



**HITACHI**

**GE Hitachi Nuclear Energy**

Richard E. Kingston  
Vice President, ESBWR Licensing

P.O. Box 780 M/C A-65  
Wilmington, NC 28402-0780  
USA

T 910.675.6192  
F 910.362.6192  
rick.kingston@ge.com

MFN 09-580

Docket No. 05200010/2009-201

September 1, 2009

Yamir Diaz-Castillo  
U.S. Nuclear Regulatory Commission  
Mail Stop T-7D24  
Washington, D.C. 20555-0001

Subject: **Transmittal of GEH 2007 Audit Plan, Checklist, and Report of Empresarios Agrupados (EA) in Support of NRC Inspection of GEH Quality Assurance (QA) Program Implementation and QA Implementation of ESBWR Radiation Shielding Calculations**

The purpose of this letter is to submit documentation, as requested by the NRC, related to GEH's 2007 audit of its supplier, Empresarios Agrupados. The subject documentation is in preparation for the NRC Limited Scope Inspection scheduled for September 14 to 18, 2009 (Reference 1), and was requested by Mr. Diaz-Castillo, NRC, during a telephone conversation with Tim Enfinger, GEH Regulatory Affairs, on August 31, 2009. The documents are provided as Enclosures 1, 2 and 3.

If you have any questions or require additional information, please contact me.

Sincerely,

Richard E. Kingston  
Vice President, ESBWR Licensing

DO68  
NRC

Reference:

1. Letter from John A. Nakoski, Chief - Quality and Vendor Branch 2 - Division of Construction Inspection & Operational Programs - Office of New Reactors, to Russell Bastyr, Quality Assurance Manager - GE Hitachi Nuclear Energy, *Limited Scope Inspection of GE Hitachi Nuclear Energy's Quality Assurance (QA) Program Implementation and QA Implementation of Radiation Shielding Calculations*, August 21, 2009

Enclosures:

1. Transmittal of GEH 2007 Audit Plan, Checklist, and Report of Empresarios Agrupados (EA) in Support of NRC Inspection of GEH Quality Assurance (QA) Program Implementation and QA Implementation of ESBWR Radiation Shielding Calculations – GEH Audit Plan (October 2007) - Supplier Quality Assurance Program, Supplier: Empresarios Agrupados, Madrid, Spain
2. Transmittal of GEH 2007 Audit Plan, Checklist, and Report of Empresarios Agrupados (EA) in Support of NRC Inspection of GEH Quality Assurance (QA) Program Implementation and QA Implementation of ESBWR Radiation Shielding Calculations – GEH Audit Checklist (October 2007), Supplier: Empresarios Agrupados, Madrid, Spain
3. Transmittal of GEH 2007 Audit Plan, Checklist, and Report of Empresarios Agrupados (EA) in Support of NRC Inspection of GEH Quality Assurance (QA) Program Implementation and QA Implementation of ESBWR Radiation Shielding Calculations – GEH Audit Report (October 2007), Supplier: Empresarios Agrupados, Madrid, Spain

cc: JG Head           GEH/Wilmington (with enclosures)  
   DH Hinds         GEH/Wilmington (with enclosures)

**Enclosure 1**

**MFN 09-580**

**Transmittal of GEH 2007 Audit Plan, Checklist, and Report of  
Empresarios Agrupados (EA) in Support of NRC Inspection  
of GEH Quality Assurance (QA) Program Implementation and  
QA Implementation of ESBWR Radiation Shielding  
Calculations**

**GEH Audit Plan (October 2007) –  
Supplier Quality Assurance Program  
Supplier: Empresarios Agrupados, Madrid, Spain**



**Audit Plan - Supplier Quality Assurance Program**

**Supplier:** Empresarios Agrupados, Madrid, Spain

**Scope of Supply:** GEH ESBWR and ABWR New Plant Projects Engineering Services

- DCD and COLA support activities
- ASME Code Section III items
- Engineering/SW Design and Analysis

**Applicable QAM:** OO-MC-X-0001 and applicable documents

**Audit Team:** Y. C. Lee - Lead Auditor  
Paul Ragan - Auditor  
Kim Yu - Technical Specialist

**Scope of Audit:** NRC 10CFR50 Appendix B  
ANSI N45.2  
ANSI/ASME NQA-1, 1994 plus addenda  
10CFRPart 21  
ISO-9001  
Verification of Effectiveness of EA's corrective actions for Audit Findings from previous audits.

**Audit Checklist:** Audit Objective Evidence will be recorded on the NIAC Checklist, Revision 8, dated 8/3/2006

**Applicable Checklist Sections**

- Order Entry
- Organization/QA Program
- Nonconforming Items / 10CFR21
- Audits
- Corrective Action
- Training / Certification
- QA Records
- Design Control
- Procurement
- Document Control
- Software Quality Assurance
- Material Control and Handling, Shipping, and Storage (If applicable)
- Fabrication and Assembly and Special Processes (If applicable)
- Inspection and Test - applicable activities
- Calibration of Testing & Measuring Equipment (N/A)



**Date of Audit:** October 3 through October 5, 2007  
**Pre-Audit Meeting** 9:00 AM October 3, 2007  
**Post-Audit Meeting** 3:00 PM October 5, 2007

Audit Plan Prepared by:

YU-Chuan Lee  
Lead Quality Engineer  
Date Oct. 10, 2007

Audit Plan Approved by:

Mark Harvey  
Manager, NPP Quality  
Date: Oct. 10, 2007

**Enclosure 2**

**MFN 09-580**

**Transmittal of GEH 2007 Audit Plan, Checklist, and Report of  
Empresarios Agrupados (EA) in Support of NRC Inspection  
of GEH Quality Assurance (QA) Program Implementation and  
QA Implementation of ESBWR Radiation Shielding  
Calculations**

**GEH Audit Checklist (October 2007)  
Supplier: Empresarios Agrupados, Madrid, Spain**



**NIAC  
AUDIT CHECKLIST**

SUPPLIER: Empresarios Agrupados  
 AUDIT NO. Q0710 PAGE 2 OF 41

**SUMMARY SHEET**

Supplier QA Manual 00-MC-X-00001-/I Revision 6 Date June 30, 2006

AUDIT SEC.	SECTION DESCRIPTION	S	M	E	PROGRAM ELEMENT MEETS REGULATORY REQUIREMENT	QA PROGRAM REFERENCE	IMPLEMENTATION STATUS	COMMENTS / FINDINGS
OE	ORDER ENTRY	✓	✓	✓	S		S	
1-A	ORGANIZATION / PROGRAM	✓	✓	✓	S		S	
1-B	NONCONFORMING ITEMS / PART 21	✓	✓	✓	U		U	CAR 43894
1-C	AUDITS	✓	✓	✓	S		S	RECOMMENDATION CAR 43899
1-D	CORRECTIVE ACTION	✓	✓	✓	S		S	
1-E	TRAINING / CERTIFICATION	✓	✓	✓	S		S	
1-F	RECORDS	✓	✓	✓	S		U	CAR 43895, 43896
2	DESIGN	✓		✓	S		U	CAR 43897, 43898, 43900
3	PROCUREMENT	✓	✓	✓	S		S	
4	DOCUMENT CONTROL	✓	✓	✓	S		S	
5	MATERIAL CONTROL, HANDLING, SHIP. & STORAGE	✓	✓		N/A		N/A	
6	FABRICATION, ASSEMBLY & SPECIAL PROCESSES	✓	✓		N/A		N/A	
7	INSPECTION AND TEST	✓	✓		N/A		N/A	
8	CALIBRATION	✓	✓		N/A		N/A	
9	SOFTWARE QUALITY ASSURANCE	✓		✓	S		S	
10	DEDICATION / UNQUALIFIED SOURCE MATERIAL	✓	✓	✓	N/A		N/A	

S = NQA-1 / 10CFR50/71/72 M = MATERIAL ORGANIZATION E = ENGINEERING SERVICES

**IMPLEMENTATION STATUS KEY**

S = SATISFACTORY U = UNSATISFACTORY N/A = NOT APPLICABLE

This checklist is to be used as a guideline in conjunction with specific requirements of the appropriate industry document imposed via procurement documents.

