10 Part 53

Quantitative Health Objectives as a Performance Metric

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March 29, 2022

BREAKTHROUGH INSTITUTE

The Breakthrough Institute

- Independent research center that identifies and promotes technological solutions to environmental and human development challenges.
- We represent Society and its collective interests.
- The Breakthrough Institute does not receive funding from industry.

Guidelines for a RIPB regulation

- NEIMA directed the NRC to develop a technology-inclusive risk-informed, performance-based licensing pathway.
- A risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment including the principle of defense-in-depth and the incorporation of safety margins, and performance history are used, to **
  1. Focus attention on the most important activities
  2. Establish objective criteria for evaluating performance
  3. Develop measurable or calculable parameters for monitoring system and licensee performance
  4. Provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes
  5. Focus on the results as the primary basis for regulatory decision-making

**SRM-SECY-98-144

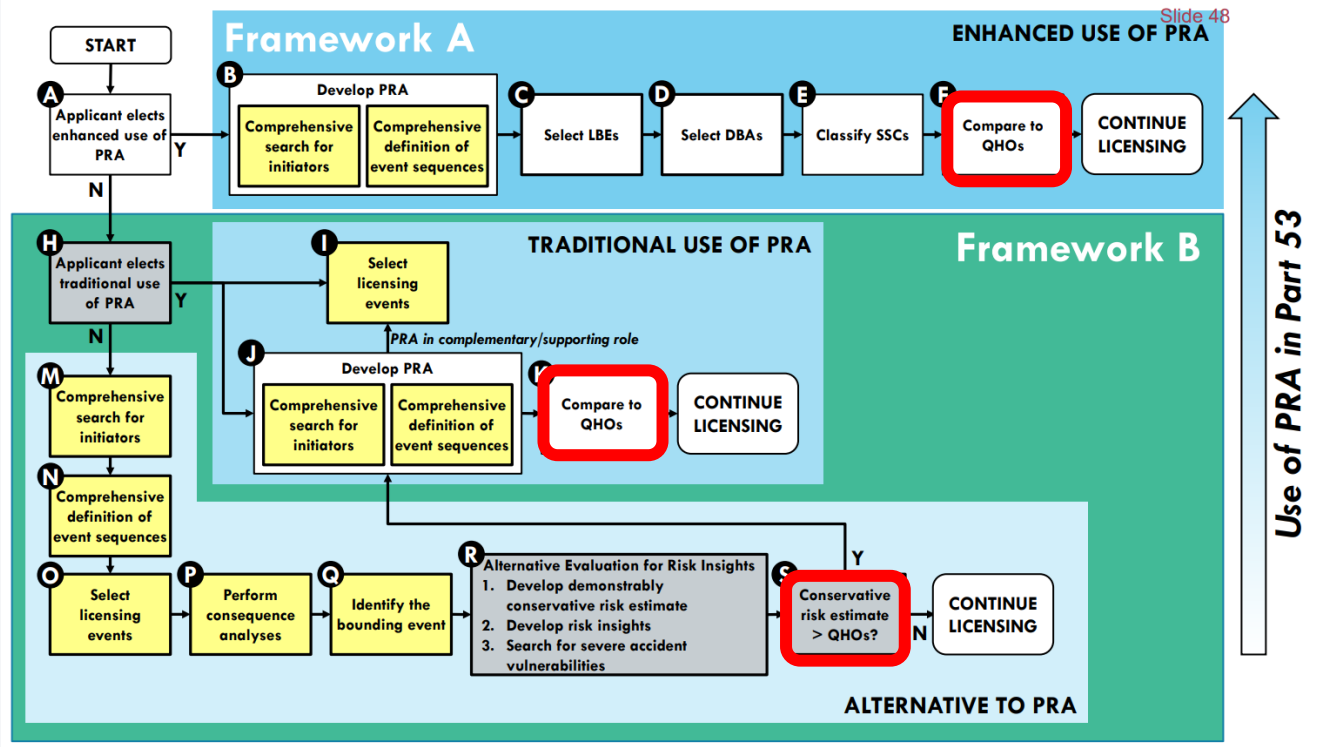
Quantitative Health Objectives in Part 53

- The Commission has repeatedly stated that the Safety Goals are guidance on acceptable societal risk and should be used to provide guidance to the NRC staff on how new regulations should be considered. They are not in current licensing regulations.*
  - The Commission chose not to include surrogate measures in the revision to the Safety Goals (e.g., core damage frequency)
  - Has the Commission changed the position of the NRC on use of the Safety Goals or QHOs in a different SRM?

