

**Example of  
Audits and Inspection Activities  
for a Modification Performed  
Under the ISG-06, Rev. 2  
Alternate Review Process**

**Draft ISG-06, Rev. 2  
NRC Inspection Workshop  
November 15, 2018**

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# Example Purpose

To identify the types of LAR Review Audits and Post-LA NRC Inspection Activities that would be performed in relation to an ISG-06 Alternate Review Process License Amendment Request (LAR).

The example is based on the Oconee RPS/ESFAS digital instrumentation and controls (DI&C) Modification using the Alternate Review Process.

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# Reference Material

Oconee License Amendment (with Safety Evaluation): [ML100220016](#)

Oconee Audit Reports:

- July 23, 2008: [ML081900197](#)
- November 12, 2008: [ML083080453](#)

Note: June 11, 2009 and June 22, 2009 audit reports are proprietary

Oconee Recommended Inspection Items: See Section 3.14 of the Safety Evaluation

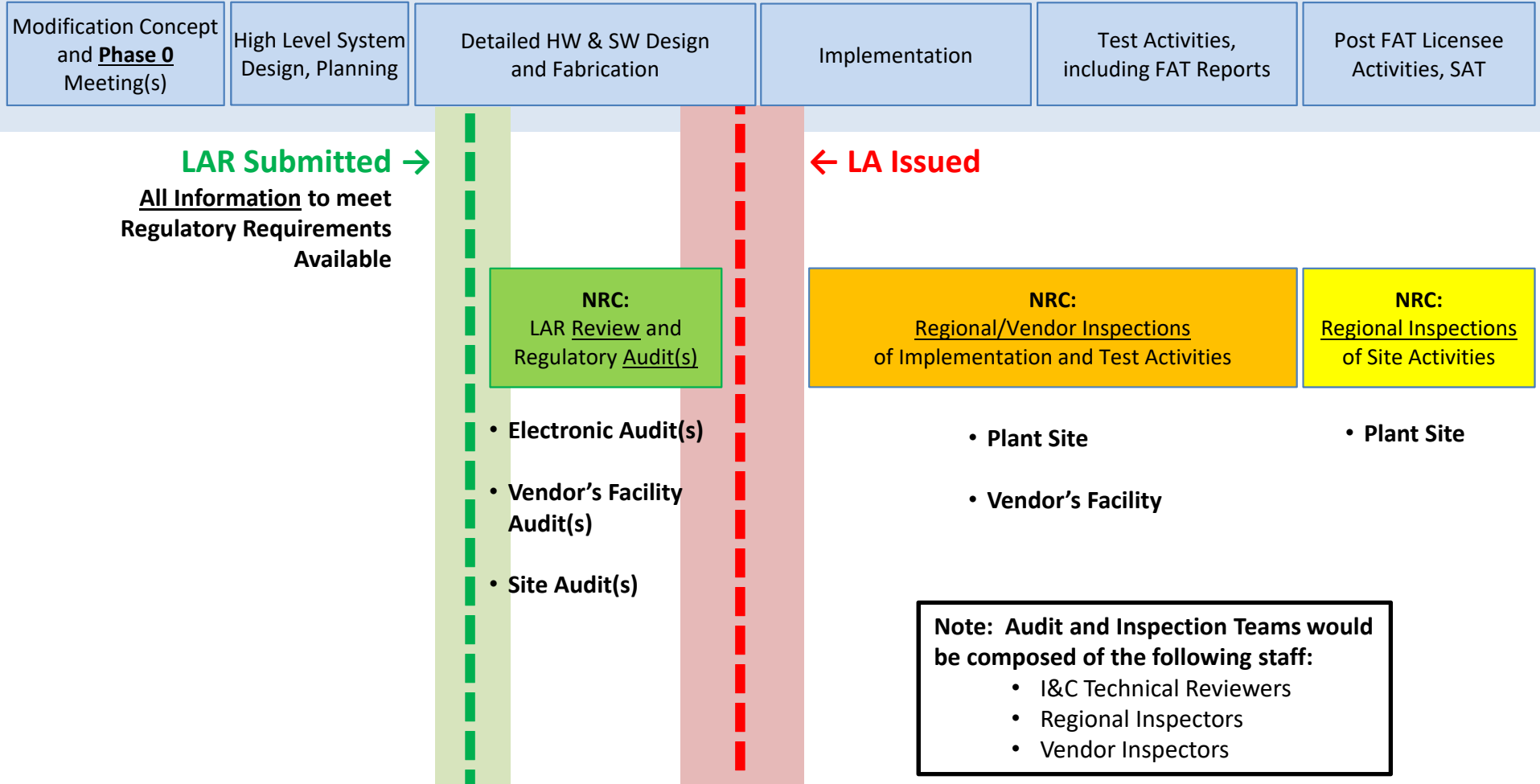
Oconee Inspection Reports:

- March 0, 2012: [ML12069A088](#)

Vendor Oversight Plan (VOP) Description Example: Provided by NEI

# Alternate Review Process Licensing and Oversight Activities

## Timeline →



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# LAR Review Audit(s)

## Electronic Audit(s):

- Audit of non-docketed material in response to open items\*

## Audit(s) at the Vendor's Facility and/or Plant Site:

- Audit of non-docketed material in response to open items
- Application Configuration Management
- Application Secure Development and Operational Environment
- Vendor Quality
- Licensee Vendor Oversight

\* Closure of the open items will determine if the audited material needs to be submitted to the docket in response to Request for Additional Information

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# Post-License Amendment Inspections: Regional/Vendor Inspections

May Include the Following:

- Licensee Vendor Oversight
- Requirements Traceability
- FAT Test Coverage and Results
- Time Response
- Configuration Management
- Secure Development and Operational Environment
- Vendor Quality
- Site Acceptance Testing
- Installation
- Procedures, Plans and Training

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# Post-License Amendment Inspections: Regional/Vendor Inspections

- Verify what vendor oversight activities the licensee is performing, per the VOP
  - Includes inspections of VOP Reports at the plant
- Verify how the licensee and the vendor are performing those activities
  - Includes inspections at the vendor facility
- Verify site installation and testing

# **NRC Perspectives on Vendor Oversight Activities**

Key Elements

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# Design Implementation

- Confirmation that the plans have been followed by the software developer.
- Evidence of Implementation to be reviewed should include the following:
  - Safety Analysis Reports
  - Verification and Validation Reports
  - Configuration Management Reports
  - Testing Activity Reports

**Example:** The acceptance criterion for software safety analysis implementation is that the tasks in that plan have been carried out in their entirety. Documentation exists to show that the safety analysis activities have been successfully accomplished for each life cycle activity group and that the proposed digital system software is, in fact, safe.

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# Design Outputs

- Confirmation that Design Outputs are acceptable.
- Design Outputs to be reviewed should include the following:
  - Software Requirements Specification
  - Software Architecture Description
  - Software Design Specification
  - Code Listings
  - System Build Documents
  - Installation Configuration Tables
  - Operations Manuals
  - Software Maintenance Manuals
  - Software Training Manuals

**Example:** Review Guidance for SRSs - Each requirement should be traceable to one or more safety system requirements, and the requirements traceability matrix should show where in the software the required action is being performed. The requirements traceability matrix should also show where the particular requirement is being tested.

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# NRC Perspectives and Questions on VOP Summary

1. Scope and depth of VOP Summary provided in the LAR
2. Reference to specific licensee oversight activities
3. Reference to IEEE 1012 or other standards
4. Scope and depth of licensee vendor oversight reports
5. Schedule of application life cycle development and vendor oversight activities