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.)

		YES	NO	N/A
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 i	

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.)

		YES	NO	N/A
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 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