From:	Adam Stein
To:	RulemakingComments Resource
Cc:	Rani Franovich; Beall, Bob
Subject:	[External_Sender] Docket Docket ID NRC-2019-0062, 10 CFR Part 53, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors
Date:	Friday, February 04, 2022 2:45:52 PM
Attachments:	Comment-BreakthroughInsitute-Part53-Feb2022.pdf

Please find the attached comments from the Breakthrough Institute on 10 CFR Part 53 rulemaking. Docket Docket ID NRC-2019-0062

CC Robert Beall

Best regards,

Adam Stein, Ph.D.
Associate Director for Nuclear Innovation, Climate and Energy
The Breakthrough Institute

BREAKTHROUGH INSTITUTE

January 31, 2022

Subject: "Draft for the NRC's Rulemaking on Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" (RIN-3150-AK31; NRC-2019-0062)

Dear Mr. Tappert,

This letter and its enclosure provide the perspective of the Breakthrough Institute on the proposed rule for Title 10 Code of Federal Regulations (CFR) Part 53.

The Breakthrough Institute is an independent 501(c)(3) global research center that identifies and promotes technological solutions to environmental and human development challenges. We advocate appropriate regulation for licensing and oversight of advanced nuclear reactors to enable the timely deployment of safe, innovative, and economically viable emerging nuclear technologies. We believe new and advanced reactors represent critical pathways to climate mitigation and deep decarbonization. The Breakthrough Institute does not receive funding from industry.

There has been extensive discussion related to the inclusion of specific risk metrics in the Part 53 rule that are equivalent to the quantitative health objectives (QHOs) derived from the NRC Safety Goals. These risk metrics initially were labeled "second tier" safety criteria in Part 53 draft language[1]. In response to stakeholder feedback, the NRC staff revised the label but has not changed the language in material respects. In a September 23, 2021 meeting with the Advisory Committee for Reactor Safeguards (ACRS) the NRC staff indicated its position that inclusion of the QHOs is necessary to provide reasonable assurance of adequate protection of public health and safety[2]. The Commission held a meeting with interested stakeholders to further discuss the matter and hear differing perspectives regarding inclusion of the QHOs in Part 53.

To this point the debate has centered around whether or not the QHOs should be included in Part 53. The Breakthrough Institute contends that there is no technical basis for including the QHOs in a performance-based rule. The attached whitepaper demonstrates (with supporting

[1] NRC ADAMS No. ML21112A195

[2] NRC ADAMS No. ML21313A025

technical basis) that the QHOs do not meet the criteria to be a valid performance metric and should not be included in Part 53 rule.

Some stakeholders and the NRC staff have indicated that the QHOs are an important feature of a risk-informed performance-based rule and suggest that including them in a rule will increase regulatory predictability. While this opinion may seem valid on the surface, deeper examination of the matter (as discussed in the attached whitepaper) reveals that inclusion of the QHOs will make verification of performance intractable. Specifically, of concern is that the QHOs, which are not a valid performance metric as defined by the NRC, cannot be objectively calculated or measured in the population. This will significantly increase uncertainty in regulatory oversight.

The NRC Commissioners recently asked a more appropriate question, "If not the QHOs, then what?" Dose can be a valid performance metric, is measurable, supported by 10 CFR part 20, and already part of the current consolidated Part 53 preliminary language[3]. Using dose is more accurate because it is fundamentally a lower-order variable that can be measured directly instead of a consequence metric, which is extrapolated from dose. A dose-risk profile can be developed to consider risk significance, as has been done in several other NRC guidance documents. Development of a dose-risk profile is beyond the scope of this comment and will be addressed separately.

Sincerely,

Dr. Adam Stein
Associate Director for Nuclear Innovation, Climate and Energy
The Breakthrough Institute

Enclosure: Stein, Adam. "Quantitative Health Objectives in a Performance-based Regulation". January 31, 2022

[3] NRC ADAMS No. ML22024A066

BREAKTHROUGH INSTITUTE

Quantitative Health Objectives in a Performance-based Regulation

Adam Stein, Ph.D.
adam@thebreakthrough.org
January 31, 2022

1 Summary

The quantitative health objective (QHO) risk metrics are not a viable metric for a performance-based rule. The very low radiation-related excess risk of the QHOs tends to be buried under the noise created from statistical and other variations in the baseline lifetime risk of cancer.

Requiring applicants to demonstrate compliance with QHOs in a performance-based rule will result in reduced regulatory efficiency and effectiveness while increasing regulatory burden and cost. The use of the QHOs as a performance metric will not increase safety to the public in any measurable way or provide additional net benefit to society.

2 Background

The NRC has moved towards the application of risk-informed and performance-based rulemaking. Performance-based regulation is a regulatory approach that focuses on performance, as well as the desired results and outcomes. This differs from the traditional, prescriptive regulatory approach in that it emphasizes *what* must be achieved rather than *how* the desired results and outcomes must be obtained. Typically, the application of performance-based rulemaking is applied only if a set of guidelines are met.

The performance-based process explicitly emphasizes making observations and applying decision criteria, consistent with the priority that the Commission has placed on using sound science and state-of-the-art methods to establish risk-informed and performance-based regulation.

