

July 8, 2009

Mr. Russ Bell, Director  
New Plant Licensing  
Nuclear Generation Division  
Nuclear Energy Institute  
1776 I Street, NW, Suite 400  
Washington, DC 20006-3708

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION RESPONSE REGARDING THE NUCLEAR ENERGY INSTITUTE (NEI) REQUEST FOR ENDORSEMENT OF NEI 08-02 "PROBLEM IDENTIFICATION AND RESOLUTION FOR NEW NUCLEAR PLANTS UNDER CONSTRUCTION" REVISION 1, APRIL 2009.

Dear Mr. Bell:

This letter responds to your letter dated April 22, 2009, which requested NRC review and further discussion on NEI 08-02, *Problem Identification and Resolution for New Nuclear Power Plants During Construction*, with the goal of NRC endorsement in a regulatory guide (ADAMS Accession No. ML0911705940). The NRC has held various public meetings to discuss NEI 08-02, and has documented the March 9, March 24, and May 13, 2009, meetings in meeting summaries (ADAMS Accession Nos. ML090990033, ML091140058, and ML091630136, respectively). The public meeting held on May 13, 2009, provided NEI with the staff's written comments regarding NEI 08-02, Revision 1. Following constructive dialogue on each of the comments, NEI representatives agreed to consider the NRC staff comments and address them, as appropriate, in the next revision of NEI 08-02. The list of staff comments discussed at the May 13, 2009, public meeting is enclosed with this letter for your convenience.

In addition to resolving the comments discussed at the public meeting on May 13, 2009, the following issues must be resolved in order for NRC to endorse NEI 08-02.

1. NEI 08-02, Revision 1, states that the document provides guidance for meeting the requirements of Appendix B to 10 CFR Part 50. The depth and extent of this document does not provide for complete implementation of Appendix B independent of the implementation of other licensee quality assurance commitments as described in the quality assurance program descriptions. Implementation of NEI 08-02, Revision 1, with appropriate adjustments, would appear to implement Criterion XVI of 10 CFR 50 Appendix B for new nuclear reactors under construction; this should be clearly reflected in NEI 08-02. NEI 08-02 should make clear that the document will not supersede any corrective action program already defined in an NRC-approved quality assurance program description.
2. NEI 08-02 must adequately describe the process to determine significance of conditions adverse to quality. NEI 08-02, Attachment 1, *PI&R Process Flow*, illustrates two instances where significance of an issue is determined but the description provided in the narrative does not provide detail regarding what criteria (e.g. timeliness) are required to accomplish the objective. One of the two instances to determine significance is independent of the NEI 08-02 processes to address conditions adverse to quality or significant conditions adverse to quality, allowing a potentially significant issue to be outside of both processes for an indeterminate amount of time.

3. The process to disposition ITAAC-related conditions within NEI 08-02 must be detailed enough to implement NEI 08-01, *Industry Guideline for the ITAAC Closure Process Under 10 CFR Part 52*. NEI must address how safety-related and non-safety-related ITAAC-related conditions will be dispositioned (e.g. significance, timeliness, management reporting) within this program.
4. NEI should reconsider the use of the term Problem Identification and Resolution (PI&R) for this application as it is a term already in use in the reactor oversight program for operating reactors and could create confusion. Alternatively, NEI 08-02 could be developed to have all the attributes of an operating reactor PI&R program, such as, tracking and resolving conditions adverse to quality and significant conditions adverse to quality within the same process.

We await your response in order to proceed with our review. If you have any questions with regard to this letter, or its enclosures, please contact Joelle Starefos at (301) 415-6091, or email [Joelle.Starefos@nrc.gov](mailto:Joelle.Starefos@nrc.gov).