* Nuclear Regulatory Commission, "Modifications to the Safety Goal Policy Statement," SECY-00-0077

Quantitative Health Objectives in Part 53

- QHOs included in all of the most recent pathways
- QHOs are not a viable performance metric*
  - A viable performance metric must be a measurable (or calculable) parameter to monitor acceptable plant and licensee performance that exists or can be developed



*Graphic from March Advanced Reactor Stakeholder meeting slides

* Refer to Breakthrough Institute Comments and Whitepaper submitted 2/4/2022 for detailed discussion

Calculation of Performance Metric

- Health outcomes can be estimated using a multitude of consequence models. However, these projected consequences are not direct calculations or conclusions and contain significant uncertainty.
- This uncertainty can be addressed in multiple ways but cannot be eliminated to the point of determining if a level of performance is achieved.

Calculation Models

- Multiple consequence projection models exist and provide different results.*
- The NRC uses the Linear No Threshold (LNT) model to estimate health outcomes
- The NRC recently confirmed the use of LNT by denying a petition to use other models ^
- In that decision the NRC and other agencies stated very clearly that the LNT model remains uncertain
  - It is NOT a direct calculation of risk or effects

*National Research Council, Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2. Washington, D.C.: The National Academies Press, 2015. doi: 10.17226/11340.

Brenner et al., "Cancer risks attributable to low doses of ionizing radiation: Assessing what we really know," Proceedings of the National Academy of Sciences, vol. 100, no. 24, pp. 13761–13766, Nov. 2003, doi: 10/cb877r.

Nuclear Regulatory Commission, "State-of-the-Art Reactor Consequence Analyses - Reporting Offsite Health Consequences," SECY-08-0029, Mar. 2008. [Online]. Available: https://www.nrc.gov/docs/ML0803/ML080310041.pdf

^ Nuclear Regulatory Commission, "Linear No-Threshold Model and Standards for Protection Against Radiation," FR, vol. 86, no. 156, pp. 45923–45936, Aug. 2021

