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*This form is to be filled out (typed or hand-printed) by the person who announced the meeting (i.e., the person who issued the meeting notice). The completed form, and the attached copy of meeting handout materials, will be sent to the Document Control Desk on the same day of the meeting; under no circumstances will this be done later than the working day after the meeting.
Do not include proprietary materials.*

DATE OF MEETING

09/10/2003

The attached document(s), which was/were handed out in this meeting, is/are to be placed in the public domain as soon as possible. The minutes of the meeting will be issued in the near future. Following are administrative details regarding this meeting:

Docket Number(s)	<u>Project No. 718</u>
Plant/Facility Name	<u>Exelon Early Site Permit</u>
TAC Number(s) (if available)	<u>MB5354</u>
Reference Meeting Notice	<u>ML032410163</u>
Purpose of Meeting (copy from meeting notice)	<u>To discuss plans for the NRC staff to conduct inspections</u> <u>of Exelon quality assurance measures in support of its</u> <u>prospective ESP application for the Clinton site.</u>

NAME OF PERSON WHO ISSUED MEETING NOTICE

Nanette Gilles

TITLE

Senior Project Manager

OFFICE

NRR

DIVISION

DRIP

BRANCH

RNRP

Distribution of this form and attachments:

Docket File/Central File

PUBLIC



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

Kevin Coyne

Paul Prescott

Quality and Maintenance Section

Emergency Preparedness and Plant Support Branch (IEPB)

