

DESIGN CONTROL

1.0 Objective

The objective of this surveillance is to evaluate the effectiveness of the laboratory's design control program. The surveillance encompasses design input, design output, and design control. The Facility Representatives or Environmental, Safety, and Health Support Specialists will evaluate implementation of the program as well as compliance with applicable DOE requirements.

2.0 References

- 2.1 DOE 5700.6C, *Quality Assurance*
- 2.2 10 CFR Part 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*
- 2.3 10 CFR 830.120, *Quality Assurance Requirements for DOE Nuclear Facilities*
- 2.4 NQA-1-1989, *Quality Assurance Program Requirements for Nuclear Facilities*

3.0 Surveillance Activities

The Facility Representative or Environmental, Safety, and Health Support Specialist reviews a design change package that has been approved and released to the maintenance or construction organization for implementation. The Facility Representative also reviews a design change package that has been implemented and closed out.

**Surveillance Guideline
DESIGN CONTROL**

Surveillance No.: _____

Facility: _____

Date Completed: _____

YES NO N/A

Activity One - Review of Design Change Package Released for Implementation

- | | | | | |
|----|--|-------|-------|-------|
| 1. | Were the design requirements clearly established? | _____ | _____ | _____ |
| 2. | Were appropriate codes and standards, including the requirements of DOE's general design criteria (DOE 6430.1A) properly applied in the design? | _____ | _____ | _____ |
| 3. | Were appropriate drawings, specifications, instructions, or procedures prepared based on the design requirements? | _____ | _____ | _____ |
| 4. | Was an independent technical review of the design change performed before it was released for installation? | _____ | _____ | _____ |
| 5. | Was the review performed by a technically qualified reviewer independent of the original design? | _____ | _____ | _____ |
| 6. | Were all potentially affected groups, such as Operations, Radiological Control, and Industrial Safety, given an opportunity to review the design change package? | _____ | _____ | _____ |
| 7. | Were appropriate calculations or analyses performed to substantiate the adequacy of the design? | _____ | _____ | _____ |
| 8. | Are complete records available to substantiate intermediate steps in the design process such as calculations, computer programs and pertinent testing? | _____ | _____ | _____ |

**Surveillance Guideline
 DESIGN CONTROL (cont.)**

	<u>YES</u>	<u>NO</u>	<u>N/A</u>
9. Was the design change reviewed to determine if it might create an Unreviewed Safety Question?	_____	_____	_____

Depending on laboratory programs, a screening may have been performed to determine if a formal evaluation of the potential for an Unreviewed Safety Question was required.

NOTE

Activity Two - Review Implementation of a Design Change

10. Are complete records available documenting the design change, any changes to the design documents subsequent to first issuance, and final acceptance testing?	_____	_____	_____
11. Do design records include substantiation of intermediate steps in the design process such as calculations, computer programs, and pertinent testing?	_____	_____	_____
12. Was the original design subjected to an independent design review before the design was released for fabrication/installation?	_____	_____	_____
13. Was the review performed by a technically qualified reviewer who was independent of the original design?	_____	_____	_____
14. Were all changes to the design after its initial issue, including field changes, modifications, and nonconformances, also subjected to an independent technical review?	_____	_____	_____
15. Did acceptance testing verify that the design change met the		o	r

ginal design requirements?

16. Did acceptance testing address the most adverse conditions under which a component must perform its function?

**Surveillance Guideline
 DESIGN CONTROL (cont.)**

	<u>YES</u>	<u>NO</u>	<u>N/A</u>
17. Does the as-installed configuration match the final design documents?	_____	_____	_____
18. Have procedures, shift orders, round sheets or other operations documents been modified to reflect the design modification?	_____	_____	_____
19. Have operations personnel been trained on the modification and does training material correctly reflect the modification?	_____	_____	_____
20. Have documents that define the facility's configuration, including Safety Analysis Reports, drawings, system descriptions, etc., been revised to reflect the modification?	_____	_____	_____
21. Was the design change reviewed to determine if it might create an Unreviewed Safety Question?	_____	_____	_____

Depending on laboratory programs, a screening may have been performed to determine if a formal evaluation of the potential for an Unreviewed Safety Question was required.

NOTE

22. Were all changes to the design also reviewed to determine if they might result in an Unreviewed Safety Question? (S e n

ote above)

OTHER:

Surveillance Guideline
DESIGN CONTROL (cont.)

YES NO N/A

OTHER (cont.)

NOTES/COMMENTS:

PERSONNEL CONTACTED: _____

**Surveillance Guideline
DESIGN CONTROL (cont.)**

DESIGN CHANGE PACKAGES REVIEWED: _____

**IF MORE SPACE IS NEEDED FOR FINDINGS, OBSERVATIONS, AND FOLLOWUP
ITEMS - USE ADDITIONAL SHEETS**

FINDINGS:

Finding No.: _____

Description: _____

Finding No.: _____

Description: _____

Surveillance Guideline
DESIGN CONTROL (cont.)

Finding No.: _____

Description: _____

OBSERVATIONS:

Observation No.: _____

Description: _____

Observation No.: _____

Description: _____

Surveillance Guideline
DESIGN CONTROL (cont.)

Observation No.: _____

Description: _____

FOLLOWUP ITEMS:

Followup Item No.: _____

Description: _____

Followup Item No.: _____

Description: _____

Surveillance Guideline
DESIGN CONTROL (cont.)

Followup Item No.: _____

Description: _____

LABORATORY MANAGEMENT DEBRIEFED AND RESULTS: _____

Signature: _____ Date: _____

Facility Representative or
Environmental, Safety, and Health Support Specialist