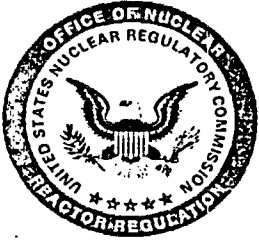


Pre-Application Meeting for Early Site Permit (ESP) Quality Assurance (QA) Review

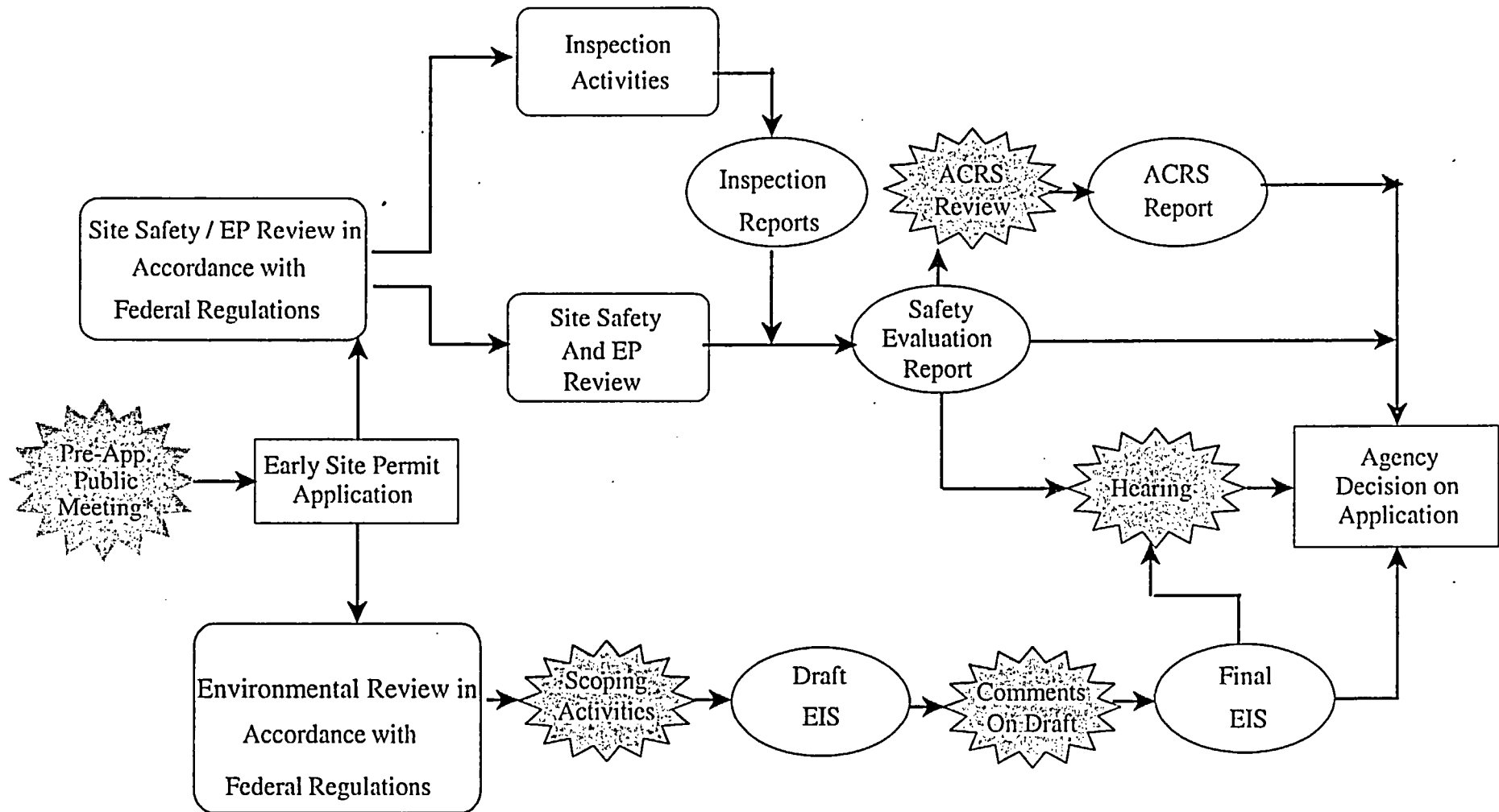
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Overview:

