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October 8, 2004

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

Subject: Response to NRC Inspection of Applicant and Contractor Quality Assurance Activities Involved with Preparation of the Application for an Early Site Permit, Report 0520007/2004001

Re: Letter, U.S. Nuclear Regulatory Commission (C. D. Pederson) to Exelon Generation Company, LLC, (M. C. Kray), dated February 20, 2004, NRC Inspection of Applicant and Contractor Quality Assurance Activities Involved with Preparation of the Application for an Early Site Permit, Report 0520007/2004001

Enclosed is additional information related to open items associated with the topic of quality assurance as related to the Exelon Generation Company, LLC (EGC) ESP.

Please contact Eddie Grant of my staff at 610-765-5001 if you have any questions regarding this submittal.

Sincerely yours,



Marilyn C. Kray
Vice President, Project Development

TPM/erg

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U.S. Nuclear Regulatory Commission
October 8, 2004
Page 2 of 2

cc: U.S. NRC Regional Office (w/ enclosure)
Ms. Nanette V. Gilles (w/ enclosure)

Enclosure:

- 1) Additional information for Open Item 52-007/2004-01-01
- 2) Additional information related to QA measures used for various activities
- 3) Additional information for Open Item 52-007/2004-01-02
- 4) Additional information related to copies of QA documents

Additional Information Related to NRC Inspection Open Item 52-007/2004-01-01

NRC IR Section 2.B.b,

QA Measures for Control of Publicly Accessible Internet Data

The team noted that the applicant used publicly accessible internet web sites to obtain information referenced in various parts of the ESP application. For example, the ESP application referenced internet web sites controlled by the United States Department of Commerce Census Bureau and the National Oceanic and Atmospheric Administration (NOAA). This data was used, in part, to establish population distributions and growth estimates as well as the meteorological profile for the planned ESP site. During the inspection, the applicant provided a matrix of internet web sites used in the application and their associated disclaimer information. However, objective evidence that demonstrated that the applicable web site data was identical to the official data controlled by the web site sponsoring organization was not available.

In reviewing the Census Bureau and NOAA web sites used by the applicant, the team noted that each of these agencies offered certification services to verify that data supplied to users was identical to the agency officially archived data. NOAA indicated in publication Environmental Information Summary C-1, "Weather records in Private Litigation," that, in accordance with 28 U.S.C 1733, only properly authenticated copies or transcripts of records can be admitted as evidence in a court of law.

The team was concerned that data posted to web sites may not be subject to the same degree of review and verification as data obtained directly from the sponsoring organization or that malicious computer data tampering could impact the integrity or reliability of the web site data. This issue is identified as Open Item 52-007/2004-01-01, "Validation Requirements for Web site Data Used in License Applications."

Additional Information for Open Item 52-007/2004-01-01

Subsequent to the inspection, the NRC staff has also requested additional information on this topic in its letter, U.S. Nuclear Regulatory Commission (N.V. Gilles) to Exelon Generation Company, LLC (M. Kray), dated July 26, 2004, Request for Additional Information (RAI) Letter No. 9 – Exelon Early Site Permit (ESP) Application for the Clinton ESP Site (TAC No. MC1122). Because this information is process related rather than a specific request based on the technical review of the information in the application, the information is provided herein in response to the process related inspection.

The data retrieved from internet websites that supports information in the SSAR has been utilized to support development of site characteristics that may be used as design inputs for a future facility on the site. As such, these activities are not safety-related design, construction, or operation activities and thus, specific quality assurance measures are not required by regulation. Nevertheless, EGC employed quality measures sufficient for the

use of this information in its ESP application. The measures utilized to authenticate data retrieved from internet websites include formally documenting the website used, peer review of the resulting application information, and independent examination of the source.

1) Documentation

The project procedure, "Technical Editing and Formatting," includes guidance to task leads regarding the expectation of documenting web site sources on a reference source form and printing a copy of a screen shot of the web page(s). Once filled out, these forms were forwarded to the peer review manager for "peer review."

2) Peer Review

A peer review was held of each section of the ESP Application to determine if the approach and conclusions reached were accurately represented and supported within the context of the data used.

