support changing the technical basis regarding radiation exposure from the LNT model to the hormesis concept. One commenter stated that the proposal to increase allowable public radiation doses to the

[88] 80 FR 35870.
[89] 80 FR 50804.

same as those of nuclear industry workers neglects the fact that the workers made a voluntary choice to work in the nuclear industry, and thus be subject to accompanying exposure to radiation, whereas the general public did not make that choice. Another commenter stated that the LNT model is satisfactory and that there is no substantial science upon which to base any change to the current 10 CFR part 20 public and occupational dose limits. One commenter stated that no threshold exists because every organism's adaptive response varies considerably, with the very young being the most vulnerable. Another commenter stated that "the existing standard needs to be retained, or at least, retained unless and until an undeniable and clear preponderance of the evidence indicates that the existing standard definitely should be replaced by some specific alternative."

Response: The NRC agrees that the petitions should be denied. The NRC's rationale is set forth earlier in this document. Therefore, the NRC will not amend its radiation protection regulations in response to the petitioners' requests.

Comments Supporting the Petitions

There were 100 unique comment submissions that agreed with the petitioners. These commenters provided varied responses, and so to simplify the analysis and address each type of comment ~~in support of the petition~~, the NRC grouped the comments by subject and separated them into subject areas. A review of the comments and the NRC's responses follow.

Comments Supporting the Petitions—General Comments; Assertions that NRC Regulations Lead to Unjustified Fear of Radiation by Authorities and the Public

Comment: The NRC received several comments that expressed support for the petitions without providing a specific rationale.

Response: These comments expressed support for the petitions in general terms and did not provide any further rationale or explanation for why the petitions should be considered for rulemaking. Therefore, no detailed response is being provided separate from the justification presented above for the NRC's denial of the petitions.

Comment: The NRC received a comment that supports the petitions based on the commenter's experiences working in the radiation protection field. The commenter concludes that, outside of individuals with experience in a nuclear facility, most individuals do not have proper authority or experience to appropriately determine proper radiation protection practices.

Response: The NRC interprets this comment to mean that those who lack experience working in a nuclear facility cannot properly understand radiation protection principles. The NRC disagrees with this comment. The NRC's radiation protection regulations, policies, and guidance are informed by operational experience, the findings and recommendations of national and international authoritative scientific advisory bodies, and academic and government research. This comment did not persuade the agency that the petitions should be granted. ~~No change was made to the 10 CFR part 20 radiation protection regulations as a result of the comment.~~

Comment: Several commenters expressed concern that the LNT model and the ALARA concept create an unjustified fear of radiation exposure that could lead to authorities directing mass evacuations in the event of a major nuclear incident. The commenters expressed concern that such a mass evacuation would result in casualties, some of which may be caused by mass panic, and also result in significant socioeconomic costs.

Response: The NRC disagrees with this comment. The appropriate Federal, State, and local decision-makers take many factors into account when deciding to recommend or order an evacuation, including the size and nature of the incident and the potential impacts on affected communities. With respect to evacuation decisions, the State and local authorities who make those decisions are not subject to the AEA or to the NRC's ALARA requirement.

Moreover, ALARA is an operating principle designed to minimize the potential stochastic effects of low levels of ionizing radiation that members of the public and occupational workers may be exposed to as a result of routine licensee activities. The long-term potential (in terms of years or even decades) for the induction of cancer from these routine activities is the primary stochastic effect that the application of ALARA seeks to minimize. In an emergency situation involving the release of radioactive material, the overriding concern associated with evacuation decisions is to avert potential acute radiation exposure.

The NRC has concluded that the selection of a specific dose response model, LNT in this case, and the ALARA concept, which is premised upon the LNT model, do not lead directly to an unjustified fear of radiation, and thereby do not directly contribute to evacuation casualties and associated socioeconomic costs after a nuclear incident.

The NRC's rationale for continuing to use the LNT model as the basis for its radiation protection regulations is set forth earlier in this document. The costs of mass evacuation scenarios described by the commenters do not provide an adequate basis to discontinue the use of the LNT model. This comment did not persuade the agency that the petitions should be granted. ~~No change was made to the 10 CFR part 20 radiation protection regulations as a result of the comments.~~

Comment: One commenter asserted that "there may be cases where, in efforts to minimize even low radiation exposure to workers and the public in the design, operation, and accident management of nuclear facilities, we may actually increase the probability of much larger exposures from severe accidents."

Response: The NRC disagrees with this comment. The operating experience of nuclear facilities has not shown any relationship between severe accident risk and radiation protection practices. This comment did not persuade the agency that the petitions should be granted. ~~No change was made to the dose limit requirements in 10 CFR part 20 as a result of the comment.~~

Comment: Several commenters ~~asserted~~ expressed concern that the public's fear of radiation exposure due to the NRC's continued use of the LNT model could result in patients postponing or foregoing CT scans and other diagnostic radiology procedures, thereby resulting in adverse medical consequences to the patient. Other commenters asserted that the use of LNT in the medical field can inhibit lifesaving processes that require a higher radiation dose than what is currently acceptable or can add to the cost of certain procedures, also inhibiting patients from receiving important treatment.

