Samuel Lawrence Foundation

Reforming and Modernizing the Radiation Protection Framework

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U.S. Nuclear Regulatory Commission

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Re: Formal Administrative Comment Reforming and Modernizing the Radiation Protection Framework

I. Introduction

The Samuel Lawrence Foundation respectfully submits this comment to the NRC's proposed rule to eliminate the ALARA (As Low As Reasonably Achievable) principle and replace it with a graded dose-management approach. While recognizing the Commission's legitimate drive toward regulatory modernization and clarity, the current scientific unknowns and contemporary research emphasize the need for more caution and further research before redesigning radiation frameworks, not less. The potential alleviation of a modest regulatory burden, as stated by NRC while publishing the comment, is not commensurate with the potential harm to public health and is not supported by the administrative record. The proposed rule is particularly problematic with respect to vulnerable populations: pregnant workers, fetuses, and children living near or working at nuclear facilities.

The scientific record demonstrates:

1. Since 1906, it has been shown that rapidly dividing, undifferentiated cells are more sensitive to radiation. The fetus is composed of cells that meet these criteria and are more sensitive to radiation.
2. Scientific advisory groups assume that radiation exposure before birth may be 2 or 3 times more likely to cause cancer over a person's lifetime than the same amount of radiation received as an adult.

3. There exists a previously unexplored association between nuclear power plant proximity and cancer mortality, which is both robust to sensitivity analyses and observed across multiple datasets and geographic aggregations.

These factors collectively weigh heavily against dismantling a protective framework while uncertainty persists. The Samuel Lawrence Foundation recommends the NRC rescind the proposed rule or substantially revise it to better reflect the scientific record.

II. Statutory and Regulatory Context

A. ALARA Was an Approximate Solution, but Evidence Suggests It Should Remain a Core Statutory Pillar, Not Abandoned for Discretionary Industry Optimization

One purpose of this rulemaking is to "restore to the NRC's regulations the original intent of the ALARA principle", which is to ensure that dose reductions below the dose limits are only required to the extent that they are reasonable and are supportive of compliance with those doses. However, this framing obscures a critical distinction: ALARA is not merely an internal NRC preference for administrative clarity. The Atomic Energy Act of 1954 and the Energy Reorganization Act of 1974 establish public health and safety as the NRC's foundational mandate. ALARA – that radiation exposures should be kept "As Low As Reasonably Achievable" to protect workers, the public and the environment is not a rhetorical flourish; it is a structural legal requirement that protects against regulatory drift.

By eliminating ALARA, the proposed rule would convert what is currently a positive legal obligation to protect the public (to minimize exposures below regulatory ceilings) into a passive compliance verification exercise. That transformation violates the NRC's duty to ensure "reasonable" public health outcomes and inverts the precautionary logic that should govern a public health agency. See *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29 (1983) (agency action is arbitrary and capricious where agency has failed to articulate a rational connection between facts found and choice made).

B. The Proposed Rule Is Responsive to Executive Direction, Not to Demonstrated Safety Findings or Current Scientific Evidence and Inquiry

The proposed rule was issued in response to Executive Order 14300, signed by President Trump in May 2025, which pushed for a rushed reconsideration of the science underlying the NRC's radiation protection regulations. While executive direction carries weight in the rulemaking process, the Administrative Procedure Act ("APA") requires the NRC to articulate reasons grounded in the public record and scientific evidence. Despite the EO's

directive to "specifically consider adopting determinate radiation limits," the NRC has concluded that establishing a determinate regulatory dose limit for stochastic health effects (i.e., a brightline threshold below which radiation is deemed categorically safe) is not currently supported by scientific evidence. The NRC considered shifting to a framework based entirely on determinate dose limits for both stochastic and non-stochastic effects – a "go/no-go" regulatory approach – but ultimately rejected that approach after lengthy deliberation.

The NRC rejected the EO's most aggressive directive because scientific consensus does not support it. Removing ALARA in the absence of an evidence-based threshold cannot be supported by royal decree alone.

III. Novel Epidemiological Evidence: Dr. Alwadi's Work And Implications

A. The Alwadi Studies: Nature and Significance

U.S. counties located closer to operational nuclear power plants have higher cancer mortality rates than those farther away. Using nationwide mortality data from 2000-2018, the assessment shows long-term spatial patterns of cancer. The findings are substantial on their own, but at the ***very least*** merit further investigation and caution on the part of regulators. Investigators estimated 115,586 cancer deaths (95% CI, 56,964-173,326) during the 19-year study period — or approximately 6,400 per year across the country — could be attributed to nuclear power plant proximity.

