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From: RulemakingComments Resource
Sent: Thursday, September 10, 2015 4:20 PM
To: Rulemaking1CEm Resource
Subject: PRM-20-28, PRM-20-29, and PRM-20-30 - LNT Model and Standards for Protection Against Radiation
Attachments: NRC-2015-0057-DRAFT-0194.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: 8/26/15
TITLE: Linear No-Threshold Model and Standards for Protection Against Radiation
COMMENT#: 233

Hearing Identifier: Secy_RuleMaking_comments_Public
Email Number: 1014

Mail Envelope Properties (d1c459cac42f4a848c628d8ce558bc4a)

Subject: PRM-20-28, PRM-20-29, and PRM-20-30 - LNT Model and Standards for Protection Against Radiation
Sent Date: 9/10/2015 4:19:34 PM
Received Date: 9/10/2015 4:19:35 PM
From: RulemakingComments Resource

Created By: RulemakingComments.Resource@nrc.gov

Recipients:
"Rulemaking1CEm Resource" <Rulemaking1CEm.Resource@nrc.gov>
Tracking Status: None

Post Office: HQPWMSMRS05.nrc.gov

Files	**Size**	**Date & Time**
MESSAGE	292	9/10/2015 4:19:35 PM
NRC-2015-0057-DRAFT-0194.pdf	648085	

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

PUBLIC SUBMISSION

As of: 9/5/15 9:16 AM
Received: August 26, 2015
Status: Pending_Post
Tracking No. 1jz-8krq-hydg
Comments Due: September 08, 2015
Submission Type: API

Docket: NRC-2015-0057
Linear No-Threshold Model and Standards for Protection Against Radiation

Comment On: NRC-2015-0057-0010
Linear No-Threshold Model and Standards for Protection Against Radiation; Notice of Docketing and Request for Comment

Document: NRC-2015-0057-DRAFT-0194
Comment on FR Doc # 2015-15441

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General Comment

See attached file(s)

Attachments

Greenpeace Comments to NRC re 80FR35870

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August 26, 2015

Annette Vietti-Cook, Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Rulemakings and Adjudication Staff:

Dear Sir or Madam:

Pursuant to Federal Register 80 FR 35870, June 23, 2015 Greenpeace submits the following comments. Additionally, Greenpeace has reviewed the comments of Dr. Ian Fairlie (attached) and here by incorporates them by reference.

As stated by Dr. Fairlie, these petitions "do not merit serious consideration." The petitions, "appear to be based on preconceptions, or even ideology, rather than the scientific evidence which points in the opposite direction." http://www.ianfairlie.org/wp-content/uploads/2015/08/US-NRC-Consultation-4-1.pdf

Sadly, Greenpeace couldn't agree more. Dr. Marcus herself has acknowledged and embraced the fact that her stance on radiation is an outlier. Why is the NRC even entertaining these petitions that border on junk science?

The US National Academy of Sciences released its *Biological Effects of Ionizing Radiation (VII)* report, nearly a decade ago. This report focused on the health effects of radiation doses below 100 millisieverts. This consensus review assessed the world's scientific literature and concluded that, "there is a linear dose-response relationship between exposure to ionizing radiation and the development of solid cancers in humans. It is unlikely that there is a threshold below which cancers are not induced."

http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/beir_vii_final.pdf

Does this NRC, made up of lawyers and engineers, really have the credentials to overturn the scientific consensus adopted by the US National Academy of Sciences? Or has the agency merely replaced the word Commission with Cheerleader?

Perhaps if the NRC placed more value on human life, the agency would do a better job regulating the nuclear industry. But the NRC seems to have lost sight of its mission and is more concerned with extending the life of dangerous and uneconomical reactors. As the Union of Concerned Scientist has pointed out, the NRC undervalues human life. The estimates used by the NRC are one third to one half lower than those used by other US federal agencies. Rather than waste time and effort on these petitions, the NRC should move to bring its estimates more in line with other federal agencies.
http://allthingsnuclear.org/the-nrc-and-the-value-of-life/

Please deposit these petitions in the nearest available shredder and stop wasting limited regulatory resources advancing a position that will and should embarrass anyone who works at the U.S. Nuclear Regulatory Commission.

