

From: glenn.stewart@exeloncorp.com
Sent: Thursday, October 02, 2008 11:15 AM
To: Christopher Gratton
Cc: Pamela.Cowan@exeloncorp.com; david.helker@exeloncorp.com; michael.hayse@exeloncorp.com
Subject: Potential Issue with Exelon/AmerGen QATR, Chapter 7, Section 2.4.8, "Acceptance of Calibration Services"

By telecon dated September 29, 2008, between the Exelon Fleet Project Manager, USNRC, and the Manager of Licensing, Exelon Generation Company, LLC (Exelon), the NRC notified Exelon of a potential issue with a change made to the Exelon and AmerGen Energy Company, LLC (AmerGen) Quality Assurance Topical Report (QATR), NO-AA-10. A description of the issue is provided below.

Description of Issue

By letter dated February 6, 2008 (ADAMS Accession No. ML080380099), Exelon/AmerGen submitted Revision 80 of the Exelon/AmerGen QATR, NO-AA-10. This revision of the QATR was submitted to the NRC in accordance with the requirements of 10 CFR 50.54(a)(3) to provide the NRC with an update of changes to the quality assurance program (QAP) description over the previous two years that did not reduce commitments in the program description, and therefore, did not require NRC approval prior to implementation. Attachment 1 to the February 6, 2008 letter provided a summary of the changes for Revisions 77 through 80 of the QATR. One of the changes pertains to QATR, Chapter 7, Section 2.4.8, "Acceptance of Calibration Services." This section was added to the QATR to allow calibration services to be procured from commercial-grade suppliers that have received accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) or another accrediting body recognized by NVLAP. This change to the QATR states, in part, that:

For suppliers of commercial-grade calibration services with accreditation by a nationally recognized accrediting body, a documented review of the supplier's accreditation by the purchaser may be used in lieu of inspections or tests following delivery or in-process surveillances during performance of the service. This review shall include, at a minimum, all of the following:

- The accrediting body is either National Voluntary Laboratory Accreditation Program (NVLAP) or an accrediting body recognized by NVLAP through an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

In accordance with 10 CFR 50.54(a)(3)(ii), a licensee may make a change to a previously accepted QAP description included or referenced in the Safety Analysis Report, without prior NRC approval, if the change uses a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility. The above change regarding calibration services was based on invoking 10 CFR 50.54(a)(3)(ii) as a quality assurance alternative approved by an NRC safety evaluation. Specifically, this change was based on an NRC safety evaluation dated September 28, 2005 (ADAMS Accession No. ML052710224), associated with a QAP change submitted by Arizona Public Service (APS).

The APS QAP change, for Palo Verde Nuclear Generating Station (PVNGS), was submitted to the NRC by letter dated September 5, 2004 (ADAMS Accession No. ML042590501). In its letter, APS requested that the NRC approve a change to the PVNGS QAP that would provide for acceptance of accreditation of

commercial-grade calibration services by a nationally recognized accrediting body, using procedures consistent with international standards and guidelines. The NRC found APS' proposed change acceptable with clarifying bases as documented in the staff's safety evaluation dated September 28, 2005. The staff's approval of APS's proposed change was limited to only NVLAP and the American Association for Laboratory Accreditation (A2LA), which were the two US-based signatories to the ILAC MRA at the time.

Although the basis for the NRC's approval of the APS request was limited to only NVLAP and A2LA, the wording added to the QATR (i.e., the bullet shown above) could be interpreted to recognize all accrediting bodies through the ILAC MRA.

The NRC requested that Exelon clarify the intent of this change in the QATR.

Exelon Actions to Address This Issue

Exelon has generated Issue Report (IR) 824587 in the Exelon Corrective Action Process (CAP) to address this issue. In response to this IR, an assignment has been generated to Corporate Nuclear Oversight (NOS) to revise NO-AA-10, Chapter 7, Section 2.4.8, to clarify that the accrediting bodies for accrediting suppliers of commercial-grade calibration services are limited to National Voluntary Laboratory Accreditation Program (NVLAP) and American Association for Laboratory Accreditation (A2LA). This clarification will be incorporated into the next revision of NO-AA-10.

In addition, the Exelon NOS procedure for qualifying suppliers and adding them to the Approved Suppliers List (ASL) is being revised, consistent with the change to the QATR, to limit suppliers of calibration services to only those suppliers accredited by either NVLAP or A2LA.

Also, in the interim, until the change to the QATR is effective, appropriate administrative controls have been put in place to ensure that only suppliers accredited by either NVLAP or A2LA are included on the ASL. A review of the ASL indicated that five suppliers of calibration services are currently on the ASL, all of which have been accredited by either NVLAP or A2LA.

These actions should address the NRC concern with the QATR change as expressed on the September 29, 2008 telecon.

Glenn Stewart
Exelon Nuclear
Licensing & Regulatory Affairs
Tel.: 610-765-5529

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From: glenn.stewart@exeloncorp.com

Created By: glenn.stewart@exeloncorp.com

Recipients:

Christopher.Gratton@nrc.gov (Christopher Gratton)
Tracking Status: None
Pamela.Cowan@exeloncorp.com (Pamela.Cowan@exeloncorp.com)
Tracking Status: None
david.helker@exeloncorp.com (david.helker@exeloncorp.com)
Tracking Status: None
michael.hayse@exeloncorp.com (michael.hayse@exeloncorp.com)
Tracking Status: None

Post Office:
mobmsxch06.energy.power.corp

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