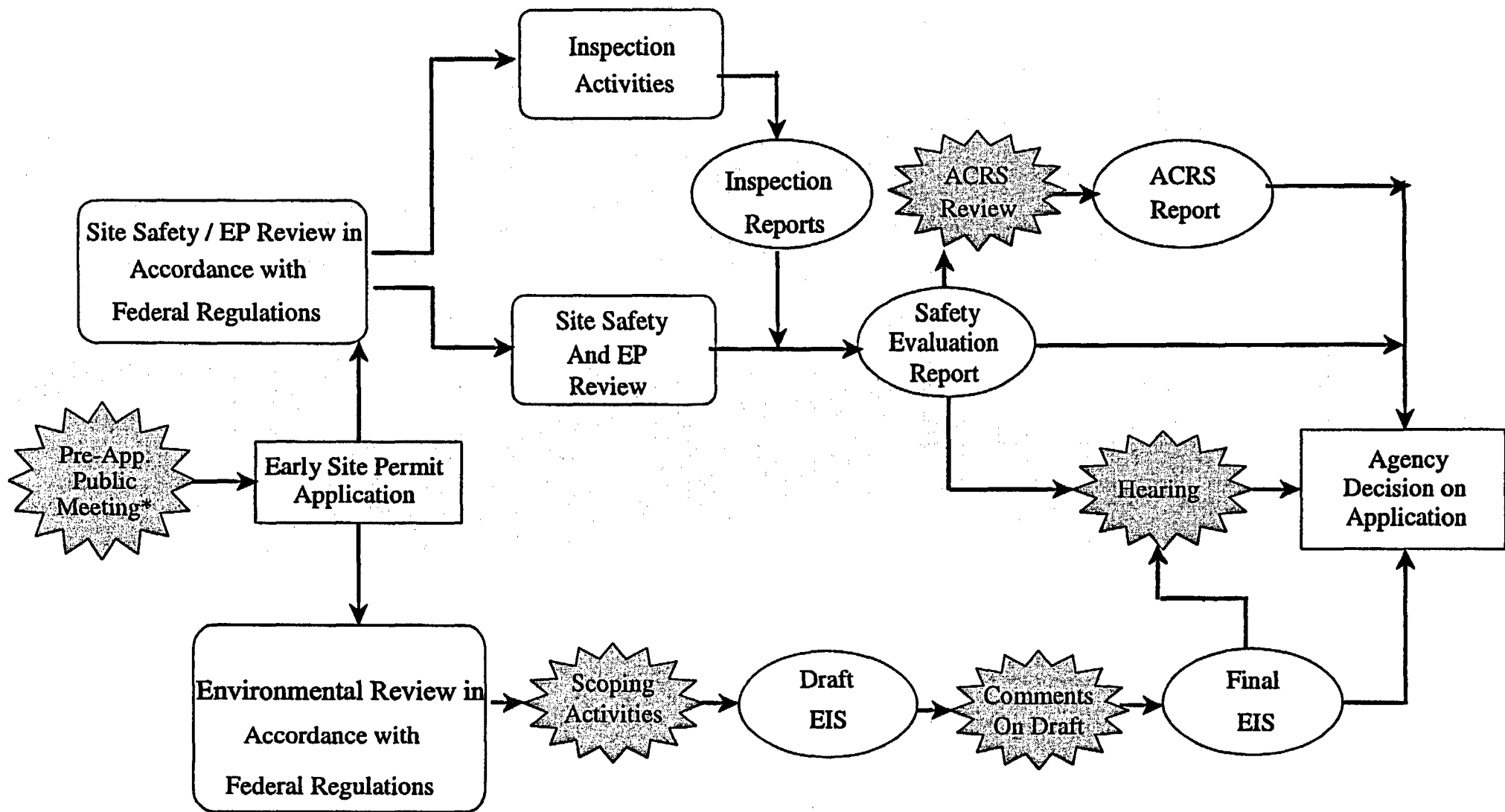
Office of Nuclear Reactor Regulation



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.**
- **Intent is to not apply operating reactor QA program to ESP (e.g., Reg. Guides, ANSI Standards, etc.).**
- **Deficiencies in QA measures, if any cited based on lack of assurance of the integrity and reliability of the data .**



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.

*Broader than safety-related
- Post-TMI*

- Explains the Pre-Docketing and Post-Docketing activities.
- IMC-2501 inspection activities will support development of ESP safety evaluation report (SER).



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 *technical acceptability required for support*
 - 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)** *like other inspection issues*
- **Record Retention**
- **Training**



IMC-2501 QA-Related Inspection Procedures

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. *activities involve sitting at computer & manual gathering of data*



QA Inspections

■ Inspections:

