

**Project Justification Statement**  
**Proposed Revision to:**

**DOE-STD-1112-2016, *Department of Energy Laboratory Accreditation Program for Radiobioassay***

1. Organization Name/Code.

Office of Worker Safety and Health Policy, AU-11

2. Author's Name (Contact Information: Phone, E-mail).

James R. Dillard

Phone: 301-903-1165

E-mail: [james.dillard@hq.doe.gov](mailto:james.dillard@hq.doe.gov)

3. Senior Line Manager (First SES-level manager above the author).

Bill McArthur, Director, AU-11

4. How will this new or proposed revision to the DOE Technical Standard support DOE?

DOE-STD-1112-2016, *Department of Energy Laboratory Accreditation Program for Radiobioassay* be updated to include the requirements that are currently used to conduct on-site assessments of accredited programs and to reflect current practices and standards. The update aims to increase the quality of DOELAP accreditation, but should only have a minor impact on current DOELAP programs through the streamlining of DOELAP requirements. It will have a major positive impact on new DOELAP programs because it will provide clear direction on DOELAP requirements.

5. After conducting a search for Voluntary Consensus Standards, what possible standards were considered for use in lieu of developing or revising the subject DOE Technical Standard?

No consensus standard meets all of the requirements needed for this Technical Standard. This technical standard does reference the following standards:

- ISO 17025, *General requirements for the competence of testing and calibration laboratories.*
- ANSI N13.30, *Performance Criteria for Radiobioassay*

6. Provide reasoning for not using potentially applicable Voluntary Consensus Standards.

DOE-STD-1112 describes the requirements for the Department of Energy Laboratory Accreditation Program (DOELAP) for Radiobioassay. Because DOELAP is specific to DOE, there are no Voluntary Consensus Standards that set forth all of the requirements for a

radiobioassay program to obtain and maintain DOELAP accreditation. When possible, DOELAP does incorporate Voluntary Consensus Standards and this standard refers to ANSI N13.30 for performance testing requirements.

7. Will this new or proposed revision to the DOE Technical Standard have an impact on any DOE Directives or a Rule? If so, please list the impacted Directive(s) or Rule(s).

10 CFR 835 requires programs to participate in DOELAP; however, the Rule does not specifically refer to this revised standard.

8. Provide reasoning for selecting document type (DOE Standard, DOE Handbook, DOE Specification). Please refer to DOE O 252.1A, Technical Standards Program, Appendix A, Technical Standard Document Types. Note: DOE Handbooks must not include requirements statements (“shall” statements).

This document is consistent with DOE O 252.1A, Appendix A;

1. DOE Standards
  - a. Provide specific standardized approaches, methodologies, and technical criteria, or other information on accomplishing a task, developing a plan, and/or performing a calculation or assessment to implement a DOE requirement.
9. Provide target development milestones:
  - a. Planned Start (October/2018) – Start developing draft
  - b. Planned Coordination (February/2018) – Submit for TSP RevCom Review
  - c. Planned Completion (May/2018) – Approval and Issuance