Response: The NRC disagrees with this comment. Tthe NRC does not regulate machine-generated radiation, which is the type generated by the use of x-ray machines and CT devices. Machine-generated radiation is regulated by the states, and as such, any application of the LNT model to the NRC's radiation protection requirements would not affect these medical uses. Moreover, tThe NRC's regulations do not apply to the decisions of a physician to prescribe a certain diagnostic or therapeutic modality to treat a patient. The physician's recommendation and the patient's decision to undergo a CT scan are ~~wholly~~ informed by the professional judgement of the medical provider and are not addressed by NRC regulations ~~therefore outside the scope of the NRC's regulatory authority~~. ~~Furthermore, the NRC does not regulate machine-generated radiation, which is the type generated by the use of x-ray machines and CT devices. Machine-generated radiation is regulated by the States, and as such, any application of the LNT model to the NRC's radiation protection requirements would not affect these medical uses.~~

Moreover, current evidence demonstrates that the use of radiation producing devices in medical diagnostic tests and therapies in the United States is increasing—all while LNT has been in place as the underlying dose-response assumption for radiation protection~~. For example, the NCRP reported that the average medical exposure in 2006 had increased substantially from the early 1980s, primarily due to the increased use of CT, interventional fluoroscopy, and nuclear medicine~~.[90] ~~With respect to CT, the NCRP stated that "[t]echnological advances in CT and the ease of use of this technology have led to many clinical applications that have increased the use of CT at a rate of 8 to 15%~~

[90] NCRP, "Ionizing Radiation Exposure of the Population of the United States," Report No. 160 (2009), at 5.

per year for the last 7 to 10 years [prior to 2006]."[91] CT scanning further increased from 2006 to 2012.[92] The use of interventional fluoroscopy and nuclear medicine have also similarly increased.[93] The commenters' claims that patients are postponing or foregoing radiology procedures is cannot be supported. These commenters did not present evidence to support the assertion that the NRC's use of the LNT model results in adverse medical treatment consequences, such that the NRC should amend its regulations in 10 CFR part 20. This comment did not persuade the agency that the petitions should be granted. No change was made to the 10 CFR part 20 radiation protection regulations as a result of the comment.

Comment: One commenter stated that the summary of the petitioners' position as described in the NRC's June 23, 2015, notice of docketing (80 FR 35870), characterized the petitions inaccurately, by stating that the petitioners wanted the NRC to amend the basis for radiation protection under 10 CFR part 20 from the LNT model to the hormesis model. The commenter expressed concerns that readers would be negatively biased against the petitions due to this representation of the petitioners' position.

Response: The NRC disagrees with this comment. In her petition, Dr. Marcus requested that the NRC amend its radiation protection regulations in 10 CFR part 20 to

[91] *Id.*, at 85 (alteration added).

[92] Fred A. Mettler, MD, Professor Emeritus and Clinical Professor, Department of Radiology, Mew Mexico School of Medicine, presentation entitled "Dose, Benefit, Risk and Safety" at the 2018 Annual Meeting of the NCRP (March 5, 2018). Dr. Mettler's presentation is expected to be published in the *Health Physics Journal* in 2019.

[93] *Id.*, at 117 (the number of procedures in radiographic fluoroscopy increased by 54% between 2002 and 2005) and at 195 (5% annual growth in the number of nuclear medicine procedures between 1995 and 2005).

"take radiation hormesis into account."[94] Dr. Marcus then made several specific recommendations, including the complete removal of ALARA from the NRC's radiation protection regulations; the end of "differential doses to pregnant women; embryos and fetuses, and children under 18 years of age"; and an increase in radiation dose limits to members of the public so that the public dose limit would be equal to the dose limits for occupational workers. In her petition, Dr. Marcus states that the removal of ALARA is "not only harmless but may be hormetic," and in requesting that "[p]ublic doses should be raised to worker doses," asked "[w]hy deprive the public of the benefits of low dose radiation?"[95] In addition, Dr. Marcus referenced studies which she argued ~~purportedly~~ suggest that low doses of radiation decrease cancer rates and asserted "[h]ormesis is a perfectly good alternative explanation" for such results.[96] Similarly, in his petition, Mr. Miller recommends that "[p]ublic dose limits should be raised to match worker dose limits, as these low doses may be hormetic," and that "[l]ow-dose limits for the public perpetuates radiophobia."[97] Moreover, in its June 23, 2015, *Federal Register* notice, the NRC stated that the petitions were publicly--available and should be consulted for additional information.[98] Thus, the NRC concludes that it accurately summarized the petitions in its June 23, 2015, *Federal Register* notice. This comment did not persuade the agency that the petitions should be granted.~~No change was made to the 10 CFR part 20 radiation protection regulations as a result of the comment.~~

Comment: One commenter stated that a public education system should be put in place to dispel fear of low-level radiation.

