NRC OVERSIGHT OF THIRD-PARTY ORGANIZATIONS IMPLEMENTING QUALITY ASSURANCE REQUIREMENTS

PROGRAM APPLICABILITY: 2507 and 2700

43005-01 INSPECTION OBJECTIVES

01.01 To verify, by direct observation, the effectiveness of the independent oversight activities performed by third-party organizations to qualify vendors in accordance with the requirements of Appendix B to 10 CFR Part 50.

01.02 To verify that the vendor has established and implemented an adequate system for evaluating deviations and reporting defects and noncompliance in accordance with 10 CFR Part 21 requirements.

This procedure is to be used concurrent with the following inspection procedure: Inspection Procedure (IP) 36100, “Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Noncompliance.”

43005-02 INSPECTION REQUIREMENTS

02.01 Observe third-party organization's implementation of oversight activities (i.e., safety-related audits, commercial grade surveys, and vendors certifications) used to qualify vendors who supply safety-related components or services to the nuclear industry.

02.02 Conduct an inspection of the vendor’s 10 CFR Part 21 program utilized for reporting defects and noncompliance.

43005-03 INSPECTION GUIDANCE

03.01 Observation of oversight activities.

a. Preparation activities. Notify appropriate contact person of the organization (e.g., Nuclear Utility Procurement Issues Committee Chairman) of intent to observe activities within a reasonable time frame, between 30 to 90 days, prior to the scheduled start date.

   It is expected that the organization:

   1. Communicate the NRC's interest to participate as an observer to the appropriate team leader.

2. Include the NRC inspector(s) on distribution of all correspondence, including notification letter, activity plan, schedule and logistics, audit report and follow-up correspondence, including significant notifications issued to other members of the organization as a result of the activities performed.

b. Observation activities. Observe the third-party organization's implementation of activities, including daily meetings.

In the event of a situation in which the organization's team is not recognizing a compliance issue, communicate the issue to the organization's team leader and, as appropriate, document the issue in the trip report, including any actions taken by the appropriate organization's team leader. Allow enough time for the organization's team to recognize the issue before communicating it to the organization's team leader.

c. Documentation. Prepare a trip report documenting the effectiveness of the independent oversight activities performed by third-party organizations, including any issue discussed during the observation with the organization's team leader. The trip report is directed to the Director of the Division of Construction Inspection and Operational Programs (DCIP) in the Office of New Reactors and the Director of the Division of Engineering in the Office of Nuclear Reactor Regulation.

d. Follow up. As needed, send a letter to the organization to address any issue documented in the trip report. When possible, the NRC will discuss the trip report at the next scheduled periodic meeting with the organization.

03.02 10 CFR Part 21 inspection.

a. Preparation activities.

1. Through an initial telephone call and followup with a letter, inform the vendor of the NRC's participation as observer in the oversight activities performed by the third-party organization and of the NRC's plans to inspect the vendor's 10 CFR Part 21 program.

2. Prepare an Inspection Plan following the guidance of Manual Chapter 0613.

b. Inspection activities. Follow IP36100 for inspection activities. Participate in entrance and exit meetings performed by the organization and communicate to the vendor the areas to be inspected by the NRC. As needed, participate in daily meetings during the course of oversight activities to communicate any issue to the vendor related to its 10 CFR Part 21 program and to discuss preliminary findings.

c. Documentation. Prepare an Inspection Report following the guidance of Manual Chapter 0613 to communicate observations and any findings in the area of 10 CFR Part 21 program implementation to the vendor.

43005-04 RESOURCE ESTIMATE

The resource estimate for this inspection procedure is approximately 80 hours of direct observation and inspection.

END

Attachment 1: Revision History

Attachment 1

Revision History Sheet for IP 43005

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Ascension #
N/A	10/03/07 CN 07-030	1. Initial issue to support inspections of vendor programs described in IMC 2507 and 2700. 2. Researched commitments for 4 years and found none.	N/A	N/A	N/A