NIAC  
AUDIT CHECKLIST

SUMMARY SHEET  
SECTION OE - ORDER ENTRY

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY	
<p>1-OE Verify that Customer Purchase Order (PO) technical and quality requirements are correctly interpreted and translated onto the supplier's work control documents (i.e., travelers, shop work orders, work tracking documents, etc.)</p> <p>Verify that exceptions to Customer Purchase Order (PO) technical and quality requirements are promptly communicated to the Customer and resolved.</p> <p>NOTE: Technical and quality requirements include such items as: inspection/test, documentation, C of C, packaging/shipping, hold points, etc.</p> <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107, 71.105/10CFR72 Subpart G 72.146, 72.144 ASME Section III NQA-1 Supplement 4S-1 Vendor Program Ref:</p>	<p>S</p>	<p>EA International has generated Project specific Quality Plan that defines the scope of work and quality requirements of Lungmen, STP and ESBWR projects. These project specific quality plans are</p> <ol style="list-style-type: none"> <li>1. ESBWR Design Certification &amp; COL Activities Quality Plan: Doc. # 092-134-PCP-Z-00001 Rev. 9 per GE Hitachi PO 43100</li> <li>2. STP NPP Licensing Process Support, Quality Plan, Doc. # 209-001-pcp-z-00001 Rev. 1 per per GE Hitachi PO 43100</li> <li>3. Lungmen Small Bore Piping Routing Services Quality Plan Doc. # 207-103-pcp-j-00001 Rev. 4 per GE Hitachi PO 43100</li> </ol> <p>In each QP, it describes the Scope of work, QA requirements, Appendix B applicable requirements, applicable Empresarios Agrupados (EA) procedures and project contact and responsible engineers.</p>	
<p>2-OE Describe and verify the measures that are established and implemented for controls of Items returned for Repair/Rework.</p> <p>Appendix B/ANSI N45.2 Ref: (15/16) ASME Section III 10CFR71 Subpart H 71.131/10CFR72 Subpart G 72.170 NQA-1 Supplement 15S-1 Vendor Program Ref:</p>	<p>NA</p>		
<p>Identify below the major / key customer orders used during this audit to verify implementation and effectiveness of the supplier's Quality Assurance Program.</p> <p>NOTE: Not all customer orders need be listed below. Only those considered 'key' in providing objective evidence of implementation of the supplier's QA Program.</p>			
<p><u>Customer</u></p> <p>GE Hitachi Nuclear Energy GE Hitachi Nuclear Energy GE Hitachi Nuclear Energy</p>	<p><u>Customer P. O.</u></p> <p>431006971 431008457 431000146</p>	<p><u>Supplier Work Order / Project No.</u></p> <p>092134 209001 207103</p>	<p><u>Item / Component / Description</u></p> <p>ESBWR DCD and COLA Engineering and Design Services STP COLA/FSAR Engineering Services Lungmen – Modeling /Analysis of Small Bore Piping System</p>

SECTION 1 - PROGRAM COMPLIANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>1.A.1 Verify that the individual/organization responsible for defining the overall effectiveness of the QA Program:</p> <p>a) is designated; (i.e., authority, organizational structure and responsibility is documented); b) is independent of production pressures; c) has direct access to appropriate management levels; d) Regularly reviews, assesses and reports on the applicability, status and effectiveness of the QA Program.</p> <p>Appendix B/ANSI N45.2 Ref: (1-3) 10CFR71 Subpart H 71.103, 71.105/10CFR72 Subpart G 72.142, 72.144 ASME Section III NQA-1 Supplement 1S-1, NCA3851.3 (b) Vendor Program Ref:</p>	<p>a) S b) S c) S d) S</p>	<p>a) Verified that the organization responsible for defining the overall effectiveness of the QA Program is designated per Section 2 of Quality and Environmental Management Manual, 00-MC-X-00001-1, Revision 6. Organizational structure is established in procedure 00-A-X-10101-1, Revision 12 and Appendix 00-A-X-10101-A1/1, Revision 12.</p> <p>b) The Quality and Environmental Management organization is independent from direct production management units as specified in Section 2.3 of 00-MC-X-00001-1.</p> <p>c) The Quality and Environmental Management organization has direct access to the General Manager per Section 2.3 of 00-MC-X-00001-1.</p> <p>d) The Quality and Environmental Management organization has the responsibility to assess the effectiveness of the QA Program and inform the General Manager of the state of implementation of the Quality Program per 00-A-X-10130-1. Reviewed xxx report and conforms with requirements of procedure 00-A-X-10130-1.</p>
<p>1.A.2 Assess whether personnel performing verification activities have the authority, independence and organizational freedom to:</p> <p>a) Identify quality problems; b) Initiate, recommend or provide solutions to problems; c) Verify implementation of solutions; d) Control further processing of nonconformance until proper disposition has occurred.</p> <p>Appendix B/ANSI N45.2 Ref: (1-3) 10CFR71 Subpart H 71.103/10CFR72 Subpart G 72.142 ASME Section III NQA-1 Supplement 1S-1, NCA 3851.3 (c) Vendor Program Ref:</p>	<p>a) S b) S c) S d) S</p>	<p>Yes, Empresario Agrupados' Quality and Environmental Management Manual, 00-MC-X-00001-1, Revision 6. Section 2 does specify the authority, independence and organizational freedom of the QA and personnel performing verification activities. Throughout the audits process, it was verified by all the items samples and interviewing results.</p>
<p>1.A.3 Verify the supplier has developed a Quality Program which will assure that supplies and/or services provided will conform to Customer P.O. requirements.</p> <p>a) Is there supplemental written policies, procedures, or instructions to the Quality Program? b) Describe the method the supplier uses to notify the Customer in writing of any changes to the Quality Program; c) Are process control procedures an integral part of the suppliers Quality Program when such procedures are a part of the referenced specification or the P.O.?</p> <p>Appendix B/ANSI N45.2 Ref: (1-3) ASME Section III NQA-1 Supplement 2S-1, NCA3851.1 Vendor Program Ref:</p>	<p>a) S b) S c) S</p>	<p>a) Verified that supplemental procedures/instructions are in place to implement the requirements of the Quality Manual. EA has a Quality Procedures Manual, Index 00-A-X-10000-1, Revision 24 and a Quality Instructions Manual, Index 00-Y-X-10000-1. These procedure manuals establish the instructions for implementing the overall Quality Program. There are also project specific QA Plans defining the project quality requirements.</p> <p>ESBWR – 092-134-PCP-Z-00001, Issue 9 STP – 209-001-PCP-Z-00001, Issue 1 Lungmen – 207-103-PCP-J-0001, Issue 4</p> <p>b) Section 3.3.2 of Procedure 00-Y-X-10102-1 requires the Project Manager to send a copy of the Project Quality Plan to the Customer for his approval, when required by contract. Latest revision of the ESBWR Project Quality Plan 092-134-PCP-Z-00001, Issue 9 was distributed to Matthew Carmona (GEH PM) and David Hinds (Eng Mgr).</p> <p>c) EA develops Quality Plans for each project. The Project Quality Plans for Lungmen, ESBWR and STP activities were reviewed during the audit. Each of the Project Quality Plans includes procedure requirements applicable to the scope of activities that are an integral part of the Quality Program. In addition, STP PO 431008457 requires specific training requirements for EA personnel performing work in support of the subject PO. These PO requirements were carried through to the STP Project Quality Plan, 209-001-PCP-Z-00001, Issue 1. The specific training requirements are listed on Attachment A of the Project Quality Plan. Completion of these specific training requirements were confirmed complete, as noted in Section 1.E.1 of this checklist.</p>

SECTION 1 - PROGRAM COMPLIANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>1.B.1 Verify that measures are established and implemented to:</p> <ul style="list-style-type: none"> <li>a) identify nonconforming items;</li> <li>b) ensure that responsibility and authority for review/disposition is identified;</li> <li>c) control further processing, delivery and installation of items until disposition is completed;</li> <li>d) provide notification to the customer of nonconforming conditions when required by customer P.O.</li> </ul> <p>Appendix B/ANSI N45.2 Ref. (15/16) 10CFR71 Subpart H 71.131/10CFR72 Subpart G 72.170 ASME Section III NQA-1 Supplement 15S-1, NCA3858.5 Vendor Program Ref.</p>	<p>S S S S</p>	<p>Item a), b), and c) EA's Quality Document System Procedure: 00-A-X-11301 Rev. 4 Dated 2006-04-07: Disposition and Control of Non-Conformities defines the identification, responsibility, disposition and control processes for all non-conformance items.</p> <p>Item d) Requirement - GEH NEDO-33260, LQAR-1, NEDC-33282 Section 4.6 require notification to buyer with NCR with "Use-as-is" and "Repair" disposition. EA Quality Document System Instruction 00-Y-X-10106 Rev. 5 Dated 2005-02-037: Disposition and Control of Non-Conformities Section 3.1.1 requires all NCR with disposition of Use-as-is" and "Repair" to be approved by customer.</p>
<p>1.B.2 Verify that nonconforming items are reviewed and dispositioned such that:</p> <ul style="list-style-type: none"> <li>a) the disposition is identified;</li> <li>b) documented justification is provided verifying the acceptability of nonconforming items which are dispositioned repair or use-as-is;</li> <li>c) the disposition/close-out is approved by the responsible authority;</li> <li>d) procedures or instructions for repair and rework are provided;</li> <li>e) repaired &amp; reworked items are reinspected.</li> </ul> <p>Appendix B/ANSI N45.2 Ref. (15/16) 10CFR71 Subpart H 71.131/10CFR72 Subpart G 72.170 ASME Section III NQA-1 Supplement 15S-1, NCA3858.5 Vendor Program Ref.</p>	<p>S N/A  S N/A N/A</p>	<p>All the hard copies of the NCR listed in Table -1 B were reviewed and verified that proper dispositions, signatures, and closure to be completed and satisfactory.</p> <p>There were NO "Use-as-is" and "Repair" disposition NCR. Thus there was none for review. However EA's Quality Document System Instruction 00-Y-X-10106 Rev. 5 Dated 2005-02-037: Disposition and Control of Non-Conformities section 3.1.1 requires customer acceptance for all non-compliances (NO "Use-as-is" and "Repair") to contract requirements.</p>
<p>1.B.3 10CFR21</p> <ul style="list-style-type: none"> <li>a) Are appropriate documents posted at premises where activities subject to Part 21 are conducted? Appropriate documents may be a copy of 10CFR21 and Section 206 of the Energy Reorganization Act of 1974 and company implementing procedure(s) - or - Section 206 of the Energy Reorganization Act and a notice describing regulations and procedures along with the name of the company individual to whom reports should be made.</li> <li>b) Is there a mechanism to determine if a Part 21 condition exists?</li> <li>c) Is there a mechanism to provide for notification to the customer or the NRC when a failure to comply or defect is discovered?</li> <li>d) Have there been any reportable instances within the previous three years (or since the last NIAC audit)?</li> </ul> <p>Regulatory Reference: 10CFR21.6 and .21 Vendor Program Ref.</p>	<p>U   U U U</p>	<p>EA Quality Document System Instruction 00-Y-X-10106 Rev. 5 Dated 2005-02-037: Disposition and Control of Non-Conformities Section 3.1.1 requires notification to customer on any 10CFR21 applicable non-conformance. But it does not address all Part 21 requirements.</p> <p>EA has no program and no procedure for 10CFR21 compliance.</p>