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[94] Marcus petition (PRM-20-28), at 7.
[95] *Id.*
[96] *Id.*, at 4.
[97] Miller petition (PRM-20-29), at 6-7.
[98] 80 FR, at 35872.

Response: The NRC considers this comment to be outside the scope of the issues raised by the petitions., because the establishment of a public education system to dispel fears of low-level radiation is not a mission or responsibility of the NRC and is beyond the NRC's statutory authority. The NRC supports communication efforts to accurately convey the radiological risks associated with any given regulated activity. The NRC, through its communication efforts, engages stakeholders in order to foster transparency and communication between the NRC and the public (e.g., through public meetings, public comment on NRC rulemakings and guidance development, the NRC's public Web site, and the NRC's use of social media). This comment did not persuade the agency that the petitions should be granted.No change was made to the 10 CFR part 20 radiation protection regulations as a result of the comment.

Comment: The NRC received several comments requesting that the NRC conduct research on topics raised by the petition.

Response: The NRC considers disagrees with these comments to be outside the scope of the issues raised by the petitions. The comments requesting that the NRC engage in additional research is outside the scope of the subject petitions. Other Federal agencies are charged with conducting basic radiation research, such as the Department of Energy and the National Institutes of Health. This comment did not persuade the agency that the petitions should be granted.No change was made to the 10 CFR part 20 radiation protection regulations as a result of the comment.

Comments Supporting the Petitions—Assertions that the LNT Model Lacks an Adequate

Scientific Basis

Comment: Several commenters questioned the scientific basis of the LNT model and asserted that it should no longer be the premise of the NRC's radiological protection regulations.

Response: The NRC disagrees with these comments. The NRC's goal as a regulatory agency is to protect both the public and occupational workers from the radiological hazards associated with NRC-licensed material, activities, and facilities. The NRC uses the LNT model to establish radiation protection measures that quantify radiation exposure and set regulatory limits. The premise of the LNT model is that the long-term biological damage caused by ionizing radiation (i.e., risk of cancer induction or adverse hereditary effects) is directly proportional to the dose received by the human receptor. The LNT model provides for a conservative, comprehensive radiation protection scheme that protects individuals in all population categories (male, female, adult, child, and infant) and exposure ranges by reducing the risk from low-dose radiation exposure.

As described earlier in this document, the consensus among various domestic and international authoritative scientific advisory bodies and the three Federal agencies that submitted comments (NCI, NIOSH, and EPA) is that the LNT model should remain the basis for the NRC's radiological protection regulations. Similarly, the ACMUI recommends that the NRC continue to use the LNT model. Based upon the external organizations' recommendations, the ACMUI's recommendation, and its own professional and technical judgment, the NRC has determined that the LNT model continues to provide a ~~prudent~~ sound basis for minimizing the risk of unnecessary radiation exposure to both members of the public and occupational workers. This

comment did not persuade the agency that the petitions should be granted. ~~No change was made to the dose limits requirements in 10 CFR part 20 as a result of the comment.~~

Comment: One commenter noted that multiplying the LNT-based risk coefficient by a population dose to derive a hypothetical number of cancer deaths in no way shows, proves, or demonstrates that anyone is getting cancer.

Response: The NRC disagrees with this comment. ~~This comment is out of scope~~. ~~The petitions for rulemaking request that the NRC amend 10 CFR Part 20 to discontinue use of the LNT model as the primary scientific basis for the agency's radiation protection standards.~~ The NRC does not use the LNT model for deterministic mortality projections. ~~However, we do use LNT in cost-benefit analysis for regulatory analysis where the dollar per person-rem averted from some regulatory action is the product of a cancer mortality risk coefficient and the value of a statistical life.~~ This comment did not persuade the agency that the petitions should be granted. ~~No change was necessary to the 10 CFR part 20 radiation protection regulations as a result of the comment.~~

Comment: One commenter noted that the LNT model is flawed, because it lacks timescale modeling to account for the differences between getting a large dose over a long period of time as opposed to a large dose in a short period of time.

Response: The NRC disagrees with this comment. The LNT model, as applied by the NRC in its licensing and regulatory decisions, effectively addresses the potential health impacts of any given dose received either acutely or chronically.