3) Independent Examination

Independent of the peer review process, each reference source form is reviewed to determine if the information was obtained from an authoritative source, i.e., State, Federal, educational, or industry web site. The data was examined to determine that the information found at the source site accurately represented the author's published information.

The NRC Staff Inspection Report noted that some agencies offer certification services to verify that data supplied to users was identical to the agency officially archived data. The inspection report, however, fails to acknowledge that these services are provided to simplify evidentiary burden in court proceedings. For example, the NOAA indicates in their publication Environmental Information Summary C-1, "Weather Records in Private Litigation," (the publication referenced in the Inspection Report) that in accordance with 28 U.S.C 1733, only properly authenticated copies or transcripts of records can be admitted as evidence in a court of law. Consequently, NOAA offers a data certification service to authenticate data. Similarly, the Census Bureau offers a certification service for their archived data. However, EGC did not utilize this service because EGC had no reason to presume that it would be necessary to introduce the data as evidence.

Upon further review, EGC found that the U.S. Census Bureau responds to Frequently Asked Questions (FAQs) regarding certification on their website at: <http://www.census.gov/mso/www/certification/certfaq.html> - and extensively addresses information quality at: http://www.census.gov/qdocs/www/quality_guidelines.htm.

NOAA similarly addresses information quality at: <http://www.noaanews.noaa.gov/stories/iq.htm> but no data certification service information was readily identifiable at this website location.

Each of these organizations indicates that considerable care is taken to post reliable data to their web sites.

In summary, EGC has obtained data from authoritative sources, peer reviewed the data and its use, and examined the data for accurate representation. Finally, since the data is

not being utilized in a manner for which certification is intended, i.e., as evidence in a judicial proceeding, no certification is considered necessary.

Additional information related to QA measures used for various activities

Although no open item was identified in the NRC Inspection Report, the NRC staff requested (subsequent to the inspection) additional information on this topic in your letter, U.S. Nuclear Regulatory Commission (N.V. Gilles) to Exelon Generation Company, LLC (M. Kray), dated July 26, 2004, Request for Additional Information (RAI) Letter No. 9 – Exelon Early Site Permit (ESP) Application for the Clinton ESP Site (TAC No. MC1122). Because this information is process related rather than a specific request based on the technical review of the information in the application, the information is provided herein in response to the process related inspection.

NRC REQUEST:

- a) *Section 8 of Exelon Generation Company's (EGC's) document AP-AA-1000, "Early Site Permit Project Quality Assurance Instructions," Revision 0, and Section 2.8 of CH2M HILL's "Project Quality Plan for Exelon Early Site Permit," Revision 4, state that the safety-related scope of the development of the ESP application would not involve the use of QA measures for identification and control of materials, parts, or components. Please describe why these QA measures were not applicable to the development of the ESP application. Alternatively, if these QA measures were applicable to the ESP application, please describe the QA measures used by EGC and the primary contractor (CH2M HILL) for these activities.*
- b) *Section 9 of EGC's document AP-AA-1000, "Early Site Permit Project Quality Assurance Instructions," Revision 0, and Section 2.9 of CH2M HILL's "Project Quality Plan for Exelon Early Site Permit," Revision 4, state that the safety-related scope of the development of the ESP application would not involve the use of QA measures for control of special processes. Please describe why these QA measures were not applicable to the development of the ESP application. Alternatively, if these QA measures were applicable to the ESP application, please describe the QA measures used by EGC and the primary contractor (CH2M HILL) for these activities.*
- c) *Section 10 of EGC's document AP-AA-1000, "Early Site Permit Project Quality Assurance Instructions," Revision 0, and Section 2.10 of CH2M HILL's "Project Quality Plan for Exelon Early Site Permit," Revision 4, state that the safety-related scope of the development of the ESP application would not involve the use of QA measures for inspection. Please describe why these QA measures were not applicable to the development of the ESP application. Alternatively, if these QA measures were applicable to the ESP application, please describe the QA measures used by EGC and the primary contractor (CH2M HILL) for these activities.*
- d) *Section 14 of EGC's document AP-AA-1000, "Early Site Permit Project Quality Assurance Instructions," Revision 0, and Section 2.14 of CH2M HILL's "Project Quality Plan for Exelon Early Site Permit," Revision 4, state that the safety-related scope of the development of the ESP application would not involve the use of QA measures for inspection, test, and operating status.*

Please describe why these QA measures were not applicable to the development of the ESP application. Alternatively, if these QA measures were applicable to the ESP application, please describe the QA measures used by EGC and the primary contractor (CH2M HILL) for these activities.

