

**ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT FOR THE
DIRECT FINAL RULE AMENDING 10 CFR PART 50:
DEFINITION OF A UTILIZATION FACILITY**

**Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
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I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to add SHINE Medical Technologies, Inc.'s (SHINE) proposed accelerator-driven subcritical operating assemblies to the NRC's definition of a "utilization facility" under Part 50 of Title 10 of the Code of Federal Regulations (10 CFR), "Domestic Licensing of Production and Utilization Facilities." In 2013, SHINE submitted a two-part construction permit application for a medical radioisotope production facility that SHINE proposes to build in Janesville, Wisconsin. The proposed accelerator-driven subcritical operating assemblies, to be housed in SHINE's irradiation facility, would be used to produce molybdenum-99 (Mo-99), a radioisotope used in medical imaging.

This rule allows the NRC staff to apply appropriate regulations to the application and conduct an efficient and effective licensing review of the irradiation facility described in the SHINE construction permit application and any subsequent operating license application 10 CFR Part 50. Therefore, in support of this rulemaking, and as required by 10 CFR 51.21, the NRC staff has performed an environmental assessment.

II. Environmental Assessment

Facility Site and Environs:

If licensed, the SHINE facility would be constructed and operated on a 91 acre (36.8 hectare) site in Rock County, approximately 4 miles (6.4 kilometers) south of the Janesville, WI city center.

Identification of the Action:

The action will amend the NRC's regulations in 10 CFR 50.2 to add SHINE's accelerator-driven subcritical operating assemblies, as described in the application assigned docket number 50-608, to the definition of utilization facility in 10 CFR 50.2.

The action allows the NRC staff to review the irradiation facility described in SHINE's construction permit application in docket number 50-608 (the NRC's Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML130880226 and ML13172A324) under the regulations in 10 CFR Part 50.

The Need for the Action:

As summarized in SHINE's Preliminary Safety Analysis Report (PSAR), SHINE has proposed to construct eight irradiation units to be collectively housed in an irradiation facility. Each irradiation unit is an independent accelerator-driven subcritical operating assembly used for the irradiation of an aqueous uranyl sulfate target solution, resulting in the production of Mo-99 and other fission products. The proposed irradiation units do not fit the definitions of either production facility or utilization facility currently found in 10 CFR 50.2. However, based on SHINE's proposed use of special nuclear material, the Commission could use its authority under the Atomic Energy Act of 1954, as amended, to promulgate a rule that adds the SHINE irradiation units to the Commission's definition of utilization facility in 10 CFR Part 50. Furthermore, each irradiation unit has many of the attributes of existing non-power reactors, which are licensed as utilization facilities. Therefore, the NRC will modify the definition of utilization facility found in 10 CFR 50.2 to add SHINE's proposed accelerator-driven subcritical operating assemblies. The amended regulation allows the NRC staff to review the irradiation units discussed in SHINE's construction permit application using the most appropriate regulations to ensure protection of the public health and safety and promotion of the common defense.

Environmental Impacts of the Action:

This environmental assessment focuses on the environmental effects of the change to the NRC's regulation defining a utilization facility. This action will have no environmental effect on existing or future applications or licenses. As a result of this rule change, the accelerators integrated into the SHINE irradiation units will be considered part of the utilization facilities, and will be under the regulatory jurisdiction of the NRC. Because the rule is narrowly focused to only add the accelerator-driven subcritical operating assemblies proposed under docket number 50-608 to the definition of utilization facility in 10 CFR 50.2, this rule change only impacts the regulatory framework for the review of the SHINE construction permit application (and if requested in the future, an operating license), and therefore involves no adverse environmental impacts.

The principal effect of this action is to revise the definition of utilization facility to encompass the SHINE irradiation units, therefore enabling the NRC staff to conduct a technical review of the SHINE irradiation facility under the regulations that are most appropriate for adequate protection of the health and safety of the public. This action does not authorize the issuance of a construction permit or operating license for the SHINE irradiation units and is not a determination that the SHINE irradiation units can meet the applicable requirements in 10 CFR Part 50. A determination of whether the SHINE irradiation units can be licensed under 10 CFR Part 50 will be evaluated separately by the NRC staff as part of the review of the SHINE preliminary and final safety analysis reports. Additionally, an opportunity for the public to request for leave to intervene and request a hearing on the application will be provided by a separate notice in the *Federal Register*. Therefore, the amendment to the regulations does not authorize any release of effluents, involve any individual or cumulative exposures, or create any potential for radiological accidents. In addition, the rule does not authorize any construction, land disturbance, or transportation. As a result, there are no significant radiological or non-radiological environmental impacts associated with the action.

Accordingly, the NRC staff has concluded that there are no significant radiological environmental impacts, non-radiological impacts, or cumulative impacts associated with this change to the definition of utilization facility in 10 CFR 50.2, and pursuant to 10 CFR 51.32, determined that the granting of this exemption will not have a significant effect on the quality of the human environment as it is administrative in nature. Therefore, the NRC concludes that there are no significant environmental impacts associated with the action.

Environmental Impacts of the Alternatives to the Action:

As an alternative to the action, the NRC staff considered not taking the action (i.e., the no action alternative). This alternative would result in no changes in environmental impacts. The no action alternative would result in the NRC staff reviewing the irradiation units under 10 CFR part 70. Reviewing the irradiation units under 10 CFR part 70 would have no different environmental impacts than reviewing them under 10 CFR part 50. In either case, the NRC staff would perform a thorough safety, environmental, and security review, and would determine whether to issue a construction permit or operating license using applicable regulatory and statutory requirements. Because this rulemaking does not authorize the issuance of a construction permit or operating license, any eventual licensing decisions would be a separate action from this rulemaking and the environmental impacts of those licensing actions, if authorized, would be evaluated separately.

Given that the direct final rule and the no action alternative do not constitute actions that authorize issuance of a construction permit or operating license, and hence, do not cause any radiological or non-radiological impacts, the environmental impacts of the action and the alternative actions are the same.

Alternative Use of Resources:

There are no irreversible commitments of resources determined in the environmental assessment of this rulemaking action.

Agencies and Persons Consulted:

No agencies or persons outside of the NRC were consulted about the potential environmental impacts of this rulemaking action.

III. Finding of No Significant Impact

The NRC is issuing a direct final rule that will amend 10 CFR Part 50 to add SHINE's accelerator-driven subcritical operating assemblies to the definition of utilization facility in 10 CFR 50.2. On the basis of the environmental assessment included in Section II of this document and incorporated by reference in this finding, the NRC concludes that the action will not have significant effects on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the action. Additional information on the SHINE environmental report submitted under docket No. 50-608 in support of the SHINE construction permit application is publicly available in ADAMS, Accession No. ML13172A324.