



DEPARTMENT OF ENERGY & ENVIRONMENTAL PROTECTION SMALL BUSINESS IMPACT STATEMENT

**Adoption of RCSA sections 22a-153-1 through 22a-153-150;
 Amendment of RCSA sections 22a-6b-3, 22a-6b-7 and 22a-6b-8;
 Repeal of RCSA sections 19-24-1 through 19-24-14, 19-25a-1 through 19-25a-5 and
 19-25d-1 through 19-25d-11:
 Use and Control of Radioactive Materials, Civil Penalties: Agreement State Phase 1**

Prior to or concomitant with the posting of a notice pursuant to CGS § 4-168a, as amended by Public Act 16-32, each agency shall prepare a regulatory flexibility analysis. Agencies must complete this document and upload it into the eRegulations System prior to posting the Notice of Intent described in CGS § 4-168(a)(1).

Agency Submitting Regulatory Action: Department of Energy and Environmental Protection (DEEP)

Subject of Regulatory Action: Use and control of radioactive material, civil penalties: Agreement State Phase 1

Date Prepared: 11 September 2023

Scope and Objectives of the Proposal:

The main action in this proposal is the adoption of new sections of the Regulations of Connecticut State Agencies (RCSA) concerning users of radioactive material. While the Department currently regulates ionizing radiation through RCSA sections 19-24-1 through 19-24-14 (sources and materials), 19-25a-1 through 19-25a-5, and 19-25d-1 through 19-25d-11 (x-ray devices), those regulatory sections are proposed for repeal. New RCSA sections in the 22a-153-xx series take into account changes in the science and understanding of radiation safety as set out in federal regulations of the Nuclear Regulatory Commission (NRC). The new regulations are consistent with the NRC's regulations, which will result in a more uniform regulatory environment for the regulated sources. Consistency with the federal regulations is achieved through incorporation by reference of the federal regulations.

The requirements incorporated by reference include the NRC's requirements for radioactive materials, particularly licensing, transfers, transportation, monitoring and safety. Because current NRC license holders are now subject to these requirements, they will experience minimal change in the nature of the requirements but will experience improved efficiency by the transfer of the administration of the regulations to the state. Current overlapping state requirements are eliminated, thereby streamlining the requirements on the regulated sources. Licensees will pay the same fee to the state as the fee currently paid to NRC. The proposal incorporates by reference the NRC's small entity provisions,¹ whereby qualifying small entity licensees pay reduced annual fees. Overall, the proposal will result in improved administrative efficiency for businesses with no change in fees charged to businesses.

¹ The NRC identifies several categories of small entities, which are generally defined as having average gross receipts of \$8 million or less over the last 5 years, or 500 or fewer employees. See 10 CFR 171.16(c). The businesses identified as small businesses under CGS section 4-168a are included within the NRC's small entities.

In addition to the incorporation by reference of the NRC's regulations for radioactive material, the proposal adds specific civil penalties for violations of the radioactive materials requirements to the Department's existing civil penalty schedule. Civil penalties for violations are assigned based on the harm to human health and the environment, not the type of violating business. The civil penalties that will be charged by the Department are essentially the same as those now imposed on violators by the NRC.

Please check the appropriate box:

- ☐ The regulatory action will not have an effect on small businesses. *If you check this box, do not complete the remainder of this form.*
- ☒ The regulatory action will have an effect on small businesses but will not have an adverse effect on such small businesses. *If you check this box, complete the remainder of this form.*
- ☐ The regulatory action may have an adverse effect on small businesses, but no alternatives considered would be both as effective in achieving the purpose of the action and less burdensome to potentially effected small business. *Note: alternatives considered may include those listed in C.G.S. § 4-168a(b)(6). If you check this box, complete the remainder of this form.*
- ☐ The regulatory action will have an adverse effect on small businesses that cannot be minimized in a manner that is consistent with public health, safety and welfare. *If you check this box, complete the remainder of this form.*

ANALYSIS

Types of Businesses Potentially Affected by the Proposed Regulation: This set of regulations affects medical, industrial and academic users of radioactive material. This group of entities includes single users such as private practice medical offices that use nuclear medicine and small construction outfits that use road density gauges all the way up to major hospitals and universities.

Total Number of Small Businesses Potentially Subject to the Proposed Regulation: About 110 businesses will obtain licenses under the proposed regulations, and a subset of these businesses (approximately 25%) likely qualify as small businesses as defined in CGS section 4-168a(a)(2).

Will small businesses, in order to comply with the proposed regulation, have additional requirements as listed in C.G.S. § 4-168a(b)(4)? If so, identify the requirements and provide an explanation for each. No, no small businesses will have to newly engage in any of the activities listed in CGS section 4-168a(b)(4) as a result of the adoption of this proposal. Currently, such businesses now are licensed by the NRC and may be conducting such activities as a result of the NRC licensing provisions. As the proposal incorporates the NRC regulations

by reference, putting DEEP into the place of the NRC in administering the regulations, the regulated businesses will continue to perform the same activities under the regulatory authority of DEEP. The proposal does not add new requirements on the regulated businesses.

Has the agency communicated with small businesses or small business organizations in developing the proposed regulation and the regulatory flexibility analysis, if applicable? If so, to what extent? DEEP is conducting outreach to a group of stakeholders from the regulated community, some of whom are small businesses. DEEP has been accompanying NRC personnel on inspections including inspections of small businesses with radioactive material licenses. As part of these inspections, DEEP personnel are meeting with the small business owners to explain the process and address concerns. DEEP has also reached out to the Connecticut Chapter of the American College of Cardiology to reach small cardiology offices using nuclear medicine.

Does the proposed regulation provide alternative compliance methods for small businesses that will accomplish the objectives of applicable statutes while minimizing the adverse impact on small businesses? If so, to what extent? In general, the proposal does not provide new compliance methods for small businesses. The standards in the proposal are risk-based such that regulatory requirements are commensurate with the level of radiation risk. The regulations include appropriate exemptions for low-risk activities engaged in by small businesses, to limit the administrative burden on small businesses while still protecting public health and safety. High risk activities are necessarily more highly regulated, but such activities are not engaged in by small businesses.

With regard to licensing fees, the proposal incorporates by reference the NRC's "small entity" provisions, where qualifying small entities are assigned reduced annual licensing fees. Small businesses will experience no change in the level of fee from that currently charged by the NRC.