HPS Specialists in Radiation Protection

HISTORY OF THE LNT MODEL AND LASTING IMPACT ON RADIOLOGICAL PROTECTION STANDARDS

CIRMS ANNUAL MEETING

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HPS PRESIDENT 2021-2023

APRIL 19, 2023

Disclaimer

This presentation was prepared by John Cardarelli II in his personal capacity. The opinions expressed in this article are the author's own and do not reflect the view of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, the Department of Health and Human Services, or the United States government.

OVERVIEW

- HPS Positions Statements
- Radiation Protection Standards
- History of the LNT Video Documentary
- Impact of the LNT Model on Environmental, Medical & Nuclear Power Industries
- What can we do from here?

Radiation Risk in Perspective

https://hps.org/documents/radiationrisk.pdf Adopted 1996, Revised 2010, 2016, & 2019

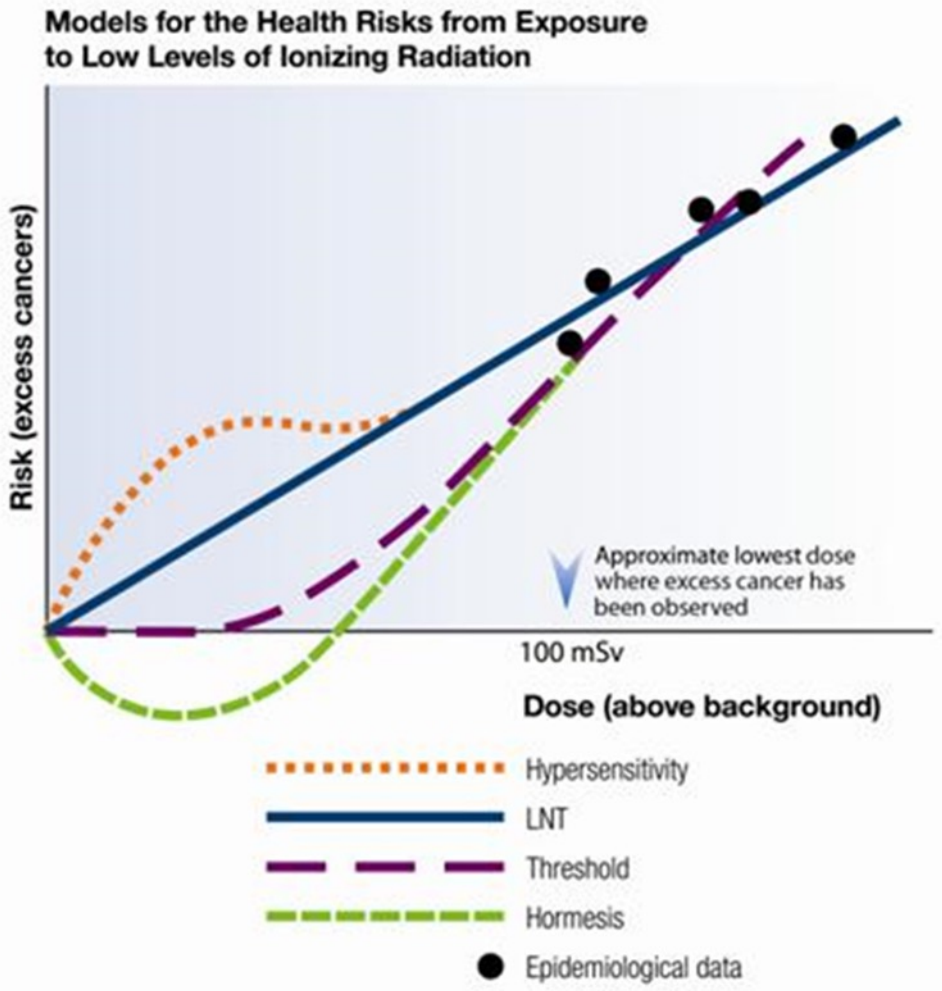
The Health Physics Society advises against estimating health risks to people from exposures to ionizing radiation that are near or less than natural background levels because statistical uncertainties at these low levels are great.

" … below levels of about 100 mSv above background from all sources combined, the observed radiation effects in people are not statistically different from zero."

"Molecular-level radiation effects are nonlinear"

Note: 100 mSv is equal to 10 rem or 10,000 mrem

Cancer Risk Models



- LNT assumes long term, biological damage caused by ionizing radiation (cancer risk) directly proportional to dose
- LNT conveys message: “There is no safe level of radiation dose”
- ICRP Publication 103 supports LNT for radiation protection purposes