Critically, the signal observed is strikingly robust and consistent, perhaps giving some pause as to its validity. That is a reasonable concern. However, skepticism for lack of casual mechanisms and effect size do not obviate the agency’s mandate to investigate and safeguard public health. The associations between proximity and cancer mortality persisted in multiple sensitivity analyses. In one, researchers adjusted the distance from nuclear power plants to county centers, changing by increments of 10 km until it reached a 100-km radius. In another, investigators varied the average proximity window across five intervals, ranging from 2 years to 20 years. The consistency of the results demonstrated that they are not obviously driven by arbitrary choices in model variables or parameters.

B. Causality vs. Regulatory Weight: A False Dichotomy

Critics have emphasized that the researchers "cannot prove causality" and "do not establish causality.” This observation, while technically sound, is irrelevant to the regulatory question at hand. A public health regulator need not await definitively proven

causation to exercise precaution. Epidemiological associations are precisely the data that trigger further investigation and, pending investigation, heightened protective measures.

Researchers agree that there exists all the evidence needed to justify going to the next level of investigation. "Epidemiological studies progress in stages. If you find a signal, you keep going." The NRC's position should align with the standard epidemiological approach: when a robust, geographically consistent national association is observed between proximity to nuclear facilities and elevated cancer mortality, and that association persists across sensitivity analyses, the proper regulatory response is not to deregulate, but to investigate and protect.

C. Acknowledged Limitations Do Not Undermine the Signal

The investigators acknowledged study limitations. The analysis assumed equal impact of all nuclear power plants rather than incorporating direct radiation measurements, and it assessed all malignancies combined. No epidemiological study is perfect, and perfect studies are impossible in observational research. The question is whether the noted limitations are fatal to the study's central finding or merely indicative of areas for future refinement.

The use of county-level proximity rather than individual-level dosimetry is a limitation of ecological design, not a disqualification of the findings. Indeed, when Dr. Alwadi conducted a similar study comparing nuclear power plant proximity to county-level data on cancer mortality from the US Centers for Disease Control, researchers commented that doing the analysis nationally might have enough statistical power to depict effects that truly exist or simply vanish. The effects did not vanish. The design was deliberately amplified to achieve statistical power. That the effect was detected and sustained across robustness checks suggests genuine signal, not artifact.

D. Specific Gender and Age Vulnerability Patterns

Notably, women ages 65-74 living two km away from a nuclear power plant had 2-times higher relative risk of cancer, and men in this age group had 1.75-times higher risks. This gender and age specificity is scientifically notable: it suggests differential susceptibility or exposure pathways that warrant regulatory attention and further investigation, not less.

IV. Developmental Vulnerability: Fetuses, Pregnant Workers, And Children

A. Biological Sensitivity of Embryos and Fetuses

The record is unambiguous regarding fetal radiosensitivity. The human embryo and fetus are sensitive to ionizing radiation at doses greater than 0.1 gray (Gy). Depending on the stage of fetal development, the health consequences of exposure at doses greater than 0.5 Gy can be severe, even if such a dose is too low to cause an immediate effect for the mother. The health consequences can include growth restriction, malformations, impaired brain function, and cancer.

The fetus is most sensitive to radiation effects between 8 and 15 weeks of pregnancy. Risk of having childhood cancer, particularly leukemia, increases by a factor of 1.5 to 2 when exposed to 0.01 to 0.02 Gy (10 to 20 mGy; 1 to 2 rad) levels of radiation in utero.

Crucially, the developing human brain has been shown to be especially sensitive to radiation. Severe developmental issues have been observed in the survivors of the atomic bombing in Japan in utero during sensitive periods. When exposure occurs in the 16 to 25 week window, the average IQ loss is approximately 13 to 21 points per Gy at doses above 0.7.

B. Current Regulatory Framework Reflects Science-Based Fetal Protection

The NRC requires licensees to "limit exposure to the fetus of an occupationally exposed individual to 500 mrem (5 mSv) or less during pregnancy for a declared pregnant worker who is exposed to radiation from licensed radioactive materials." This lower dose limit is "based on a consideration of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure."

Substantial **variations in a uniform monthly exposure rate**, as is contemplated in this proposed rule, should be avoided. This requirement embodies the ALARA principle applied to the most sensitive population. By removing ALARA, the proposed rule would eliminate the operative requirement that pregnant workers receive a consistent, minimized monthly dose and would permit lumpy exposure patterns so long as the total pregnancy dose remained under 500 mrem.

C. Children's Unique Vulnerability Requires Preservation of Protective Margins

Radiation exposure can affect the embryo and fetus, as they are particularly sensitive to radiation. Children, by definition, are continuously developing organisms. Since 1906, it has been known that rapidly dividing, undifferentiated cells are more sensitive to radiation. The fetal child is composed of cells that meet these criteria and are more sensitive to radiation. This principle extends to infancy, childhood, and adolescence—periods of ongoing cellular differentiation and growth.

