Samuel Lawrence Foundation

Exemptions From Materials Licensing

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U.S. Nuclear Regulatory Commission

11555 Rockville Pike,

Rockville, MD 20852

Re: Exemptions From Materials Licensing Rulemaking

I. Introduction

The Samuel Lawrence Foundation respectfully submits this comment to the NRC's proposed rule on exempting materials from licensing. Beneficial medical, scientific, and industrial radioisotope applications deserve a regulatory framework that is efficient, proportionate to risk, and understandable to those responsible for implementing it.

Our concern is not that every licensing exemption is unsafe. It is that an exemption's safety depends on the exposure circumstances and protective systems that remain after licensing requirements are removed. SLF asks the Commission to examine this action together with related regulatory changes, rather than assuming that a finding supporting one change necessarily establishes the safety of their combined implementation.

The rule expands exemptions for certain materials and quantities, including revisions connecting Schedule B to Appendix C of Part 20. It also establishes conditional exemptions from individual Commission approval for certain temporary training activities performed under Department of Energy or NRC contracts. These are distinct changes that warrant distinct worker-protection analyses, especially in the wake of loosening workers protections up to and over the previous maximum rem dose.

We request withdrawal of the direct final rule and consideration through the companion proposed-rule process, unless the Commission can resolve the substantive concerns below before implementation. Our objection is specific: exemption thresholds and contract-based safeguards should not substitute for a demonstrated assessment of repeated exposure, internal contamination, chemical hazards, and the interaction of concurrent regulatory changes.

This comment does not claim that the rule has already caused injury or that every newly exempt use will produce a meaningful health risk. Instead, we seek an adequately documented basis for distinguishing genuinely negligible-risk uses from activities whose safety depends on training, containment, monitoring, or oversight that exemption recipients may not possess.

Our principal recommendations are:

1. Publish a provision-by-provision assessment of interactions with related materials-licensing and radiation-protection changes.
2. Explain why the selected exemption quantities remain protective outside licensed radiation-protection programs.
3. Establish explicit safeguards for temporary training activities, including protection of host-site and cleanup workers.
4. Evaluate both radiological and nonradiological hazards where relevant.
5. Identify the agency responsible for each remaining protection and explain how compliance will be verified.

We would support appropriately bounded exemptions if the supporting record demonstrates that these conditions are satisfied. Regulatory modernization should remove unnecessary process while ***preserving*** the functions that prevent exposure and protect workers.

1. Evaluate the combined regulatory environment

The NRC published *Modernizing Materials Licensing* on June 24, 2026, proposing changes to licensing, reporting, recordkeeping, and provisions accommodating new and advanced nuclear fuels. On July 15, 2026, it published *Reforming and Modernizing the NRC's Radiation Protection Framework*, including reconsideration of ALARA and development of a graded approach to dose management. These are relevant companion initiatives, although their publication as proposals must not be confused with completed implementation.

We ask NRC to identify their status when deciding this docket and analyze both the regulatory requirements actually in effect and reasonably foreseeable combinations of finalized changes. This comment does not assume that every proposal will be adopted.

The potential interaction is straightforward, but requires verification: expanded exemptions could place more material outside individual licensing oversight, while other changes could alter the exposure-management or reporting practices used to establish that such exemptions are protective. If an exemption analysis assumes safeguards that another action subsequently changes, the analysis should be revisited.

We recommend a public comparison addressing:

- Which affected activities currently require a license or individualized exemption;
- Which training, surveys, dosimetry, contamination controls, records, and incident reports currently apply;
- Which protections would remain after each relevant change;
- Whether the remaining protections are enforceable requirements, contractual commitments, or voluntary guidance;
- Which agency will inspect or otherwise verify compliance.

This assessment should distinguish licensed manufacturers and distributors from exempt recipients. Safeguards at the point of production should not be presumed to address every exposure during recipient use, maintenance, cleanup, or disposal.

2. Explain the relationship between labeling and licensing thresholds

The connection to Appendix C merits a transparent technical explanation. NRC should identify which assumptions underlying those quantities are appropriate for exempt use and which depend on a controlled workplace.

Our concern is not that Appendix C is intrinsically unsuitable. Rather, a quantity acceptable within one regulatory context should not automatically be treated as suitable in another without examining the different conditions of use.

For each materially changed exemption, NRC should provide the previous and revised quantities, relevant radionuclide characteristics, assumed handling frequency, exposure pathways, and sensitivity to spills or loss of containment. The analysis should explicitly explain whether it assumes trained personnel, intact containers, limited handling, or access to radiation-protection expertise.