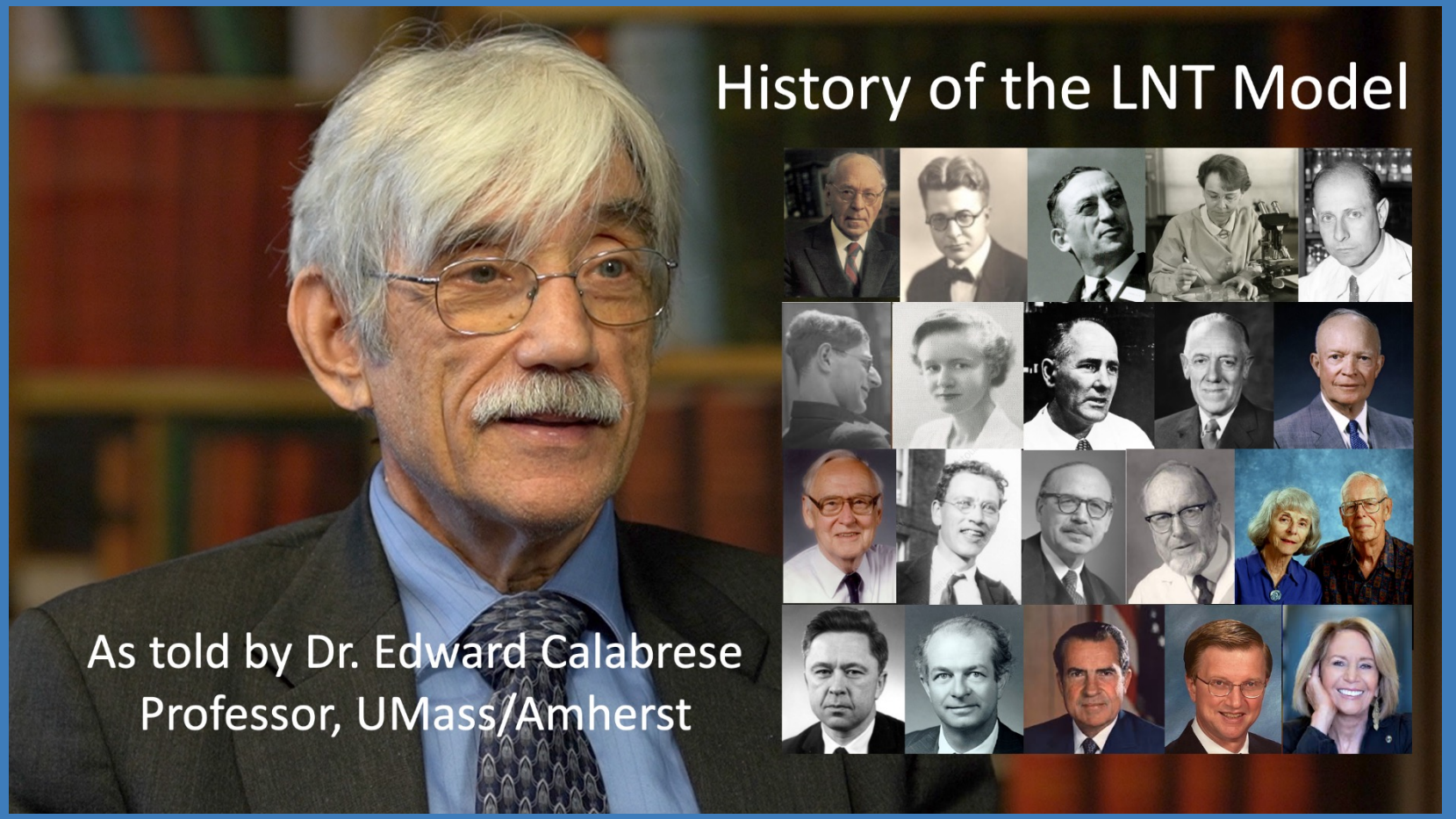
Figure reproduced from Canadian Nuclear Safety Commission
http://nuclearsafety.gc.ca/eng/resources/health/linear-non-threshold-model/index.cfm

Radiation Dose Limits and ALARA

https://orise.orau.gov/cer/rems/dashboard.html

- Current U.S. radiation protection limits are safe*
  - 5,000 mrem for workers (annual total effective dose equivalent)
  - 100 mrem/y for members of the public
- As Low As Reasonably Achievable (ALARA) principle is derived directly from the LNT hypothesis of no threshold
- This means that it's not enough to comply with the limit, but must make every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical (precautionary principle)
- Average measurable dose to DOE workers over past 5 years is **52 mrem/y**

* (100 mrem = 1 mSv)

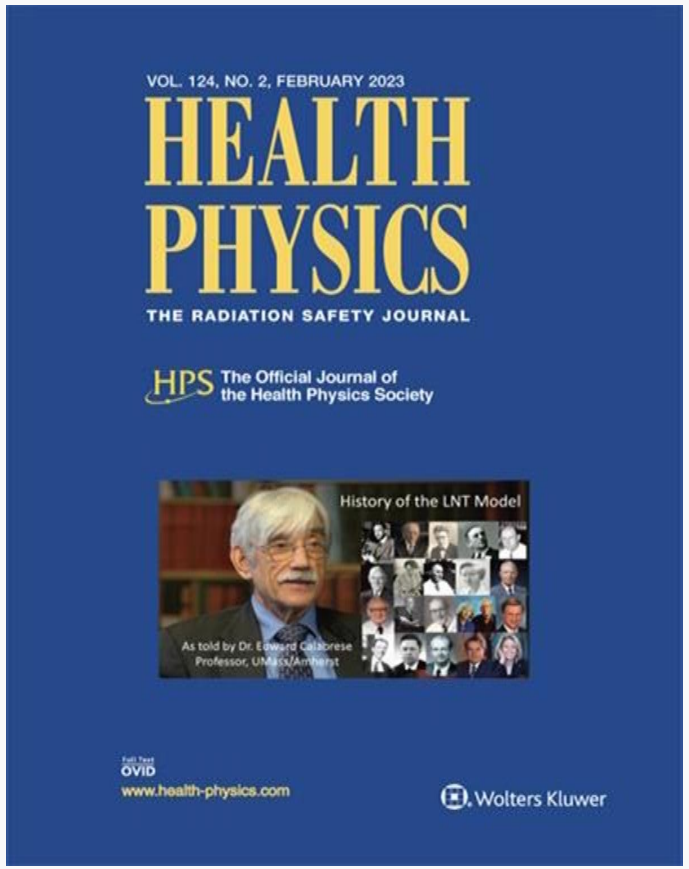


HISTORY OF THE LINEAR NO-THRESHOLD MODEL

February 2023

History of the LNT Model and Path Forward

https://journals.lww.com/health-physics/Fulltext/2023/02000/The_History_of_the_Linear_No_Threshold_Model_and.8.aspx



…to inform scientific community about the historical foundations that underpin the linear no-threshold (LNT) model's use for cancer risk assessment

Forum Article

The History of the Linear No-Threshold Model and Recommendations for a Path Forward

John Cardarelli II, Barbara Hamrick, Dan Sowers, and Brett Burk[1]