- e) *Section 15 of EGC's document AP-AA-1000, "Early Site Permit Project Quality Assurance Instructions," Revision 0, and Section 2.15 of CH2M HILL's "Project Quality Plan for Exelon Early Site Permit," Revision 4, state that the safety-related scope of the development of the ESP application would not involve the use of QA measures for nonconforming materials parts, or components. Please describe why these QA measures were not applicable to the development of the ESP application. Alternatively, if these QA measures were applicable to the ESP application, please describe the QA measures used by EGC and the primary contractor (CH2M HILL) for these activities.*

EGC RESPONSE:

Justification for the exclusion of each of the identified items is provided below as documented in the referenced document AP-AA-1000. However, these QA measures are not discussed in the EGC SSAR, and are not considered as part of the application.

- a) As indicated in Section 8 of AP-AA-1000, the development of the ESP application does not involve the fabrication, erection, installation, and use of materials, parts, or components in the development of an ESP application. Thus, no quality assurance measures are necessary to prevent the use of incorrect or defective fabricated, erected, or installed materials, parts, or components.
- b) As indicated in Section 9 of AP-AA-1000, the development of the ESP application does not involve special processes such as welding, heat-treating, and nondestructive testing. Thus, no quality assurance measures are necessary for the control of special processes.
- c) As indicated in Section 10 of AP-AA-1000, the development of the ESP application does not involve safety-related material or product processing. Thus, no quality assurance inspection activities are expected or planned.
- d) As indicated in Section 14 of AP-AA-1000, the development of the ESP application does not involve inspection, testing, or operation of structures, systems, and components of a nuclear power plant. Thus, no quality assurance measures relating to inspection, testing, or operation of such structures, systems, and components are necessary.
- e) As indicated in Section 10 of AP-AA-1000, the development of the ESP application does not involve fabrication, erection, installation, and use of materials, parts, or components. Thus, no quality assurance measures are necessary to prevent the use or installation of nonconforming materials, parts, or components.

Additional Information Related to NRC Inspection Open Item 52-007/2004-01-02

NRC IR Section 3,

10 CFR Part 21 Applicability

The team identified one open item regarding an issue which was not addressed during the inspection but which will require follow up action at a later time. The open item involves the applicability of 10 CFR Part 21, "Reporting of Defects and Noncompliance," to the Exelon ESP project. The open item stems from an NRC workshop held on August 27, 2003, on the NRC's Construction Inspection Program Framework Document. During that workshop, an Exelon representative asked a question about NRC Inspection Procedure 35002, "Early Site Permit Pre-Docketing Quality Assurance Controls Meeting," that referred to 10 CFR Part 21 reporting requirements. The Exelon representative stated that he did not believe that 10 CFR Part 21 applied to ESP applicants. During that meeting, the NRC staff stated that it believed that 10 CFR Part 21 does apply to ESP applicants but that the staff would evaluate Exelon's statements after the workshop and respond to Exelon's question in more detail. This issue is identified as Open Item 52-007/2004-01-02, "Applicability of 10 CFR Part 21 to ESP applicants."

Additional Information for Open Item 52-007/2004-01-01

Subsequent to the inspection, the NRC staff has also requested additional information on this topic in its letter, U.S. Nuclear Regulatory Commission (N.V. Gilles) to Exelon Generation Company, LLC (M. Kray), dated July 26, 2004, Request for Additional Information (RAI) Letter No. 9 – Exelon Early Site Permit (ESP) Application for the Clinton ESP Site (TAC No. MC1122). Subsequently, EGC requested a meeting with the NRC Staff to discuss its position regarding the applicability of Part 21 in an effort to assist the staff in its understanding of the particulars of this issue. However, during a telecom between the NRC staff and EGC on September 24, 2004, the NRC staff declined the opportunity to meet with EGC until the staff had an opportunity to review the EGC written position on the subject. Because this information is process related rather than a specific request based on the technical review of the information in the application, the information is provided herein in response to the process related inspection.