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AUDIT CHECKLIST

SUPPLIER: Empresarios Agrupados  
AUDIT NO. Q0710 PAGE 6 OF 41

1-B - PROGRAM COMPLIANCE  
NON-CONFORMANCES

ITEM ID / DESCRIPTION	NCR / CAR NUMBER	DATE INITIATED	DISCREPANT CONDITION	DISPOSITION	REINSPECTION / VERIFICATION	FOR USE-AS-IS OR REPAIR, WAS THE CUSTOMER NOTIFIED	CLOSURE DATE
092 134-FQ-G-00601 - NCR	092134-AC-G-I-00011	07-07-2007	SW (AVACO) validation not documented	Document validation process as required	Doc 207-109-1PV-EA-001 and / -002 documented & verified.	No	Open
092 134-FQ-G-00601- CAR	092134-AC-G-D-00010	30-06-2007	List of project documentation not updated per new PO revision	CA to update project document	Update 092-134-L-D-00001 to Revision 3 as required	No	26-07-2007
207-026-FQ-G-00501- CAR	207026-AC-G-A-00007	31-07-2006	Design. Record File temporary backup not performed	CA to establish and perform temp. backup.	Doc. 207-026-A-VAR-070109 verified	No	09-01-2007
207 026-FQ-00601 - CAR	207103-AC-G-J-00001	02-10-2007	Project Quality Plan not updated per PO revision	CA to update document	PCP 207-103-PCP J-0001 Rev. 4 verified.	No	02-10-2007
207 026-FQ-00601 - CAR	207026-AC-G-A-00008	02-10-2007	Project Quality Plan not updated per PO revision	CA to update PCP	PCP 207-026-PCP-J-0001 Rev. 7 verified.	No	02-10-2007
CAR	207100-INC-G-00001	20-10-2006	C. Nieto's Training Record not updated	Update training record	Training record updated and accepted	No	13-10-2006

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AUDIT CHECKLIST

SECTION 1 - PROGRAM COMPLIANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>1. C. Verify that measures are established and implemented to ensure a comprehensive system of planned and periodic internal audits.</p> <p>NOTE: Document details of the internal audit program here. Document details of the supplier audit program at Question 3.3. Table 1-C may be used to record details for both internal and supplier audits.</p> <p>a) Verify that the participants have no direct responsibility in the areas audited,</p> <p>b) Verify that procedures and/or checklists were used with objective evidence documented,</p> <p>c) Verify that follow-up action, including re-audit of deficient areas, is taken where needed.</p> <p>Appendix B/ANSI N45.2 Ref: (18/19) 10CFR71 Subpart H 71.137/10CFR72 Subpart G 72.176 ASME Section III NQA-1 Supplement 18S-1, NCA3859.1 Vendor Program Ref: _____</p>	<p>a) S b) S c) S</p>	<p>a) Section 3.2.1 of procedure 00-A-X-11701-1, Revision 2 states that the audit team shall be independent from personnel directly responsible for the activity to be audited. This is also documented in instruction 00-Y-X-10104-1, Revision 2, Section 3.2.1. This independence criteria was verified in the following audits: 1. ESBWR Design Certification and COL Activities - 092-134-FQ-G-00601 2. Lungmen - 207-026-FQ-G-00601</p> <p>b) Section 3.2.2 of procedure 00-A-X-1170-1, Revision 2 states that checklists shall be used to carry out audits, enabling the audit team to perform the analysis systematically. Section 3.2.3 states that the auditors shall obtain documented evidence to a degree of detail necessary to prepare the Audit Report. This is also documented in instruction 00-Y-X-10104-1. Verified use of checklist for the ESBWR and Lungmen Audits. ESBWR Checklist – 092134-LQA-G-00601 Lungmen Checklist – 207026-LQA-G-00601</p> <p>c) List of audit findings and status is provided on Table 1-C. All corrective actions have been completed and closed.</p>
<p>1. D. Verify that measures are established and implemented to assure that conditions adverse to quality are promptly identified and corrected. These measures shall include as a minimum:</p> <p>a) Identification and description of the condition adverse to quality;</p> <p>b) Determination of the cause and actions taken to prevent recurrence for significant conditions adverse to quality;</p> <p>c) Review and approval by responsible authority on the adequacy of the corrective action;</p> <p>d) Follow-up action for close-out to verify that the corrective action has taken place or is scheduled.</p> <p>Appendix B/ANSI N45.2 Ref: (16/17) 10CFR71 Subpart H 71.133/10CFR72 Subpart G 72.172 ASME Section III NQA-1 Basic Requirement 16, NCA3859.2 Vendor Program Ref: _____</p>	<p>S S S S</p>	<p>EA Quality Document System Procedure 00-A-X-10106 Rev. 4 Dated 2006-04-07: Disposition and Control of Non-Conformities Section 3.2.3 establishes the requirement for Corrective /Preventive Actions</p> <p>EA Quality Document System Procedure 00-A-X-11401 Rev. 2 Dated 2005-02-03: Implementation and Control of Corrective and Preventive Action establishes initiation and process for documenting, monitoring, analysis, and closure of the CARs.</p> <p>The objective evidences are listed in Table 1B</p>

NIAC  
AUDIT CHECKLIST

1-C - PROGRAM COMPLIANCE  
AUDITS / SURVEILLANCES

REPORT ID NUMBER	PERFORMANCE DATE	SCOPE	INTERNAL/ EXTERNAL	ITEMS CONSIDERED AND SUPPLIER PROCESSES EVALUATED (SPECIFY)	AUDITING ORGANIZATION TEAM MEMBERS	NUMBER OF DEFICIENCIES (OPEN/CLOSED)	CORRECTIVE ACTION STATUS - DATE VERIFIED / METHODS USED (SPECIFY)
092-134-FQ-G-00601	2007-05-11	ESBWR Design Certification & COL Activities	Internal	All applicable criteria	J. Ramon Sabin Seijas (Lead) Angel Fernandez Gonzales	(5/x) 1. 092134-AC-G-D-00008 2. 092134-AC-G-D-00009 3. 092134-AC-G-D-00010 4. 092134-AC-G-I-00011 5. 092134-AC-G-D-00012	1. Closed 2. Closed 3. Closed 4. Closed 5. Closed
207-026-FQ-G-00601	2007-09-11	Lungmen Activities	Internal	All applicable criteria	Javier Goicoechea (Lead)	(2/x) 1. 207026-AC-G-A-00008 2. 207103-AC-G-J-00001	1. Closed 2. Closed