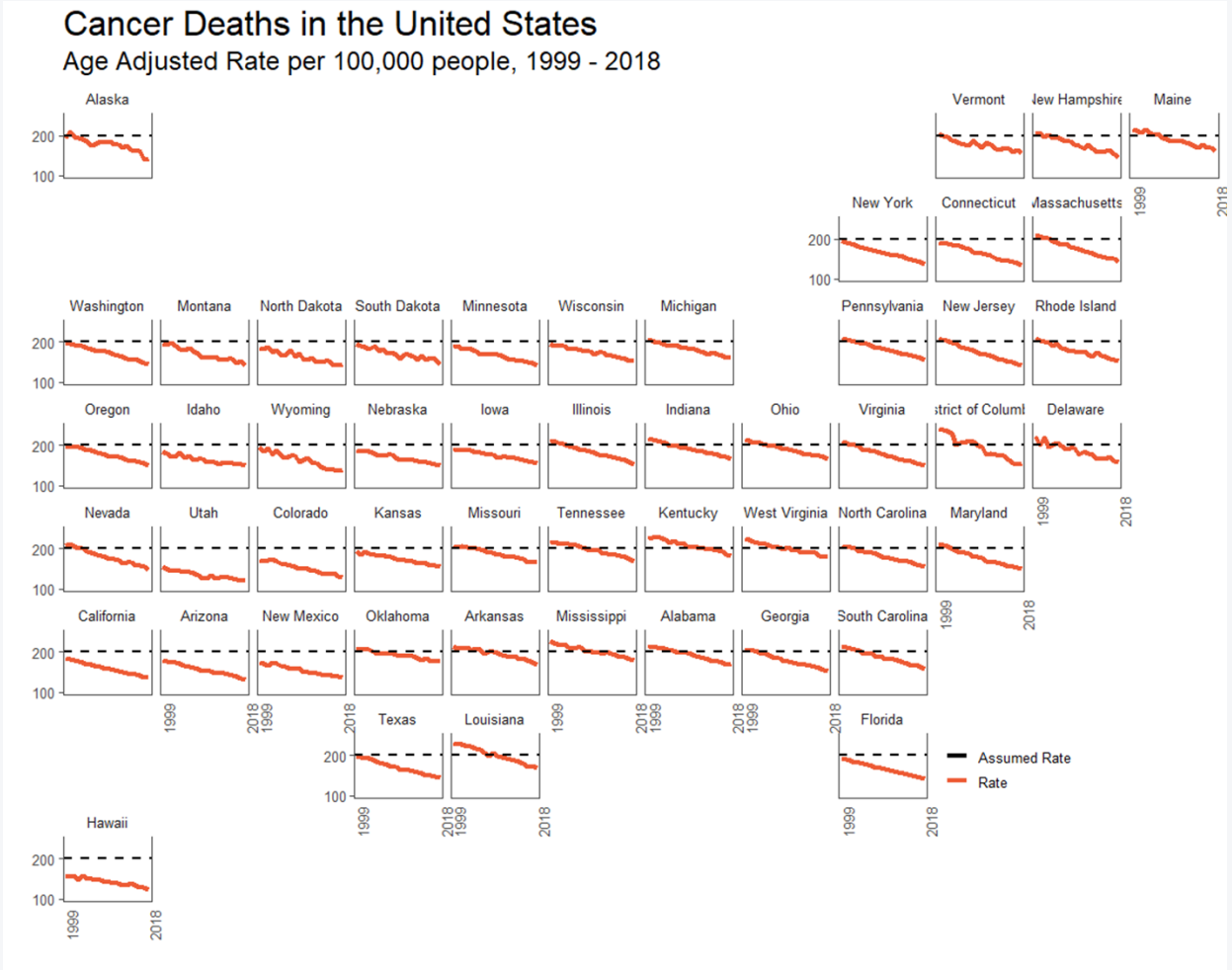
Uncertainty in LNT

- NRC reasserted that, "*based upon the current state of science, the NRC concludes that the actual level of risk associated with low doses of radiation remains uncertain.*"
- The International Atomic Energy Agency stated that a Linear No-Threshold model *"…is not proven—indeed it is probably not provable—for low doses and dose rates.*"
- The National Council on Radiation Protection and Measurements said, "*the LNT model is an assumption that likely cannot be scientifically validated by radiobiologic or epidemiologic evidence in the low-dose range*."
- 10 CFR Part 20 final rule, in which 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.*" and further states that there is "*considerable uncertainty in the magnitude of the risk at low doses and low dose rates*."

*Nuclear Regulatory Commission, "Linear No-Threshold Model and Standards for Protection Against Radiation," FR, vol. 86, no. 156, pp. 45923–45936, Aug. 2021.