Abstract—**The intent of this paper and the accompanying video series is to inform the scientific community about the historical foundations that underpin the linear no-threshold (LNT) model's use for cancer risk assessment. There is a clear distinction here: this effort is about the history of how LNT came to be the regulatory paradigm and model for cancer risk assessment that it is today and not a discussion of the pros and cons of the LNT model. The overarching goal of this effort is to reframe the conversation around low-dose response models in light of this history and to determine how this history influences the scientific understanding of low-dose radiation responses. The timing of this series is intentional, as the International Commission on Radiological Protection (ICRP) has embarked on a mission to review the entire system of radiation protection. This effort necessarily requires rigorous scientific debate that must be based in fact. The history of the LNT model is paramount to this discussion, and it warrants consideration. Unfortunately, rather than engendering respectful debate, the topic of cancer risks associated with low dose radiation exposures has forged two disparate and sometimes contentious camps: (1) low doses, no matter how low, present some form of health risk and (2) an alternative model better represents the actual risks. The video series, conceived by John Cardarelli II, current President of the Health Physics Society (HPS), features Edward Calabrese, professor of toxicology in the School of Public Health and Health Sciences at the University of Massachusetts at Amherst, being interviewed by HPS Past-President Barbara Hamrick, CHP, JD, with support from Daniel Sowers, the Chair of the HPS Public Information Committee, and HPS Executive Director Brett Burk. Emily Caffrey, the Chief Editor of our Ask-the-Experts website (https://hps.org/publicinformation/ate/), was invited to watch the completed series as an independent peer reviewer. Further, an email address, factcheck@hps.org, was created to allow for peer-review by the scientific community to facilitate ongoing discussion and allow for corrections to the record as necessary. It is the sincere hope of this team that this work inspires new discussions about the system of radiological protection. We encourage everyone in this field to watch all 22 episodes to be informed about the underpinnings of current regulatory policy in the US.**
Health Phys. 124(2):131–135; 2023

Key words: cancer; health effects; linear hypothesis; radiation, low-level

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The authors declare no conflicts of interest.
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0017-9078/22/0

DOI: 10.1097/HP.0000000000001645

INTRODUCTION

THE INTENT OF this forum article and the accompanying video series is to inform the scientific community about the historical foundations that underpin the linear no-threshold (LNT) model's use for cancer risk assessment (available at http://hps.org/hpspublications/historylnt/index.html). The timing of this series is intentional, as the International Commission on Radiological Protection (ICRP) has embarked on a mission to review the entire system of radiation protection (Clement et al. 2021). The Health Physics Society (HPS) provided comments to ICRP in 2021. This effort necessarily requires rigorous scientific debate that must be based in fact. The history of the LNT model is paramount to this discussion, and it warrants consideration. Unfortunately, rather than engendering respectful debate, the topic of cancer risks associated with low-dose radiation exposures has forged two disparate and sometimes contentious camps: (1) low doses, no matter how low, present some form of health risk and (2) an alternative model better represents the actual risks. HPS position statements have supported the latter position for more than 20 y. These are summarized in 2020 and 2021 letters from HPS Past-President Eric Goldin, CHP, to the International Radiation Protection Association (IRPA) in response to their request for associate member input into the ICRP review efforts.

Following Comte's mantra "To understand a science, it is necessary to know its history," a team was developed to understand and communicate how these differing views came to fruition. The end result was a video series, conceived by John Cardarelli II, CHP, Certified Industrial Hygienist, Professional Engineer. The series features Edward Calabrese, a professor of toxicology in the School of Public Health and Health Sciences at the University of Massachusetts at Amherst, being interviewed by HPS Past-President, Barbara Hamrick, CHP, JD, with support from the Chair of the HPS Public Information Committee Daniel Sowers, CHP, and HPS Executive Director Brett Burk. Emily Caffrey, CHP, the Chief Editor of the HPS Ask-the-Experts website,

Cardarelli, John II; Hamrick, Barbara; Sowers, Dan; Burk, Brett. The History of the Linear No-Threshold Model and Recommendations for a Path Forward. Health Physics 124(2):p 131-135, February 2023. | DOI: 10.1097/HP.0000000000001645

History of the Linear No-Threshold Model

https://hps.org/hpspublications/historylnt/index.html

American Academy of Health Physics

The American Academy of Health Physics has preapproved 10 continuing education credits for certified health physicists watching all 22 episodes of this video series.

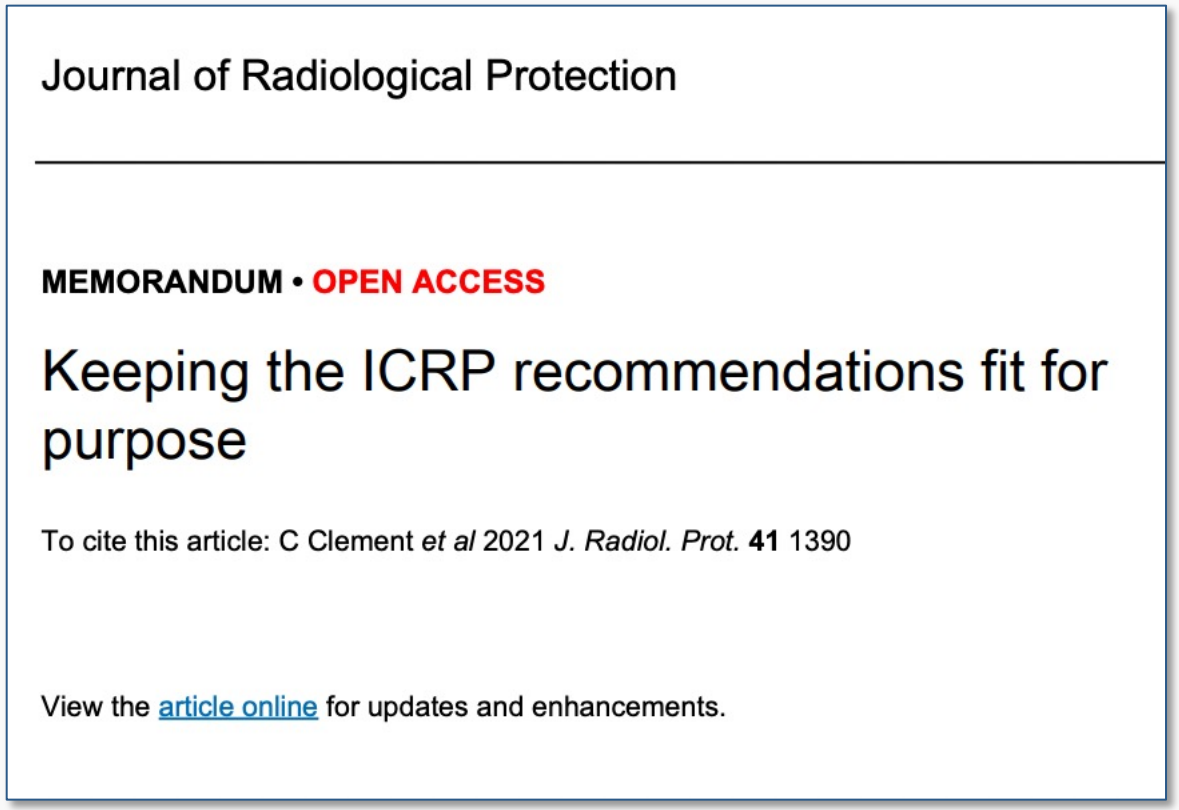
Preapproval lookup code: 2022-04-21-185

https://www.aahp-abhp.org/

Why did HPS produce these videos?

