

## **Rulemaking1CEm Resource**

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**From:** RulemakingComments Resource  
**Sent:** Monday, November 23, 2015 4:59 PM  
**To:** Rulemaking1CEm Resource  
**Subject:** Comment on PRM-20-28, PRM-20-29, and PRM-20-30  
**Attachments:** NRC-2015-0057-DRAFT-0565.pdf

### **DOCKETED BY USNRC—OFFICE OF THE SECRETARY**

**SECY-067**

**PR#:** PRM-20-28, PRM-20-29, and PRM-20-30

**FRN#:** 80FR35870

**NRC DOCKET#:** NRC-2015-0057

**SECY DOCKET DATE:** 11/19/15

**TITLE:** Linear No-Threshold Model and Standards for Protection Against Radiation

**COMMENT#:** 573

**Hearing Identifier:** Secy\_RuleMaking\_comments\_Public  
**Email Number:** 1382

**Mail Envelope Properties** (bc0766aa63df401f9a144bd70c6b511f)

**Subject:** Comment on PRM-20-28, PRM-20-29, and PRM-20-30  
**Sent Date:** 11/23/2015 4:58:57 PM  
**Received Date:** 11/23/2015 4:58:59 PM  
**From:** RulemakingComments Resource

**Created By:** RulemakingComments.Resource@nrc.gov

**Recipients:**  
"Rulemaking1CEM Resource" <Rulemaking1CEM.Resource@nrc.gov>  
Tracking Status: None

**Post Office:** HQPWMSMRS02.nrc.gov

<b>Files</b>	<b>Size</b>	<b>Date &amp; Time</b>
MESSAGE	288	11/23/2015 4:58:59 PM
NRC-2015-0057-DRAFT-0565.pdf		112226

**Options**  
**Priority:** Standard  
**Return Notification:** No  
**Reply Requested:** No  
**Sensitivity:** Normal  
**Expiration Date:**  
**Recipients Received:**

# PUBLIC SUBMISSION

<b>As of:</b> 11/23/15 2:37 PM
<b>Received:</b> November 19, 2015
<b>Status:</b> Pending_Post
<b>Tracking No.</b> 1jz-8mck-wka3
<b>Comments Due:</b> November 19, 2015
<b>Submission Type:</b> Web

**Docket:** NRC-2015-0057

Linear No-Threshold Model and Standards for Protection Against Radiation

**Comment On:** NRC-2015-0057-0086

Linear No-Threshold Model and Standards for Protection Against Radiation; Extension of Comment Period

**Document:** NRC-2015-0057-DRAFT-0565

Comment on FR Doc # 2015-20722

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## Submitter Information

**Name:** Edwin Lyman

**Submitter's Representative:** Edwin Lyman

**Organization:** Union of Concerned Scientists

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## General Comment

See attached file(s)

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## Attachments

hormesis petition comments

**Comments of the Union of Concerned Scientists on Rulemaking Petitions  
PRM-20-28, 20-29 and 20-30, “Linear No-Threshold Model and Standards for Protection  
Against Radiation,” Docket ID NRC-2015-0057**

Edwin Lyman, PhD  
Senior Scientist, Global Security Program  
Union of Concerned Scientists  
Washington, DC  
November 19, 2015

**Summary**

The Union of Concerned Scientists strongly opposes the three rulemaking petitions PRM-20-28, -29, and -30. In our view, these misguided requests utterly fail to meet the threshold sufficiency requirements for rulemaking petitions under 10 CFR §2.802 and the NRC should not have accepted them. However, UCS believes that the NRC should now take this opportunity to decisively reject these poorly reasoned, error-ridden petitions and reaffirm the validity of the broad technical basis underlying its current rules for protecting the public from injury caused by ionizing radiation exposure. Even if the petitions had any merit from a technical or a regulatory standpoint—which, to be clear, they do not—the remedies they propose would only confuse licensees and disrupt long-established radiation protection programs for both personnel and for the public.

