



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

8th NRC Workshop on Vendor Oversight

**Yamir Diaz-Castillo
NRR/DRO/IQVB
June 1, 2022**

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