~~It is established from h~~Human epidemiologic studies have established that there is an increased incidence of certain cancers associated with radiation exposure at high doses and high dose rates (acute exposure). The principal source of information for risk estimation is the Japanese survivors of the atomic bombing of Hiroshima and Nagasaki in 1945, who were exposed to a range of doses at a high dose rate.[99] The NCRP defines high dose rate as a dose rate above which recovery and repair processes are unable to ameliorate the radiation damage.[100] Both the ICRP and NCRP estimate that the risk of death from radiation-induced cancer resulting from an acute exposure is 10 x 10^{-2} per Sv for a population of all ages.[101] However, experimental results in animals and other biological systems suggest that cancer induction from acute exposures at low doses and involving low dose rates should be less than that observed after high doses involving high dose rates.[102]

If the radiation dose is received chronically (i.e., over a long period of time), the biologic response differs because much of the radiation damage is effectively and efficiently repaired.[103] To account for this difference in response to chronic low dose and low dose rate radiation exposure as compared to high dose and high dose rate radiation exposure, the ICRP and NCRP recommend, and the NRC has adopted, adjusting the risk of death from radiation exposure using a DDREF of two.[104] The DDREF is assumed

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[99] NAS BEIR VII, at 6.

[100] NCRP Report No. 116, at 60.

[101] ICRP, "1990 Recommendation of the International Commission on Radiological Protection," Pub. No. 60 (1991), at 22; NCRP Report No. 116, at 29.

[102] ICRP Pub. No. 60, at 111.

[103] UNSCEAR, "Non-stochastic effects of irradiation," Report to the General Assembly, ANNEX J (1982) at 575.

[104] ICRP Pub. No. 103, at 53; ICRP Pub. No. 60, at 18; NCRP Report No. 116, at 29. Although the NRC has not formally adopted a DDREF in regulation, it has relied upon a DDREF in computer modeling. *E.g.*, NUREG-2161, "Consequence Study of a Beyond-Design-Basis Earthquake Affecting the Spent Fuel Pool for a U.S. Mark I Boiling Water Reactor," (September 2014) at 195 (incorporating DDREF into computer modeling for offsite consequences of a postulated spent fuel pool accident).

to apply whenever the absorbed dose is less than 200 mSv (20 rem) and the dose rate is less than 100 mSv (10 rad) per hour.[105] Consequently, the risk coefficient for members of the public pertaining to low dose and low dose rate radiation exposure is 5 x 10^{-2} per Sv. This risk coefficient is further reduced to 4 x 10^{-2} per Sv for occupational workers because this population excludes both the very young and elderly who may be slightly more sensitive to radiation-induced carcinogenesis.[106] The risks of radiation exposure to occupational workers are described further in Regulatory Guide (RG) 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," Revision 1 (1996).

Although the appropriate value of the DDREF may depend on the specific low or very low dose scenario,[107] the use of a DDREF, particularly one with a high value, does not mean that there are no harmful health effects from low and very low doses of radiation. The use of a DDREF also does not demonstrate the presence of a threshold below which no permanent harmful effects will occur. The NRC staff concludes that the use of a DDREF in its dose calculations aligns with the LNT model. This comment did not persuade the agency that the petitions should be granted. ~~No change was made to the 10 CFR part 20 radiation protection regulations as a result of the comment.~~

Comment: Several commenters observed that mammals evolved in an environment with a constant low dose of radiation. One commenter noted that humans developed DNA repair mechanisms to compensate. This commenter further stated that we experience far more DNA double strand breaks during mitotic cell division than we do

[105] ICRP Pub. No. 60, at 19; NCRP Report No. 116, at 60.
[106] ICRP Pub. No. 60, at 22; NCRP Report No. 116, at 29.
[107] For example, a DDREF value of "1" (no dose and dose rate effect) is used for certain tissues such as the thyroid and a higher value (e.g., a "2" or a "3") is used for other, less radio-sensitive tissues.

from exposure to background radiation. As the biological mechanisms deployed to repair DNA damage caused by mitotic cell division are well documented, the commenter concludes that the rate of DNA damage that we can accommodate is also documented. This commenter reasons that because the rate of damage is substantially greater than zero, the LNT model cannot be correct.

Response: The NRC disagrees with this comment. There is substantial scientific uncertainty regarding the ability of the human body's immune system, or other forms of adaptive response, to repair cells damaged by ionizing radiation. According to the NCI comments, the available data does not show that any immune or other adaptive response offsets the carcinogenic damage caused by a given dose of ionizing radiation.[108] NCI~~, in its comments,~~ states that the "repair of [DNA] double strand breaks (DSBs) relies on a number of pathways," and that these pathways are "prone to errors," which may result in cell mutations, a fraction of which may lead to cancer.[109] NCI further notes that the petitioners, and by extension, the commenter, do not reference data which shows that various cohorts subjected to "protracted radiation exposures" develop "an increase in stable chromosome aberrations and other markers of biological damage in the peripheral blood lymphocytes."[110] NCI~~, in its comments,~~ states that such chromosome aberrations may increase the risk of cancer, and concluded that "there is little data to suggest a threshold in dose, or possible hormetic (beneficial) effects of low-dose radiation exposure."[111] This comment did not persuade the agency that the petitions should be granted.~~No change was made to the 10 CFR part 20 radiation~~

[108] NCI 2015, at 3.
[109] *Id*. (alteration added).
[110] *Id*.
[111] *Id*.

protection regulations as a result of the comment.