**Technical Basis**

UCS fully endorses the comments on the petitions submitted by the Environmental Protection Agency (EPA) by Jonathan D. Edwards, Director of the Radiation Protection Division. In our view, these comments succinctly and comprehensively outline the vast body of evidence that supports the use of the linear no-threshold (LNT) model in radiation protection, both from the standpoint of cellular biology and from a scientifically valid interpretation of the available epidemiological data.

In contrast, the petitioners merely recycle a handful of cherry-picked studies that they assert should be accepted by the NRC as the basis for a radical revision of its rules despite an overwhelming technical consensus in favor of retaining the LNT model. The petitioners employ a double standard by seeking to dismiss all the studies supporting the LNT by highlighting problems with their methodology while turning a blind eye to the numerous flaws in the studies they promote. While there is no doubt room for varying interpretations of any epidemiological study, it is the NRC’s obligation to maintain scientific integrity by basing its regulations on

studies with the best statistics, the best control of confounding factors and the broadest acceptance within the scientific community. Accordingly, we concur with the EPA's recommendation that the petitions be rejected.

UCS also notes that the NRC's own Advisory Committee on the Medical Uses of Isotopes (ACMUI), in comments dated October 14, 2015, despite expressing some sympathy for the petitioners' position, recommends that the NRC "continue to base the formulation of radiation protection standards on the LNT model."

## **PRM-20-28**

The February 9, 2015 petition of Dr. Carol Marcus is confusing and is filled with errors, unsupported assertions and hyperbolic allegations. Here are but a few examples of issues with the petition.

Dr. Marcus implies that the NRC's rules assume that "the rate of radiation delivery is irrelevant" (p. 1). This is incorrect, as in many regulatory applications the NRC applies a dose and dose-rate reduction effectiveness factor (DDREF) of 2 to reduce estimated cancer risks at low doses and dose rates (which the NRC is maintaining despite the fact that the BEIR VII committee recommends using a smaller DDREF of 1.5). For example, the 100 millirem per year limit for public exposure in 10 CFR Part 20 corresponds to a recommendation of the International Commission on Radiological Protection, which is derived from a limit on lifetime risk to the public assuming the application of a DDREF of 2 (see, for example, <https://www.oecd-nea.org/rp/reports/2011/nea6920-ICRP-recommendations.pdf>, p. 32).

Dr. Marcus' discussion of the "healthy worker effect" is nonsensical. She implies that radiation hormesis "is a perfectly good alternative explanation" for the reduction in morbidity and mortality from all causes generally seen in nuclear workers compared to the general population. However, the healthy worker effect, which was first observed in 1885 (well before Roentgen's 1895 discovery of x-rays, not to mention the establishment of a nuclear industry) is seen in studies across a wide range of occupations, with disease endpoints ranging from asthma to circulatory diseases. One recent study identified a healthy worker effect in major league baseball players

(<http://www.tandfonline.com/doi/abs/10.1080/15438620500528406?journalCode=gspm20>).

Does Dr. Marcus believe that radiation hormesis is a perfectly good alternative explanation for that?

Fundamentally, the core of Dr. Marcus' argument why the NRC should reject the linear no-threshold hypothesis despite the fact that "nationally and internationally respected bodies recommend and advocate it," (as Dr. Marcus admits in her own words), is that there is a massive

conspiracy to cover up the truth because of some unexplained “conflict of interest,” and the NRC is a prime co-conspirator. If the NRC were to accept Dr. Marcus’ petition, and by extension this argument, that would be tantamount to an admission that the NRC indeed is a corrupt agency that has endangered the health and safety of the public to further the benefits that she alleges it receives from continued use of the LNT. Is the NRC prepared to accept this conspiracy theory?

Let’s consider one of the studies that Dr. Marcus cites as evidence of hormesis: a 1994 study of groups exposed to radiation after the 1957 radioactive waste tank explosion in the South Urals. Dr. Marcus claims that the study found that all exposed groups had lower cancer rates than the baseline expected in the area, and that the differences were statistically significant. This is one of the handful of papers that hormesis advocates circulate among themselves to support their views.