Part 21 applies to safety-related structures, systems, and components (SSC), and to the activities and services that are associated with the SSCs. However, the EGC ESP application has not identified, nor requested approval of any SSCs, and it has not designated any SSCs or activities as safety-related. Therefore, even if an error associated with a site characteristic is subsequently identified by EGC or its contractors, there can be no means of evaluating the error in the context of Part 21.

Under the provisions in 10 CFR 52.37, compliance with Part 21 is not required until an ESP is issued. Thus EGC is under no obligation to impose Part 21 reporting requirements on contractors until that time. Nonetheless, EGC recognizes and shares the NRC's concern for the identification and ultimate evaluation of errors made in the

development of the site characteristics. However, EGC continues to maintain that Part 21 in its current form is not the appropriate means to address the NRC's concern. EGC's position is supported in further detail below.

Notwithstanding EGC's disagreement as to the application of Part 21 to the EGC ESP, EGC intends to work with the NRC to resolve its concerns to the satisfaction of both the NRC and EGC. One possible action EGC is considering would be to contractually impose a requirement on certain EGC's ESP contractors to notify EGC of a significant error identified in the work provided to EGC following expiration of its ESP contract. EGC would need to identify which contractors it would impose such a requirement. (Note that during the period when its contract is in effect, the contractor is obligated to report and address significant errors as required by the EGC ESP Project corrective action program). These notifications could then be compiled and evaluated against a design once the safety functions of a specific design are known (i.e., in connection with the submittal of a COL application).

EGC will supplement this response and identify the final actions it intends to take to address the NRC's concern, subject to the NRC's review and further discussion with EGC on this topic, and subject to the outcome of further discussion on this topic between the NRC and the Nuclear Energy Institute's ESP Task Force.

SUPPORTING INFORMATION

The additional information below provides material supportive of EGC's position that Part 21 does not apply in the context of EGC's ESP (either as an applicant or permit holder) because EGC's ESP does not conduct any safety-related activities. The basis addresses the consideration of safety functions, consideration of the pertinent standards, design certification considerations, consideration of Part 100 language, and consideration of construction requirements and allowances.

Consideration Of Safety Function

Identification of a safety-related scope must be based on specified safety functions as identified in the definition of *basic component* in §21.3. However, in the EGC ESP, there are no specific structures, systems, or components (SSC) identified, no safety functions for such SSCs identified, nor are there any SSCs or related safety functions being submitted for approval within an ESP. The definition of *basic component* is based upon the SSCs themselves. The definition also includes "*safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.*" However, since no specific SSC is being approved and no specific plant design is being proposed at the ESP stage, there can be no design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the structure, system, or component hardware. Therefore, no safety-related design, analysis, or services activities can be involved.

An ESP essentially addresses three areas: environmental impacts, emergency planning, and site characteristics. Clearly, environmental impact evaluation under Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," is not subject to Part 21 requirements. Similarly, emergency planning does not utilize safety related SSCs and has not been subject to Part 21 requirements. Finally, the development of site characteristics is primarily a review of site parameters intended to determine the bounding site properties. This is typically accomplished through a review and manipulation of available data, such as population data or meteorological data. This determination of site characteristics can be complicated (such as in determination of the safe shutdown earthquake acceleration), however complexity does not mandate safety-related. Further, while these site properties will become inputs to a design process when such a design process is initiated (at the combined license stages), the determination of these inputs at the ESP stage is not part of the design process and thus, is not a safety-related activity.