Background Rates

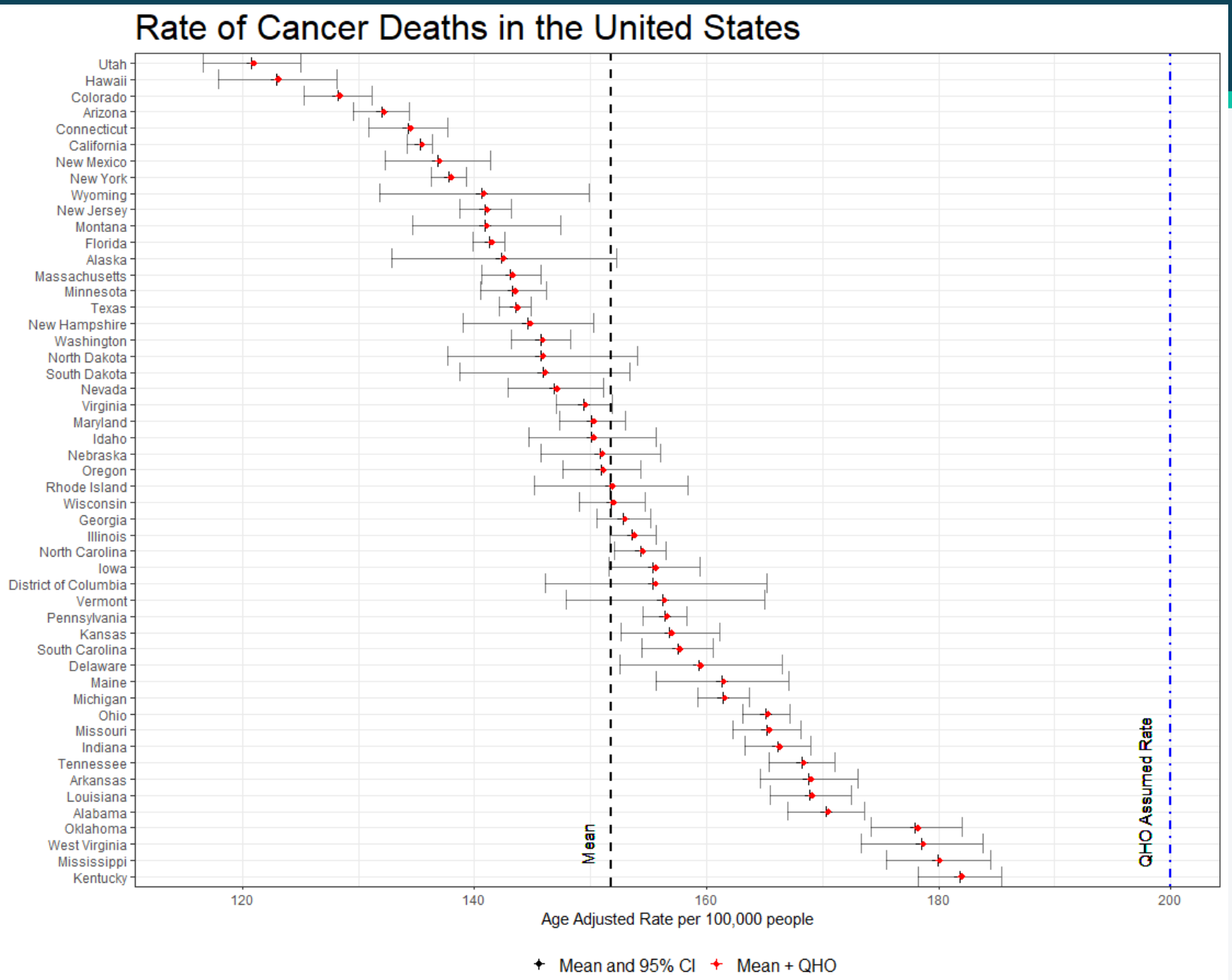
- NRC assumed cancer rate 2 latent cancer fatalities per one thousand people in Safety Goal Policy Statement
- Observations of background cancer rates are not consistent geographically
- Not static values
  - Downward trends
- Most are more than +20% below assumed rate
- This provides a changing and non-uniform basis for regulation.
- The assumed background rate that is the current regulatory standard is inconsistent with observations



*Data from: U.S. Cancer Statistics Working Group, "U.S. Cancer Statistics Data Visualizations Tool, based on 2020 submission data (1999-2018)." U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute, Jun. 2021

Uncertainty in Observations

- Assumed rate does not match observed
  - Age-adjusted rate of all cancer deaths in the United States 2014-2018*
  - NRC assumed cancer rate 2 latent cancer fatalities per one thousand people.
- State level adjusted Quantitative Health Objectives indicated on chart as "one tenth of one percent" or 2 latent cancer fatalities per one million people.
- Confidence Interval much wider than QHO
  - 95% CI of total cancer death rates generally 4 deaths per 100,000 people
- Even a state level adjusted QHO is in the statistical noise



*Data from: U.S. Cancer Statistics Working Group, "U.S. Cancer Statistics Data Visualizations Tool, based on 2020 submission data (1999-2018)." U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute, Jun. 2021