Comments Supporting the Petitions—Assertions That There Are No Observable Adverse Effects from Background Radiation

Comment: Several commenters remarked that background levels of ionizing radiation, which vary significantly around the world, have never been demonstrated to be a health hazard to humans. Some commenters also noted that in regions of the world such as Brazil or India where background radiation levels are higher than normal, epidemiological studies of large cohorts of subjects living in these areas did not reveal excess cancers or diseases linked to radiation exposure. On this basis, these commenters conclude that the LNT model is based on a premise that is not supported by evidence.

Response: The NRC disagrees with these comments. The NRC notes that, in general, the inability to observe an effect does not mean that the effect has not occurred. These high background exposure studies are epidemiological in nature. They cannot be used as quantitative estimates of disease risk associated with the radiation exposure levels found in the areas studied, because the studies lack sufficient quantifiable evidence of the absence of cancer risk. As explained by NCI, in its comments, there are limitations associated with reliance on epidemiological studies in any effort to invalidate the LNT model. NCI, in its comments, noted that "[c]ancer risks predicted by the LNT model are likely to be small at low doses; so small as to be difficult to detect in the presence of large numbers of cancers resulting from other causes."[112] In this regard,

[112] *Id*., at 1.

NCI further stated that "because epidemiologic studies are observational in nature and not controlled experiments, differences in risks in exposed and unexposed [populations] may reflect differences in life style factors such as smoking and may not necessarily result from radiation exposure."[113]

In addition, the BEIR VII report prepared by NAS indicates that studies of populations exposed to natural background radiation are limited in their ability to define risk of disease in relation to radiation dose. In discussing four studies of populations exposed to natural background radiation, the BEIR VII Phase 2 report states:

> These studies did not find higher disease rates in geographic areas with high background levels of radiation exposure compared to areas with lower background levels. However, these studies were ecologic in design and utilized population-based measures of exposure rather than individual estimates of radiation dose. Thus, they cannot provide any quantitative estimates of disease risk associated with the exposure levels found in the areas studied.[114]

Also, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) has recently published a review of cancer risk due to low dose rate radiation from environmental sources.[115] UNSCEAR concluded that "the results of the studies of cancer risk due to radiation exposure at low dose rates from environmental radiation do not provide strong evidence for materially lower risks per unit exposure than in studies of high radiation doses and dose rates."[116] In this regard, UNSCEAR noted that methodological improvements in environmental studies are needed to overcome "low statistical power, dosimetric uncertainties, imperfections in control of confounding,

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[113] *Id*.

[114] NAS BEIR VII, at 228.

[115] UNSCEAR, "Sources, Effects and Risks of Ionizing Radiation, Annex B: Epidemiological studies of cancer risk due to low-dose-rate radiation from environmental sources," Report to the General Assembly with Scientific Annexes (2017) (UNSCEAR 2017 Report, Ann. B).

[116] UNSCEAR 2017 Report, Ann. B, at 153.

and any other biases" to include "under-ascertainment of cases (deaths or diagnoses), inaccurate cancer diagnosis, imprecise dose assessment, and residual confounding."[117]

Therefore, no direct inferences about radiation effects can be drawn from studies where background radiation levels are higher than normal. ~~Currently available information regarding population studies in high natural background areas does not provide sufficient evidence to conclude that exposure to background radiation is completely risk-free.~~ This comment did not persuade the agency that the petitions should be granted.~~No change was made to the 10 CFR part 20 radiation protection regulations as a result of the comment.~~

Comments Supporting the Petitions—Objections to ALARA

Comment: One commenter asserted that current regulations are too restrictive and focus too heavily on radiation protection, thus creating a system that emphasizes compliance with ALARA at the expense of "basic lab safety," such as somebody falling and hitting their head. The commenter posits that such accidents are far more likely than receiving a "fatal radiation dose."

Response: The NRC disagrees with this comment. The NRC interprets the commenter's use of the phrase "basic lab safety" as meaning compliance with non-radiologic safety requirements. Non-radiologic safety issues are the oversight responsibility of the Occupational Safety and Health Administration (OSHA)~~, U.S. Department of Labor,~~ and appropriate State and local government agencies. NRC and

[117] *Id.*, at 155.

Agreement State ~~L~~licensees are required and expected to comply with both applicable NRC requirements as well as those of OSHA and the pertinent State and local authorities. Moreover, these licensees demonstrate compliance with ALARA by such actions as establishing appropriate procedures and engineering controls, providing the proper training and equipment, restricting access to radiation areas, and ensuring appropriate facility design. Therefore, ALARA practices should complement and work in concert with "basic lab safety," rather than degrade it.