The proposed rule provides no evidence that the elimination of ALARA will not result in higher routine exposure rates for children in communities near nuclear facilities. The NRC's assertion that dose ceilings will remain unchanged does not answer whether, in practice, licensees will operate closer to those ceilings absent the "as low as reasonably achievable" mandate.

V. Logically Inconsistent: Reaffirm the LNT Model, While Abandoning ALARA

The NRC acknowledges that establishing a determinate regulatory dose limit for stochastic health effects is not currently supported by scientific evidence, and the linear dose-response model remains the most appropriate available consensus model for formulating radiation protection standards and planning radiation protection programs.

This position is scientifically sound. However, it is fundamentally at odds with the elimination of ALARA. The LNT model—which the NRC has now twice reaffirmed (in the 1991 rule and again in this 2026 proposed rule)—holds that exposure to radiation at any level can be harmful to human health and result in potentially deadly cancers. There is no safe level of exposure to radiation, and the risk of cancer is proportional to the received dose of radiation.

If no safe level exists, then the regulatory principle of optimization—ALARA—logically follows. To accept LNT while rejecting ALARA is to accept the premise without embracing its logical consequence. This internal contradiction suggests that the proposed rule is driven by policy directive rather than scientific reason or public benefit.

The NRC claims that the NRC's implementation of the ALARA principle as part of its use of the LNT model—in particular, the no threshold aspect of the model—has led to regulatory burden that is not commensurate with the resulting public health and safety benefits. This determination is a policy judgment about cost-benefit trade-offs, not a scientific finding. The NRC has **not provided quantified evidence** of the burden attributable to ALARA, nor has it quantified the specific health benefit foregone by the removal of ALARA.

For a regulator to justify removing a protective principle on grounds of "unnecessary burden," the burden must be **demonstrably disproportionate**, and the protective gain must be **demonstrably minimal**. The NRC has not made a credible argument for either in the administrative record, making this proposed rule arbitrary, capricious, and reckless.

VI. Cumulative Exposure and Vulnerable Population Drift

A. The Case-by-Case Flexibility Creates Incentives for Cumulative Exposure Creep

The proposed rule would apply a graded approach to dose management framework that involves determinate thresholds for radiation protection, methods for dose management, and acceptable exposures. This framework will, inevitably, result in more frequent case-by-case approvals for exposures that would previously have been subject to the categorical mandate that all doses be kept as low as reasonably achievable.

Where regulatory standards shift from "mandatory minimization" to "case-by-case justification," the path of least resistance gravitates toward the regulatory limit. Licensees will develop practices that operate consistently at or near the maximum approved levels for specific situations, because such practices simplify planning and are, by definition, compliant. Individual decisions are rational; aggregate exposure in the regulated industry will increase. Adverse health outcomes and deaths will increase, though for what economic benefit remains uncertain.

B. Pregnant Workers and Their Families Face Dispersed, Persistent Exposures

The problem is compounded for pregnant workers. Pregnant employees who work with or around radiation have the option of declaring their pregnancy, once they themselves are aware of it. But the option to declare would carry an even greater cost. The NRC has taken the position that special protection of the unborn child should be based on decisions made by the workers and employers who are well informed about the risks involved. For the NRC position to be effective, it is important that both the employee and employer understand the risk to the unborn child from radiation received as a result of the occupational exposure of the mother.

Without robust ALARA requirements, employers have less incentive to reorganize work tasks to minimize fetal exposure before a worker declares pregnancy. The burden of risk mitigation falls on the individual, informed worker in a coercive employment context. This is inconsistent with the regulatory principle that occupational hazards should be engineered out, not left to worker vigilance.

C. Communities, Not Just Workers, Require Cumulative Exposure Tracking

The NRC must consider not only occupational exposure to workers but also public exposure. The proposed rule provides no evidence of systems for tracking cumulative community-level exposure over time. If ALARA requirements are removed and case-by-case flexibilities are introduced, how will the NRC prevent a scenario where multiple licensees in proximity to a community, each acting within their approved case-by-case authority, collectively result in untracked cumulative public exposure above reasonable levels?

Ecological data such as Dr. Alwadi's county-level associations suggest that cumulative environmental exposure (whether from routine releases, facility accidents, or occupational pathways) correlates with health outcomes. The regulatory framework must maintain tools to prevent such cumulative effects.

VII. Procedural and Administrative Law Concerns

A. Arbitrary and Capricious: Failure to Respond to Competing Evidence

Under the Administrative Procedure Act, an agency decision is arbitrary and capricious if the agency fails to respond to significant comments or evidence in the record. The presence of Alwadi et al.'s peer-reviewed, Nature Communications findings regarding national associations between nuclear plant proximity and cancer mortality is a significant piece of evidence. The NRC's proposed rule provides no meaningful engagement with these findings.

