

A large, stylized graphic of an atomic symbol, consisting of a central blue sphere and three intersecting elliptical orbits in shades of blue, positioned on the left side of the slide.

Assessment by Licensees, Applicants, and Suppliers of Laboratories Owned by the U.S. Department of Energy

8th NRC Workshop on Vendor Oversight

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Agenda

- Background
- Department of Energy's National Laboratories
- Regulatory Position
- Examples
- Regulatory Issue Summary
- Questions

Background

- In a letter dated May 9, 2013, the NRC staff issued its Final Safety Evaluation Report for Technical Report NEI 11-04, “Quality Assurance Program Description,” Revision 0.
- NEI 11-04 provides a Quality Assurance (QA) template for applicants of Part 52 permits or licenses to use in meeting the requirements of Appendix B to 10 CFR Part 50.

Background

- QA template stated:
 - *[...] considers that other 10 CFR Parts 50 and 52 licensees, Authorized Nuclear Inspection (ANI) Agencies, National Institute of Standards and Technology (NIST), or other State and **Federal Agencies** which may provide items or services to the [...] plants are not required to be evaluated or audited.”*

Background

- The NRC staff determined this exception to be acceptable in the Final Safety Evaluation Report.
- The NRC staff received several questions from stakeholders regarding the applicability of this exception to Department of Energy's (DOE) national laboratories.
- The NRC staff held two briefings with DOE Senior staff to ensure alignment.

Department of Energy's National Laboratories

- DOE maintains the national laboratories as **GOCOs** - **G**overnment **O**wned and **C**ontractor **O**perated.
- Contractors may be individual universities, university consortia, private companies, or nonprofits.
- GOCO researchers are **NOT** Federal employees.

Regulatory Position

- National laboratories owned by the DOE are **NOT** considered to be a Federal agency.
- When procuring an items or services for use in a safety-related application, licensees, applicants, and suppliers are responsible for:
 - verifying the effective implementation of the laboratories' programmatic quality controls
 - maintaining 10 CFR Part 21 responsibility

Examples

- Example 1: An advanced reactor applicant procures a safety-related item or service from DOE.
 - Is the applicant required to audit the DOE?
 - **No, DOE is a Federal agency covered under the exception.**

Examples

- Example 2: An advanced reactor applicant procures an item or service that will be used in a safety-related application from Idaho National Laboratory (INL).
 - Is the applicant required to verify the effectiveness of INL's QA program?
 - **Yes, INL is not a Federal agency.**

Examples

- Example 3: I need to procure a testing service for a safety-related application from Argonne National Laboratory.
 - How can I procure this service?
 - Perform commercial-grade dedication of the testing service.

Regulatory Issue Summary

- NRC staff working on a Regulatory Issue Summary (RIS) to document the staff's regulatory position.
- RIS expected to go out for public comment in the Summer.
- Expected issue date towards the end of 2022/early 2023.

Questions

