10 Part 53

Perspective on Rule Development

Dr. Adam Stein

Director for Nuclear Energy Innovation

March 25, 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.

Comments on 10 CFR Part 53 Rulemaking

- Presents once in a generation opportunity for regulatory innovation that considers public interests
- Must meet the mandate of NEIMA to enable innovation and commercialization
- A performance-based rule is easier to be technology-inclusive
- Be disciplined and apply ***reasonable*** assurance of ***adequate*** protection, consistent with NRC's mandate
- Be risk-informed. Focus on detectable risks and impacts relative to other forms of energy

Qualitative Safety Goals

Risk to Individuals	Societal Risk
Individual members of the public should be provided a level of protection from the consequences of nuclear power plant operation such that individuals bear no significant additional risk to life and health.	Societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks of generating electricity by viable competing technologies and should not be a significant addition to other societal risks.

Efficient Rulemaking

- How will the NRC use the 9-month extension?
- Major policy issues should be elevated to the Commission to avoid major changes in the proposed rule.
  - ACRS recommended this approach.
- Iterative process is less straightforward but allows for more stakeholder interaction
- Disposition feedback
  - Provides clarity to stakeholders regarding why the staff has made a particular choice in draft rule language
  - Questions by stakeholders are often "taken back for consideration." Similar questions posed by ACRS are answered immediately

Focus was initially on LMP -> Part 53

- Risk-informed but not necessarily performance-based
- LMP type - Focus on probability - PRA in a "leading role"
- Added Part 5X – deterministic option that enables use of international standards

Part 5X →

The Traditional PRA Approach

- Use of a PRA to support/confirm a more deterministic safety analysis (e.g., current Part 52 approach, use of IAEA Specific Safety Requirements SSR-2/1 approach, etc.).