NIAC  
AUDIT CHECKLIST

SECTION 1 - PROGRAM COMPLIANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>1. E.1 Verify that measures are established and implemented for indoctrination and training of personnel who perform activities affecting quality.</p> <p>NOTE: Evidence to be obtained from Sections 2 through 7.</p> <p>Appendix B/ANSI N45.2 Ref: (2/2) 10CFR71 Subpart H 71.105/10CFR72 Subpart G 72.144 ASME Section III NQA-1 Supplement 2S-4, NCA3852.1 (a) Vendor Program Ref:</p>	<p>S</p>	<p>Training requirements for new employees and refresher courses for EA personnel are specified per procedure 00-Y-X-10112-/I, Issue 2. Project specific training requirements are to be specified per procedure 00-Y-X-10115-/I, Issue 1. The project training plan for the ESBWR project was reviewed during the audit. The training plan included such requirements as the project quality plan (092-134-PCP-Z-00001, Issue 9), ESBWR Project Instructions, and various EA Instructions.</p> <p>STP Project PO 431008457 requires EA personnel work to the GEH QA Program. Specific GEH training material is required per PO. A selection of training records was reviewed and confirmed complete.</p> <p>Reviewed the training records for the following personnel and confirmed complete:</p> <ol style="list-style-type: none"> <li>1. Alfonso Junquera Delgado – 092-134-RF-M61-6795, Issue 1 (ESBWR Project)</li> <li>2. Ana de Lucas – 209-001-RF-A-3078, Issue 1 (STP Project)</li> <li>3. Jose Manuel Arroyo Macias – 209-001-RF-Z-7369</li> </ol>
<p>1.E.2 Verify that inspection/test personnel, auditors, NDE, Welding and similar specialists (i.e., ASME Code work design personnel to ASME Section III Appendix XXIII) are qualified and have certifications on file in accordance with Industry and/or supplier QA Program requirements.</p> <p>NOTE: Evidence to be obtained from Sections 1, 2, 3, 4, 6, and 7.</p> <p>Appendix B/ANSI N45.2 Ref: (2, 9, 10, 11, 18/2, 10, 11, 12, 19) 10CFR71 Subpart H 71.105, 71.119, 71.137/10CFR72 Subpart G 72.144, 72.158, 72.176 ASME Section III NQA-1 Supplement 2S-1, 2S-2, 2S-3, NCA3852.1(b), NCA3852.2(b), NCA3857.3 Vendor Program Ref:</p>	<p>S</p>	<p>1. Verifiers are qualified per procedure 00-Y-X-10107-/I, Issue 5. Verifier certification is required. See Table 1-E for confirmed verifier certification.</p> <p>2. Auditors qualification is specified per procedure 00-Y-X-10105-/I, Issue 3. Lead Auditor Qualification is for one year. See Table 1-E for confirmed Lead Auditor Certifications.</p>

NIAC  
AUDIT CHECKLIST

SUPPLIER: Empresarios Agrupados

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1-E - PROGRAM COMPLIANCE  
AUDIT / INSPECTION / CALIBRATION / NDE PERSONNEL

NAME / STAMP	QUALIFICATION / CERTIFICATION CERT TYPE AND LEVEL	CERT EXPIRATION DATE	EYE EXAM EXPIRATION DATE
Jose Ramon Sabin Seijas	Lead Auditor	March 2008	N/A
Francisco Javier Goicoechea Sanchez	Lead Auditor	March 2008	N/A
Alfonso Junquera Delgado	Verifier	February 2008	N/A

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SUPPLIER: Empresarios Agrupados

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1-E - PROGRAM COMPLIANCE  
WELDER / WELD OPERATOR

NAME / STAMP	CERT TYPE (PROCESS & POSITION)	CODE QUALIFIED TO	WPS PROCEDURES / REV / DATE	MAINTENANCE OF QUALIFICATION

SECTION 1 - PROGRAM COMPLIANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>1.F.1 Verify that measures are established and implemented to assure that sufficient records are:</p> <ul style="list-style-type: none"> <li>a) available to furnish documentary evidence of the quality of delivered items;</li> <li>b) available to furnish documentary evidence of the quality of generic activities affecting the quality program;</li> <li>c) provided to the customer in accordance with contract / P.O. requirements.</li> <li>d) Only authorized personnel sign Compliance/Conformance Certificates.</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (17/18) 10CFR71 Subpart H 71.135/10CFR72 Subpart G 72.174 ASME Section III NQA-1 Supplement 17S-1, 6S-1, NCA3853.4, NCA3853.5 Vendor Program Ref:</p>	<p>S</p> <p>S</p> <p>S</p> <p>S</p>	<p>EA Quality Document System Instruction 00-A-X-11601 Rev. 2 Dated 2003-02-05: defines the process and controls of records including identification, inspection, recording, filing, conservation, final archive and disposal.</p> <ul style="list-style-type: none"> <li>A) Various records such as Auditor's qualification records, design verifier's certification, STP/ESBWR engineers training records were verified. In addition, numerous design control and verification records. Assessment summary and objective evidences are written in each respective checklist items.</li> <li>B) See above comment.</li> <li>C) Same as comment A</li> <li>D) Approval and certification requirement of above mentioned Training records and Lead auditor's records were verified to be in compliance with procedure requirement.</li> </ul>
<p>1.F.2 Verify that measures are established and implemented to assure that records are:</p> <ul style="list-style-type: none"> <li>a) legible;</li> <li>b) identifiable and retrievable;</li> <li>c) retained for proper periods of time;</li> <li>d) stored to provide protection against damage, deterioration or loss.</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (17/18) 10CFR71 Subpart H 71.135/10CFR72 Subpart G 72.174 ASME Section III, NCA3853.4 Vendor Program Ref:</p>	<p>a) S</p> <p>b) U</p> <p>c) S</p> <p>d) S</p>	<p>b) Project-specific training records are documented per procedure 00-Y-X-10115-/I. ESBWR Project Training record 209-001-RF-Z-7369 does not have an Issue (Revision) number listed as required.</p>
<p>(Applies only to NCA3800 Audits of Non QSC Certificate Holders)</p> <p>1. F.3 Verify CMTRs include actual results of all required chemical analysis tests and examinations.</p> <ul style="list-style-type: none"> <li>a) Verify the material identification is described in either a CMTR or a Certificate of Compliance;</li> <li>b) For material ¾" &amp; less nominal pipe size, and 1" and less bolting, verify that CMTR or C of C is provided with material spec, grade, class, and heat treatment condition (as applicable);</li> <li>c) Verify the Material Organization Quality System Program revision and date are stated on the CMTR or C of C;</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (17/18) ASME Section III, NCA3853.4, Vendor Program Ref:</p>		<p>N/A</p>

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SECTION 1 - PROGRAM COMPLIANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>(Applies only to NCA3800 Audits of Non QSC Certificate Holders)</p> <p>1.F.4 Review CMTRs or C of C's to verify:</p> <ul style="list-style-type: none"> <li>a) The certification affirms the contents of the report are correct and accurate and that all test results and operations performed by the Material Organization or its subcontractors are in compliance with the material specification and specific applicable material requirements;</li> <li>b) Chemical Analysis, tests examinations and heat treatments required by the material specification that were not performed are listed on the CMTR of C of C (may be listed as an attachment);</li> <li>c) When the Material Organizations scope of work includes product form conversion, the organization shall also certify that the material conforms to the applicable dimensional requirements;</li> <li>d) Document how the supplier establishes authorized personnel for certifications, and verify Certifications are signed by those authorized personnel.</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III, NCA3861 Vendor Program Ref: _____</p>		<p>N/A</p> <p>Empresario Agrupados is not an ASME NCA 3800 supplier.</p>
<p>(Applies only to NCA4000 Audits)</p> <p>1. F.5 Verify the Certificate Holder completes all operations not completed by the Material Organization and provide a CMTR for all operations performed by him or his approved suppliers, or the Certificate Holder may provide a CMTR for operations performed and at least one CMTR for each of its approved suppliers for operations they had performed.</p> <p>Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III, NCA3862.1 Vendor Program Ref: _____</p>	<p>N/A</p>	<p>N/A</p> <p>Empresario Agrupados is not an ASME NCA 4000 Supplier.</p>

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AUDIT CHECKLIST

SECTION 1 - PROGRAM COMPLIANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>(Applies only to 10 CFR 71 Subpart H vendors)</p> <p>1. F.6 Verify records are retained in accordance with the provisions of 10 CFR Part 71. Specifically:</p> <ul style="list-style-type: none"> <li>a) Records of each shipment of licensed material shall be maintained for 3 years minimum after that shipment [10 CFR 71.91(a)];</li> <li>b) Records providing evidence of packaging quality shall be maintained for 3 years after the life of the packaging [10 CFR 71.91(c)];</li> <li>c) Records describing activities affecting packaging quality shall be maintained for 3 years after the Quality Assurance Program Approval is terminated [10 CFR 71.135].</li> </ul> <p>NOTE: These requirements may not apply to vendors if the purchaser is retaining the appropriate records for the vendor. The reasoning for this approach is that it is typically not always possible for the vendor to know the life of a particular storage or transportation device. When this is the case, the applicable requirements of the vendor's QA Program or other applicable regulatory requirements shall apply and be verified utilizing Checklist Items 1.F.1 and 1.F.2.</p> <p>10 CFR 71 Subpart H Vendor Program Ref: _____</p>		<p>N/A</p> <p>Empresario Agrupados is not a 10CFR71 Subpart H vendor</p>
<p>(Applies only to 10 CFR 72 Subpart G vendors)</p> <p>1. F.7 Verify records are retained in accordance with the provisions of 10 CFR Part 72. Specifically:</p> <ul style="list-style-type: none"> <li>a) Records that are required must be maintained until the Commission terminates the license [10 CFR 72.80(c)].</li> </ul> <p>NOTE: These requirements may not apply to vendors if the purchaser is retaining the appropriate records for the vendor. The reasoning for this approach is that it is typically not always possible for the vendor to know the life of a particular storage or transportation device. When this is the case, the applicable requirements of the vendor's QA Program or other applicable regulatory requirements shall apply and be verified utilizing Checklist Items 1.F.1 and 1.F.2.</p> <p>10 CFR 72 Subpart G Vendor Program Ref: _____</p>		<p>N/A</p> <p>Empresario Agrupados is not a 10CFR71 Subpart G vendor</p>