https://iopscience.iop.org/article/10.1088/1361-6498/ac1611

"The ICRP has embarked on a review and revision of the system of Radiological Protection that will update the 2007 general recommendations in ICRP Publication 103. This is the beginning of a process that will take several years, involving open and transparent engagement with organisations and individuals around the world."



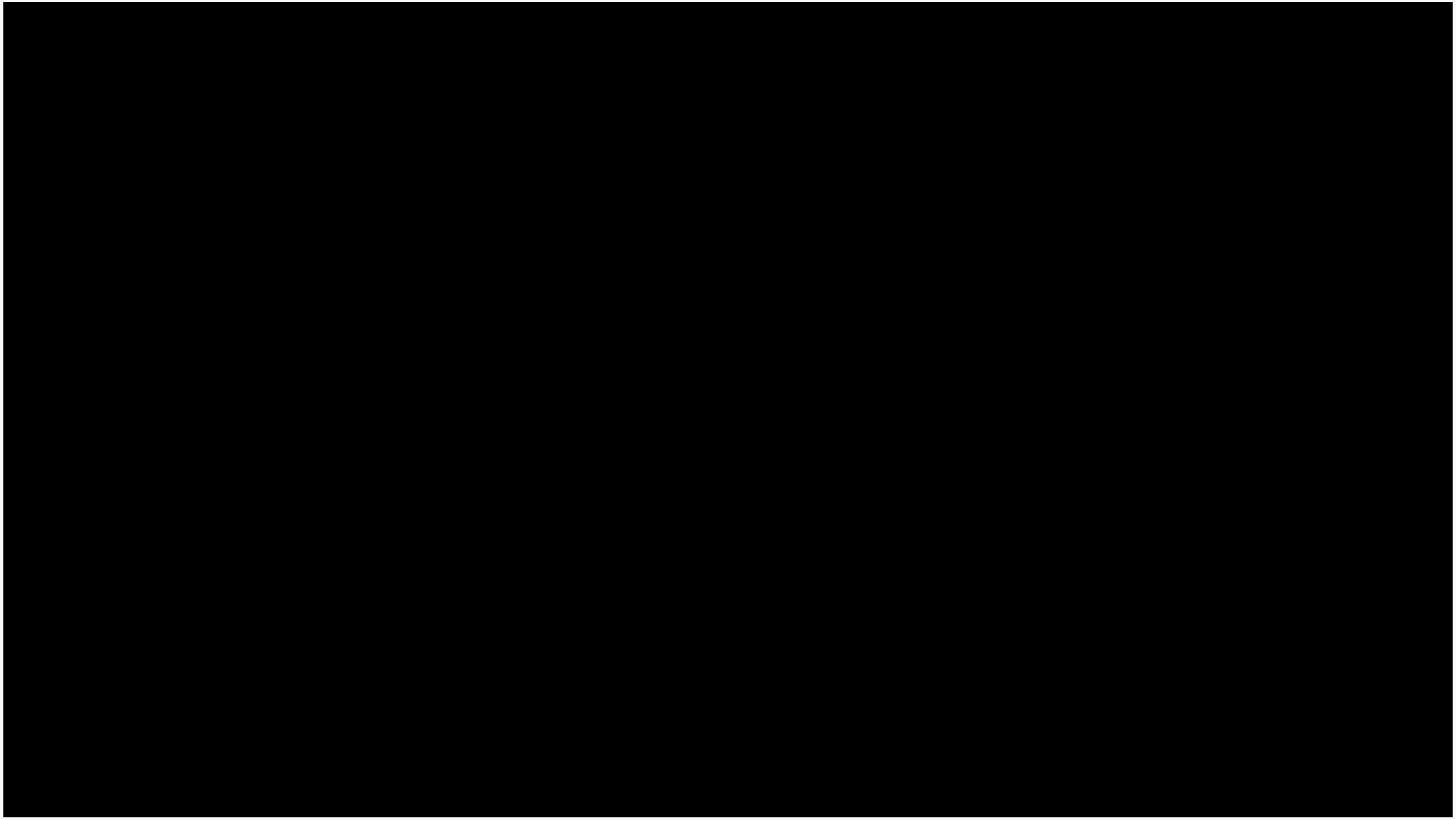
Journal of Radiological Protection

MEMORANDUM • **OPEN ACCESS**

Keeping the ICRP recommendations fit for purpose

To cite this article: C Clement *et al* 2021 *J. Radiol. Prot.* **41** 1390

View the article online for updates and enhancements.

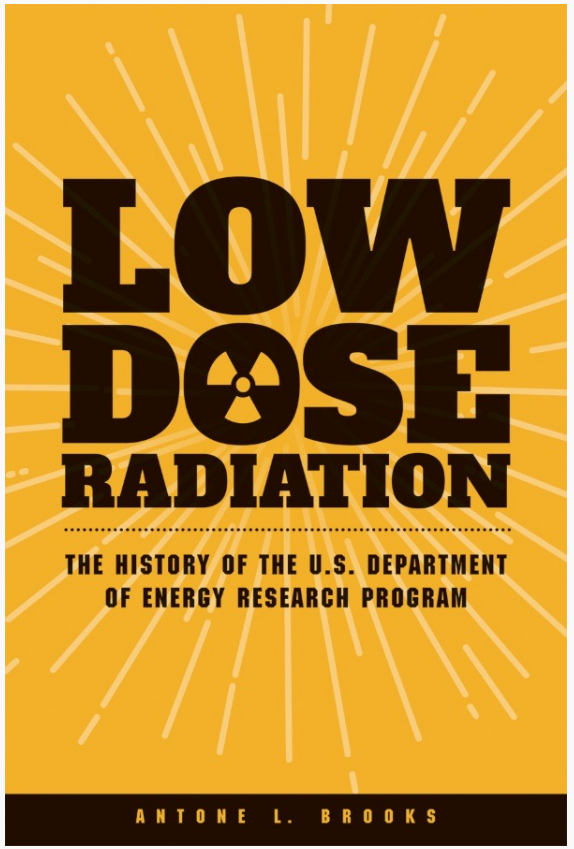


Low-Dose Radiation Research

https://wsupress.wsu.edu/product/low-dose-radiation/

We need more research in the low-dose area

- Bystander effects
- Genomic instability
- Adaptive protective responses (hormesis)
- Biological mechanistic basis
- Dose response models
- Communicate findings
- Impact on radiation protection standards
- Risk assessment