Part 53 →

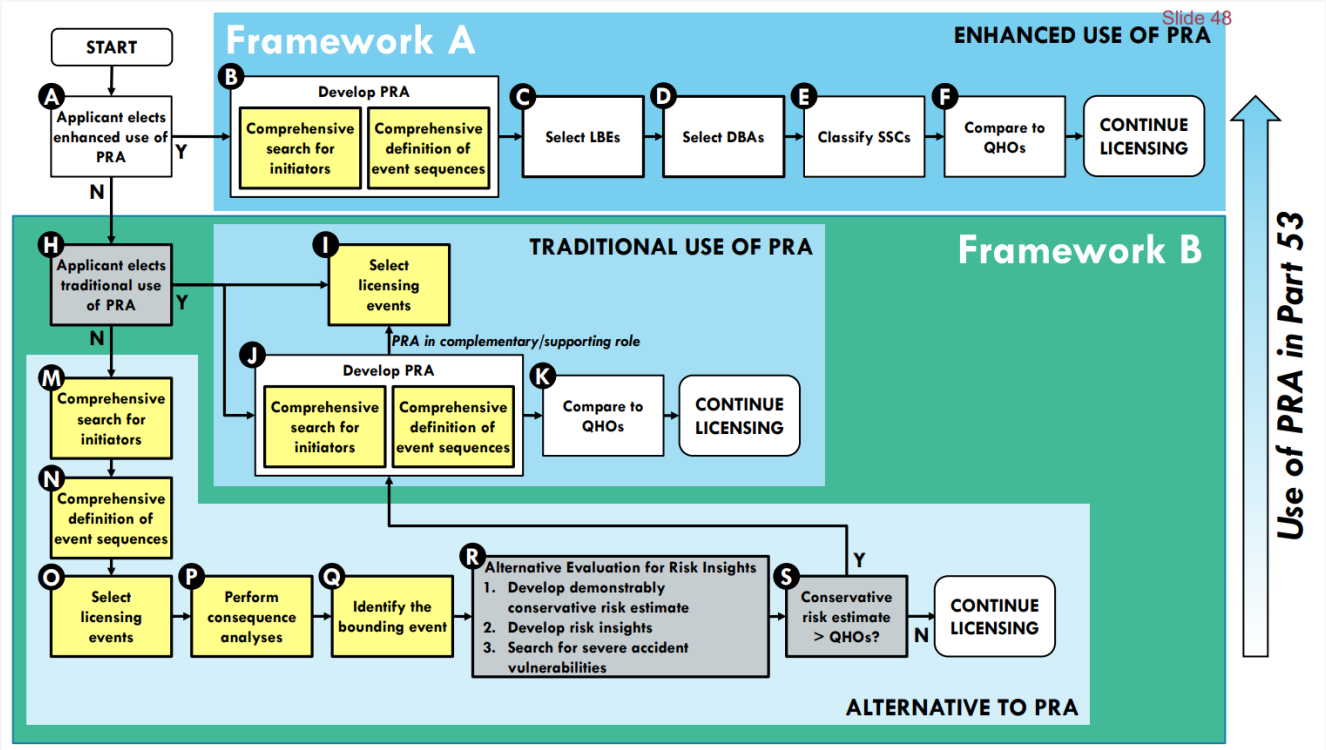
The Enhanced PRA Approach

- Use of a PRA in a leading role in the safety analysis (e.g., the LMP approach and preliminary Part 53 as currently envisioned).

*Graphic from Aug 2021 Advanced Reactor Stakeholder meeting slides

Re-Focus of Part 53

- March 2022 – new pathways based on two "frameworks"
  - "enhanced" use of PRA similar to LMP
  - "traditional" use of PRA that enables use of international standards (formerly 5X)
  - "alternative" to PRA such as maximum hypothetical accident



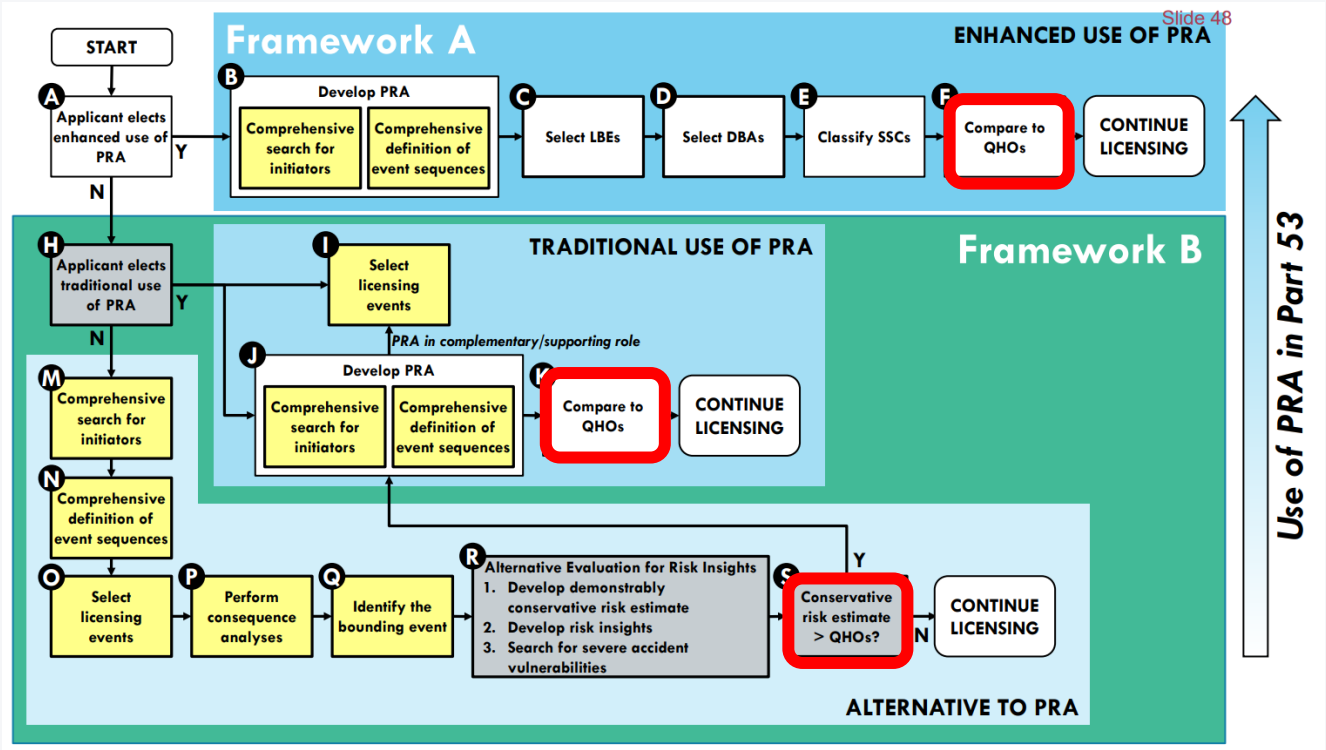
*Graphic from March Advanced Reactor Stakeholder meeting slides