Sincerely,

Jim Riccio
Senior Nuclear Analyst
Greenpeace

Dr Ian Fairlie
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US Nuclear Regulatory Commission (NRC): Consultation

https://www.federalregister.gov/articles/2015/06/23/2015-15441/linear-no-threshold-model-and-standards-for-protection-against-radiation

Introduction

On June 26 2015, the US Nuclear Regulatory Commission (NRC) stated it was seeking public comments by September 8, on petitions stating that the Linear No Threshold theory of radiation's effects was not a valid basis for setting radiation standards and that the hormesis model should be used instead.

In more detail, the NRC has received 3 petitions for rulemaking requesting that the NRC amend its "Standards for Protection Against Radiation" regulations and change the basis of those regulations from the Linear No-Threshold (LNT) model of radiation protection to the hormesis model. (See the Appendix for details of the petitions.) The LNT model assumes that biological damage from radiation is linearly related to exposure and is always harmful, ie without a threshold. The hormesis model assumes that exposures to low radiation levels is beneficial and protects the human body against deleterious effects of high levels of radiation.

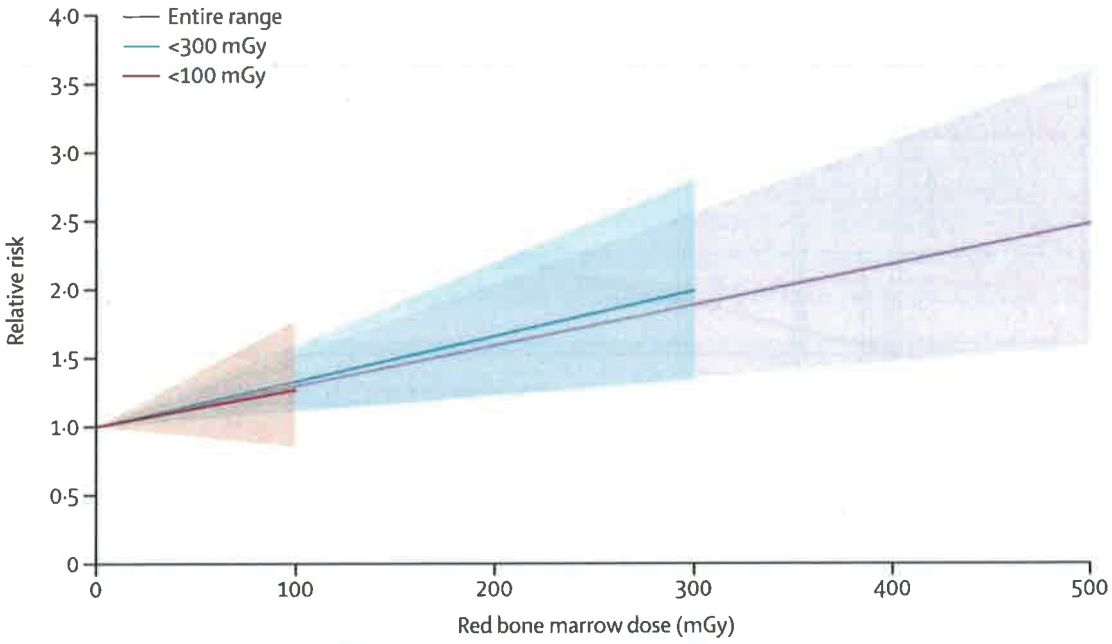
The NRC has stated it is examining these petitions to determine whether they should be considered in rulemaking and is requesting public comments. US environmental groups are concerned that, if the NRC agreed with the petitions, it would introduce rules to weaken radiation protection standards at US nuclear facilities. On the other hand, the NRC apparently pays attention to the evidence on the risks of low levels of radiation according to two NRC staffers (Brock and Sherbini, 2012). See references at end.