22 Episodes

https://hps.org/hpspublications/historylnt/episodeguide.html - HPS Website

https://www.youtube.com/@healthphysicssociety5037/videos - HPS YouTube Channel

1. Who is Dr. Edward Calabrese?
2. LNT Beginnings – Extrapolation from 100,000,000 x Background
3. Muller Creates a Revolution
4. Muller: How Ambition Affects Science
5. The Big Challenge
6. The Birth of the LNT Single-Hit Theory
7. Pursuit to be the First to Discover Gene Mutation
8. "Fly in the Ointment"
9. Why the First Human Risk Assessment Was Based on Flawed Fruit-Fly Research
10. The Birth of LNT Activism
11. Creation of the Biological Effects of Atomic Radiation (BEAR) I Committee
12. Was There Scientific Misconduct Among the BEAR Genetics Committee Members?
13. Is Lower Always Better?
14. Should the Genetics Panel *Science* Paper be Retracted?
15. Follow the Money Trail: "We are just all conspirators here together"
16. The Most Important Paper in Cancer Risk Assessment That Affects Policy in the U.S.
17. Studies With a Surprising Low-Dose Health Effect
18. Ideology Trumps Science, Precautionary Principle Saves the LNT
19. Genetic Repair Acknowledged
20. BEIR I Acknowledges Repair but Keeps LNT, Why?
21. BEIR I Mistake Revealed, LNT Challenged, Threshold Supported
22. Making Sense of History and a Path Forward by Dr. Calabrese

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Episodes 1 – 9 provide a detailed background of how the concept of the linear no-threshold model developed.

You may observe:

- Raw Ambition
- Blatant lying
- Veiled Threats
- Ethical Dilemmas

22 Episodes

https://hps.org/hpspublications/historylnt/episodeguide.html - HPS Website

https://www.youtube.com/@healthphysicssociety5037/videos - HPS YouTube Channel

Episodes 10 – 16 provide a detailed background of how money influences science.

You may observe:

- Scientific misconduct
- Ethical dilemmas
- Political influences
- Mass Media influences
- Activism

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Episodes 17 – 22 provide a detailed background on how & why the LNT model remains today and suggests a path forward.

You may observe:

- Ethical Dilemmas
- Selective interpretations
- Path forward

13. Is Lower Always Better?
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Another Version of LNT History

HPS Newsletter, October 1971 (Free to HPS Members)

The Linear Nonthreshold Model as Developed for Large-Population Radiation Protection Guides in the Low-Dose Domain

"The linear nonthreshold model for somatic effects was introduced and quantified gradually between 1950 and 1964 with special reference to the biopolitical necessity for making quantitative estimates of the maximum effects of world-wide fallout from the atmospheric testing of nuclear weapons. The linear nonthreshold model was specifically chosen on a basis of mathematical simplicity and prudence to represent the upper limit of risk in the low-dose domain, for somatic radiobiological effects which had been observed only in a higher-dose domain. The linear nonthreshold model was not based on radiobiological data for somatic effects in the low- dose domain." [emphasis added]

By. Robley Evans, HPS Past-President

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"In the absence of knowledge about the effects of permissible doses on human beings biologists have been forced into awkward and unhappy extrapolations from what is known about the effects of very large doses, and it has become conventional to interpret such information in the most pessimistic way, by assuming proportionality between dose and harmful effect at all levels… This then is the new testament of radiological priestcraft, the comfortable and insidious worship of the straight line. After a while the mathematics becomes more important than the biology; the dogma more important than those in whose service it has been enunciated." [Emphasis Added]

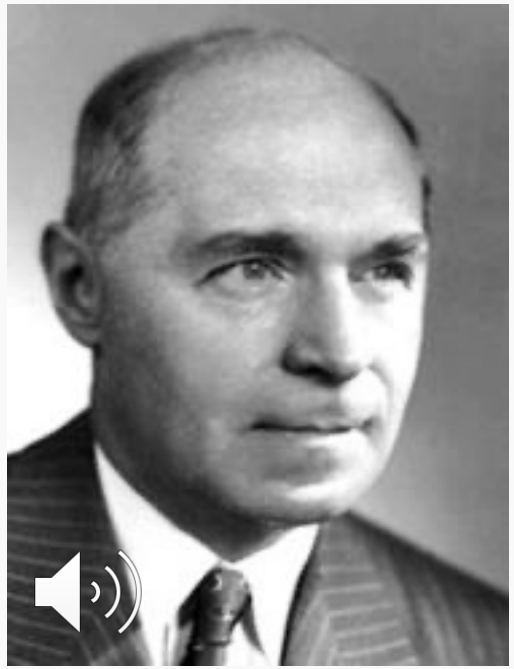
Dr. Andrew S. McLean

Director of the Health and Safety Branch of the United Kingdom

Muller – Russell's mice data

The Effect of Radiation and other Present Day Influences Upon the Human Genetic Constitution

Lindau Nobel Laureate Meeting, July 14, 1955



Now, Russell's data on mice, of the organism studied in this respect which is nearest to man, show that it would take about 40 Roengten units (40 R) of radiation to produce mutations at a frequency equal to the natural frequency.