Remaining concerns

- Unclear why multiple pathways are needed in the regulation instead of approved pathways in guidance
- Structural concerns
  - E.g. - ALARA in design stage
  - Duplicate programmatic controls
  - How Beyond Design Basis events are included/addressed
- Still not performance-based
  - Not built around clear performance metrics
  - Uses some metrics that are not viable as a performance metrics (QHOs)

Quantitative Health Objectives in Part 53

- QHOs included in all of the most recent pathways



*Graphic from March Advanced Reactor Stakeholder meeting slides

Quantitative Health Objectives in Part 53

- Example of major policy issue that has received extensive stakeholder feedback
- 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 purpose of including the QHOs in the rule has not been made clear (dispositioned)
- The Quantitative Health Objectives should not be in the rule
  - QHOs are not a viable performance metric*

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

Guidelines for performance-based reg

- Guidelines have been developed to determine if there is benefit or justification to change an existing regulation to performance-based regulation.
- NEIMA directed the NRC to develop a technology-inclusive risk-informed, performance-based licensing pathway. Therefore, these guidelines must be considered to determine how a performance-based licensing pathway should be created.
- The guidelines for assessment are as follows*:
  - 1) Maintain safety and protect the environment and the common defense and security
  - 2) Increase public confidence
  - 3) Increase effectiveness, efficiency, and realism of the NRC's activities and decision making
  - 4) Reduce unnecessary regulatory burden
  - 5) The expected result of using a performance-based approach is an overall net benefit
  - 6) The performance-based approach can be incorporated into the regulatory framework
  - 7) The performance-based approach would accommodate new technology
- <u>A viable performance metric must be a measurable (or calculable) parameter to monitor acceptable plant and licensee performance that exists or can be developed</u>