Congress mandated that the NRC develop a technology-inclusive, risk-informed, and performance-based rule in the Nuclear Energy Innovation and Modernization Act [1]. Accordingly, the NRC staff are developing a new licensing pathway known as Part 53 [2] to meet this mandate. NUREG/BR-303 provides a brief overview of the NRC's history of performance-based regulation [3].

The NRC's Safety Goals are an expression of the high-level safety policy of the Commission [4]. The Commission has reaffirmed on multiple occasions that the Safety Goals should remain high-level guidance on acceptable societal risk and should be used to provide guidance to the NRC staff on how new regulations should be considered [5]. The quantitative health objectives (QHO) are derived from the Safety Goals and establish the acceptable level of radiological risk to the public. The QHOs are considered goals and not limits [5]. These objectives are currently used as guidance for the NRC staff and are not included in existing licensing regulations. The subsidiary or surrogate objectives of core damage and large early release frequencies were explicitly developed for existing large light-water reactor technologies and are therefore not technology-inclusive.

The inclusion of the QHOs as a performance metric in the Part 53 draft [6] has been the subject of debate between the NRC staff and external stakeholders. In addition, the inclusion of QHOs in the Part 53 rule was also an important point of discussion at the NRC Commissioner public meeting on December 9th, 2021, and at the NRC Advisory Committee on Reactor Safeguards (ACRS) Future Plant Subcommittee meeting on December 17th, 2021.

3 Discussion

The Safety Goals were developed to define the acceptable risk from all nuclear power facilities in the United States. The qualitative and quantitative health objectives that were derived from the Safety Goals further defined the meaning of the safety goals in general terms that could be applied broadly.

Use of assumptions (e.g., an average adult in the vicinity of a plant) or simplified metrics (e.g., a rounded value for prevalence from all cancers) allow for simplified and

more consistent application of the goals, reduce regulatory uncertainty, and potentially reduce the burden that would be imposed by a more specific and shifting goal that provided no additional benefit. However, this simplification does not precisely match observable values, as would be used for a performance metric.

3.1 Performance-based metrics

A performance-based rule shifts away from the use of risk-based probabilistic metrics to metrics that can be objectively evaluated and show that a licensee has performed to an acceptable level. The NRC defined risk-informed performance-based regulations in SRM-SECY-98-144 as [7]:

> *"Stated succinctly, 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, and (5) focus on the results as the primary basis for regulatory decision-making."*

This study evaluates the implementation of the QHOs as a performance-based metric. The guidelines developed by the NRC for a performance-based approach will be used as a framework [3], [8].

4 Viability as a Performance Metric

The NRC guidelines for performance-based regulation specify how to determine if a metric is viable. One component of viability is that the metric must be a measurable (or calculable) parameter to monitor acceptable plant and licensee performance that exists or can be developed. Following this framework, the QHOs cannot be used in a performance-based rule. The reasons for this are further expanded upon in the following sections. In brief:

1) The QHOs are not directly measurable (or calculable) parameters and cannot be monitored on a timescale that allows oversight of acceptable plant and licensee performance.
   a) Direct measurement is effectively impossible in the population sample size in the vicinity of an NRC-licensed facility on a reasonable timescale.
   b) Direct calculation of the parameter is not possible. Theoretical risk projections are possible with significant uncertainty. Risk projections are not objective performance metrics.
   c) QHOs are not parameters that a licensee can readily access in real-time and may not be able to quantify statistically even in the long term.

It is unclear if typical considerations of uncertainty and defense-in-depth requirements could be maintained in the presence of the significant uncertainty inherent in a cancer risk study

4.1 Calculation of Performance

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.

In determining performance to a specific metric, the performance must be measured or calculated. Measuring changes in cancer incidence in a population requires the use of epidemiological or ecological methods that consider the characteristics of the population. Each defined population has a unique cancer mortality rate. That is, the national cancer mortality rate does not match the rate defined in the safety goals, states have a range of rates, and even census tracts within those states present a variety of rates. Cancer risks in the population can change over time due to improved medical interventions (e.g., detection and treatment), as well as systematic bias (e.g., sampling and analysis protocols or capabilities). These factors can create shifts in observed cancer rates that are not present in risk projection calculations and are decoupled from any influence due to nuclear energy production. To show an actual change in latent cancer mortality

incidence, the change of cancer incidence must be measured against the local rates, not the assumed rate in the Safety Goals.

4.1.1 Risk Projection Models

The calculation of the QHO latent cancer risk (i.e., 1/10 1% * $2x10^{-3}$ = $2x10^{-6}$) is relatively straightforward. Calculations of surrogate metrics from QHOs are more complicated but still use a generic equation of risk [9]. These calculations are useful for planning when designing a power plant or considering changes to the safety margin. However, they do not indicate the realized change in mortality risk to the population.

When using the QHO equations above, there is no way to objectively determine if the risk to the population actually increased or if latent cancer mortality increased. Even when assuming the conditional risk (i.e., the probability of occurrence is equal to one) the equation simply results in the QHO as an outcome. Therefore, simplified equations such as this one may be useful under certain conditions but are not suited to objectively confirming performance by the licensee.

Risk-projection models often involve using dose data related to the exposures of individuals living near nuclear facilities and quantifying the risk by transferring[1] that observed in other exposed populations. These models would calculate a theoretical excess risk of cancer for the relevant populations by using relevant risk estimates and interpolation models, as well as population characteristics like age structure and population mobility. Estimates of changes in risk can then be projected. Multiple risk projection models exist and provide different results [11]—[13]. Bounding analysis can be used to demonstrate that any increase is smaller than some upper limit (e.g., the QHOs). This method is currently used to show operational risk levels that comply with the QHOs.