Sincerely,

*/RA John Tapper for/*

Glenn M. Tracy, Director  
Division of Construction Inspection  
& Operational Programs  
Office of New Reactors

Project No. 0698

Enclosure:  
As stated

cc w/ encl: see next page

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**NRC Staff Comments for Discussion at Public Meeting on May 13, 2009**

**NEI 08-02 “Problem Identification and Resolution for  
New Nuclear Power Plants During Construction, Revision 1**

- ***The description of the Problem Identification and Resolution (PI&R) program lacks consistency with the terms and concepts present in 10 CFR 50 Appendix B Criterion XVI and other regulatory documents. The program document should demonstrate how it is implementing regulatory requirements and commitments specified in the licensing basis documents.***
  - The use of terms like PI&R and corrective action program (CAP) can be a source of confusion. The document should state more clearly how it is trying to implement requirements of 10 CFR 50 Appendix B Criterion XVI and NQA-1-1994.
  - The licensing documents under review by the NRC state that the CAP, within the quality assurance program (QAP), will identify all Conditions Adverse to Quality (also identified in NEI 06-14A Rev 6). Once identified, further review will be performed to determine if it is a Significant condition Adverse to Quality; at which time, causal analysis and proper management notification will be done. NEI 08-02 Rev 1 doesn't appear to consider CAQs as part of the CAP.
  - Should NEI 08-02 address evaluation of conditions for reporting requirements? For example, reporting under 50.55e.
  - NEI 08-02, section 3.4, states “If the program has been contracted to others then the purchaser is responsible for the overall program...” Language should reflect that suppliers/contractors may be made responsible for the implementation of the program but licensees are responsible for the overall program effectiveness.
  - The specific concepts defined in the document can be confused with the same terms as defined by the licensing documents (e.g. CAP, extent of condition, SCAQ). The document should refrain from creating new definitions and use terminology already in use.
  - The concept of work processes is confusing within the framework of the document. It does not make it clear how they are part of the Corrective Action Program (currently highlighted as part of the PI&R), nor does it define each as a “quality” process. NEI 08-02 states in Section 5 that the QAP will make reference to the work processes but a sample QAP currently submitted to NRC does not address the work processes.

- **The document should clearly define the baseline program for implementing the Corrective Action Program. Including how determination of thresholds would capture conditions adverse to quality (CAQ) and exactly what process would drive a CAQ to be processed as a significant condition adverse to quality (SCAQ). It should be clear how the process will effectively implement trending that would drive an identified CAQ to become an SCAQ.**
  - The method or process from identification to disposition should be clearer. For example, what will initiate the process? Who will determine significance?
  - NEI 08-02 states “The PI&R process is the primary means for workers to identify problems. There are additional processes that can be used by workers to identify problems including reporting to management, reporting to QA, Employee Concerns program, reporting to NRC, etc.” The references to these alternative sources should be eliminated if they infer equivalent controls outside of regulatory requirements. Otherwise, the statement should make it clear how these programs inform the CAP for proper disposition.
- **Description of how ITAAC will be handled by NEI 08-02 should be in alignment with intentions described in NEI 08-01. Conditions identified to have affected an ITAAC should reflect the appropriate characterization (e.g. CAQ, SCAQ, new process, etc.) consistent with needs of NEI 08-01.**

## **Construction Inspection Program Mailing List**

cc:

Mr. Glenn H. Archinoff  
AECL Technologies  
481 North Frederick Avenue  
Suite 405  
Gaithersburg, MD 20877

Mr. Lionel Batty  
Nuclear Business Team  
Graftech  
12300 Snow Road  
Parma, OH 44130

Ms. Michele Boyd  
Legislative Director  
Public Citizens Critical Mass Energy  
and Environmental Program  
215 Pennsylvania Avenue, SE  
Washington, DC 20003

Mr. Ian M. Grant  
Canadian Nuclear Safety Commission  
280 Slater Street, Station B  
P.O. Box 1046  
Ottawa, Ontario  
K1P 5S9

Mr. Eugene S. Grecheck  
Vice President  
Nuclear Support Services  
Dominion Energy, Inc.  
5000 Dominion Blvd.  
Glen Allen, VA 23060

Manager  
GT-MHR Safety & Licensing  
General Atomics Company  
PO Box 85608  
San Diego, CA 92186-5608

Mr. Edward L. Quinn  
Longenecker and Associates  
Utility Operations Division  
23292 Pompeii Drive  
Dana Point, CA 92629

Mr. Robert E. Sweeney  
IBEX ESI  
4641 Montgomery Avenue  
Suite 350  
Energy Program Bethesda, MD 20814