3. Preserve effective prevention under any terminology

We are open to a graded approach that focuses resources on consequential hazards. However, replacing terminology should not inadvertently remove practical incentives for preventing avoidable exposure.

We recommend retaining enforceable expectations for proportionate engineering controls, contamination prevention, and investigation of abnormal exposure. If the Commission concludes that these functions are unnecessary for a particular exempt use, it should explain why that

conclusion remains valid under foreseeable repeated handling and reasonably foreseeable deviations from normal conditions.

4. Evaluate exposure, not activity alone

Radioactivity is an important input, but worker exposure also depends on radiation type, geometry, handling duration, containment, and the potential for intake. NRC's radiation-protection framework recognizes radionuclide-specific exposure limits and monitoring requirements; its exemption assessment should explain how those considerations are addressed when individual licensing no longer applies.

We recommend separately evaluating:

- External whole-body, skin, and extremity exposure;
- Inhalation, ingestion, and contamination of wounds;
- Routine handling and reasonably foreseeable accidents;
- Repeated work involving multiple exempt items;
- Exposure during maintenance, cleanup, and waste handling.

For example, NRC should test scenarios involving frequent handling of intact sources, an unsealed-material spill, and accumulation of multiple exempt items at one work location. These are proposed analytical scenarios, not assertions that the rule authorizes every such practice.

The Commission should also explain how existing aggregation or anti-circumvention provisions address cumulative inventories. Where those provisions are sufficient, clearer guidance may be preferable to new requirements. Where they leave an exposure pathway unaddressed, an appropriately tailored restriction should be considered.

5. Interpret low-dose evidence accurately

The 2023 International Nuclear Workers Study examined 309,932 monitored workers and reported a positive association between protracted radiation exposure and solid-cancer mortality. Its relevance is that occupational decisions should consider accumulated exposure over time, not merely the quantity involved in a single task.

This observational evidence does not establish the exact risk of every exempt material, nor does it mean that every very small exposure produces a measurable individual health effect. Its principal focus on monitored external exposure also limits direct extrapolation to different

radionuclides and internal exposures. Nevertheless, uncertainty at very low doses should not be represented as affirmative evidence of zero risk.

We ask NRC to present estimated doses and associated uncertainties, explain the risk model used, and identify assumptions that materially influence its conclusions. It should distinguish estimated individual risk from population effects and avoid implying precision beyond the evidence.

6. Include relevant chemical and physical hazards

Newly exempt radionuclides are not necessarily chemically new materials, and this rule should not be characterized as a general authorization of advanced fuels. Nevertheless, where affected activities involve uranium-bearing materials or other hazardous constituents, a radiological assessment alone may be incomplete.

CDC and ATSDR identify uranium's chemical toxicity, particularly kidney effects, alongside its radiological hazards. The relative importance of those hazards depends on material form and exposure circumstances.

We therefore recommend screening relevant uses for chemical toxicity, airborne particulates, corrosive constituents, and other process hazards. NRC should evaluate these concerns where they actually occur, not assume that all exempt materials exhibit them.

Likewise, combined exposure should be investigated without presuming biological synergy. Where evidence does not support a quantitative interaction estimate, the Commission should describe the uncertainty and identify which controls address each hazard independently.

7. Make contract-based protections explicit and verifiable

Emergency-response and law-enforcement training can serve an important public-safety purpose. We recognize that repetitive approval of substantially identical, well-controlled exercises may impose administrative costs without commensurate benefits.

The rule includes contract-based requirements concerning operating, emergency, leak-testing, and security procedures. Its preamble also identifies DOE occupational radiation protection under 10 CFR Part 835 as a protective framework for the relevant materials. These are meaningful safeguards that should be acknowledged, not overlooked.

The unresolved question is how those safeguards protect everyone who may encounter the materials, particularly at a nonfederal host site. We recommend that NRC explain:

- Who confirms that an activity qualifies for the exemption;

- Who verifies compliance with the contractual procedures;
- Whether trainees, host employees, custodians, and subcontractors receive applicable protection;
- Who can stop an exercise when conditions become unsafe;
- Who investigates a spill, missing source, or unexpected dose;
- Who confirms that the location is suitable for unrestricted subsequent use.

A contract may provide robust protection, but the existence of contractual language alone should not be treated as a complete answer to these implementation questions.