[1] Transferring involves the use of dose data and quantified risk related to other exposed populations and extrapolating that risk to individuals living near other nuclear facilities. Data from the Japanese atomic bombing survivors' cohort are most often used for the purposes of assessing the risks arising from exposure to radiation. [10]

However, these risk projections do not calculate the licensee's performance to meet a safety objective. The inherent uncertainty in the risk projection model, transferability between populations, and other factors prevent conclusive effect calculations.

4.1.1.1 Supporting NRC Decisions

Several prior decisions and guidance by the NRC support the conclusions of this study that risk projections using QHOs are not practical for use as a performance metric.

In response to a petition for rulemaking, the 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.*" [14] In the decision to deny the petition for rulemaking, the NRC chose to cite other governmental bodies, which further support the position that the response to low dose rates is uncertain and possibly undeterminable. 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.*"

The decision to deny the petition for rulemaking further cited the 1991 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.*" [15]

These statements support the conclusion that a direct calculation of latent cancer fatalities due to low doses, as expected with the QHOs, cannot be directly calculated as a performance metric.

4.1.2 Effects of Low-dose Radiation

There is ongoing debate related to the health impacts of low-dose ionizing radiation. Several models exist. Many of these models ignore the impacts of low-dose

ionizing radiation by implementing a dose-truncation below which no consequences are calculated. The NRC reviewed several of these models for the State of the Art Reactor Consequence Analysis (SOARCA) set of studies [13]. The SOARCA study ultimately compared three consequence models — the Linear No Threshold (LNT) model, the current standard for the NRC, the Health Physics Society (HPS) truncation model, and dose truncation at the average annual background radiation. Each model resulted in different event-specific conditional and annualized risks [16]. Prescribing a model to calculate consequences, and thereby performance, would eliminate this specific source of uncertainty. The LNT model would be the most likely option as it is the standard model for the NRC.

The LNT model assumes that all doses of ionizing radiation may be hazardous, no matter how small. However, as discussed in Section 4.1.1.1, there is significant uncertainty if this assumption is correct, and if it is correct, how the dose-response curve should be defined. Ongoing studies, including the LLT (Japan) and Chernobyl, are inconclusive. At the request of the U.S. Congress, the National Academies of Science, Engineering and Medicine started a new program to address this uncertainty in the coming years [17].

4.1.3 Uncertainty in Data

The U.S. Cancer Statistics Working Group states that the rates for cancer deaths for different locations (Figure 1) contain uncertainty and, therefore, a confidence interval is provided. This interval indicates that with 95% confidence, the actual rate of cancer mortality is within that range. Therefore, a detected rate within that range, even if it diverges from the stated mean, is within the statistical possibility. Without other compelling information such as a cluster of known exposed individuals, it is unlikely to be meaningfully distinguishable from the population distribution.