Mr. Gary Wright, Director  
Division of Nuclear Facility Safety  
Illinois Emergency Management Agency  
1035 Outer Park Drive  
Springfield, IL 62704

Mr. Paul Leventhal  
Nuclear Control Institute  
1000 Connecticut Avenue, NW  
Suite 410  
Washington, DC 20036

Mr. Brendan Hoffman  
Research Associate on Nuclear Energy  
Public Citizens Critical Mass Energy and  
Environmental Program  
215 Pennsylvania Avenue, SE  
Washington, DC 20003

Mr. Ed Wallace, General Manager  
Projects  
PBMR Pty LTD  
PO Box 9396  
Centurion 0046  
Republic of South Africa

Mr. Dobie McArthur  
Director, Washington Operations  
General Atomics  
1899 Pennsylvania Avenue, NW, Suite 300  
Washington, DC 20006

Mr. Ron Simard  
6170 Masters Club Drive  
Suwanee, GA 30024

Leslie Compton Kass  
Nuclear Energy Institute  
Suite 400  
1776 I Street NW  
Washington, DC 20006-3708

Mr. Carl E. Parry, President  
Utilities Service Alliance, Inc.  
9200 Indian Creek Parkway  
Suite 201  
Overland Park, KS 66210

## **Construction Inspection Program Mailing List**

### Email

APAGLIA@Scana.com (Al Paglia)  
APH@NEI.org (Adrian Heymer)  
awc@nei.org (Anne W. Cottingham)  
BrinkmCB@westinghouse.com (Charles Brinkman)  
Carellmd@westinghouse.com (Mario D. Carelli)  
carey.fleming@constellation.com (Carey Fleming)  
chris.maslak@ge.com (Chris Maslak)  
christian.martel@aerojoule.com (Christian Martel)  
CumminWE@Westinghouse.com (Edward W. Cummins)  
cwaltman@roe.com (C. Waltman)  
david.hinds@ge.com (David Hinds)  
david.lewis@pillsburylaw.com (David Lewis)  
donald.woodlan@luminant.com (Donald Woodlan)  
draleigh@scientechnet.com (Denna Raleigh)  
ecullington@earthlink.net (E. Cullington)  
erg-xl@cox.net (Eddie R. Grant)  
garry.miller@pgnmail.com (Garry D. Miller)  
gcesare@enercon.com (Guy Cesare)  
GovePA@BV.com (Patrick Gove)  
greshaja@westinghouse.com (James Gresham)  
gwcurtis2@tva.gov (G. W. Curtis)  
gzinke@entergy.com (George Alan Zinke)  
james.beard@gene.ge.com (James Beard)  
jason.parker@pillsburylaw.com (Jason Parker)  
jerald.head@ge.com (Jerald G. Head)  
jgutierrez@morganlewis.com (Jay M. Gutierrez)  
jim.riccio@wdc.greenpeace.org (James Riccio)  
jim@ncwarn.org (Jim Warren)  
JJNesrsta@cpsenergy.com (James J. Nesrsta)  
John.O'Neill@pillsburylaw.com (John O'Neill)  
Joseph\_Hegner@dom.com (Joseph Hegner)  
junichi\_uchiyama@mnes-us.com (Junichi Uchiyama)  
KSutton@morganlewis.com (Kathryn M. Sutton)  
kwaugh@impact-net.org (Kenneth O. Waugh)  
Ichandler@morganlewis.com (Lawrence J. Chandler)  
Marc.Brooks@dhs.gov (Marc Brooks)  
maria.webb@pillsburylaw.com (Maria Webb)  
marilyn.kray@exeloncorp.com  
mark.beaumont@wsms.com (Mark Beaumont)  
matias.travieso-diaz@pillsburylaw.com (Matias Travieso-Diaz)  
media@nei.org (Scott Peterson)  
mgiles@entergy.com (M. Giles)  
mike\_moran@fpl.com (Mike Moran)  
MSF@nei.org (Marvin Fertel)