- **Purpose of the Meeting:**
 - ▶ **Describe the process used to review QA measures related to an ESP application.**
 - ▶ **Provide opportunity to discuss QA review process and respond to questions.**

Early Site Permit Review Process



*Formal Public
Participation*

** Not required*



Overview

- A Draft Review Standard (RS-002) was developed and issued for interim use.
- A new Section of RS-002 was developed to review ESP QA measures (Section 17.1.1).
- A new Inspection Manual Chapter (IMC-2501) and supporting Inspection Procedures were developed.



Quality Assurance Approach

- 10 CFR Part 52 does not require a Part 50 Appendix B program.
- In general, 10 CFR Part 52.39 provides finality for issues resolved at the ESP stage.

The staff must ensure site characterization data is accurate, reliable and can support the design and operation of future systems, structures and components (SSCs) important to safety.



IMC-2501 Inspection Program for ESP

Overview

- Establishes guidance for inspection of activities associated with the ESP application.
- Used in conjunction with, and references RS-002, Section 17.1.1.
- Purpose is to verify that data and analyses supporting the ESP application are supported by an adequate QA framework.



IMC-2501 Inspection Program for ESP

Continued

- Determine if applicant's QA measures are "equivalent in substance" to Appendix B.
- Inspection reviews data collection, analysis and evaluation methodologies.
- Key quality elements include data integrity, traceability, document control, evaluation, and record storage.



Section 17.1.1 “Early Site Permit Quality Assurance Controls”

- Purpose is to determine if the applicant has included within the scope of QA measures, activities that would affect SSCs important to safety.
- Explains the Pre-Docketing and Post-Docketing activities.
- IMC-2501 inspection activities will support development of ESP safety evaluation report.



Section 17.1.1 “Early Site Permit Quality Assurance Controls”

- The SER review and evaluation will determine:
 - the organizations and persons performing QA functions had independence and authority to be effective;
 - QA procedures and controls, when properly implemented, were equivalent in substance to the criteria of Appendix B and conform to the guidance in RS-002, Section 17.1.1; and
 - QA measures were applied to all ESP activities that establish information for: (1) the design and construction of future SSCs important to safety; or (2) the establishment of site characteristics for comparison to the values of site parameters postulated in a certified design.



Section 17.1.1 “Early Site Permit Quality Assurance Controls”

Focus Areas of Inspection

- Procurement
- Test / Inspection Controls
- Control of Site Characterization Data and Analyses Activities
- Procedures (QA and Technical)



IMC-2501 QA-Related Inspection Procedures

- “Pre-Docketing Early Site Permit Pre-Application Quality Assurance Controls Meeting” (IP35002A)
- “Pre-Application Early Site Permit Quality Assurance Controls Inspection” (IP 35004A)
- “Early Site Permit Quality Assurance Controls Assessment and Conclusion” (IP 35006A)
- “Post-Application Early Site Permit Quality Assurance Controls Inspection” (IP 35012A)



Substantive Findings

- A QA finding is considered substantive if:
 - an activity important to safety associated with site characterization, data or analysis was not performed;
 - an activity important to safety associated with site characterization, data or analysis was performed incorrectly; or
 - the applicant lacks objective evidence to establish that the activity important to safety associated with site characterization, data or analysis was adequately completed.



QA Inspections

■ Inspections:

- ▶ To ascertain QA controls, for input to the SER;
- ▶ Led by Regional inspector(s);
- ▶ Technical support provided from NRR; and,
- ▶ Conducted during periods of significant site characterization activities.