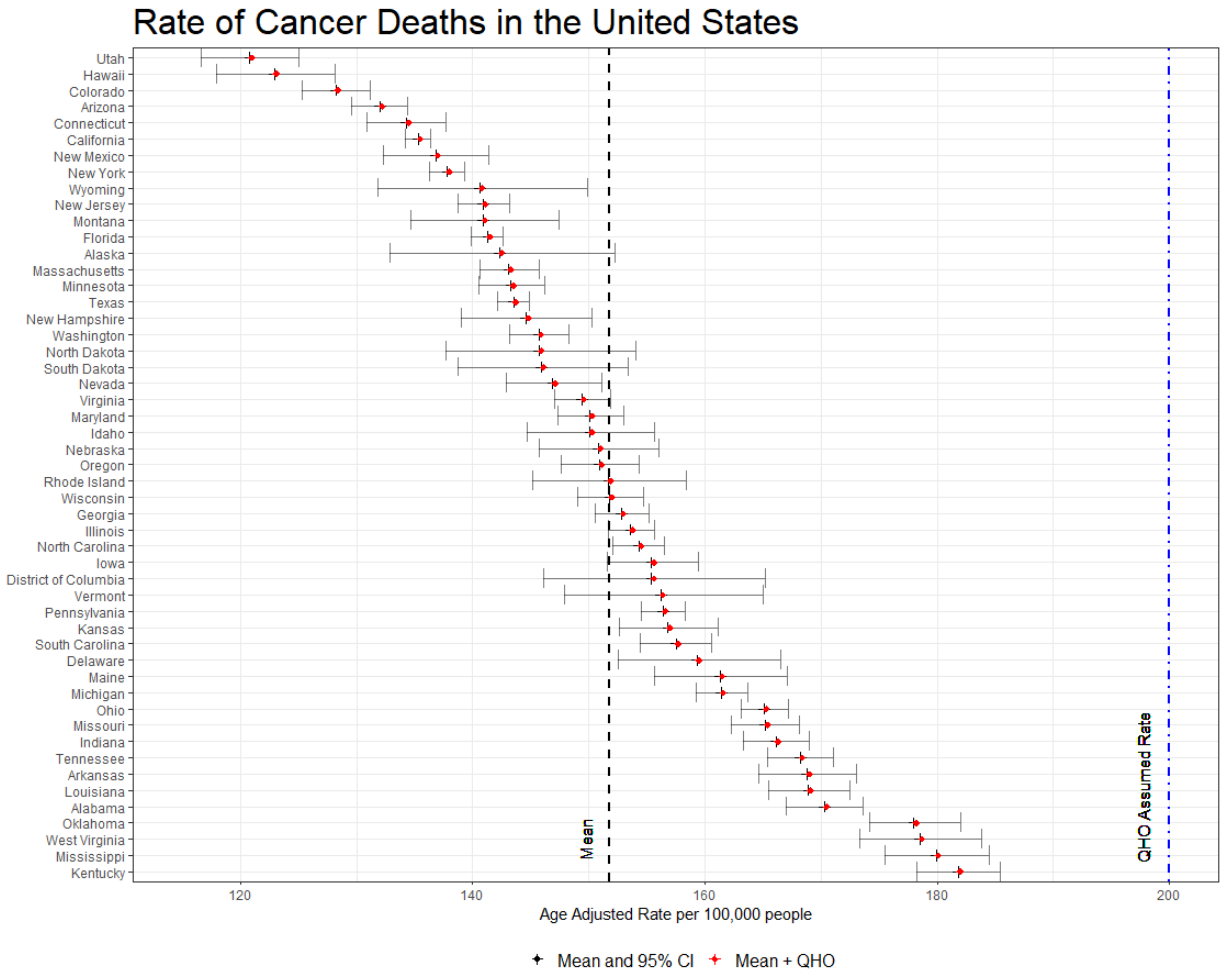

Figure 1: Age-adjusted rate of all cancer deaths in the United States 2014-2018 from [18]. Quantitative Health Objectives calculated as 2 latent cancer fatalities per one million people.

The national combined cancer death rate in 2018 was 155.6 per 100,000 people. This range easily encompasses the one-tenth of one percent goal, equalling 0.1556. <0.02 deaths per 100,000. This relative risk is well within the 95% confidence interval of total cancer death rates, which are generally 4 deaths per 100,000 people.

4.2 Challenges with Direct Measurement

There are limitations to what effects can be measured using epidemiological or ecological studies. The EPA has stated that epidemiology lacks the statistical power to detect risks from acute doses of radiation below about 100 mGy [19]. This dose level is notably higher than several other accepted limits for nuclear power facilities, including

the EPA protective action guidance limit of 10 mSv (1 rem) [20], the dose limit in the boundaries in the Part 53 rulemaking, and the risk-informed emergency planning zone proposed rule for small modular reactors and other new technologies [21].

In line with the Commission's priority on using state-of-the-art methods to develop risk-informed and performance-based regulation, the NRC enlisted the National Academy of Science (NAS) to perform a state-of-the-art study on cancer risk for populations surrounding NRC-licensed facilities. The study was designed to determine cancer risk near NRC-licensed facilities [22]. After a $1.5M expense and completion of the planning phases, the study was canceled. While the NRC agreed that the study design was scientifically sound, the three-year, $8M pilot study was unlikely to answer key basic risk questions. The NRC ultimately decided the time and money would not be well spent for the possible lack of useful results.

4.2.1 Relative risk

Excess Relative Risk (ERR) is a term used in epidemiological studies to represent the ratio of risk increase attributable to exposure. For example, the ERR for latent cancer fatalities from radiation exposure is the ratio of increase in latent cancer fatalities compared to the baseline in the population.

The NRC Safety Goal Policy defines the ERR in the QHO for latent cancers to be the risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation, which should not exceed one-tenth of one percent (0.1 percent) of the sum of cancer fatality risks resulting from all other causes.

However, excess relative risks of less than 20% from minimum dose ranges of 500-1,000 mSv are generally not feasible to evaluate in a population with sufficient statistical power [23].

4.2.2 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.

The NAS Cancer Risk study, commissioned by the NRC, concluded that even for leukemia, which is considered one of the most radiosensitive cancer types, the expected increase in risk is small, resulting in an excess relative risk for leukemia of 0.0143 for 1 mSv [23]. It concluded that "*such a risk would be virtually impossible to detect for any cancer given the statistical and other variability on the baseline risk.*" Due to the low statistical power and low relative risk, precise computations of statistical power would have little meaning.

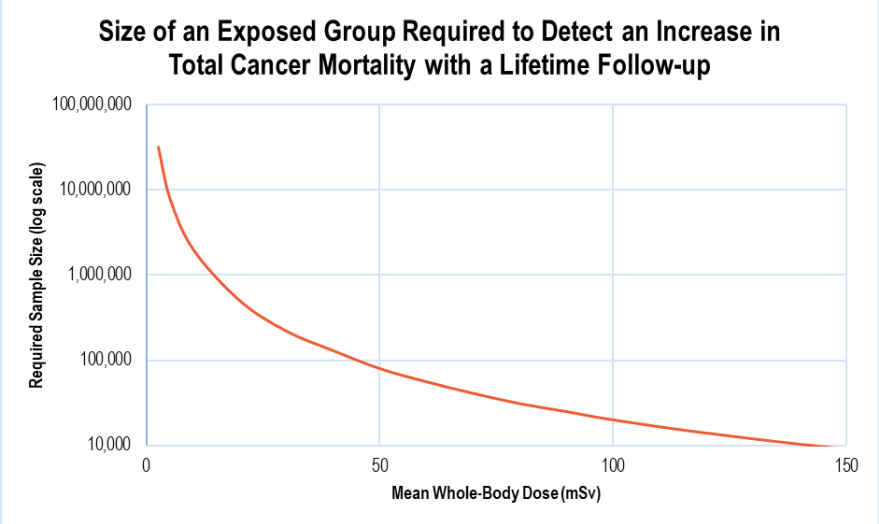

Figure 2: Size of an exposed cohort group required to detect an increase in total cancer mortality with a lifetime follow-up. These values are based on BEIR V [24] and predicated on achieving a 80% statistical power with a 5% alpha level. Data from [25].