## **Construction Inspection Program Mailing List**

murawski@newsobserver.com (John Murawski)  
mwetterhahn@winston.com (M. Wetterhahn)  
nirsnet@nirs.org (Michael Mariotte)  
patriciaL.campbell@ge.com (Patricia L. Campbell)  
paul.gaukler@pillsburylaw.com (Paul Gaukler)  
Paul@beyondnuclear.org (Paul Gunter)  
pshastings@duke-energy.com (Peter Hastings)  
rclarly@scana.com (Ronald Clary)  
regservices@scientechn.com (Reg Service)  
RJB@NEI.org (Russell Bell)  
RKTemple@cpsenergy.com (R.K. Temple)  
robert.kitchen@pgnmail.com (Robert H. Kitchen)  
sabinski@suddenlink.net (Steve A. Bennett)  
sandra.sloan@areva.com (Sandra Sloan)  
SauerB@BV.com (Robert C. Sauer)  
sfrantz@morganlewis.com (Stephen P. Frantz)  
stephan.moen@ge.com (Stephan Moen)  
steven.hucik@ge.com (Steven Hucik)  
Support@SaporitoEnergyConsultants.com (Thomas Saporito)  
trsmith@winston.com (Tyson Smith)  
Vanessa.quinn@dhs.gov (Vanessa Quinn)  
VictorB@bv.com (Bill Victor)  
Wanda.K.Marshall@dom.com (Wanda K. Marshall)  
whorin@winston.com (W. Horin)

(From DCIP list)

kenneth.ainger@exeloncorp.com (Kenneth Ainger)  
jaudis1@txu.com (John Audas)  
darin.benyak@pseg.com (Darin Benyak)  
pmblanch@comcast.net (Paul Blanch)  
david\_m\_collins@dom.com (David Collins)  
tdcosby@tva.gov (Thomas D. Cosby)  
mtc@nei.org (Mike Coyle)  
steven\_dolley@platts.com (Steven Dolley)  
cxe@nei.org (Chris Earls)  
jrfergus@duke-energy.com (J. Robert Ferguson)  
fitzpatrickwe@inpo.org (Bill Fitzpatrick)  
mark.flaherty@constellation.com (Mark Flaherty)  
frickwg@songs.sce.com (Willis Frick)  
equinox.consulting.llc@earthlink.net (Eric Fries)  
jfulto1@entergy.com (Jack Fulton)  
bpgarde@aol.com (Billie Garde)  
ecg@nei.org (Ellen Ginsberg)  
sbhaber@hpacorp.com (Sonja Haber)  
ghalnon@firstenergycorp.com (Greg Halnon)  
kah@nei.org (Tony Harris)  
dllaberdee@firstenergycorp.com (Dee Haskins)  
hlhay@bechtel.com (Howard Lane Hay)

hundrupa@gao.gov (Alyssa Hundrup)  
wrkanda@firstenergycorp.com (Bill Kanda)  
kolarick@gao.gov (Carol Kolarik)  
richard.leckey@fpl.com (Richard Leckey)  
howard\_levin@msn.com (Howard Levin)  
lynchje@inpo.org (Jim Lynch)  
rich.mallory@eh.doe.gov (Rich Mallory)  
fcmarshburn@tva.gov (Fred Mashburn)  
brian.mccabe@pgnmail.com (Brian McCabe)  
wemookhoeke@stpegs.com (W.E. Mookhoeek)  
arp@nei.org (Tony Pietrangelo)  
caprice@firstenergycorp.com (Clark A. Price)  
drepka@winston.com (David Repka)  
elliot.rosenfeld@dep.state.nj.us (Elliot Rosenfeld)  
dashurberg@hpacorp.com (Debbie Shurberg)  
strikkersd@gao.gov (Dave Strikkers)  
jrsumpt@nppd.com (Jim Sumpter)  
marlene.taylor@exeloncorp.com (Marlene Taylor)  
satconsult@msn.com (Spyros Traiforos)  
ctyler@winston.com (Catherine Tyler)  
lfvaughn@duke-energy.com (Lisa Vaughn)  
dwoodla1@txu.com (D.R. Woodlan)  
zemenskir@dtenergy.com (Robert Zemenski)  
kenneth.wade@nuclear.energy.gov (Kenneth Chuck Wade)