Comments on Hormesis

It is true that some cell and animal experiments indicate that if small amounts of radiation were administered before later larger amounts, the damage done is less than if no previous small amount were given. (The word "tickle" is used in radiobiology lingo to denote such small amounts.) On the other hand, other cell and animal studies using different doses, durations and endpoints fail to show this effect, and there is no human evidence, ie from epidemiology, of this. But it is true that some evidence from chemistry indicates the same effect, and there is some theoretical support for an adaptive effect in animals and plants.

Hormesis advocates typically argue that although radiation attacks DNA and causes mutations, DNA repair mechanisms quickly correct these. These mechanisms are

Graph 1



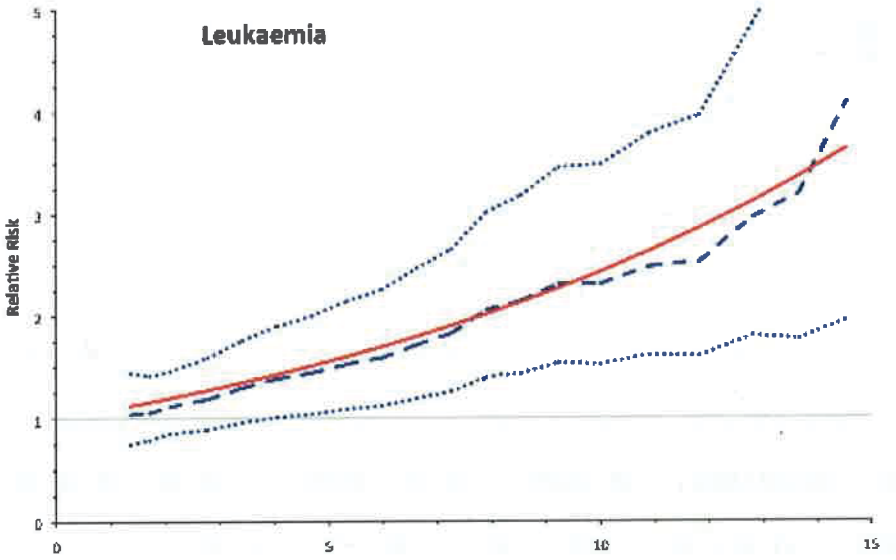
Two interesting things about this study are that 5 of the 13 authors are from US scientific institutes, including the Centers for Disease Control and Prevention, the National Institute for Occupational Safety and Health, the Department of Health and Human Services, University of North Carolina, and Drexel University School of Public Health. Also that the study was funded by many international agencies, including the US Centers for Disease Control and Prevention, US National Institute for Occupational Safety and Health, US Department of Energy, and the US Department of Health and Human Service.

It is legitimate to ask whether the NRC is in contact with any of these official US agencies about these issues.

The Leuraud et al study is merely the latest of many studies providing good evidence for the LNT model. Second is the Zablotska study after Chernobyl. Graph 2 below, reproduced from Zablotska et al (2012), shows statistically significant risks for all leukemias and for chronic lymphocytic leukemia (CLL) in over 110,000 Chernobyl cleanup workers. It can also be seen that there are 6 data points showing increased risks below 100 mSv - a commonly cited cut-off point.

In graph 4 below reproduced from their study, the x-axis represents cumulative gamma ray doses in mGy. The red line shows not merely a linear but a slightly supralinear curve fitted to the data. The small dotted lines mark a 95% confidence interval.

Graph 4



Fifth is the final analysis of the UK National Registry for Radiation Workers (NRRW). This study of observed 11,000 cancer cases and 8,000 cancer deaths in 175,000 UK radiation workers with an average individual cumulative dose of 25 mSv and an average follow-up of 22 years. Graph 5 reproduced from the study shows the relative risks for all solid cancers with the continuous blue line representing the NRRW data, and the continuous red line the results from the US BEIR VII report for comparison – the two are very similar, as can be seen. An estimated ERR of 0.27 per Sv can be derived from this graph.

No evidence below 100 mSv?