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

Exelon Early Site Permit Project

Quality Framework

**NRC/Exelon Public Meeting
Kennett Square, PA**

Agenda

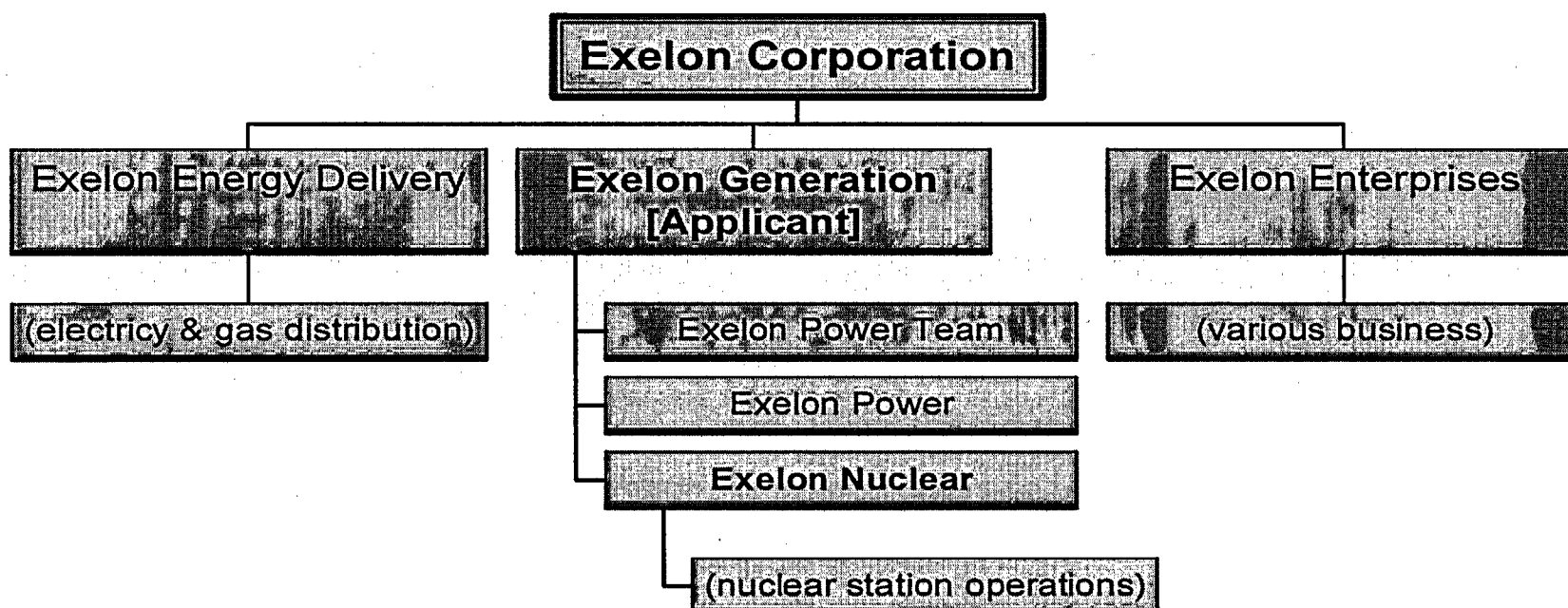
- ☐ Purpose
- ☐ Organization
- ☐ Quality Structure
- ☐ Quality Processes
- ☐ Quality Elements
- ☐ Implementation

Purpose

- ☐ Exelon ESP Application
 - o Establish repeatable & efficient process
 - o Obtain ESP for Clinton site

- ☐ Pre-application Meeting
 - o Provide overview of quality framework
 - o Understand NRC plans for inspection related to the integrity & reliability of the data & analyses
 - o Determine post-application actions for NRC inspection