Figure 2 shows the size of the exposed population needed at various doses to observe an excess in cancer mortality against general population rates [25]. This consensus study further states that

> *"It is notable that at doses of 20 mSv (2 rem) or less the required sample sizes are prohibitively large, ranging from 500 thousand to 32 million persons. The sample sizes come into the realm of possibility only when the mean dose is above 50 mSv (5 rem)."*

The United Nations Scientific Commission on the Effects of Atomic Radiation (UNSCEAR) report on health effects from the Fukushima Daiichi event supports this assessment. The event involved three large boiling water reactors at the same site. The report estimates that two million people were in the exposed population with a mean dose of 2 mSv in Fukushima Prefecture. This dose is ten times less than what the NAS study found to be feasible for determining an effect on any timescale in a population this size, and two orders of magnitude less than deemed feasible for the study "rule out" a certain level of risk [10]. The UNSCEAR report concluded that "future radiation-associated health effects are unlikely to be discernible." [26]

4.2.3 The Vicinity of the Plant

The vicinity of the plant is generally defined as the 10 miles surrounding the plant and is correlated to the emergency planning zone around the site [5]. Future plants may have smaller emergency planning zones that are scaled to the risk to the population [21] or sited closer to population centers [27].

Changes to siting relative to the population or revision to the size of the area defined as the vicinity around the power plant can significantly impact the viability of this metric. Location of the site in areas of higher population density will improve statistical power. Statistical viability would be reduced if the vicinity of the plant is defined as a smaller radius, as it will encompass a smaller population and further limit the ability to complete a statistically valid study to determine performance to a standard.

4.2.4 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. In addition, changes with time are hard to factor out of ongoing long-term studies.

4.2.4.1 Changes in the background rate

Cancer mortality rates change over time and vary geographically (Figure 3) for reasons unrelated to nuclear power. This impacts the minimum detectable effect, but it also means there would be a difference between how plants are regulated based on geographic and population characteristics not coupled to plant safety or performance. Changes to population characteristics have to be continually evaluated and determined prior to comparing changes in the population from radiation exposure. This will result in several years of lag in determining performance. Such a lag would not be useful for the NRC to maintain oversight in a useful manner.