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SECTION 2 - DESIGN

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>2.1 Verify that measures to control the translation of design requirements into design documents are implemented.</p> <p>a) Review engineering/production documents for inclusion of applicable technical and quality requirements.</p> <p>b) Verify inclusion of contractually identified design bases, (regulatory requirements, Code requirements, codes, standards, EQ/Seismic report numbers, analyses etc.) in design/quality documents.</p> <p>c) Assure the P.O. requirements that cannot be met by supplier are promptly communicated back to the buyer. This includes notification of design deviations.</p> <p>NOTE: Evidence reviewed to be used in Sections 6 and 9.</p> <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III NQA-1 Supplement 3S-1 Vendor Program Ref:</p>	<p>U</p>	<p>Taking one item from the ESBWR PO to review - item 19 of PO 431006971 rev. 2 att. T – Top Level Documentation, in particular Flood Protection Requirements.</p> <p>This project has a Project Quality Plan – doc. 092-134-PCP-Z-00001 issue 9</p> <p>Reviewed Doc # 092-134-F-M-01400-LDP issue 1 there is a list of document input data, and in the Doc. 26A6007 issued 31 Oct 2005, Composit Design Specification, there is statement that Sec. 3.4.1 of the SRP that applies to flooding analysis. A copy of the List of Document Input Data is attached.</p> <p>For evidence that one of the data input items has been used in the flooding analysis, there is no direct reference in the document to refer for ex. the reactor building general arrangement item 4 of the data input list was applied, but informed that evidence is to be seen in design verification. See later Section 2.3 on design verification.</p> <p>When EA identifies new necessary input data, EA stated that they will inform to GE in order to update the Att. T.</p> <p>For changes to design inputs due to update of 'preliminary' information, evidence is seen in updates of the List of Document Input Data from Issue 0 and Issue 1. For the list of documents, one recommendation is to clarify ome titles in the Title of Document. For example, item 35 "Re Flooding Analysis" is vague. The problem is that the title only states "Flooding Analysis" but it actually means "GE Replies to EA Comments to Flooding Analysis Rev. XXX"</p> <p><b>Recommendation:</b> Clean up the list of input data in this table, do not include items that do not apply. For example, letters related to EA Comments to GE on data input issues should not be included in this list.</p> <p><b>Finding</b> – input data has been transmitted by emails and not by Project Letter, contrary to Project Procedure.</p> <p>In Document 092-134-F-M-01400-LDP issue 1 items 31, 32 shows documents that are emails.</p> <p>The ESBWR Design Cert &amp; COL Activities Quality Plan 092-1134-PCP-Z-00001 sheet 2 of 6 specifically stated that official transmission of information and documents via Letter. ESBWR Project Instruction EPI-20-01 rev. 4 section 4.2 states that "When the correspondence is electronic (e-Mail) and includes technical content, only a transmittal letter is to be sent by eMail."</p> <p>Finding – Work performed per PO 431006971 rev. 2 should be performed per accompanied Att. T and there is doubt that parts of it is performed per this the technical requirements listed in Att. T. This does not conform with NEDO-33260 rev. 2 Section 4 and this document is referenced in page 1 of the EA ESBWR Quality Plan doc. 092-134-PCP-Z-00001 issue 9 dated June 30, 2007.</p> <p>In PO 431006971-2 transmitted 2-21-07, Table 1 identifies the input requirements for each Line Item. For Line item 19 Top Level Documentation, Table 1 stated "See Documents associated with Line item 15". Enquiring the EA Project Manager, whether or not all the documents of Line item 15 are required for Line item 19, the Project Manager is uncertain. She believes that part of the documents associated with Line item 15 are applied to Line item 19. Confirmation of which of the documents are requirements for Line item 19 should be performed via an evaluation by EA and the results communicated by project letter to GEH. Furthermore, by EOP 42.5, GEH project manager should then by project letter, approve this confirmation and revise Att. T accordingly. The revised Att. T resulting in a revised PO should be transmitted to EA in a timely manner.</p>
<p>2.2 Verify that measures are established and implemented for the identification and control of design interfaces.</p>		<p>Measures used to identify and control design interfaces for EA's ESBWR project is the PO and Att. T from GEH. They are reviewed in Section 2.1. See summary and comments in Section 2.1.</p>

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<p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III NQA-1 Supplement 3S-1 Vendor Program Ref: _____</p>	
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SECTION 2 - DESIGN

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>2.3 Verify that measures are established and implemented for the verification of design adequacy.</p> <p>a) Review design records for evidence that the verification is performed by individuals or groups other than those who performed the design.</p> <p>b) Assure that the verification method to be used is identified. (design review, alternate calculations, or tests)</p> <p>c) When the verification method used is qualification test, verify that a prototype unit is tested under the most adverse design conditions.</p> <p>Appendix B/ANSI N45.2 Ref. (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III NQA-1 Supplement 3S-1 Vendor Program Ref. _____</p>	<p>S</p> <p>S</p> <p>S</p>	<p>Following on the Flooding Analysis report, the independent verification for the report is simple and does not contain actual evidence of the verifier performing the verification. There is a checklist of summary checks and his signature. A checklist of summary results is used for all verification. Evidently simple ones with no comments or minor comments are not documented other than the summary sheet.</p> <p>Recommendation – as the NRC and other parties have advised that a checklist summary as the only evidence of verification is not adequate, recommend that a short summary of actions taken during the verification, signed and dated by the verifier, be added to the verification record.</p> <p>We request for a verification example including minor comments and also verification of calculations that show actual evidence of verification via alternative calculations.</p> <p>Actual evidence of verification is observed in the verification of the report for item 10 – Island Operation Mode and Full Load Rejection Turbine Trips, verification report 092-134-C-M001304-HCR.</p> <ol style="list-style-type: none"> <li>verified that verifier is different from author and acceptance of disposition by verifier</li> <li>verification method is alternative calculation per verification guide 00-GD-M-011002, alternative calculations observed with signatures of verifier. This guide leads to another document 00-G-M-11002-C that defines methods for checking by calculation. The guide documents are generic in Spanish but the actual project verification document which is a controlled document is in English.</li> <li>no qualification testing performed for this particular verification</li> </ol>
<p>2.4 Verify that measures are established and implemented to control design changes, including changes for spare/replacement parts.</p> <p>a) Review revised design documents, (e.g. calculations, drawings, stress reports), to verify that design changes are made using design control measures equal to those of the original design.</p> <p>b) Review design changes to verify that they were reviewed and approved by the same organization as originally reviewed and approved the design, or by other knowledgeable, qualified and designated organizations.</p> <p>c) Verify that design changes have been adequately evaluated to assure that performance, interchangeability and qualification are not adversely impacted.</p> <p>d) Verify that Design changes for licensed items also trigger 10CFR71 or 10CFR72 license drawing changes.</p> <p>Appendix B/ANSI N45.2 Ref. (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III NQA-1 Supplement 3S-1 Vendor Program Ref. _____</p>	<p>S</p> <p>S</p> <p>S</p> <p>S</p>	<p>Reviewing Flood Protection Analysis Report between rev. 0 and 1.</p> <ol style="list-style-type: none"> <li>a change of the rev. 0 the control valve flow rate is 73.2 m3/h – a value from generic origins. A comment was sent to GE and GE replied by letter number GEEA-SR3-2006-0002 dated 1/20/06 to change to 122.6 m3/h and this is the value used in rev. 1 page A40-4.</li> <li>see a.</li> <li>for impact see Sec. 2.4 that shows that the worst case of fire protection system flow in the reactor Building with the revision would be from CRD Pump Rom sprinkler actuation reaching 61.3 m3. This has no other impact because the max volume of 81 m3 in the worst case, the water level in the bottom of the Reactor Building would reach 20 cm in the event of flooding.</li> <li>no impact on any license drawings</li> </ol> <p>Established measures implemented to control design changes are found to be adequate.</p>

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2 - DESIGN

DESIGN DOCUMENT	BASES	SUPPORTED BY ENG / TEST DATA	METHOD OF DESIGN VERIFICATION	DESIGN CHANGE CONTROL / REV / DATE	CUSTOMER APPROVAL DOCUMENTATION
092-134-F-M-01400-LDP issue 1 List of Document Input Data for Item 19 Top Level Documentation – Flooding Analysis	basis is the EA ESBWR Design Certification & COL Activities Quality Plan #092-134-PCP-Z-00001 issue 9 06/2007	na	part of Flooding Analysis Report, independent design verification	issue 1 10/2006	by project process, EA formal issuance of "for use" and project letter is means of transmittal and acceptance by GE email from Sourcing as part of the PO.431006971 rev. 2.
T- 431006971 rev. 2	Attachment T to PO of the same number	na	na supplier (GE) requirements to EA on ESBWR project	rev. 9/2007	
092-134-C-M-01304-HCR, issue Comments and Dispositions Sheet for ESBWR Design Certification & COL Activities Island Mode Operations Main Condenser Bypass Transient Response, reviewing document 00-GD-M-16201-Q/I issue 1 Mechanical Calculations	internal verification guidelines 00-GD-M-016201-V issue 1 7/97, 00-G-M-11002-C issue 1 11/2001	yes	independent verification of Mechanical Calculations document, showing alternative calculations	issue 1 4/2007	na, internal verification record document the report was transmitted via EAGE-SR3-2007-0317 dated April 20, 2007.
ESBWR Design Certification Flood Protection Analysis Doc. # 092-134-F-M-01400 issue 1, Safety Related Record	PO 431006971	yes	design change via new information from customer, shows results change and any impact on change	issue 1 10/2006 from issue 0 11/2005	transmitted to GE via EAGE-SR3-2006-0763 dated Oct. 6, 2006.
Doc # 092-134-PCP-Z-00001 issue 9 dated June 30, 2007	PO 431006971	na	reference document	issue 9 June 30, 2007	

