Department of Energy
Office of Science
Brookhaven Site Office
P.O. Box 5000
Upton, New York 11973

December 16, 2022

Dr. Doon Gibbs, Director
Brookhaven Science Associates, LLC
Brookhaven National Laboratory
Upton, NY 11973

Dear Dr. Gibbs:

SUBJECT: SUPPLEMENTAL GUIDANCE FOR SAFETY-IN-DESIGN OF THE CLINICAL ALPHA RADIONUCLIDE PRODUCER (CARP)

Department of Energy (DOE) Standard (STD) 1189-2016, *Integration of Safety into the Design Process,* and DOE Order (O) 413.3B, *Program and Project Management for the Acquisition of Capital Assets,* require that the DOE provide expectations for the execution of safety-in-design efforts. DOE-STD-1104-2016, *Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents,* also adds that DOE expectations for safety-in-design developed during the pre-conceptual phase evolve into the Safety Design Strategy (SDS) during the conceptual phase of the project. The SDS will guide the integration of safety during the pre-conceptual, conceptual, preliminary, and final design phases.

The attachment to this letter provides SC's high-level expectations for safety-in-design integration for the CARP project. These expectations will support the tasks necessary for the critical decisions associated with the major modification of an existing below Hazard Category 3 nuclear facility into a Hazard Category 2 or 3 nuclear facility and ensures that the nuclear safety documentation submitted meets DOE expectations.

BSA is directed to implement the expectations of the attachment, utilize its lessons learned from successful prior projects, and inform BHSO of its implementation approach. This direction supersedes any previous direction and will continue until rescinded, amended, or superseded in writing.

Please contact Gary Olson at extension 3433, if you have any questions regarding this matter.

Sincerely,

Fausto R. Fernandez | Contracting Officer
Director, Business Division
U.S. Department of Energy | Brookhaven Site Office

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Attachment:
Safety-in-Design Expectations for Clinical Alpha Radionuclide Producer (CARP)

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Attachment 1

Safety-In-Design Expectations for Clinical Alpha Radionuclide Producer (CARP)

The Department of Energy (DOE) expects that safety considerations will be adequately integrated not only in the Safety Design Strategy (SDS), but also in the conceptual and preliminary design phases, and into the final design leading to the development of the Conceptual Safety Design Report and Preliminary Documented Safety Analysis. DOE further expects that the proper safety experts will be appointed to the Safety Design Integration Team (SDIT) and that they will participate and guide the design as it evolves. Safety disciplines that shall be considered in selecting SDIT members include, but are not limited to:

- Technical and process safety,
- Nuclear, criticality and radiation safety,
- Instrumentation and controls,
- Fire and explosive safety,
- Electrical safety,
- Environmental release,
- Seismic, flood and other natural hazards,
- Construction safety,
- Hazard and safety analyses,
- Quality assurance,
- Chemical hazard safety, and
- Waste management.

The Department expects that the team developing the CARP facility design and associated safety design documents will adhere to the following safety design guiding principles and key concepts in the development of the project requirements, in accordance with DOE-STD-1189-2016:

- Ensure compliance with DOE orders and standards, including DOE Order (O) 420.1 C, Chg 3, *Facility Safety*, and DOE-STD-1189-2016. Safety must be integrated into the design early, and throughout the design process through use of DOE-STD-1189-2016 [DOE O 420.1C, Chg 3].

- The nuclear facility design must include multiple layers of protection (as part of the design defense-in-depth) to prevent or mitigate the unintended release of radioactive materials into the environment [DOE O 420.1C, Chg 3].

- Minimization of hazardous materials (radiological and chemical) to those necessary to accomplish the mission [DOE O 420.1C, Chg 3].

- Requirements applicable to the design and safety basis analysis for the CARP facility shall be identified and documented.

- Seismic design considerations, along with other relevant natural phenomena hazards, will be evaluated and included in the design as required in DOE O 420.1C, Chg 3, and DOE-STD-1020-2016, *Natural Phenomena Hazards Analysis and Design Criteria for DOE Facilities*.

- Safety analyses must be used to [DOE O 420.1C, Chg 3]:

    - Identify safety-class and safety-significant structures, systems, and components (SSC) needed to fulfill the safety functions in order to prevent and/or mitigate design basis accidents, including natural and person-induced hazards and events,
    - Identify the safety functional requirements of the safety class and safety-significant SSCs, and,
    - Identify Specific Administrative Controls needed to fulfill safety functions. (Note: See DOE-STD-1186-2016, Specific Administrative Controls, for details on specific administrative controls.)

- Nuclear safety events with impacts on the in-facility or co-located workers, as outlined in DOE-STD-3009-2014, shall also be considered in the design aspects of the facility.