However, Dr. Marcus failed to mention that one of the 1994 study authors did a follow-up study, in part to address claims that the study showed evidence of hormesis (<http://www.irpa.net/irpa10/cdrom/01011.pdf>). This study found that there was no statistically significant difference in cancer rates between any of the exposed groups and controls. And it is clear from the study that there are many other confounding factors which make interpretation of the data very difficult. This study in no way indicates a hormetic effect, and does not have the statistical power to lead to any conclusions regarding differential cancer risks for different dose groups. The NRC would be well-advised to review the other references cited by Dr. Marcus to evaluate if she is making other incorrect inferences.

But perhaps the biggest flaw is that even if one accepts Dr. Marcus’ proposition, her petition provides no credible or consistent values for the zero-risk or hormetic dose thresholds that she asserts are supported by thousands of scientific papers. In fact, her language is so tentative that it does not provide any confidence. Some studies, she claims, show no effects at various doses, some suggest possible hormetic effects. Various dose values are thrown around but no attempt is made to integrate them into a coherent recommendation. She writes that “public doses should be raised to worker doses, as these low doses *may be* hormetic.” Which doses? And to what organs? Is it possible that the same exposure could be hormetic to one organ and deleterious to another? If the hormesis effect is related to whole-body external dose, would the same numerical thresholds also apply to the total effective dose equivalent? What is the proposed shape of the dose-response curve? Dr. Marcus provides no answers to any of these questions. No technically sound rule change can be based on this kind of speculation. Her request that “public doses should be raised to worker doses” is completely arbitrary.

For example (and putting aside for a moment the problems with this study that we discuss above), the 1994 study South Urals study cited by Dr. Marcus found a group of people exposed to 12 rem radiation over a thirty-year period had a lower cancer mortality than a group exposed to 50 rem over a thirty-year period, so the hormesis effect that she asserts is shown in the data

appears to decrease with increasing dose in this dose range. It is unclear how this is consistent with her recommendation for raising the annual allowable dose limit for the public from 100 mrem/year to 5000 mrem per year so that the public can receive the hormetic benefits of additional radiation. According to her logic, the occupational dose should be *lowered* to maximize the benefit to workers! Meanwhile, she cites an analysis of residential radon exposure that finds that “somewhat above” the EPA action level of 4 picocuries/liter the natural protective effect of radiation goes to zero. The EPA action level corresponds to well below 1 rem/year for typical home dwellers. Again (depending on what “somewhat above” means), this hormesis threshold is not consistent with the other data she cites, nor with her recommendation.

A general hormetic dose-response curve will have a minimum corresponding to the value of the dose where the slope changes from negative to positive. Unless that value can be specified with reasonable certainty, no one can determine whether a dose increase in a given dose range will lead to an increase or decrease in hormetic benefit. In summary, even if the NRC were to embrace the concept of hormesis, Dr. Marcus’ petition is internally inconsistent and can hardly serve as the basis for a revision of quantitative dose limits. Nor does it support her request to remove the “As Low As Reasonably Achievable” (ALARA) standard from NRC’s regulations.

#### **PRM-20-29 and PRM-20-30**

The other two petitions do not supplement the record with any compelling new evidence or arguments in addition to those provided in PRM-20-28, and for similar reasons should also be rejected. We would simply add that the changes to 10 CFR Part 20 sought by Dr. Marcus would not remedy the concern raised by PRM-20-30 that a release of radioactive materials in the United States could result in harm to the public as the result of unnecessary evacuations driven by fear of radiation. Changing 10 CFR Part 20 would have no effect on the protective action recommendations for the public that would be issued following a radiological incident, which are based on EPA guidance. In addition, the NRC’s emergency planning regulations are located in 10 CFR §50.47, which the petitioners have not requested to be changed. So the main reason for “urgency” in acting on the petition cited by PRM-20-30 would not be addressed by the petition itself.