## SECTION 3 - PROCUREMENT

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>3.1 Verify that measures are established and implemented to assure that applicable requirements are included in documents for procurement of items including spare and replacement parts and services.</p> <p>Procurement documents should include provisions for the following, as applicable:</p> <ul style="list-style-type: none"> <li>a) Statement of the scope of work.</li> <li>b) Technical requirements by reference to specific drawings, codes, specifications.</li> <li>c) Requirement for a documented quality assurance program, implemented, and meeting applicable code/regulatory requirements.</li> <li>d) Requirement for right of access to plant facilities and records for source inspection/audit.</li> <li>e) Identification of document submittals for approval.</li> <li>f) Identification of deliverable records.</li> <li>g) Requirement for reporting and approving disposition of nonconformances.</li> <li>h) Requirements for records availability, retention and disposition.</li> <li>i) Requirements for extending applicable requirements to lower tier suppliers.</li> <li>j) Applicability of 10CFR21.</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (4/5) 10CFR71 Subpart H 71.109/10CFR72 Subpart G 72.148 ASME Section III NQA-1 Supplement 4S-1, NCA3855.4 (a) &amp; (b) Vendor Program Ref: _____</p>	See Note	<p>Note:</p> <p>EA's main scope of work are for engineering and design services for GEH NPP projects, EA currently has not had any procurement activities for GEH NPP projects. However EA does have the capability and provides services for customers including GE Co-Generation Power project.</p> <p>EA Quality Document System Procedure 00-A-X-10601 Rev. 2 Dated 2005-02-03: Management of Suppliers establishes process for management of suppliers by EA.</p> <p>In addition, EA has the following Instructions for supplier management. 00-Y-X-10401 – Invitation to Tender, Bid Evaluation and Purchase Order 00-Y-X-10402 – Assessment and Qualification of Suppliers 00-Y-X-10403 – Follow up of Suppliers 00-Y-X-10404 – Control of Suppliers 00-Y-X-10405 – Special Transport</p> <p>So far, all suppliers falls into non-safety related items due to the services provided for existing customers.</p>
<p>3.2 Verify that measures are established and implemented to assure that:</p> <ul style="list-style-type: none"> <li>a) procurement documents are reviewed and approved by authorized personnel prior to release.</li> <li>b) changes / supplements are processed in a similar fashion as the original procurement document.</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (4/5) 10CFR71 Subpart H 71.109/10CFR72 Subpart G 72.148 ASME Section III NQA-1 Supplement 4S-1, NCA3855.4 (a) Vendor Program Ref: _____</p>	N/A	

## SECTION 3 - PROCUREMENT

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>3.3 Verify that measures are established and implemented for the evaluation, selection and assessment of suppliers (including distributors and calibration, NDE, testing lab and other service suppliers) consistent with the importance, complexity and quality of the product or service.</p> <p>a) Verify evaluations are performed 1) prior to award of contract, 2) at the specified frequency, and 3) ensure only approved suppliers are used.</p> <p>b) Verify that checklists or procedures are used for audits/surveys and that sufficient objective is recorded to substantiate the conclusions reached.</p> <p>c) Verify that the scope of approval of the sub-supplier is commensurate with the requirements of the procurement documents.</p> <p>d) Verify measures are established for source inspection or P.O. specific audit, as necessary.</p> <p>e) Verify when 3<sup>rd</sup> party audits are used as a basis for supplier qualification the evaluation shall be documented and shall include:</p> <p>Performed by qualified personnel, evaluation by qualified personnel, audit scope satisfies procurement, evidence of applicable elements adequate addressed, sufficient objective evidence, to support audit conclusions.</p> <p>NOTE: Record audit and surveillance data on Table 1-C.</p> <p>Appendix B/ANSI N45.2 Ref: (7/18) 10CFR71 Subpart H 71.137, 71.115/10CFR72 Subpart G 72.176, 72.154 ASME Section III NQA-1 Supplement 7S-1 &amp; 18S-1, NCA3855.3 (a) Vendor Program Ref: _____</p>	N/A	
<p>3.4 Verify that measures are established and implemented to assure that purchased material, equipment and services conform to the procurement documents (i.e., performance of receipt inspection).</p> <p>Appendix B/ANSI N45.2 Ref: (7/8) 10CFR71 Subpart H 71.115/10CFR72 Subpart G 72.154 ASME Section III NQA-1 Supplement 7S-1, NCA3855.1 Vendor Program Ref: _____</p>	N/A	
<p>3.5 Verify that where acceptance of material from an ASME Certificate holder or Material Organization is based on certification from sub-supplier, that the supplier validates the certification via surveillance, audit and/or independent tests.</p> <p>Appendix B/ANSI N45.2 Ref: (7/8) IE Notice 86-21 including supplements NQA-1 Supplement 7S-1, NCA3842.2, NCA3855.3 Vendor Program Ref: _____</p>	N/A	

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3 - PROCUREMENT

P.O. / DATE	SUPPLIER / LOCATION	ITEM DESCRIPTION (P/N, S/N, MODEL NO.)	METHOD / DATE OF SUPPLIER EVALUATION	SCOPE OF SUPPLIER APPROVAL / LIMITATIONS	ACCEPTANCE DOCUMENT / M&TE / INSPECTOR



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4 - DOCUMENT CONTROL  
PROCEDURE DATA SHEET

PROCEDURE / INSTRUCTION / DRAWING NO. & TITLE	REV. & DATE	CORRECT REVISION AT WORK STATION (YES/NO)	CHECKLIST SECTION

## SECTION 5 - MATERIAL CONTROL AND HANDLING, SHIPPING &amp; STORAGE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>5.1 Verify that measures are established and implemented to assure the traceability of items (i.e., materials, parts, weld filler material, etc.) is maintained as required throughout all processing operations.</p> <p>Appendix B/ANSI N45.2 Ref: (8/9) 10CFR71 Subpart H 71.117/10CFR72 Subpart G 72.156 ASME Section III NQA-1 Basic Requirement 8, NCA3855.1 (b), NCA3856.2 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any material control and handling, shipping &amp; Storage activities.</p>
<p>5.2 Verify that measures are established and implemented for the identification and control of items. Verify the following:</p> <p>a) Items are adequately identified as to inspection status. b) The authority for application and removal of identification markings / status indicators is defined. c) Storage areas and methods comply with specified requirements and access controls. d) Item markings are clear and not detrimental. e) Subdivided items have satisfactory transfer of markings to each item. f) Shelf-life requirements are defined and implemented.</p> <p>Appendix B/ANSI N45.2 Ref: (8, 13/9, 14) 10CFR71 Subpart H 71.129/10CFR72 Subpart G 72.168 ASME Section III NQA-1 Supplement 8S-1, 13S-1, NCA3856.1, NCA3858.4 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any material control and handling, shipping &amp; Storage activities.</p>
<p>5.3 Verify that measures are established and implemented for the control of handling, shipping and storage activities. Areas for consideration include cleaning, handling and packaging, preservation, marking, storing and shipping status.</p> <p>Appendix B/ANSI N45.2 Ref: (13, 14/14, 15) 10CFR71 Subpart H 71.127/10CFR72 Subpart G 72.166 ASME Section III NQA-1 Supplement 13S-1, NCA3857.4 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any material control and handling, shipping &amp; Storage activities.</p>
<p>5.4 Does the supplier's QA Program adequately control shipping activities to the extent necessary to assure compliance with the applicable material requirements and purchase order to allow drop shipments to third parties or customers?</p> <p>a) Review objective evidence of the supplier's measures to control shipping activities.</p> <p>Appendix B/ANSI N45.2 Ref: (4, 7) 10CFR71 Subpart H 71.127/10CFR72 Subpart G 72.166 ASME Section III NCA3842.2 (g) Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any material control and handling, shipping &amp; Storage activities.</p>