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

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

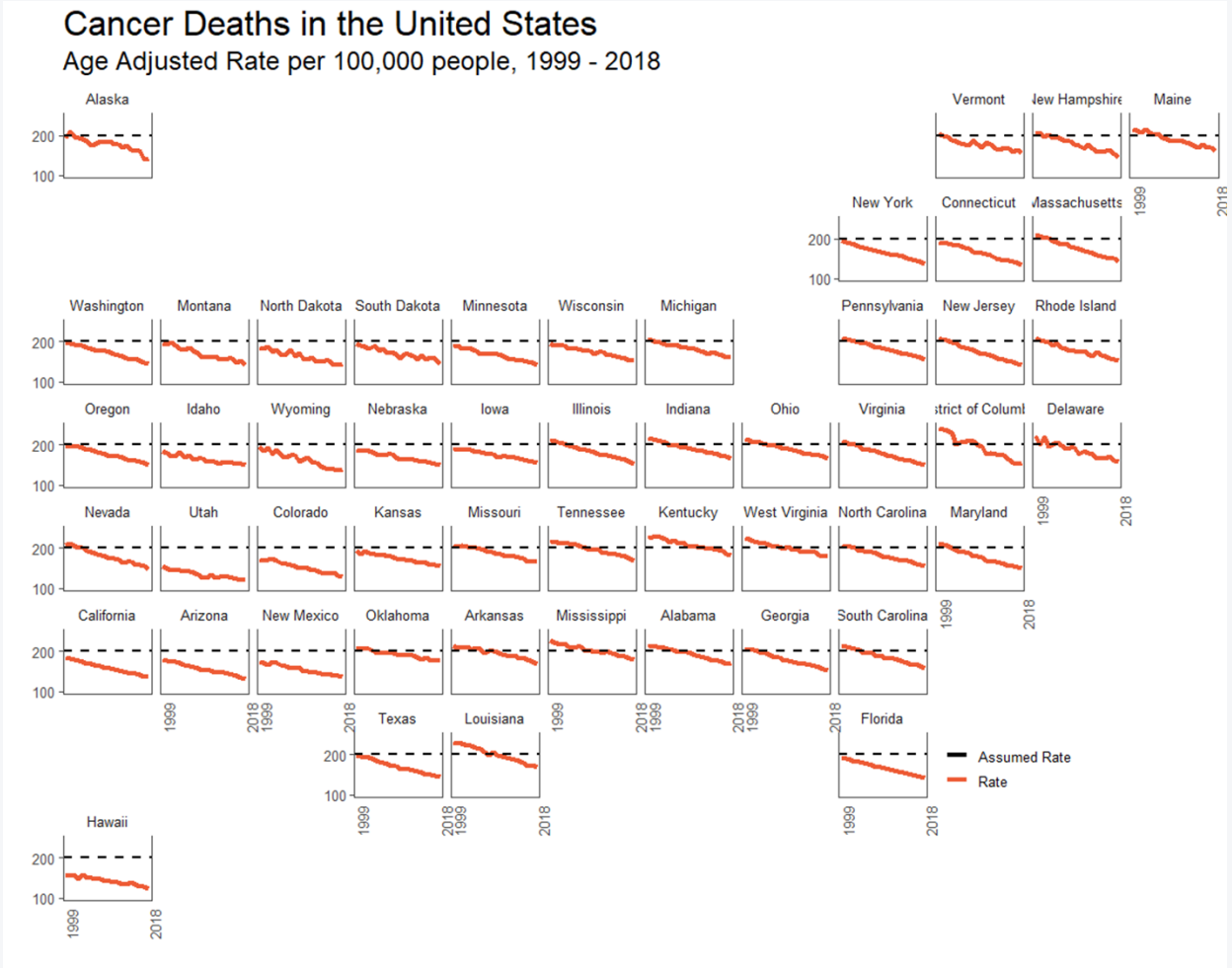
Uncertainty in LNT

- 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

- Not consistent geographically
- Not static values
  - Downward trends
- Most are be +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