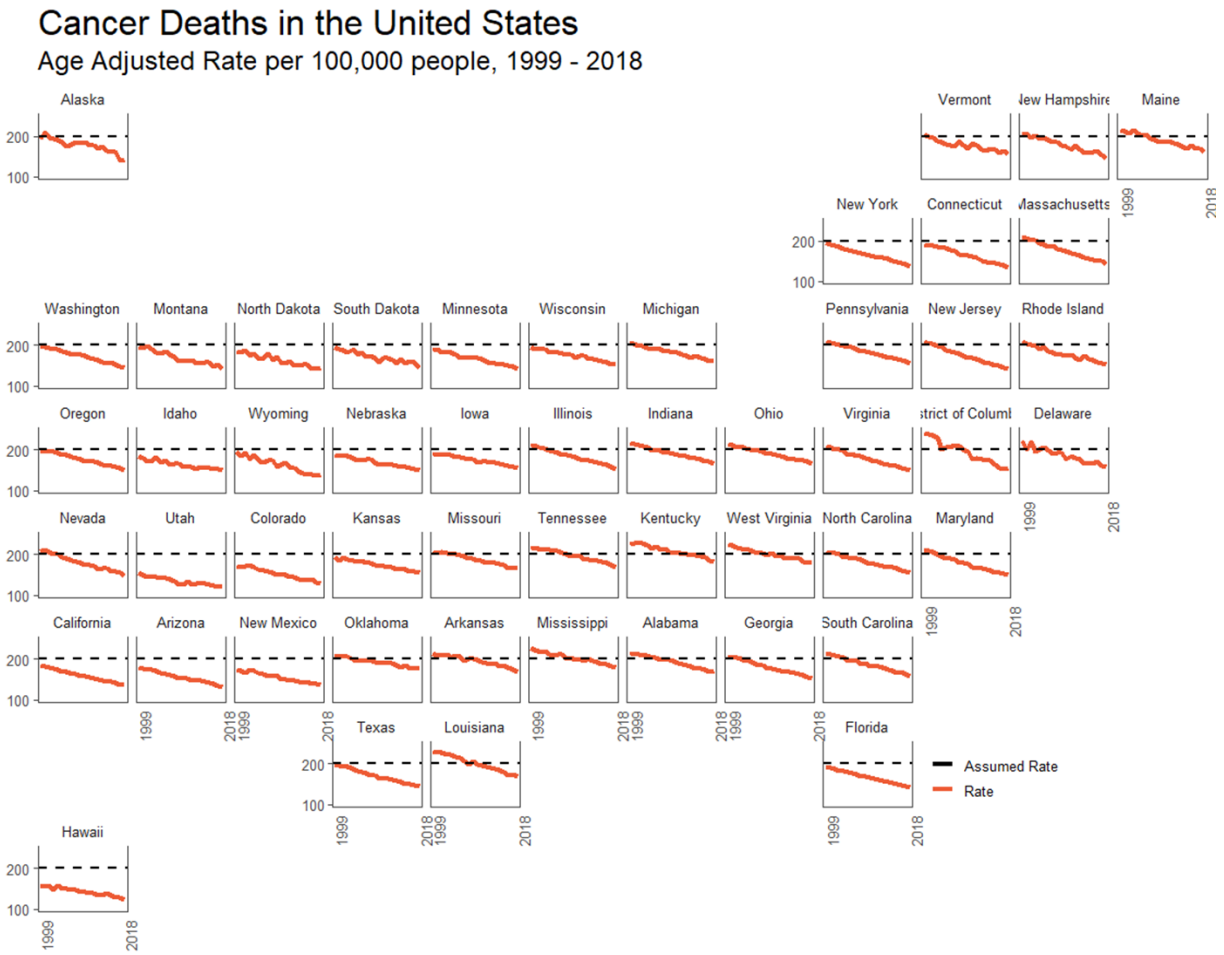

Figure 3: Age adjusted annual rate of all cancer deaths in the United States by state 1999-2018, relative to the NRC assumed rate of $2x10^{-3}$ in the population. Data from [18].

Figure 3 clearly shows that cancer rates are continually in flux, experience non-linear changes, and vary significantly even between neighboring locations. The background cancer rate is important for determining performance because the QHOs are stated as a fractional change of that rate, and because it affects the time it would take to observe enough cancer cases for a study with sufficient statistical power to be of value. These factors lead to regulatory uncertainty over time and inconsistent performance requirements between locations.

4.2.4.2 Temporal lag in effects

Cancer development is not uniform across cancer types, age at exposure, and other factors. Particularly at low dose levels, the NRC states, "*The effects of doses less than 10,000 mrem (100 mSv) over many years, if any, would occur at the cell level. Such changes may not be seen for many years or even decades after exposure.*" [28] This extended time scale is not useful for regulatory oversight of performance.

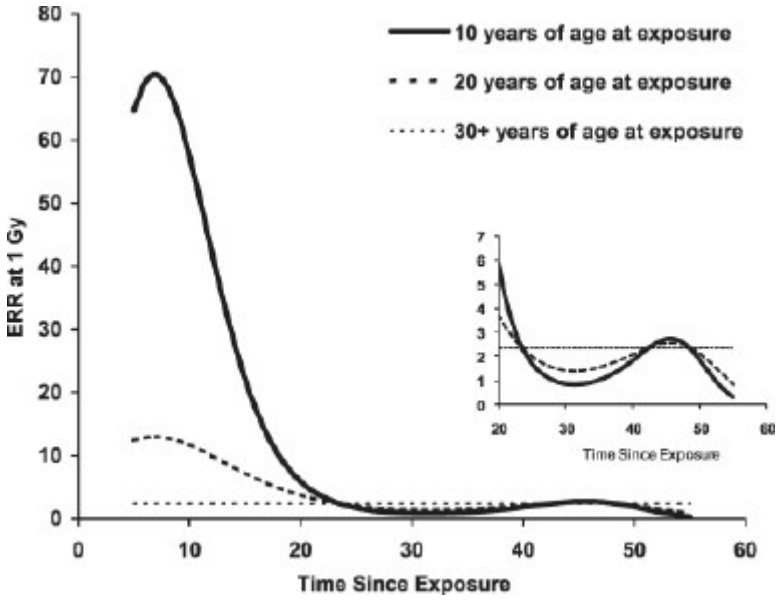

Figure 4: Predicted excess relative risk (ERR) at 1 Gy for leukemia (all types) as a function of age at exposure and time since exposure. SOURCE: Richardson et al. (2009).

4.2.4.3 Extended period to collect data

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, 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. For example, licensees are required to collect several years of weather data at a site, if the data is not already available from existing sources.

5 Assessment of Regulatory Change

Guidelines have been developed to determine if there is benefit or justification to change an existing regulation to performance-based regulation. As discussed previously, 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 [3]:

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

5.1 Maintain Safety and Safety Margin

Studies of the current state of safety margins indicate that safety margins for existing power plants are both robust and are larger than previously considered. Existing plants have safety margins that are orders of magnitude below the QHOs [29], [30]. Results from the SOARCA project further support that assessment [31].

It is important to note that safety margins and other probabilistic risk metrics do not follow the guidelines for a performance metric. Margins are instead a way to ensure sufficient time to correct a performance degradation and also to accommodate the potential underestimation of risks.

Safety margins should be robust. "Robustness" of a safety margin means that the margin between two performance levels is significantly greater than uncertainty and normal variability in performance [3]. It is important to point out that in the case of the QHOs the uncertainty and variability of the baseline that the performance will be measured against (i.e., the background cancer rate) is orders of magnitude larger than the performance limit (see Section 4.1.3).

5.2 Public Confidence

Trying to set the goal of risk to the population to a level indistinguishable from the general population provides no additional benefit to that population and is therefore overly burdensome. This has been shown to be the case for severe events like the one at Fukushima Daiichi.