REV. 5 - 6/14/06

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5 - MATERIAL CONTROL AND HANDLING, SHIPPING & STORAGE

ITEM DESCRIPTION (PART #, P.O., ETC.)	METHOD OF IDENTIFICATION / TRACEABILITY	INSPECTION STATUS

SECTION 6 - FABRICATION & ASSEMBLY and SPECIAL PROCESSES

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>6.1 Verify by record review and observation (if possible) that fabrication and/or assembly activities are controlled by a shop work order / traveler type document or equivalent system. Verify that the controlling work document (and any referenced instructions, procedures, drawings, as applicable):</p> <ul style="list-style-type: none"> <li>a) is at the location where the work activity is performed;</li> <li>b) identifies the work activities to be performed;</li> <li>c) identifies specific instructions, procedures or drawings (with correct revision levels specified) to be used for the work activity;</li> <li>d) identifies witness / hold points;</li> <li>e) contain controls to assure the use and tabulation of correct parts or materials.</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (5/6) 10CFR71 Subpart H 71.111/10CFR72 Subpart G 72.150 ASME Section III NQA-1 Basic Requirements 5/6, NCA3853.2(a), NCA3853.3, NCA3857.2 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any fabrication, assembly, or any special processes.</p>
<p>6.2 Verify that special processes are accomplished utilizing:</p> <ul style="list-style-type: none"> <li>a) qualified personnel;</li> <li>b) qualified procedures;</li> <li>c) qualified equipment, as applicable.</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (9/10) 10CFR71 Subpart H 71.119/10CFR72 Subpart G 72.158 ASME Section III NQA-1 Supplement 9S-1, NCA3857.1, NCA3857.3 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any fabrication, assembly, or any special processes.</p>

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6 - FABRICATION & ASSEMBLY and SPECIAL PROCESSES

ITEM DESCRIPTION (P/N, S/N, MODEL NO.)	SHOP W/O TRAVELER	WORK ACTIVITY/PROCESS	PROCEDURE, REV / DATE	QUALIFICATION		
				PERSONNEL	PROCEDURE	EQUIPMENT

SECTION 7 - INSPECTION AND TEST

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>7.1 Verify that measures are established and implemented for the inspection and testing of materials, parts and components. Typical inspections and tests include visual, dimensional, electrical, hydrostatic, nondestructive, operational, functional, chemical, mechanical and physical.</p> <p>Appendix B/ANSI N45.2 Ref: (10, 11/11, 12) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III NQA-1 Supplement 10S-1, 11S-1, NCA3858.1 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any fabrication, assembly, or any special processes. Thus it does not perform any Inspection and testing.</p>
<p>7.2 Verify that inspection and test documents include, as applicable, the inspection/test to be performed, characteristics to be inspected, acceptance criteria, M&amp;TE required, test prerequisites, personnel qualification requirements, results reporting and actions to take should deficiencies be found.</p> <p>Appendix B/ANSI N45.2 Ref: (10, 11/11, 12) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III NQA-1 Supplement 10S-1, 11S-1, NCA3858.1 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any fabrication, assembly, or any special processes. Thus it does not perform any Inspection and testing.</p>
<p>7.3 Verify inspections were performed by individuals other than those who performed the activity being inspected.</p> <p>Appendix B/ANSI N45.2 Ref: (10, 11/11, 12) 10CFR71 Subpart H 71.121/10CFR72 Subpart G 72.160 ASME Section III NQA-1 Supplement 10S-1, 11S-1, NCA3858.1 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any fabrication, assembly, or any special processes. Thus it does not perform any Inspection and testing.</p>



## SECTION 8 - CALIBRATION

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>8.1 Review the reference (primary) and working (secondary) standards and verify traceability to NIST or other recognized standards or natural law.</p> <p>a) Assess specific M&amp;TE Standards used as to their range and accuracy relative to items calibrated.</p> <p>b) Review calibration/certification documents for NIST or suitable traceability.</p> <p>NOTE: Calibration standards should have a definitive accuracy range, sensitivity and stability for the instrument being calibrated. The standard shall have a nominal accuracy of four times the nominal accuracy of the M&amp;TE being calibrated. If not possible, documented and authorized basis of acceptance shall be provided.</p> <p>Appendix B/ANSI N45.2 Ref. (12/13) 10CFR71 Subpart H 71.125/10CFR72 Subpart G 72.164 ASME Section III NQA-1 Supplement 12S-1, NCA3858.2 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any fabrication, assembly, or any special processes. Therefore it does not perform any Inspection and testing. Thus there are no calibration activities.</p>
<p>8.2 Verify maintenance of calibrated equipment &amp; records. Review the equipment &amp; records for the following, as a minimum:</p> <p>a) Unique identifiers (e.g., I.D., S/N, name, manufacturer);</p> <p>b) Location/person;</p> <p>c) Status indicator;</p> <p>d) Calibration (recall) interval;</p> <p>e) Calibration procedure including revision;</p> <p>f) Calibration History - Dates calibrated, by whom, results, due date, primary standard;</p> <p>g) As-found, as-left data/condition.</p> <p>Appendix B/ANSI N45.2 Ref. (12/13) 10CFR71 Subpart H 71.125/10CFR72 Subpart G 72.164 ASME Section III NQA-1 Supplement 12S-1, NCA3858.2, NCA3858.3 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any fabrication, assembly, or any special processes. Therefore it does not perform any Inspection and testing. Thus there are no calibration activities.</p>
<p>8.3 Verify that:</p> <p>a) calibrations are performed by qualified personnel;</p> <p>b) calibrations are performed in an environment controlled to the extent necessary to assure required accuracy;</p> <p>c) measures are established and implemented for the evaluation of M&amp;TE found to be "out-of-tolerance" and notification to affected customers is provided where appropriate.</p> <p>Appendix B/ANSI N45.2 Ref. (12/13) 10CFR71 Subpart H 71.125/10CFR72 Subpart G 72.164 ASME Section III NQA-1 Supplement 12S-1, NCA3858.2 Vendor Program Ref: _____</p>		<p>NA Empresario Agrupados International is an engineering and consulting provider. It does not perform any fabrication, assembly, or any special processes. Therefore it does not perform any Inspection and testing. Thus there are no calibration activities.</p>



SECTION 9 - SOFTWARE QUALITY ASSURANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>9.1 Identify in-house developed software used in safety-related applications, e.g., design, production, calibration, acceptance. Verify documented measures are established and implemented to control:</p> <ul style="list-style-type: none"> <li>a) systematic methodology used;</li> <li>b) inputs to be used as the basis for the software program;</li> <li>c) development of the computer code;</li> <li>d) documented interim and final reviews of the software program prior to release;</li> <li>e) software validation (i.e., the testing and evaluation of the completed software to ensure compliance with software control requirements);</li> <li>f) software verification (i.e., the process of determining whether or not the product of a given phase of the software development cycle fulfills the requirements imposed by the previous phase);</li> <li>g) configuration baseline of the software code after review, validation, verification, approval and release for use;</li> <li>h) changes or revisions to the software code are developed and subjected to the same levels of control as the original code.</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III NQA-1 Supplement 3S-1 Vendor Program Ref.</p>	<p>S</p> <p>S</p> <p>S</p> <p>S</p> <p>S</p> <p>S</p> <p>S</p> <p>S</p>	<p>A review is performed on AGPIPE which is a safety related code used for piping analysis in the Lungmen Project. AGPIPE is a legacy program revised into a new version.</p> <ul style="list-style-type: none"> <li>a. A "maintenance order of software" is used to track all steps – Observed an example where the user who is part of Lungmen signed and request a change input to improve the capacity of the program, etc. The next step in the process is that Juan Garcia, the owner of the software, evaluates the feasibility and estimates the amount of effort, then the work is reviewed and authorized by the Software Department Chief. Subsequently, the change is made by Juan's team, then verified by independent verifier to make sure the change conforms with Level I code requirements, then the Mechanization and Operation Support lead approves the revision number, then release the program (for use), backup the software, and make the production release. This is the final step of the process. This sheet number is 51-OMS-AOT-02838-001 version 8A dated 9/03. The software version will change and depends on the magnitude of change to use A, B or a new number. When a new number is used, there is a new version of software documentation and O&amp;M manual.</li> <li>b. within the maintenance order of software contains, on page 2, the description of the software code changes, and this description is added in the body of the code in Comment form. This code is a legacy code written in Fortran.</li> <li>c. see b.</li> <li>d. For documentation, use the same document with revisions and re-issue with each change. The document is in Spanish and entitled: Verification Manual for AGPIPE, # 51-G-A-00283-IP issue 7, 10/03. Configuration Document for every version is produced by Juan Garcia and reviewed then approved by the manager of the Software Department.</li> <li>e. see d. in the Verification Manual for AGPIPE, possible methods of verification are: using manual calculations or use different program, or use the same program using different condition. The description of verification is written into this Manual and signed for this version of the Manual. When a new version is verified, the Manual is re-issued with a new author who tested and verified.</li> <li>f. see d. regression testing is requested by the software owner. In this observed case for version 8B, as this is a relatively minor change, there is no request to perform regression testing.</li> <li>g. see d.</li> <li>h. The manager of the software department authorizes the changes or revisions of the code</li> </ul> <p>To show the association with the Lungmen Project for use of this code, I observed in the DRF # 0000-0018-7055, EA number is 207-26-DRF-EA-80000-1G41, DRF is still open. In Part 5 of the DRFk under Stress Analysis and in the output file the label shows it is run on Nov. 28, 2005 and that the version used is AGPIPE8B.</p>
<p>9.2 When software is procured from an outside source, verify adequate controls are in place to ensure that the purchased software meets technical and quality requirements.</p> <ul style="list-style-type: none"> <li>a) For software procured safety-related, assure the supplier audit addressed the sub-supplier's software manufacturing program for testing, verification and validation to ensure the software will function as intended.</li> <li>b) For software procured commercial grade, assure that dedication activities (such as verification and validation) are performed and documented to ensure the software functions as intended.</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (4/5) 10CFR71 Subpart H 71.109/10CFR72 Subpart G 72.148 ASME Section III</p>	<p>S</p> <p>S</p>	<p>For externally procured software we looked at the QAD software that is used in shielding and dose calculations by EA for the STP COLA deliverables. We were told that there is only one version of this software.</p> <p>QAD software is a public accessible code from NEA – Nuclear Energy Agency in Paris. It was first developed by Oak Ridge National Lab. There is an agreement between the NRC and the NEA concerning the use of this code. In the User's Manual, there is Annex 5 that shows the validation of the code by EA. Methodology – input file is CASK.INP, output is CASK.OUT. Verification of installation of the code was performed and this ensures the software files are not corrupted and will function as intended.</p> <p>Verification of the calculations for the STP application is performed, and the comments and resolution included in DRF-0000-0069-3931-/0000-0069-4343.</p> <p>Pilar Saenz De Tejada who verified the data input into the program is correctly done per the data</p>