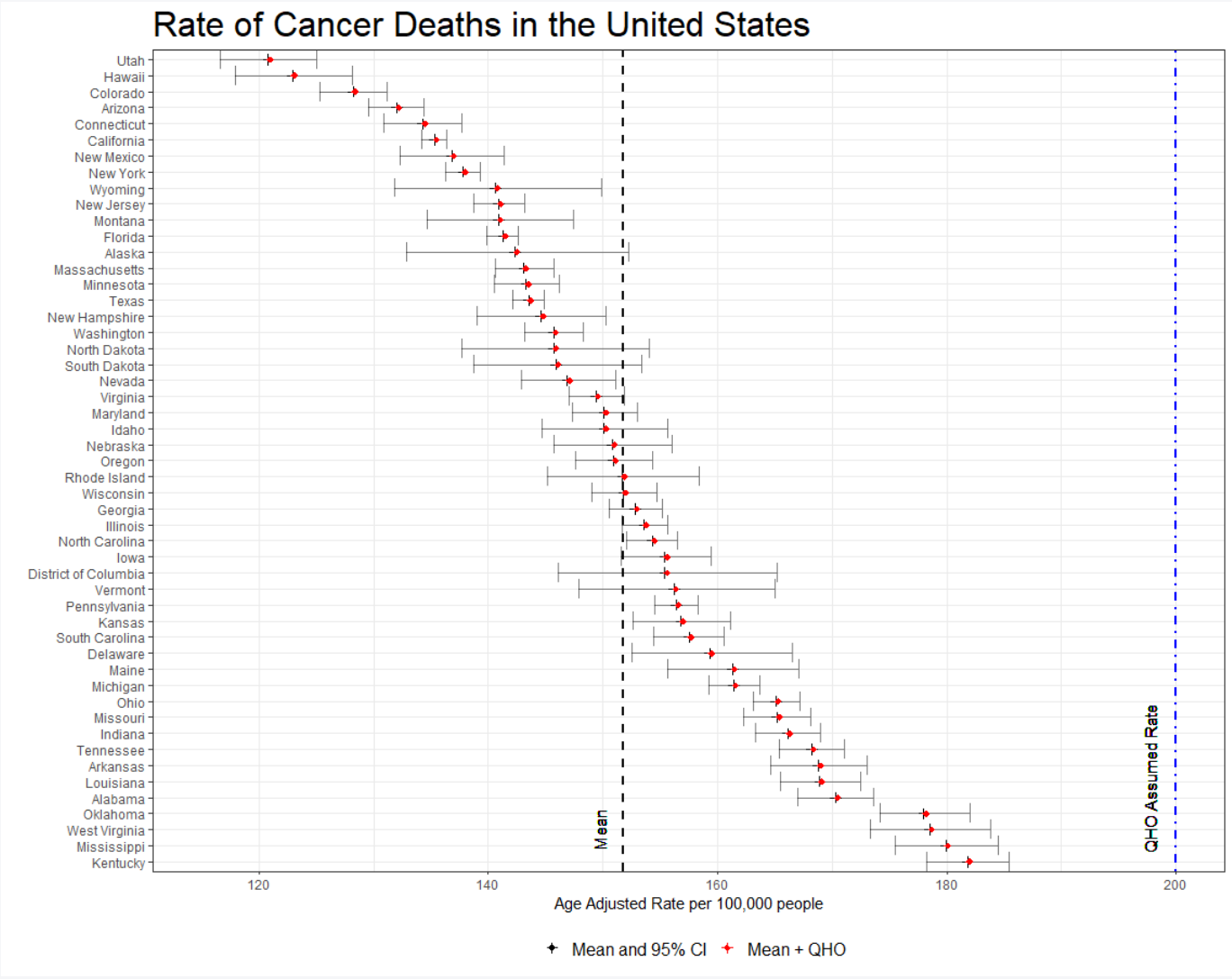


*U.S. Cancer Statistics Working Group, "U.S. Cancer Statistics Data Visualizations Tool, based on 2020 submission data (1999-2018)." U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute, Jun. 2021. [Online]. Available: https://www.cdc.gov/cancer/dataviz

Uncertainty in Observations

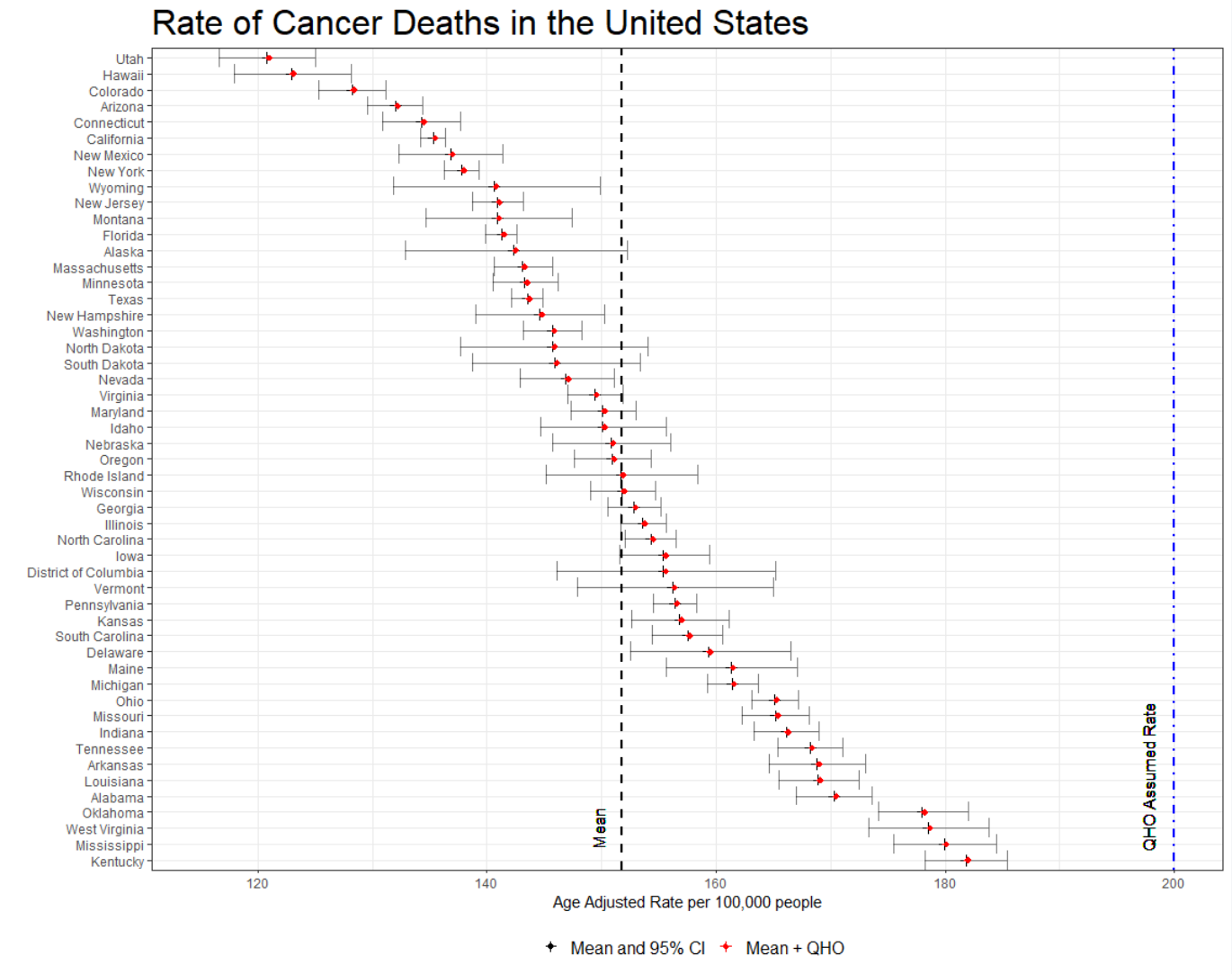
- Age-adjusted rate of all cancer deaths in the United States 2014-2018*.
- NRC assumed cancer rate 2 latent cancer fatalities per one thousand people.
- Quantitative Health Objectives indicated on chart as "one tenth of one percent" or 2 latent cancer fatalities per one million people.