Exelon Organization

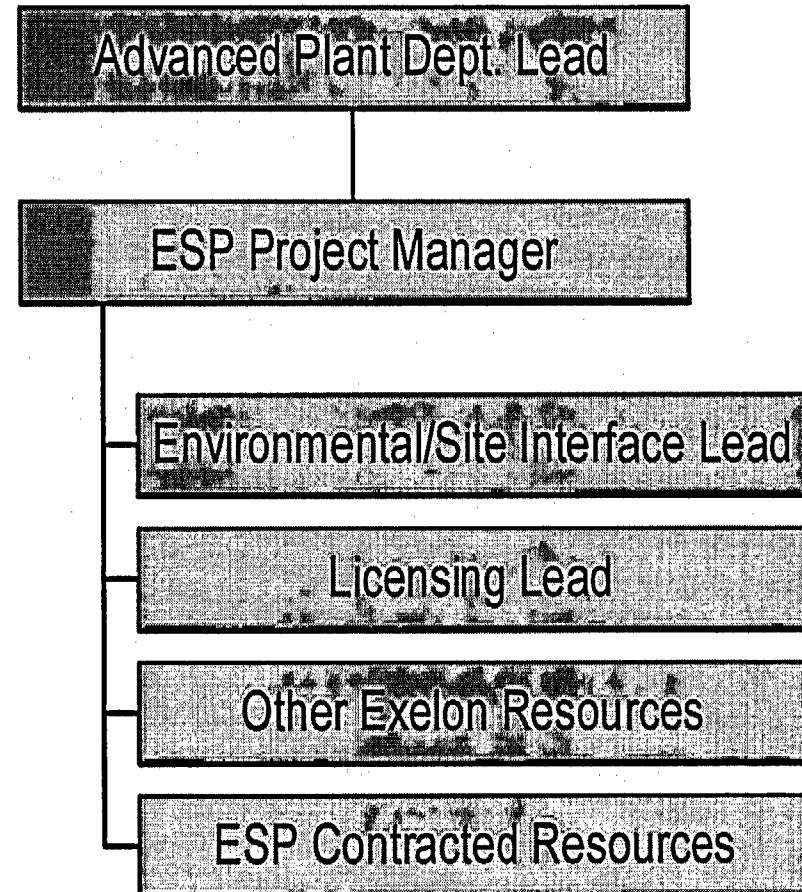


Exelon ESP Organization

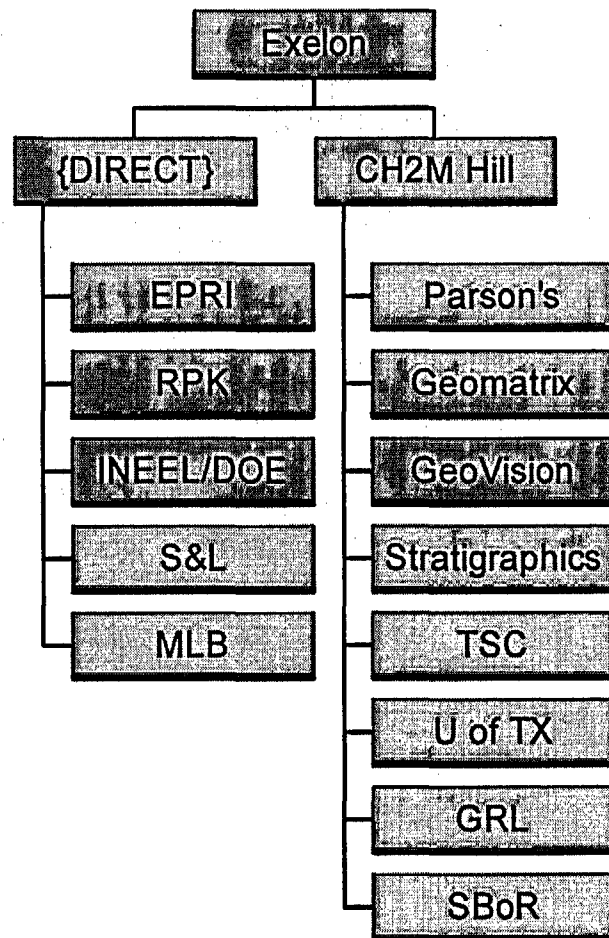
□ Marilyn Kray,
VP, Project Development

□ Thomas P. Mundy

- William Maher
- Eddie Grant
- EP, Eng., MLB, etc.
- CH2M Hill, SBoR, others



Exelon Project Organization



☐ Contract Structure

☐ QA Structure

- o Exelon ESP Project
 - Procedures
- o CH2M Hill
 - Project Quality Plan
 - Instructions
 - Procedures
 - Schedule
 - Requirements Matrix
 - Document Reviews
 - Contractor Oversight

Quality Measures

- ☐ Exelon
 - o ESP Project QA Instructions
 - o Procedures
 - o Exelon QATR for operating plants only
- ☐ Primary Contractor & Subcontractors
 - o Project Quality Plan for Exelon ESP
 - o Procedures
 - o Schedule
 - o Oversight
 - o Other

Quality Processes

- ☐ Assessment & Evaluation Control
- ☐ Application Development Control
- ☐ Application Accuracy
- ☐ Other
 - o Oversight
 - o Training
 - o Documentation

Quality Elements

☐ Variables

- o Sources of data
- o Expertise
- o Complexity of methods & analysis
- o Future use as design input for safety-related structures, systems, and components
- o Business interest

Implementation

- ☐ ESP Application Content
 - o Data source references
 - o Data evaluation references
 - o QAP description not included
- ☐ NRC Inspection Document Needs
 - o ESP Project activity matrix
 - o Entergy & Dominion Requests for Documentation
- ☐ NRC Inspection Plans
 - o Request information through Exelon personnel

Q & A