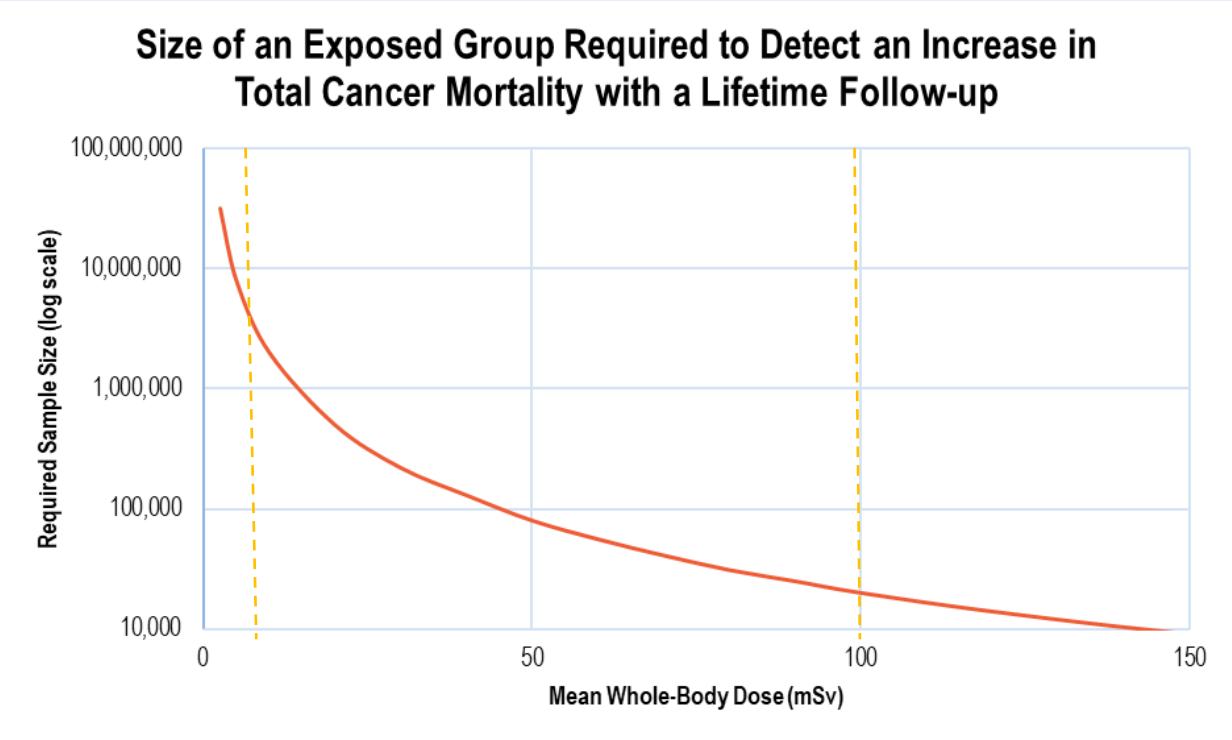
Statistical Power

- A fundamental issue regarding the estimation of risks from low-dose studies is statistical in nature.
  - Statistical power is the probability that a study of a specified size and design can detect a predetermined difference in risk in the absence of significant bias when such a difference exists.
- If the power is too low, a study is unlikely to find a difference of interest even when it exists (false-negative).
- If statistical power is too low, any "statistically significant" ($p<0.05$) result is likely to be a false-positive finding
  - The risk estimate associated with that positive finding in low-dose studies where the true risk is small tends to provide falsely exaggerated estimates of risk.*

**Analysis of Cancer Risks in Populations Near Nuclear Facilities: Phase I.* Washington, D.C.: National Academies Press, 2012, p. 13388. doi: 10.17226/13388.

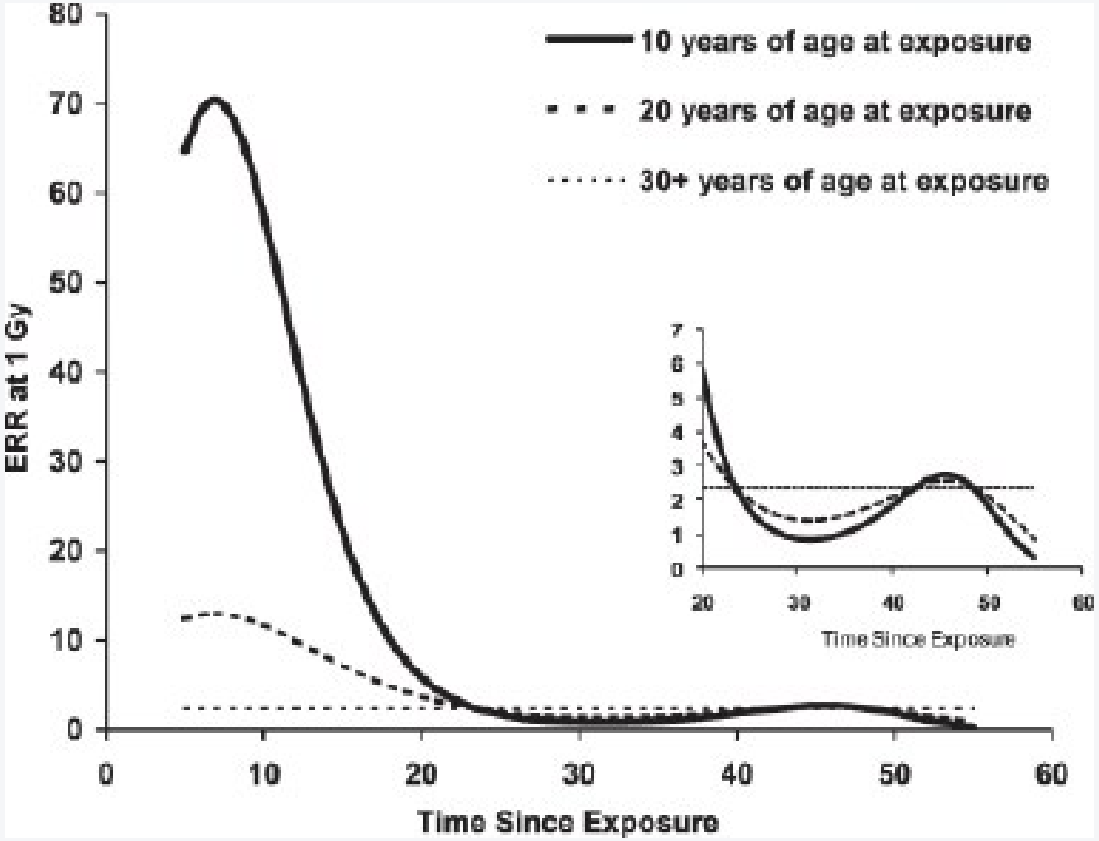
Improving Statistical Power - Sample size