The studies required to measure such metrics may erode, rather than increase, public confidence. This may occur because the required observations studies needed to determine performance imply that a lifetime cancer screening program is necessary for the safe operation of a nuclear power facility. This both undermines the public's confidence in the NRC's oversight of facilities licensed under different regulations that would not require a cancer screening program and distorts the perception and associated concerns the public has regarding the NRC's ability to provide a reasonable assurance of adequate protection [23].

The NRC stated that stakeholder engagement is an essential component of cancer risk studies and requested that the NAS to explicitly include engagement in the study design [23]. The majority of public input received during phase 1 of the 2012 NAS study was from stakeholders requesting to have their site included in the study [32]. Many stated that they believed the study would show increased cancer incidence and that they would feel the study was biased if that conclusion was not reached. As such, a continuous performance program that is unlikely to provide statistically meaningful results could reduce public trust in the NRC and industry. In turn, this will create undue opposition to nuclear innovation without benefit to society.

5.3 Effectiveness, Efficiency, and Realism

Large epidemiological or ecological studies, as would be required to show the performance of the QHOs, could provide improved realism over the current method for risk projections. However, this improved realism would be offset by substantially reduced efficiency and effectiveness. As discussed in Section 4.2, the scale of studies required to provide statistically valid results is prohibitively large. Such expensive studies would be ineffective for real-time oversight and less effective than existing regulations that do not require such a study.

5.4 Regulatory Burden

Studies to determine annual cancer incidence and mortality rates in the population in the vicinity of the plant were determined by the NRC to be cost-prohibitive, given the limited appreciable value-added. An NRC-sponsored study for a design and associated pilot study planning cost was approximately $1.5M. Completing the pilot study of seven sites would have cost $8M over three years, and expanding the project to the remaining nuclear power facility sites would have cost tens of millions more. As the QHOs are currently goals, the requirement to measure cancer incidence and mortality in the vicinity of nuclear facilities does not currently exist in licensing regulations.

Similar studies would have to be completed annually at each site to maintain an ongoing awareness and oversight of a QHO performance metric. The aforementioned

project was abandoned by the NRC that reasoned the time and money would not be well spent given the probable lack of useful results [22]. Adding such an expansive requirement would vastly increase the regulatory burden for no tangible net benefit.

5.5 No additional benefit

As previously stated, the QHOs are safety goals and are not included in licensing requirements. The shift to include QHOs, or other new metrics, directly in the licensing rule would generally be only justified "*only if NRC or licensee operations benefit from such a change.*" [8]

As the performance metric defined in the draft Part 53 rulemaking is the same as the existing safety goals and QHOs, there would be no net safety improvement to societal outcomes. As discussed in this study, even if societal outcomes increased safety to the public beyond current outcomes, they would not be statistically distinguishable with extensive long-term observations.

5.6 Performance-based framework and technology inclusion

The NEIMA mandated the development of a technology-inclusive risk-informed and performance-based framework for advanced reactors. Therefore, guidance point 6 is irrelevant because a new framework is mandated instead of determining if a performance-based metric will fit into an existing framework.

Guidance point 7 is irrelevant because the new framework is mandated to be technology-inclusive. Additionally, while a risk metric such as the QHOs may be more difficult to calculate accurately for some reactor designs, the metric is not directly tied to a specific technology.

6 Conclusions

The safety goals, particularly the QHOs for latent cancer fatalities, are not suitable for a performance-based regulation and should not be included in the Part 53 rulemaking.

QHOs are a safety goal, not a requirement of existing licensing frameworks. Calculations to show compliance with QHOs uses a projected risk estimation that relies on significant assumptions to factor out uncertainties. Similar analyses could be one method to risk-inform a performance-based rule. However, such targets do not function as a performance metric directly and are neither useful nor appropriate for such an application

The QHOs meet very few of the NRC guidelines for a performance-based metric. Critically, they are neither calculable nor measurable in a feasible sense. The contents of this study provide significant evidence and NRC concurrence that the risk is both smaller than reasonably distinguishable in the population and that the prescribed LNT model is uncertain in this low-dose range. Perhaps most importantly, QHOs cannot feasibly provide performance measures in the vicinity of the plant and cannot do so on the timescale required to provide sufficient opportunity to take corrective action if performance is lacking.

As such, the QHOs provide limited value as a requirement in any regulatory rule. Risk-informed regulation is intended to focus regulatory oversight and burden on the most important safety metrics. A more reasonable risk-informed metric should be capable of providing oversight of risk or consequences that could be distinguishable from background effects. Such a standard would be both measurable and meaningful and, therefore, not overly burdensome without benefit to society.

NRC-sponsored studies using state-of-the-art methods were canceled because they would not answer even the most basic questions about cancer risks near NRC licensed facilities [22]. Even studies of the significant accident at Fukushima Daiichi nuclear power plant are not statistically able to distinguish an increase in cancer incidence relative to background rates, if an increase does exist.