*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. [Online]. Available: https://www.cdc.gov/cancer/dataviz



Uncertainty in Observations

- Assumed rate does not match observed
- Confident Interval much wider than QHO
  - 95% confidence interval of total cancer death rates, which are generally 4 deaths per 100,000 people
- Even a state level adjusted QHO is in the statistical noise

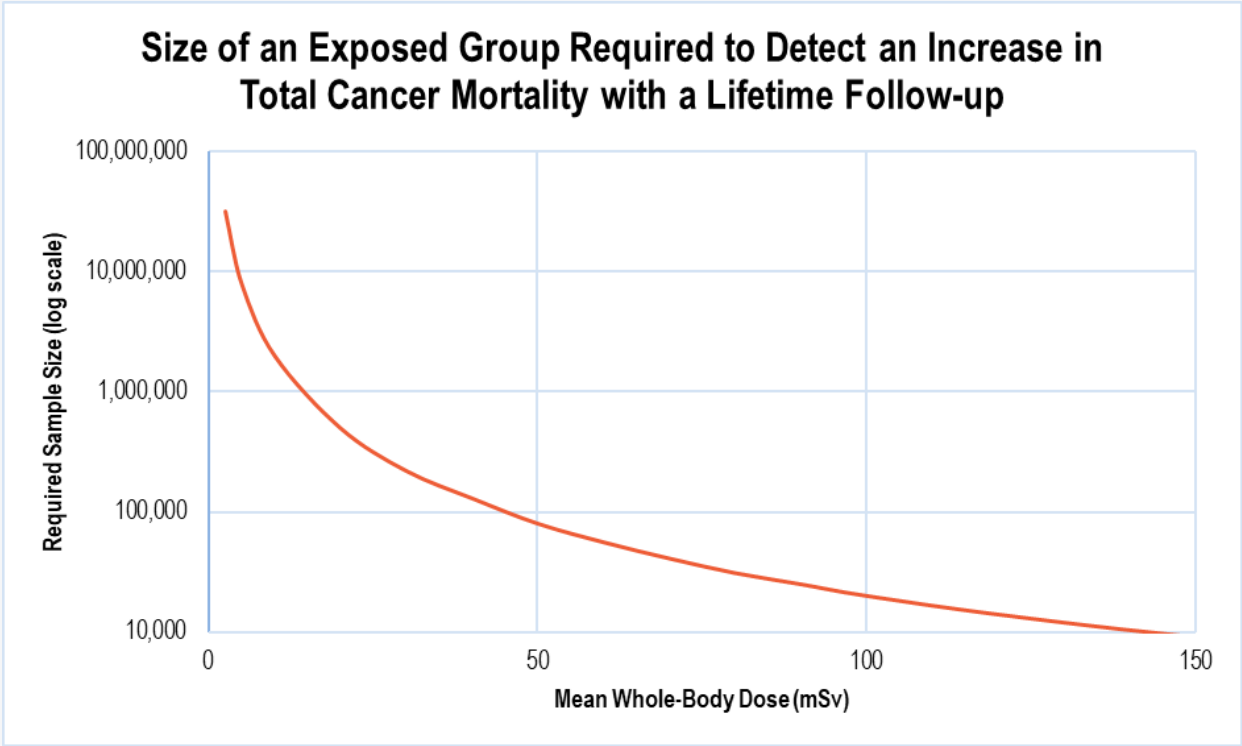


Statistical Power

- 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).
- Any "statistically significant" result is likely to be a false-positive finding, and 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.