It is necessary at this point to directly address the argument often raised by hormesis advocates – that there is little evidence of effects below 100 mSv. This is incorrect. Older evidence exists -see http://www.ianfairlie.org/news/a-100-msv-threshold-for-radiation-effects/ for a list of studies and the newer evidence, as we have just seen, clearly shows this fact as well.

B. Radiobiological Evidence

Current radiobiological theory is consistent with a linear dose-response relationship down to low doses (ie below ~10 mSv).

The radiobiological rationale for linearity comes from the stochastic nature of energy deposition of ionising radiation. It was explained by 15 of the world's most eminent radiation biologists and epidemiologists in a famous article (Brenner et al, 2003) as follows:

"1. Direct epidemiological evidence demonstrates that an organ dose of 10 mGy of diagnostic x-rays is associated with an increase in cancer risk. 2. At an organ dose of 10 mGy of diagnostic x-rays, most irradiated cell nuclei will be traversed by one or, at most, a few physically distant electron tracks. Being so physically distant, it is very unlikely that these few electron tracks could produce DNA damage in some joint, cooperative way; rather, these electron tracks will act independently to produce stochastic damage and consequent cellular changes. 3. Decreasing the dose, say by a factor of 10, will simply result in proportionately fewer electron tracks and fewer hit cells. It follows that those fewer cells that are hit at the lower dose will be subject to (i) the same types of electron damage and (ii) the same radiobiological processes as would occur at 10 mGy. 4. Thus, decreasing the number of damaged cells by a factor of 10 would be expected to decrease the biological response by the same factor of 10; i.e., the response would decrease linearly with decreasing dose. One could not expect qualitatively different biological processes to be active at, say, 1 mGy that were not active at 10 mGy, or vice versa. The argument suggests that the risk of most radiation -induced endpoints will decrease linearly, without a threshold, from ~10 mGy down to arbitrarily low doses."

C. Official Reports

Both types of evidence (epidemiology and radiobiology) have been examined in 4 international official reviews: UNSCEAR (2008), US NCRP Report No 136 (2001), US BEIR VII (2006) and ICRP 99 (2006). These reports confirmed the LNT as being the most prudent assumption for radiation protection purposes.

For example in 2006, the chair of BEIR VII, Richard R. Monson, associate dean for professional education and professor of epidemiology, Harvard School of Public Health, Boston stated "The scientific research base shows that there is no threshold of exposure below which low levels of ionizing radiation can be demonstrated to be harmless or beneficial". http://hps.org/documents/BEIRVIIPressRelease.pdf

Secondly, such phrases are often glibly made by hormesis advocates without explaining that the actual test level used is arbitrary. There is no scientific justification for using a 5% or any other test level: it is merely a matter of convenience. Indeed more recent epidemiology studies are now using the less strict 10% test. In other words, it is quite possible for results which are "not significant" when a 5% test is applied, will become "significant" when a 10% test is used. For this reason, confidence intervals should instead be quoted by hormesis advocates.

There is a third reason to oppose the use of these phrases: scientifically speaking, it is bad practice. To dismiss results (or to imply this) just because they do not meet a statistical test is wrong in principle. This is because the probability (ie p level) that an observed effect may be due to chance is affected by both magnitude of effect and size of study (Whitely and Ball, 2002). This means statistical tests must be cited with caution, as the use of an arbitrary cut-off for statistical significance (often p = 5%) can lead to incorrectly accepting the null hypothesis (ie that there is no effect) (Sterne and Smith, 2001). This is called a type II error in statistics. This more often occurs in studies due to low numbers[1] of observed cases rather than to lack of effect (Everett et al, 1998). Many scientists (eg Axelson (2004); Whitley and Ball, 2002)) consider the rejection of findings for statistical reasons is of questionable validity as it can often hide real risks.

So what should hormesis advocates do with positive findings that do not meet a self-selected 95% test? First, they should not reject them. Instead they should report the observed increase but add there is a greater than 5% probability this could have occurred by chance. And then they should discuss whether their interpretation would change if a slightly less strict 10% test were chosen (as is increasingly used nowadays). And they should discuss confidence intervals so that readers can make up their own minds.