- Large sample size needed to observe small effects in the population
- Obtaining a sample population of sufficient size would require many years of study
  - Not useful for real-time oversight



Time Response

- Delayed response to dose necessitates a very long study period to see effects
- Substantial time would be needed to conduct a study that produces statistically meaningful results.
  - There are many challenges with measuring cancer rates in a population, including age, demographics, background radiation by site, local and state-level cancer rates, and detection and treatment at local medical facilities.
- Changes with time are hard to factor out of ongoing long-term studies.



New language proposed today by NRC

- Licensing Basis Events (LBEs) includes Anticipated operational occurrences (AOOs)
  - Low dose-higher probability events
- No truncation of low dose (i.e., cutoff limit) in any sequence due to use of LNT
- Not limited to safety case analysis – interpretation that licensee must show performance throughout operation
- Does not mitigate concern that licensee could be required to show performance to a level of risk that is not observable in the population in a reasonable timeframe

§ 53.220 Safety criteria for licensing basis events other than design basis accidents.

Design features and programmatic controls must be provided to:

(a) Ensure plant structures, systems and components (SSCs), personnel, and programs provide the necessary capabilities and maintain the necessary reliability to address licensing basis events in accordance with § 53.240 and provide measures for defense-in-depth in accordance with § 53.250; and

(b) Maintain overall cumulative plant risk from licensing basis events other than design basis accidents analyzed in accordance with § 53.450(e) such that the calculated risk to an average individual within the vicinity of the plant receiving a radiation dose with the potential for immediate life-threatening health effects remains below five in 10 million years, and the calculated risk to such an individual receiving a radiation dose with the potential to cause latent life-threatening health effects remains below two in one million years.

QHOs are not a viable performance metric

- Not a calculable or observable in a meaningful timeline.
- There is a difference between using a risk metric to risk-inform and using it as a performance criteria as the requirement in the regulation.
  - A performance metric should be the objective level of performance the licensee should meet to achieve the desired fundamental objective (e.g. risk or safety)

Alternatives

- The QHOs are not in existing regulations.
  - Risk analysis is useful for risk-informing a performance-based rule.
  - Performance metrics and programs are useful to determine if the design and operations are performing to the acceptable level of safety
  - The question should be if the QHOs are necessary in this regulation to achieve performance.
- Measurement of a first-order should be used when possible. QHOs are a second-order variable (i.e., derived variable).
  - "Performance parameters should be identified at as high a level as practicable"*
  - Dose (first-order) leads to health effects such as the QHOs (second-order)
- If a metric must be used, then dose provides a more objective and measurable option.
  - Part 20 is performance-based in that it allows licensees to meet the specified dose limits in a manner that they deem most appropriate.
- However, a performance-based approach would set a performance objective (e.g., diesel reliability of 95 percent) and allow the licensee considerable freedom in how to achieve that reliability objective.*

*Nuclear Regulatory Commission, "Guidance for Performance-Based Regulation," NUREG/BR-0303, 2002.