The Lindau Nobel Laureate Meetings

https://mediatheque.lindau-nobel.org/recordings/31548/the-effect-of-radiation-and-other-present-day-influences-upon-the-human-genetic-constitution

Russells Study Gene Mutations in Mice

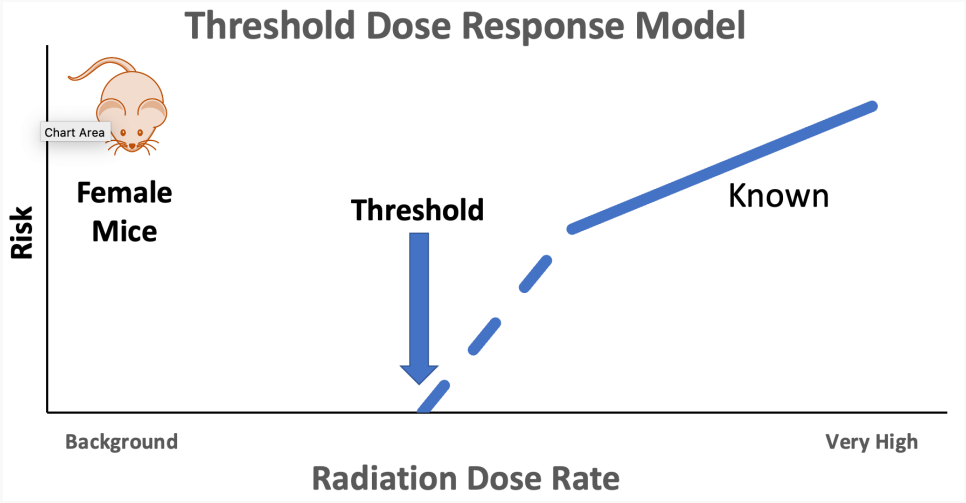
Episodes 20 and 21

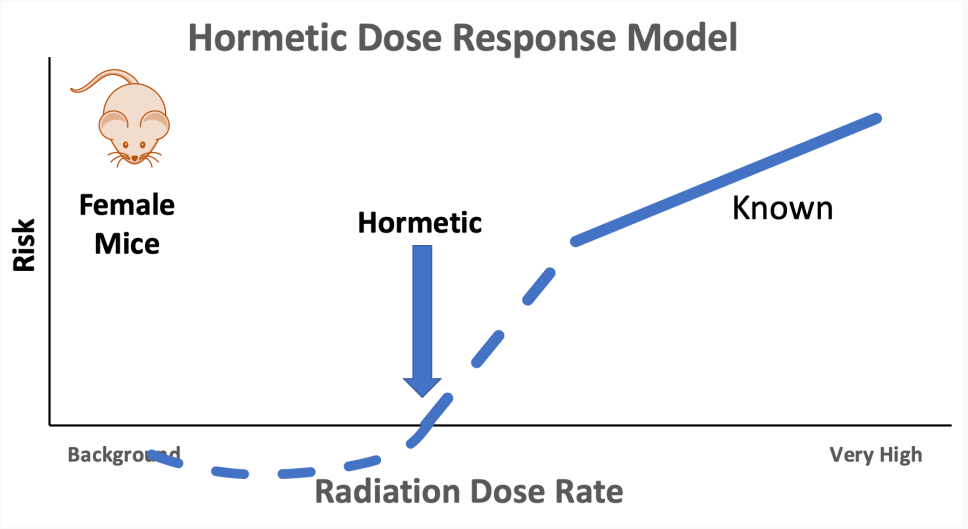
Calabrese EJ. The Threshold vs LNT showdown. Dose rate findings exposed flaws in the LNT model. Part 2. How a mistake led BEIR I to adopt LNT. Environ Res 2017b.

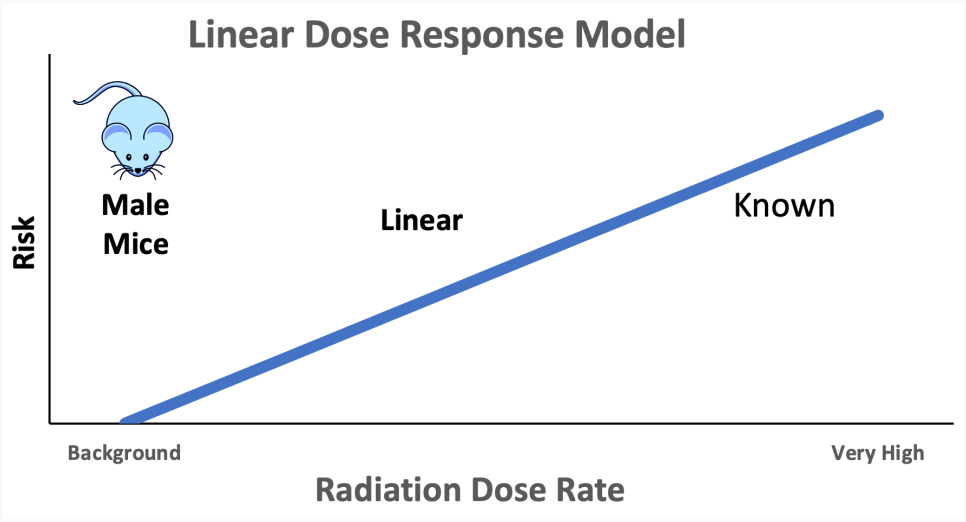
- ORNL “mega-mouse” experiments greatly influenced the use of the LNT model for cancer risk assessment.
- In 1994, Dr. Paul Selby discovered an error in the control data for experiments on male mice dating back to the 1950s.
- DOE ethics investigation required the Russells to correct the record.
- The corrected data no longer support a linear relationship.