The ALARA definition and the associated regulatory requirement also involve the concept of reasonableness, meaning that the licensee should make "every reasonable effort" to implement ALARA measures and should use procedures and engineering controls based upon sound radiation protection principles to achieve ALARA, to the "extent practical."[118] In addition, NRC guidance indicates that non-radiological hazards should be considered in determining appropriate ALARA measures. For example, ~~Regulatory Guide (~~RG~~)~~ 8.8, "Information Relevant to Ensuring That Occupational Radiation Exposures at Nuclear Power Stations Will Be as Low as Is Reasonable Achievable," states that "a comprehensive consideration of risks and benefits will include risks from nonradiological hazards. An action taken to reduce radiation risks should not result in a significantly larger risk from other hazards."[119] Similarly, RG 8.10, "Operating Philosophy for Maintaining Occupational and Public Radiation Exposures as Low as Is Reasonably Achievable," states that "the decision to implement measures to reduce occupational radiation doses should be weighed against the risk of any other occupational hazards in the workplace, to minimize the total risk to the worker's health

[118] 10 CFR 20.1003 and 10 CFR 20.1101(b).
[119] RG 8.8, Rev. 3, at 2.

and safety."[120]

Finally, the commenter did not provide any support for the assertion that a licensee's compliance with ALARA or other NRC requirements based upon the LNT model undermines or otherwise impedes a licensee's ability to comply with non-radiologic safety requirements. This comment did not persuade the agency that the petitions should be granted.~~No change was made to the ALARA requirement in 10 CFR part 20 as a result of the comment.~~

Comments: Several commenters objected to the use of the ALARA concept as a regulatory requirement by the NRC. Many of these commenters asserted that the implementation of ALARA results in excessive costs to licensees and as such, inhibits potential growth and innovation. Some commenters also asserted that ALARA does not strike the appropriate balance between safety and economy. Virtually all of these commenters requested the removal of the ALARA requirement in order to reduce costs ~~and decrease regulatory burden~~.

Response: The NRC disagrees with these comments. The NRC regulations define ALARA as "making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken."[121] ALARA takes into account the following, in relation to the utilization of nuclear energy and licensed materials in the public interest: 1) the state of technology, 2) the economics of improvements in relation to the state of technology, 3) the economics of improvements in relation to benefits to the public health

[120] RG 8.10, Rev. 2, at 5.
[121] 10 CFR 20.1003.

and safety, and 4) other societal and socioeconomic considerations.[122] The NRC requires that its licensees "use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are [ALARA]."[123] Furthermore, the NRC's 1991 rule stated that "the ALARA concept is intended to be an operating principle rather than an absolute minimization of exposures."[124]

The regulatory language of the ALARA definition sets out the considerations in making ALARA determinations, several of which include the consideration of economic factors.[125] The NRC guidance states that "'[r]easonably achievable' is judged by considering the state of technology and the economics of improvements in relation to all the benefits from these improvements."[126] In general, the NRC determines compliance with the ALARA requirement based on whether the licensee has incorporated measures to track and, if necessary, to reduce exposures; not whether exposures and doses represent an absolute minimum or whether the licensee has used all possible methods to reduce exposures. Furthermore, the level of effort expended on radiation protection programs, including compliance with the ALARA concept, should reflect the magnitude of the potential exposures—both the magnitude of average and maximum individual doses and, in facilities with large numbers of employees, collective (population) doses.[127] Thus, the size of a licensee's radiation protection program should be commensurate with the scope and extent of the licensed activities. For example, a large organization, such

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[122] *Id*.
[123] 10 CFR 20.1101(b) ~~(emphasis added)~~.
[124] 56 FR at 23366.
[125] 10 CFR 20.1003 ("the economics of improvements in relation to the state of technology," "the economics of improvements in relation to benefits to the public health and safety," and "other societal and socioeconomic considerations").
[126] RG 8.8, Rev. 3, at 2.
[127] *Id*.

as a nuclear power reactor licensee, would be expected to have a considerably larger and more extensive radiation protection program than a smaller organization that may maintain ~~only~~ lower activity sealed sources.