Consideration Of The Standards

The applicable standards provide a clear distinction between design input and design process. The ESP activities relate solely to the development of design input, i.e., development of the site characteristics, rather than the safety-related design process associated with the structures, systems and components. This distinction between "design process" and the "design input" is quite important in understanding the associated quality requirements. The NQA-1 (1983) standard, Quality Assurance Program Requirements for Nuclear Facilities (as endorsed by Regulatory Guide 1.28, *Quality Assurance Program Requirements (Design and Construction)*, Revision 3, 1985), contains the following definitions and other pertinent statements:

- ◆ **Design process (definition):** technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.
- ◆ **Design input (definition):** those criteria, parameters, design bases, regulatory requirements, or other design requirements upon which detailed final design is based.
- ◆ "Applicable design inputs shall be identified and documented, and their selection reviewed and approved." [Section 3 (200)]
- ◆ "Documentation of design analyses shall include... (b) design inputs and their sources." [Section 3 (402)]
- ◆ "Design inputs include many characteristics and functions of an item or system," including: "(e) loads such as seismic, wind, thermal and dynamic... and (f) environmental conditions anticipated during storage, construction, operation, and accident conditions, such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, exposure to weather, flooding, ..." [Appendix 3A-1 (200)].

Each of the above statements has been consistently included in appropriate standards since ANSI N45.2.11 (1974), *Quality Assurance Requirements for the Design of Nuclear Power Plants*.

Thus, the selection of design inputs (at COL application stage from the previously identified engineering characteristics of a site and its environs) would be included in the design process; however, the determination/development of the design input values (such as the engineering characteristics of a site and its environs at the ESP application stage, regulation development by a federal agency, or industry standards by the appropriate industry organizations) is not part of the design process. Since Appendix B does not apply until the design process begins, Appendix B is not applicable to ESP stage activities under the "design" activities criterion.

Consideration Of Part 100

The "Purpose" section (§100.1) of Part 100, "Reactor Site Criteria," states (emphasis added):

"(a) The purpose of this part is to establish approval requirements for proposed sites for stationary power and testing reactors subject to part 50 or part 52 of this chapter.

(b) There exists a substantial base of knowledge regarding power reactor siting, design, construction, and operation. This base reflects that the primary factors that determine public health and safety are the reactor design, construction and operation.

(c) Siting factors and criteria are important in assuring that radiological doses from normal operation and postulated accidents will be acceptably low, that natural phenomena and potential man-made hazards will be appropriately accounted for in the design of the plant, that site characteristics are such that adequate security measures to protect the plant can be developed, and that physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans are identified.

(d) This approach incorporates the appropriate standards and criteria for approval of stationary power and testing reactor sites. The Commission intends to carry out a traditional defense-in-depth approach with regard to reactor siting to ensure public safety. Siting away from densely populated centers has been and will continue to be an important factor in evaluating applications for site approval."

These above subsections of 10 CFR § 100.1 clearly highlight the distinction between siting activities versus design, construction, and operation.

Consideration For Construction

Just as site investigations are not part of the design process, they are also not part of the construction process under Part 21. This is indicated, for example, by the provisions in 10 CFR 100.23 and 50.10.

10 CFR 100.23(c) indicates that the “applicant shall investigate all geologic and seismic factors (for example, volcanic activity) that may affect the design and operation of the proposed nuclear power plant irrespective of whether such factors are explicitly included in this section.” In addition, §100.23(b) states that the investigations required in paragraph (c) of this section [Geological, seismological, and engineering characteristics] are within the scope of investigations permitted by § 50.10(c)(1) of this chapter. The activities permitted by § 50.10(c)(1) are identified therein as “borings... or other pre-construction monitoring to establish background information related to the suitability of the site or to the protection of environmental values.” Such activities, i.e., those permitted by § 50.10(c)(1), are explicitly outside the scope of the term “construction.” Therefore, site investigations are not part of construction, and cannot be brought within the scope of Part 21 under the rubric of construction activities.

SUMMARY

This additional information provides material supportive of EGC’s position that Part 21 does not apply in the context of EGC’s ESP (either as an applicant or permit holder) because EGC’s ESP does not conduct any safety-related activities.

However, as stated above, EGC intends to take action consistent with the NRC’s desire to identify and evaluate errors made in the development of site characteristics. The final actions taken by EGC will be subject to the NRC’s review and further discussion with EGC on this topic, and subject to the outcome of further discussion on this topic between the NRC and the Nuclear Energy Institute’s ESP Task Force.