The NRC may conclude that the findings do not support a change in policy, but the conclusion must be reasoned and supported. Silence or dismissal on the basis of methodological concerns—which the authors themselves acknowledge—does not satisfy the requirement for reasoned decision-making.

B. No Rational Basis for Removing Optimization While Reaffirming LNT

As discussed above, the acceptance of LNT while eliminating ALARA lacks rational basis. The NRC must explain why a non-threshold model of carcinogenic risk is compatible with a regulatory framework that does not require optimization below regulatory limits.

VIII. Specific Requests for NRC Reconsideration

A. Preserve ALARA for Declared Pregnant Workers and Occupational Exposures Affecting Fetuses

At minimum, the NRC should maintain mandatory ALARA requirements for occupational exposures to declared pregnant workers and any exposures that may affect the fetus, including:

- Occupational exposure of pregnant women to external radiation
- Occupational exposure of pregnant women to radionuclides
- Exposures to nursing mothers and their infants
- Exposures to women of childbearing age in roles where pregnancy is likely

The ICRP recommendations for the unborn child of an occupationally exposed female reflect an expectation that the concept of ALARA should be applied to these exposures. Preserving ALARA in this context is consistent with international consensus and responds to the heightened vulnerability of these populations.

B. Require Explicit Cumulative Exposure Accounting for Communities Near Multiple Facilities

The proposed rule should mandate that:

1. NRC licensees near each other coordinate to account for cumulative public and environmental exposure.
2. Where multiple facilities operate within a geographic region, the NRC establishes aggregate exposure limits below the sum of individual limits, and requires each licensee to report actual exposures to a regional registry.
3. Before case-by-case flexibility is granted for increased public exposure, the NRC performs and makes public a cumulative impact assessment at the county or regional level.

C. Commission a Dedicated Review of Alwadi Findings and Their Implications

Before finalizing the rule, the NRC should commission a peer-reviewed, science-based analysis of the Alwadi studies' findings and potential mechanistic explanations. Potential explanations include:

- Differences in occupational practices near older plants.
- Differences in emergency preparedness and accident likelihood.
- Environmental pathways for releases not captured by NRC dose estimates.

- Socioeconomic confounding (though the researchers adjusted for many of these factors).
- True increases in occupational and public exposure from licensed facilities.

The analysis should address whether the findings challenge underlying assumptions about dose-effect relationships or occupational/public exposure estimates.

D. Establish a Fetal Dose Tracking and Reporting Requirement for Declared Pregnancies

Given the heightened sensitivity of fetuses, the NRC should:

1. Require real-time notification to the NRC whenever a declared pregnant worker's cumulative monthly fetal dose approaches half of the 50 mrem monthly guidance level.
2. Require reporting of all declared pregnancies where total fetal dose exceeded 250 mrem (half the 500 mrem annual limit).
3. Establish a national registry of occupational fetal exposures from nuclear facilities, with anonymized data made available for epidemiological research.

This would enable monitoring of whether removal of ALARA leads to higher fetal exposures in practice and would provide data for future refinement of the rule.

IX. Conclusion

The NRC proposes a fundamental reorientation of radiation protection from optimization to threshold compliance. This change is not grounded in science; the NRC reaffirms the LNT model while eliminating the optimization principle that LNT rationally implies. The change is responsive to executive political preference, not to demonstrated public health needs.

At the same time, new epidemiological evidence (Alwadi et al.) raises credible questions about whether current occupational and public exposures near nuclear facilities may be associated with elevated cancer mortality. Pending investigation and explanation of these findings, a reasonable regulator would strengthen protections, not weaken them.

Finally, fetuses and children are demonstrably more sensitive to radiation than adults, and the current regulatory framework already recognizes this through specific protections for declared pregnant workers. Removing the optimization requirement that supports those protections is inconsistent with the science of developmental toxicology and represents

an unwarranted shift of burden from regulated entities to vulnerable workers and their families.

For these reasons, the NRC should:

1. **Reject the proposed elimination of ALARA** as unsupported by science and internally inconsistent with the agency's reaffirmation of the LNT model.
2. **Preserve mandatory ALARA requirements** for all occupational exposures affecting pregnant workers and fetuses, and for all public exposures to communities where children reside.
3. **Commission an independent review** of Dr. Yazan Alwadi's cumulative findings before finalizing any rule that would reduce protective margins.
4. **Establish cumulative exposure accounting and fetal dose reporting** to track whether regulatory flexibility results in higher real-world exposures.

The Samuel Lawrence Foundation acknowledges the NRC's expertise and statutory requirement to balance reasonable regulatory thresholds for the industry with public health outcomes. The proposed rule is not consistent with the agency's previous guidance and represents a step backward in its science-grounded regulatory framework. In wake of current scientific evidence and ongoing research, the rule should be withdrawn or at a minimum substantially revised.

Respectfully Submitted,

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