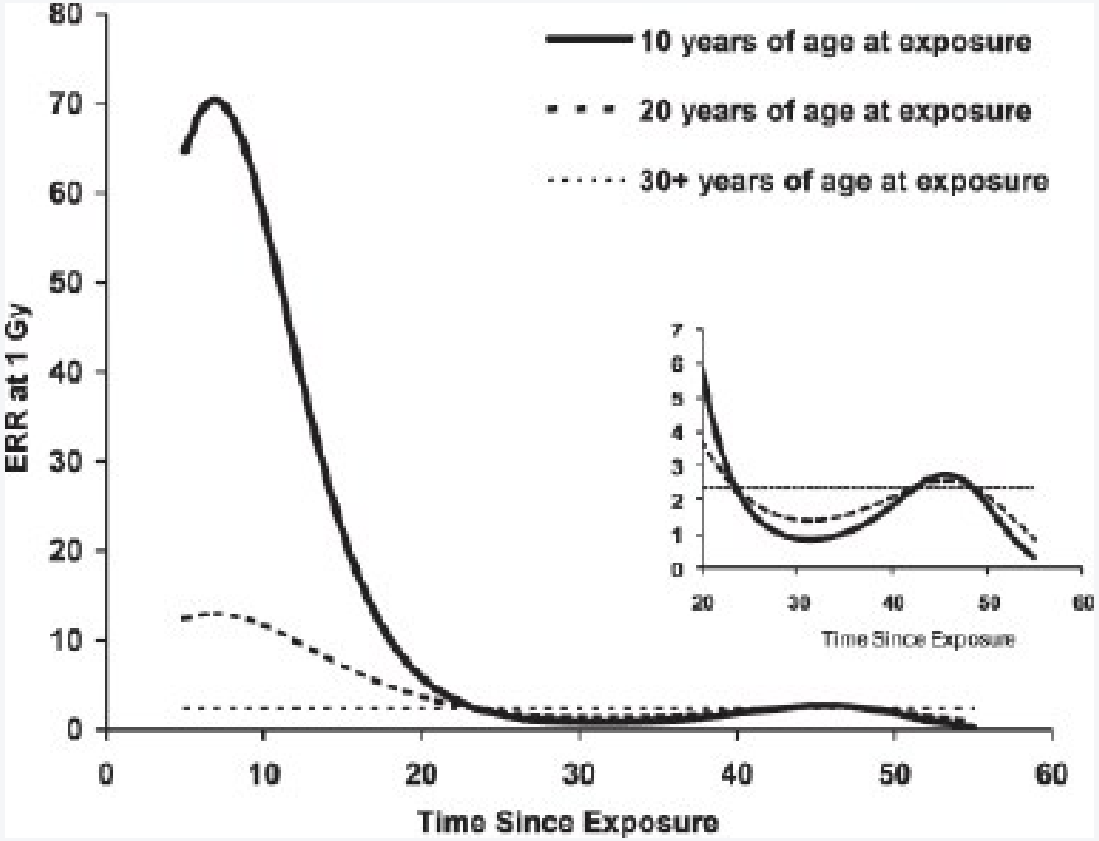
Sample size

- Large sample size needed to observe small effects in the population
- Obtaining a sample population of sufficient size would require many years of study



Time Needed

- 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.
- Delayed response to dose necessitates a very long study period to see effects



Closing Remarks

- Due to the limited population within the vicinity of the site, it is likely to take many years to reach a statistically valid sample size.
  - For the example provided in Section 4.2.2 of the Whitepaper, determining an increased rate of leukemia from a high dose of radiation, the sample size would require 31 years of data inside an expanded 50 km (30 miles).
- If sufficient sample size is required by way of NRC regulatory guidance before licensing and siting of a new facility is permitted, it would drastically extend the licensing timeline, possibly to decades.
- The Quantitative Health Objectives are not a calculable or observable in a meaningful timeline.
- QHOs are not a viable performance metric