In addition, ALARA is achieved by implementing such fundamental measures as effective planning, training of the appropriate personnel, provision of appropriate equipment (e.g., dosimeters), controlling access to radiation areas, installation of radiation monitoring systems, and preparing appropriate facility designs.[128] The regulated community has had decades of operational experience in implementing ALARA measures, and it is likely that most costs of ALARA compliance have long since been optimized. ~~Moreover, the NRC considers many of these measures to be simply the implementation of sound operating practices.~~ Moreover~~Finally~~, ~~other than their general assertions,~~ the commenters have not provided any substantive evidence demonstrating that the ALARA concept or the LNT model inhibits innovation or growth. The NRC has determined that current ALARA requirements are consistent with the LNT model of radiation protection and reasonably account for economic considerations. This comment did not persuade the agency that the petitions should be granted.~~No change was made to the ALARA requirements in 10 CFR part 20 as a result of the comment.~~

Comments Supporting the Petitions—Assertion that the NRC Relies on the LNT Model as a Result of Political Pressure or Bias

Comment: Several commenters stated that the LNT model continues to remain relevant as a regulatory framework only because of political pressure or ideological or scientific bias.

[128] RG 8.10, Rev. 2, at 5; *see also* RG 8.8, Rev. 3.

Response: The NRC disagrees with this comment. The NRC is an independent regulatory agency that ~~bases~~ establishes its radiation protection regulations based, in part, on the recommendations of domestic and international authoritative scientific advisory bodies such as the ICRP, the NAS, and the NCRP. As described previously in this document, three other Federal agencies and the ACMUI recommend that the LNT model remain the basis for the NRC's radiation protection regulations. ~~Other than the mere assertions of political pressure or bias, t~~The commenters have not provided any substantive support for their assertion that political pressure or bias is motivating the NRC to continue to rely upon the LNT model. ~~Moreover, the commenters have not shown how such pressure or bias, if it existed, would invalidate the scientific and technical bases underlying the LNT model. As explained in the comments submitted by NCI, many of the studies relied upon by the petitioners have limitations with respect to such studies being used as a basis to invalidate the LNT model.~~ The NRC continues to conclude that, in the absence of convincing evidence that there is a dose threshold or that low levels of radiation are beneficial, the LNT model remains a prudent and conservative basis for the NRC's radiation protection regulations. This comment did not persuade the agency that the petitions should be granted.~~No change was made to the 10 CFR part 20 radiation protection regulations as a result of the comment.~~

V. Availability of Documents

The following table provides information about materials referenced in this notice. The ADDRESSES section of this notice provides additional information about how to access ADAMS.

Date	Document	ADAMS Accession Number or *Federal Register* Citation
Submitted Petitions		
February 9, 2015	Petition for Rulemaking (PRM-20-28)	ML15051A503
February 13, 2015	Petition for Rulemaking (PRM-20-29)	ML15057A349
February 24, 2015	Petition for Rulemaking (PRM-20-30)	ML15075A200
***Federal Register* Notices**		
June 23, 2015	10 CFR part 20 – Linear no-Threshold Model and Standards for Protection Against Radiation – Notice of Docketing and Request for Comment (PRM-20-28, PRM-20-29, and PRM-20-30)	80 FR 35870
August 21, 2015	10 CFR part 20 – Linear no-Threshold Model and Standards for Protection Against Radiation – Notice of Docketing and Request for Comment; Extension of Comment Period (PRM-20-28, PRM-20-29, and PRM-20-30)	80 FR 50804
September 8, 2015	Advisory Committee on the Medical Uses of Isotopes: Meeting Notice	80 FR 53896
May 21, 1991	10 CFR part 20, “Radiation Protection,” Advance Notice of Proposed Rulemaking; Request for Comments.	56 FR 23360
January 27, 1987	Federal Radiation Protection Guidance for Occupational Exposure	52 FR 2822

Federal Regulations		
1991	10 CFR part 20, “Standards for Protection Against Radiation”	N/A
2006	NAS BEIR VII, “Health Risks from Exposure to Low Levels of Ionizing Radiation”	N/A
1946	U.S. Code: Title 42, Chapter 23, “Development and Control of Atomic Energy”	N/A
National and International Publications		
2005	ICRP Publication 99, “Low-dose Extrapolation of Radiation-related Cancer Risk”	N/A
1977	ICRP Publication 26, “Recommendations of the International Commission on Radiological Protection”	N/A
1993	NCRP Report No. 116, “Limitation of Exposure to Ionizing Radiation”	N/A
2001	NCRP Report No. 136, “Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation”	N/A
2005	Academy of Sciences and National Academy of Medicine (France), “Dose-Effect Relationships and Estimation of the Carcinogenic Effects of Low Doses of Ionizing Radiation”	N/A
August 1998	IAEA, “Measures to Strengthen International Co-Operation in Nuclear, Radiation and Waste Safety, Nuclear Safety Review for the Year 1997”	N/A
2014	IAEA, “Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3”	N/A