- Application of the Hierarchy of Controls will be utilized to develop a robust safety envelope for the CARP facility [DOE-STD-3009-2014]:

    - Engineered Controls (EC) and SSCs that are preventive and passive.
    - ECs and SSCs that are preventive and active.
    - ECs and SSCs that are mitigative and passive.
    - ECs and SSCs that are mitigative and active.
    - Administrative Controls (AC) that are preventive.
    - ACs that are mitigative.

- Hazard and accident analysis must meet the expectations of DOE-STD-3009-2014 unless an alternate approved safe harbor is approved by DOE. The hazard and accident analysis should consider lessons learned and best practices from Nuclear Regulatory Commission and American National Standards Institute guides and standards.

- The potential impacts of research and development (R&D) in the CARP will be considered as part of the design, and a strategy to ensure safety while allowing execution of the R&D mission will be developed. Implementing R&D missions

will need to be considered in the hierarchy of controls established via DOE-STD-3009 and required for this project.

- The CARP facility shall incorporate the following safety- in- design principles:

    - Conservative Design Margin - Safety SSCs must be designed with appropriate margins of safety, as defined in applicable DOE or industry codes and standards [DOE O 420.1C, Chg 3].
    - System Reliability - The single failure criterion, requirements, and design analysis identified in Institute of Electrical and Electronics Engineers (IEEE) 379, IEEE Standard for Application of the Single-Failure Criterion to Nuclear Power Generating Station Safety Systems (or an agreed upon standard), must be applied to safety class SSCs. SSCs for the protection of the worker must be designed to reliably perform all their safety functions [DOE O 420.1C, Chg 3].
    - Potential consequences to members of the public must be considered during the upgrade of the CARP facility. The site boundary and the challenge threshold which the facility will use for offsite consequences will be defined early in the process as part of the SDS. Alternatives for DOE consideration will be developed as part of conceptual design. Material-at-Risk from all sources will be included in this calculation.
    - Environmental Qualification – Safety class SSCs must be designed to perform all safety functions with no failure mechanism that could lead to common cause failures under postulated service conditions. The requirements of IEEE 323, Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations (or an agreed upon standard), must be used to ensure environmental qualifications of safety class SSCs. Safety SSCs located in a harsh environment must be evaluated to establish qualified life [DOE O 420.1C, Chg 3].
    - Safe Failure Modes – The facility design must provide reliable safe conditions and sufficient confinement of hazardous material during and after all design basis accidents [DOE O 420.1C, Chg 3].
    - Support System and Interface Design – Support SSCs must be designed as safety SSCs if their failures prevent safety SSCs from performing their safety functions. Interfaces such as pressure retention boundaries, electrical supply, instrumentation, cooling water, and other support systems may exist between safety SSCs and non-safety SSCs and should be identified as part of the SDS. These interfaces must be evaluated to identify SSC failures that would prevent safety SSCs from performing their intended safety function [DOE O 420.1C, Chg 3].
    - Protection Against Fire – Safety class systems must be designed with redundancy or other means, such that safety function is maintained for any

postulated fire events that credit the safety class systems [DOE O 420.1C, Chg 3].
    - Quality Assurance – Components and processes will be designed and procured considering applicable quality assurance requirements established in 10 CFR 830, Subpart A, "*Quality Assurance,"* and DOE O 414.1D, *Quality Assurance*.

- Application of the principles of integrated safety management will be utilized through the design phase [DOE-STD-1189].

    - Safety personnel are incorporated into the integrated project team from the onset of project planning such that safety decisions are made at appropriate and cost-effective times.
    - Risk and opportunity assessment consider safety-in-design, mitigating future cost escalation, and schedule inefficiencies.
    - Starting with the submittal and approval of the Preliminary Documented Safety Analysis (PDSA), apply a change control process to the PDSA, consistent with DOE-STD-1189-2016, section 3.8.3.

- Full life-cycle considerations should be analyzed to facilitate safety deactivation, decommissioning, decontamination, and demolition at the end of the facility [DOE O 420.1C, Chg 3].

- Exemptions, or equivalencies to Orders, Standards, and applicable consensus standards, will be processed in accordance with DOE O 251.1D, *Departmental Directives Program,* or alternate processes provided in the applicable directives themselves and provided to the Central Technical Authority for concurrence [DOE O 251.1D, DOE O 410.1].

DOE expects that facility management should establish a Cognizant System Engineer Program as early as possible to ensure its stability and operation at Critical Decision - 4.

DOE expects that the Safety Design Strategy will be created and updated to reflect these safety expectations throughout the design process. Codes and Standards will be updated and refined through the design process and will be captured in a Code of Record.