Conclusions

The validity or otherwise of LNT and hormesis have been the subject of hundreds of scientific articles and debates over several decades. Unfortunately, much of the literature on hormesis or adaptive response is based on faulty science or on misconceptions or on misinterpretations or all three. This is particularly the case with US and UK journalists who write with confidence on how radiation risks are exaggerated. Their knowledge and experience of radiogenic risks are limited, to say the least, but these journalists, almost on a weekly basis, misinform and mislead the public about radiation risks, so the existence of these petitions is perhaps unsurprising.

A question remains whether the NRC should have accepted the 3 petitions for review. Presumably the NRC has some discretion not to review or to refer back spurious, mischievous, or ill-founded petitions.

[1] It should be borne in mind that low case numbers are not the fault of researchers but often due to the fact that many conditions are rare (eg child leukemia) and very large numbers of exposed people are needed to pick up the few observed cases.

Muirhead et al (2009) Mortality and cancer incidence following occupational radiation exposure: third analysis of the National Registry for Radiation Workers. Br J Cancer 2009; 100: 206-212.

Pearce et al (2012) Radiation exposure from CT scans in childhood and subsequent risk of eukaemia and brain tumours: a retrospective cohort study. The Lancet. June 7, 2012. **380**: 499-505. DOI:10.1016/S0140-6736(12)60815-0, http://press.thelancet.com/ctscanrad.pdf

Puskin J (2009) Dose-Response Vol 7:284–291. Perspective On The Use Of LNT For Radiation Protection And Risk Assessment by the U.S. Environmental Protection Agency.

Sterne JAC, Smith GD. Sifting the evidence--what's wrong with significance tests? Phys Ther (2001) 81(8):1464-1469.

United Nations Scientific Committee on the Effects of Atomic Radiation (2008). UNSCEAR Report to the General Assembly, with scientific annexes – Annex B, § 153.

Whitley E, Ball J. Statistics Review 1: Presenting and summarising data. Crit. Care 2002; 6:66-71.

Zablotska et al (2012) Radiation and the Risk of Chronic Lymphocytic and Other Leukemias among Chornobyl Cleanup Workers. Environmental Health Perspectives http://dx.doi.org/10.1289/ehp.1204996 Online 8 November 2012.

Appendix: Views of US Petitioners

On February 9, 2015, Dr. Carol S. Marcus, a Professor of Radiation Oncology, of Molecular and Medical Pharmacology (Nuclear Medicine), and of Radiological Sciences at the David Geffen School of Medicine at the University of California-Los Angeles, filed a petition for rulemaking with the Commission, PRM-20-28 (ADAMS Accession No. ML15051A503). Dr. Marcus was a member of the NRC's Advisory Committee on the Medical Uses of Isotopes from 1990 to 1994. The petitioner indicated that "[t]here has never been scientifically valid support for this LNT hypothesis since its use was recommended by the U.S. National Academy of Sciences Committee on Biological Effects of Atomic Radiation (BEAR I)/Genetics Panel in 1956" and that "[t]he costs of complying with these LNT based regulations are enormous."

On February 13, 2015, Mr. Mark L. Miller, a Certified Health Physicist, filed a petition for rulemaking with the Commission, PRM-20-29 (ADAMS Accession No. ML15057A349). The petitioner indicated that "[t]here has never been scientifically valid support for this LNT hypothesis" and that "[t]he costs of complying with these LNT-based regulations are incalculable." In addition, the petitioner suggests that the use of the LNT hypothesis has "led to persistent radiophobia [radiation-phobia]."

On February 24, 2015, Dr. Mohan Doss, filed a petition for rulemaking with the Commission, PRM-20-30 (ADAMS Accession No. ML15075A200). Dr. Doss filed this petition on behalf of Scientist for Accurate Radiation Information, whose mission is to "help prevent unnecessary, radiation-phobia-related deaths, morbidity, and injuries associated with distrust of radio-medical diagnostics/therapies and from nuclear/radiological emergencies through countering phobia-promoting misinformation spread by alarmists via the news and other media including journal publications."