April 24, 2018	NCRP Commentary 27, “Implications of Recent Epidemiologic Studies for the Linear Nonthreshold Model and Radiation Protection”	N/A
2009	NCRP Report No. 160, “Ionizing Radiation Exposure of the Population of the United States”	N/A
1991	ICRP Publication 60, “1990 Recommendations of the International Commission on Radiological Protection”	N/A
2007	ICRP Publication No. 103, “The 2007 Recommendations of the International Commission on Radiological Protection”	N/A
Other Reference Documents		
July 1993	Health Physics Society, Position Statement PS008-2, “Uncertainty in Risk Assessment,” (Revised April 1995, February 2013)	N/A
2017	Dr. John D. Boice, Jr., “The linear nonthreshold (LNT) model as used in radiation protection: an NCRP update,” International Journal of Radiation Biology, Vol. 93, No. 10	N/A
June 2015	K. Leuraud et al., “Ionising Radiation and Risk of Death from Leukaemia and Lymphoma in Radiation-monitored Workers (INWORKS): An International Cohort Study, Lancet Haematology, Vol. 2”	N/A
October 28, 2015	ACMUI, “Final Report on the Hormesis/Linear No-Threshold Petitions”	ML15310A418
August 2016	RG 8.10, “Operating Philosophy for Maintaining Occupational and Public Radiation Exposures As Low As Is Reasonably Achievable,” Rev. 2	~~N/A~~ML16105A136

June 1978	RG 8.8, “Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be as Low as Is Reasonably Achievable,” Rev. 3.	~~N/A~~ML003739549
September 2014	NUREG-2161, “Consequence Study of a Beyond-Design-Basis Earthquake Affecting the Spent Fuel Pool for a U.S. Mark I Boiling Water Reactor”	ML14255A365~~N/A~~
2017	UNSCEAR, “Sources, Effects and Risks of Ionizing Radiation, Annex B: Epidemiological studies of cancer risk due to low-dose-rate radiation from environmental sources”	N/A
1996	RG 8.29, “Instruction Concerning Risks from Occupational Radiation Exposure” Rev. 1	~~N/A~~ML003739438

VI.Conclusion

The NRC reviewed the petitioners' requests ~~and supporting assertions~~, as well as public comments received on the petitions. For the reasons cited in this document, the NRC is denying the three PRMs, specifically PRM–20–28, PRM–20–29, and PRM–20–30, in their entirety. Given the current state of scientific knowledge, the NRC has determined that the LNT model continues to be an appropriate basis for its radiation protection regulatory framework. Thus, the NRC's current radiation protection regulations provide for the adequate protection of human health and safety, and as such, changes to 10 CFR part 20 are not warranted at this time.

Dated at Rockville, Maryland, this day of , 2019.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.

JMB edits – Please make these same edits to each letter to petitioners

Dr. Carol S. Marcus
1877 Comstock Avenue
Los Angeles, CA 90025-5014

Dear Dr. Marcus:

I am responding to the petition for rulemaking (PRM) that you submitted to the U.S. Nuclear Regulatory Commission (NRC), PRM–20–28, dated February 9, 2015 (Accession No. ML15051A503 in the NRC's Agencywide Documents Access and Management System). The NRC received two additional petitions on the same topic (PRM–20–29 and PRM–20–30); all three petitions were docketed using the same Docket ID (NRC-2015-0057). In these petitions, you and the other two petitioners request that the NRC amend Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection Against Radiation," based on what you ~~all assert is~~characterize as new science and evidence that contradicts the linear no-threshold dose-effect model that serves as the basis for the NRC's radiation protection regulations. The specific recommendations made by you and the other petitioners are:

- Maintain worker doses at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic;
- Remove the As Low As Is Reasonably Achievable principle entirely from the regulations, because you claim that~~as~~ it makes no sense to decrease radiation doses that are not only harmless but may be hormetic;
- Raise the public dose limits to be the same as the worker doses, because you claim that~~as~~ these low doses may be hormetic; and
- End differential doses to pregnant women, embryos and fetuses, and children under 18 years of age.

The notice of receipt and request for comment on your petition was published in the *Federal Register* (FR) on June 23, 2015 (80 FR 35870). The public comment period was initially set to close on September 9, 2015, but was subsequently extended to November 19, 2015 (80 FR 50804). The NRC received over 3,200 public comment letters.

The NRC has considered the petitions, and the arguments raised therein, as well as the comments received in response to the petitions. For the reasons stated in the enclosed *Federal Register* notice (FRN), the NRC is denying the three PRMs (PRM–20–28, PRM–20–29, and PRM–20–30) in their entirety. Given the current state of scientific knowledge, the NRC has determined that its current radiation protection regulations are effective and provide for the adequate protection of human health and safety such that changes to 10 CFR Part 20 are not warranted at this time.

The FRN denying the petitions is being transmitted to the Office of the *Federal Register* for publication.

Sincerely,

Annette Vietti-Cook
Secretary of the Commission

Enclosure:
Federal Register notice

SUBJECT: Denial Letter to Dr. Carol S. Marcus for a petition for rulemaking (PRM-20-28), dated February 9, 2015, that was submitted to the NRC.

Enclosure:
Federal Register notice

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Docket No. PRM–20–28
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