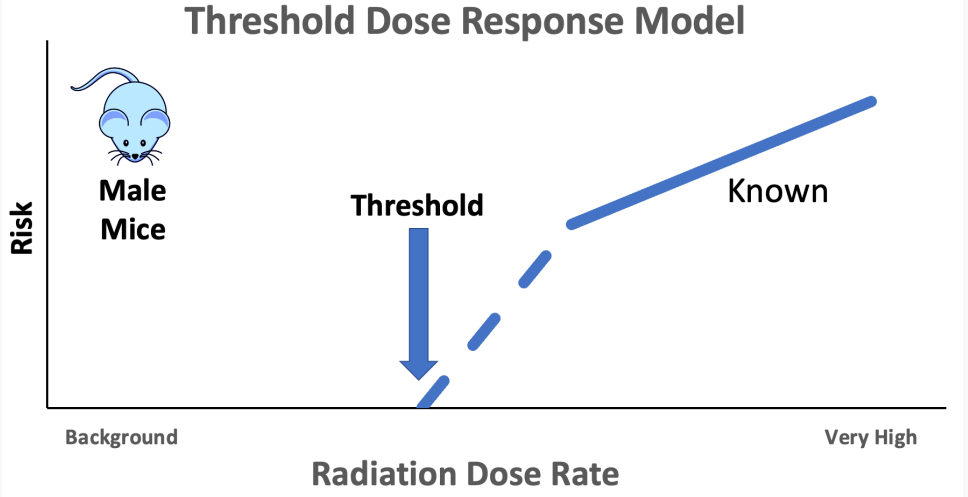
Russell results after correction

Calabrese EJ. The Threshold vs LNT showdown. Dose rate findings exposed flaws in the LNT model. Part 2. How a mistake led BEIR I to adopt LNT. Environ Res 2017b.









IMPACT OF THE LNT MODEL ON ENVIRONMENTAL, MEDICAL, & NUCLEAR POWER INDUSTRIES

Reliance on LNT – Po-210 Example

http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947411630

City of Westminster

Health Protection Agency recommended clean-up level for fixed contamination of

10 Bq/cm²

(i.e.,no doses exceeding **1.0 mSv / year**).

"Levels of contamination below this value do not need remediation on health grounds, although it is good practice to remove contamination where this is easily achievable."

Insert dose delivered!

Surface Preliminary Remediation Goal

0.000011 Bq/cm²

(LNT 1 in a million excess cancer risk)

>900,000 fold difference!

https://epa-sprg.ornl.gov/cgi-bin/sprg_search

Other Examples of Dose vs. LNT-based Criteria

Soil Surface Contamination Levels

	NUREG-1757, Vol. 1 Table B.2 (2002)	EPA PRG	
	NRC DCGL (pCi/g)	**EPA PRG (pCi/g)**	**Ratio**
Cs-137	11	0.4	27.5
Co-60	3.8	0.285	13.3
Sr-90	1.7	0.048	35.4
Tc-99	19	0.009	2111
U-238 (secular equil.)	0.5	0.017	29.4
	(25 mrem per yr)	LNT: 1 in 100,000 excess cancer risk	

NRC: Nuclear Regulatory Commission
DCGL: Derived Concentration Guideline Levels (based on 25 mrem per year)
EPA: Environmental Protection Agency
PRG: Preliminary Remediation Goals (typically based on LNT in 1 in a million excess cancers)

Impact of LNT on Environmental and Nuclear Power Industries

- Patients not willing to get necessary diagnostic or therapeutic treatments
- Mixed messages from Physicians
- Economic considerations when building nuclear power plants

From IRPA Perspective on "Reasonableness" in the Optimisation of Radiation Protection" p. 11.
https://irpa.net/docs/IRPA%20Perspective.pdf

"…governments have obligations to pursue 'the optimal use of societal resources' and 'not allow such resources to be squandered on unproductive legislation and fruitless regulatory control'."

Fruitless regulatory control?

EPA policy states that exposures greater than 12 mrem per year is not protective.