8. Adopt safeguards proportionate to the exercise

We recommend requiring, or demonstrating that an existing enforceable framework already requires:

1. A documented pre-exercise hazard assessment;
2. A designated qualified person responsible for radiation safety;
3. Material accountability before, during, and after the exercise;
4. Participant instruction appropriate to the material and task;
5. Exposure and contamination monitoring where the assessment indicates a need;
6. A response plan for loss of containment or accountability;
7. Documented post-exercise recovery and appropriate site verification.

For detection or equipment-familiarization exercises, we recommend preferential use of nonradioactive simulants or sealed sources where they meet the training objective. This is not a request to prohibit realistic training; it is a request to justify additional exposure potential when a lower-hazard alternative would accomplish the same purpose.

9. Clarify jurisdiction rather than assume a regulatory backstop

OSHA describes a division of occupational radiation responsibilities among federal agencies, Agreement States, and state occupational-safety programs. It should therefore not be assumed that removal of an NRC licensing requirement automatically produces equivalent protection under another agency's rules.

We request a public jurisdictional explanation developed with DOE, OSHA, and relevant state programs. It should identify authority over radiation exposure, chemical hazards, incident reporting, transportation interfaces, and post-activity cleanup.

Protection should follow the exposure pathway, not merely the worker's job title or employer. We particularly recommend considering temporary workers and workers performing cleanup or maintenance, who may be absent from the planning process but present when abnormal conditions are discovered.

10. Consider narrower alternatives

A balanced decision should compare the broad exemptions with alternatives that preserve most administrative savings while addressing uncertain exposure conditions.

We recommend evaluating:

- Exemptions limited to specified material forms or uses;
- Different treatment of sealed and unsealed material;
- Notification or registration instead of individual approval for qualifying exercises;
- Standardized approvals covering recurring, substantially identical activities;
- Additional review only when material, location, exposure potential, or responsible personnel materially change.

These alternatives need not all be adopted. NRC should explain which are unnecessary, which are effective, and whether their costs are proportionate to the risks addressed.

For low-risk activities, concise documentation and standardized procedures may be sufficient. For activities with greater potential for intake, repeated handling, or contamination of shared spaces, stronger conditions may be justified. An exemption framework should make that distinction understandable before work begins.

11. Assess the workers most likely to be overlooked

We recommend evaluating dose and hazard estimates for the most exposed plausible worker, rather than relying solely on an average recipient or average task. Particular attention should be given to frequent handlers, workers rotating among employers or sites, and individuals responsible for recovery after a spill.

The assessment should also consider how information reaches contractors and temporary personnel. We recommend accessible instructions, confidential reporting of safety concerns, and an explicit route for workers to obtain relevant exposure information.

These recommendations do not require collecting unnecessary medical information or presuming that particular groups will be injured. Their purpose is to prevent gaps between the personnel included in a safety analysis and the personnel actually performing the work.

12. Establish a measured implementation review

If NRC proceeds, we recommend a defined post-implementation review using practical indicators such as:

- Reported spills, contamination events, and lost sources;
- Unexpected doses or intakes where monitoring is required;
- Failures to recover training materials;
- Disputes or uncertainty concerning oversight responsibility;
- Corrective actions and lessons learned.

Reporting should be proportionate and should avoid recreating a full licensing system for genuinely negligible-risk uses. Nevertheless, implementation should generate enough information to test important safety assumptions.

We recommend reassessment when evidence shows that actual use differs materially from the scenarios supporting exemption, or when related regulatory changes remove protections relied upon in that analysis.

Conclusion

SLF supports efficient regulation and beneficial nuclear applications. We do not contend that retaining every existing license is necessary, or that administrative simplification inevitably harms workers.

Our position is narrower: **the Commission should demonstrate that the protective functions supporting these exemptions remain effective when this rule operates alongside related regulatory changes.** Where safety depends on containment, instruction, monitoring, or contractual oversight, those dependencies should be explicit and verifiable.

We respectfully request withdrawal of the direct final rule, a substantive response through the companion proposed-rule process, and publication of the interaction and exposure analyses

described above. If NRC demonstrates that existing safeguards already resolve these concerns, we would welcome appropriately targeted exemptions. If important uncertainties remain, narrower exemptions and proportionate conditions would better serve workers, communities, and the American Public.

Respectfully Submitted,

Dr. Bart Ziegler

President and CEO

Samuel Lawrence Foundation

Date: November 4th, 2026