7 References

[1] *Nuclear Energy Innovation and Modernization Act (NEIMA)*, vol. 42 USC 2011. 2019. [Online]. Available: https://www.congress.gov/115/plaws/publ439/PLAW-115publ439.pdf

[2] Nuclear Regulatory Commission, "Preliminary Proposed Rule Language: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (10 CFR Part 53)," *Federal Register*, vol. 85 FR 71002, Nov. 2020, Accessed: Jan. 10, 2021. [Online]. Available: https://regulations.gov/document/NRC-2019-0062-0012

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

[4] Nuclear Regulatory Commission, "Safety Goals for the Operations of Nuclear Power Plants: Policy Statement," 1986.

[5] Nuclear Regulatory Commission, "Modifications to the Safety Goal Policy Statement," SECY-00-0077, Mar. 2000. [Online]. Available: https://www.nrc.gov/docs/ML0036/ML003684288.pdf

[6] Nuclear Regulatory Commission, "Consolidated Part 53 Preliminary Proposed Rule Language," ML22024A066, Feb. 2022. Accessed: Feb. 04, 2022. [Online]. Available: https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML22024A066

[7] Nuclear Regulatory Commission, "Whitepaper on Risk-Informed Performance-Based Regulation," SRM-SECY-98-144, Mar. 1999. [Online]. Available: https://www.nrc.gov/docs/ML0037/ML003753601.pdf

[8] Nuclear Regulatory Commission, "High-level Guidelines for Performance-Based Activities," SECY-00-0191, Sep. 2000. [Online]. Available: https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2000/secy2000-0191/2000-0191scy.pdf

[9] Nuclear Regulatory Commission, "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing Appendices A through L," NUREG-1860, Vol. 2, Dec. 2007. [Online]. Available: https://www.nrc.gov/docs/ML0804/ML080440215.pdf

[10] *Analysis of Cancer Risks in Populations Near Nuclear Facilities: Phase 2 Pilot Planning*. Washington, D.C.: National Academies Press, 2014, p. 18968. doi: 10.17226/18968.

[11] 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.

[12] D. J. 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.

[13] 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

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

[15] Nuclear Regulatory Commission, "Standards for Protection Against Radiation: 10 CFR Parts 2, 19, 20, 30, 31, 32, 34, 35, 39, 40, 50, 61 and 70," *FR*, vol. 56, no. 98, May 1991, Accessed: Jan. 05, 2022. [Online]. Available: https://www.federalregister.gov/citation/56-FR-23391

[16] Nuclear Regulatory Commission, "State-of-the-Art Reactor Consequence Analyses Project Volume 1 : Peach Bottom Integrated Analysis," NUREG/CR-7110 Vol. 1, 2012.

[17] National Academies of Sciences Engineering and Medicine, "Developing a Long Term Strategy for Low Dose Radiation Research in the United States," Consensus Study, 2021. Accessed: Jun. 01, 2021. [Online]. Available: https://www.nationalacademies.org/our-work/developing-a-long-term-strategy-for-low-dose-radiation-research-in-the-united-states

[18] 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

[19] Environmental Protection Agency (EPA), "EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population," EPA 402-R-11-001, 2011.

[20] EPA, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents," Environmental Protection Agency, EPA-400/R-17/001, 2017. [Online]. Available: www.epa.gov/radiation/protective-action-guides-pags

[21] Nuclear Regulatory Commission, "Proposed Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies," *Federal Register*, vol. 85 Fed. Reg. 28436, May 2020, [Online]. Available: https://regulations.gov/docket/NRC-2015-0225

[22] Nuclear Regulatory Commission, "Backgrounder on Analysis of Cancer Risks in Populations Near Nuclear Facilities," *NRC Web*. https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/bg-analys-cancer-risk-study.html (accessed Dec. 29, 2021).

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

[24] *Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR V*, vol. 436, no. 9. 1990. doi: 10.1080/00330124.2011.583592.Mixed.

[25] *Radiation Dose Reconstruction for Epidemiologic Uses*. Washington, D.C.: National Academies Press, 1995, p. 4760. doi: 10.17226/4760.

[26] United Nations Scientific Committee on the Effects of Atomic Radiation, "Levels and effects of radiation exposure due to the nuclear accident at the Fukushima Daiichi Nuclear Power Station (FDNPS): Implications of information published since the UNSCEAR 2013 Report," UN, Volume I Scientific Annex B, 2020. [Online]. Available: https://www.unscear.org/unscear/en/publications/2020b.html

[27] Nuclear Regulatory Commission, "Population-Related Siting Considerations for Advanced Reactors," Nuclear Regulatory Commission, SECY-20-0045, 2020. [Online]. Available: https://www.nrc.gov/docs/ML1914/ML19143A194.pdf

[28] Nuclear Regulatory Commission, "Backgrounder on Biological Effects of Radiation," *Fact Sheets and Brochures*, Jul. 08, 2020. https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/bio-effects-radiation.html (accessed Jan. 09, 2022).

[29] Electric Power Research Institute, "Insights on Risk Margins at Nuclear Power Plants: A Technical Evaluation of Margins in Relation to Quantitative Health Objectives and Subsidiary Risk Goals in the United States," 3002012967, 2018.

[30] Electric Power Research Institute, "Consideration of Defense-in-Depth and Safety Margins in Risk Informed Decision Making," 3002020763, 2021.

[31] Nuclear Regulatory Commission, "State-of-the-Art Reactor Consequence Analyses (SOARCA) Report," NUREG-1935, 2012.

[32] Nuclear Regulatory Commission, "FOIA request 2016-0539," ML16259A145, Aug. 2016.