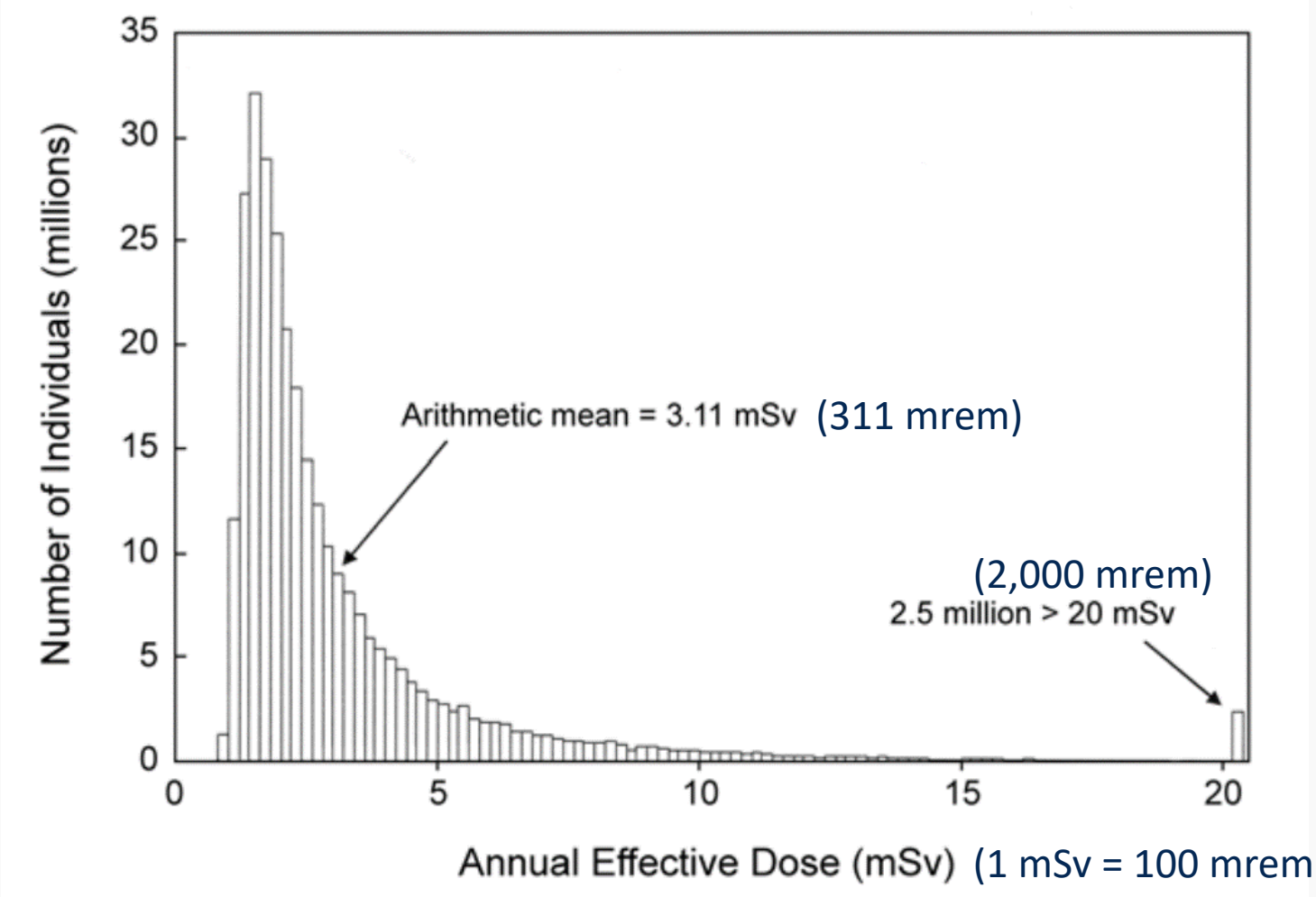


Image Source: NCRP Report 160, Fig. 3.20.

CONCLUSIONS & CHALLENGES TO CHANGE

What can we do from here?

Watch Episode 22: Dr. Calabrese's considerations

https://hps.org/hpspublications/historylnt/episodeguide.html

- Sound-science should guide us, not fear.
- Based on evolutionary biology principles, not public-health protectionist philosophy
- We are not victims which the LNT philosophy promotes
- Repair mechanisms have always existed (discovered in 1958, Episode 19)
- Carcinogenic exposures occur daily

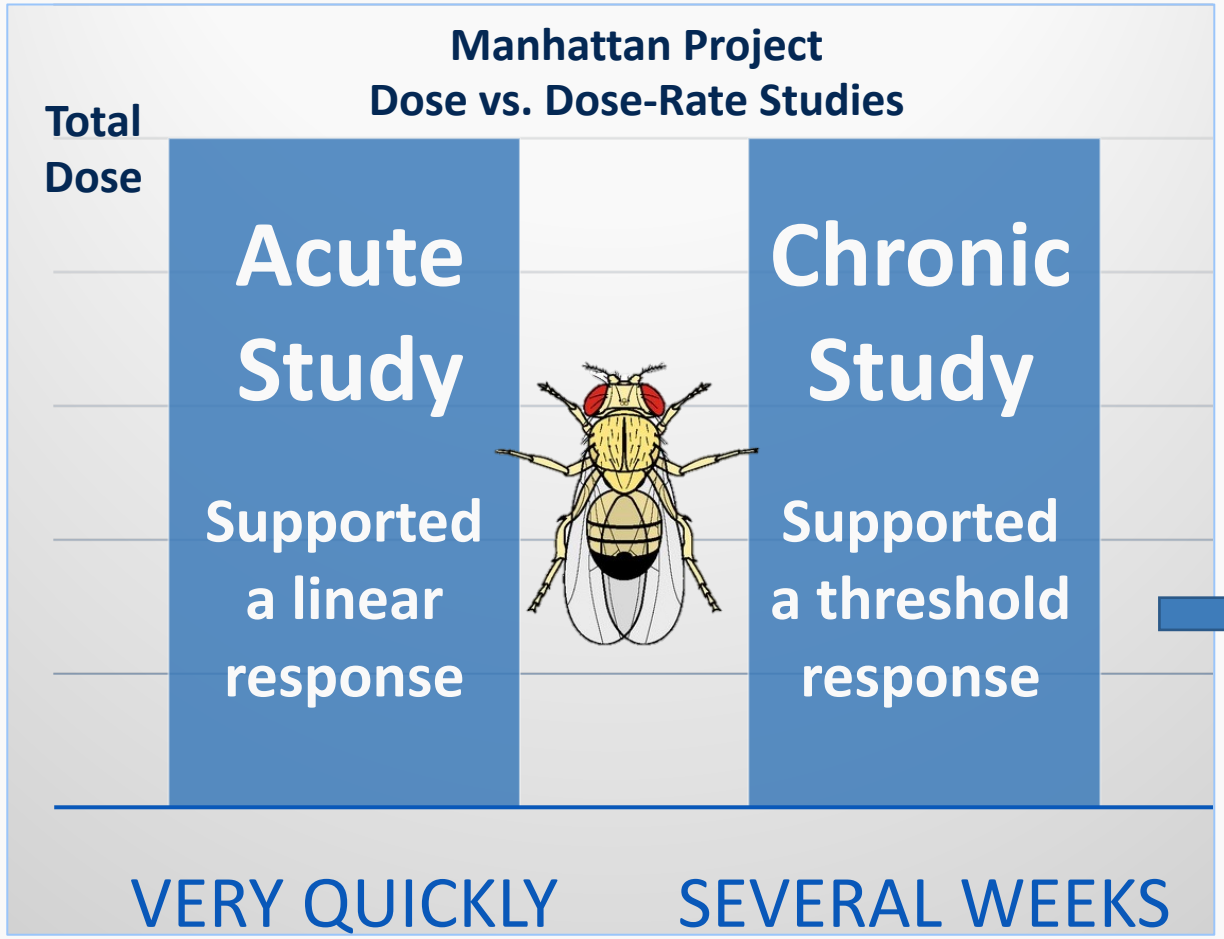
  (https://www.cancer.gov/about-cancer/causes-prevention/risk/substances)
- Model optimization (linear, linear-quadratic, threshold, & hormetic)
- Acknowledge that LNT model was based on flawed science.

What can we do from here?

- Understand the history of the development of the current radiation protection philosophy
- Limit the application of LNT to occupational settings
- Stop estimating environmental cleanup levels based on LNT model (risk-based approach)
- Harmonize radiation standards (**100 mrem to 2,000 mrem above bkgd per year**) (dose-based approach)
- Follow the science
- Communicate and Educate the public

Caspari Conclusion in 1948!

Episode 8: “Fly in the Ointment” https://hps.org/hpspublications/historyInt/episodeguide.html



Ernst Caspari (1909-1988)

“If the result turns out to be correct, it would necessitate a revision of the classical hit theory of induction of mutations…” [1948]

Caspari E. and Stern C. The influence of chronic irradiation with gamma-rays at low dosages on the mutation rate in Drosophila melangogaster. Genetics 1948; 33:75-95.