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<p>NQA-1 Supplement 3S-1 (Para 3.1) Vendor Program Ref: _____</p>	<p>input list in the DRF. She marked up the data input with checks and comments in pencil and there is evidence of this in the DRF.</p> <p>Validation Test Report of the STP QAD calculations are documented in 209-001-IPV-Z-00001 issue 1, 9/2007.</p> <p>The actual calculations are documented in the Radwaste Building Zoning Classifications doc. # 209-001-C-Z-00003 or 0000-0069-3931/0000-0069-4343 issue 1 dated 9/28/2007.</p> <p>Software QA elements (methodology, inputs, documentation, verification and validation, change process) are observed to be adequate for both in-house developed software and externally procured software.</p>
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SECTION 9 - SOFTWARE QUALITY ASSURANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>9.3 Verify that corrective action measures exist to document software problems from internal and external sources.</p> <p>Appendix B/ANSI N45.2 Ref: (16/17) 10CFR71 Subpart H 71.133/10CFR72 Subpart G 72.172 ASME Section III NQA-1 Basic Requirement 16 Vendor Program Ref: _____</p>	<p>S</p>	<p>Maintenance sheet process as described in 9.1.a.</p>
<p>9.4 Verify that controls exist and are implemented to ensure that all users (internal and external) that could potentially be impacted are notified of the software problem and corrective actions and the impact of the deficiencies on that customer.</p> <p>Appendix B/ANSI N45.2 Ref: (16/17) 10CFR71 Subpart H 71.131, 71.133/10CFR72 Subpart G 72.170, 72.172 ASME Section III NQA-1 Basic Requirement 16 Vendor Program Ref: _____</p>	<p>S</p>	<p>In the Software Quality Plan, doc # Z51-PCP-T-000001 rev. 2 Nov. 24, 2006, Section 13 Measurements, Analysis, and Improvements</p> <p>For non-conformances and failures – the failure reports for critical software (ie. safety related, GEH) will be transmitted from the user to the software lead of each department and to the department managers in order to analyze whether the failures have impact on previous or current work on the software. These reports are sent back to the EA Software Manager and open non-conformities or actions are resolved. EA QA gets a status and keeps track records of the software process.</p>

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**9 - SOFTWARE QUALITY ASSURANCE**

SOFTWARE PROGRAM (NAME, NO., REV./DATE)	PROGRAM END USE (E.G. DESIGN, PRODUCTION, CALIBRATION, ACCEPTANCE)	VERIFICATION / VALIDATION	METHOD / PROCEDURE TO CONTROL ISSUANCE OF CHANGES AND/OR ERROR NOTICES
AGPIPE rev. 8B	perform piping analysis according to ASME code, to check equations of ASME code, safety related	done in 10/03 documented in Verification Manual # 51-G-A-00283-IP	see description in Summary Section 9.1a.
QAD	perform shielding and does cacluations, Level II	Validation Test Report of the STP QAD calculations are documented in 209-001-IPV-Z-00001 issue 1, 9/2007.	see description in Summary Section 9.1a.

SECTION 10 – DEDICATION / UNQUALIFIED SOURCE MATERIAL

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>NOTE: All questions within this section apply to Commercial Grade Items (CGI) dedicated by the supplier for delivery to the customer as a basic component or portion thereof. The questions do not apply for items sold by the supplier as CGI which require member company dedication.</p> <p>10.1 Verify and assess the supplier's controls for dedication of manufactured / purchased commercial grade items. As a minimum, the supplier's process should include the following:</p> <ul style="list-style-type: none"> <li>a) Documented controls which define the dedication process.</li> <li>b) Determination of the safety function for the items intended end use by review of documents associated with the technical evaluation, such as: <ul style="list-style-type: none"> <li>- Classification of the item</li> <li>- Item equivalency evaluations</li> <li>- Consideration of credible failure modes.</li> </ul> </li> <li>c) Identification of critical characteristics for acceptance required to support the safety function.</li> <li>d) Selection of the method(s) of dedication for each identified critical characteristic: <ul style="list-style-type: none"> <li>1. Special Tests and Inspections</li> <li>2. CGI Surveys</li> <li>3. Source Verification</li> <li>4. Supplier Performance History in conjunction with methods 1, 2, or 3 above.</li> </ul> </li> </ul> <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107, 71.109/10CFR72 Subpart G 72.146, 72.148 NQA-1 Supplement 3S-1, NCA3800 Vendor Program Ref: _____</p>	<p>N/A</p>	<p>EA does not offer any commercial grade items. Thus no dedication is needed.</p> <p>Section 10 does not apply to this audit.</p>
<p>10.2 <u>Describe in detail</u> and verify the adequacy of the controls when CGI Method 1 (Special Tests and Inspections) is employed for dedication of commercial grade items.</p> <p>Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III NQA-1 Supplement 10S-1, 11S-1, NCA3800 Vendor Program Ref: _____</p>		

SECTION 10 – DEDICATION / UNQUALIFIED SOURCE MATERIAL

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>10.3 Verify that the tests and inspections specified for the acceptance of commercial grade items adequately verify the identified critical characteristics.</p> <p>Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III NQA-1 Supplement 10S-1, NCA3800 Vendor Program Ref: _____</p>		
<p>10.4 Verify and assess the implementation of any sampling procedures used for the dedication of commercial grade items.</p> <p>NOTE: The sample plans shall be controlled and their technical basis established and documented. Proper consideration should be given to:</p> <ul style="list-style-type: none"> <li>- Lot formation / degree of homogeneity / lot traceability</li> <li>- Sample selection</li> <li>- Complexity of the item</li> <li>- Adequacy of the sub supplier controls</li> <li>- Performance history of the sub supplier</li> <li>- That the plan provides for appropriate accept / reject controls.</li> </ul> <p>Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III NQA-1 Supplement 10S-1, 11S-1, NCA3800 Vendor Program Ref: _____</p>		

SECTION 10 – DEDICATION / UNQUALIFIED SOURCE MATERIAL

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>10.5 Verify and assess the Material Organization's controls for using Unqualified Source Material including:</p> <ul style="list-style-type: none"> <li>a) insuring no welding with filler metal was performed</li> <li>b) performs chemical analysis on each piece</li> <li>c) performs all other required tests on each piece.</li> </ul> <p>Alternately, testing of each heat and lot is acceptable if a CMTR is provided, material is traceable to the CMTR, the traceability system is audited and approved and upon receipt, the Material organization reviews objective evidence to confirm procurement requirements have been met.</p> <p>Appendix B/ANSI N45.2 Ref: (3/4)                      10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162                      ASME Section III                      NCA 3855.5                      Vendor Program Ref: _____</p>		

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10 - DEDICATION / UNQUALIFIED SOURCE MATERIAL

ITEM DESCRIPTION (P/N, S/N)	COMMERCIAL GRADE ITEM CRITICAL CHARACTERISTICS	METHOD(S) OF DEDICATION



**Enclosure 3**

**MFN 09-580**

**Transmittal of GEH 2007 Audit Plan, Checklist, and Report of  
Empresarios Agrupados (EA) in Support of NRC Inspection  
of GEH Quality Assurance (QA) Program Implementation and  
QA Implementation of ESBWR Radiation Shielding  
Calculations**

**GEH Audit Report (October 2007)  
Supplier: Empresarios Agrupados, Madrid, Spain**

SUPPLIER INFORMATION			AUDIT CRITERIA
SUPPLIER NAME: <b>Empresarios Agrupados</b>			ASME NQA-1, 1983 & 2000 <input checked="" type="checkbox"/>
STREET ADDRESS: Magallanes 3			ASME SEC. III, 1989 & NQA-1, 1986 <input checked="" type="checkbox"/>
CITY, STATE AND ZIP CODE: 28015, Madrid, Spain			ISO 9001, 1994 & 2000 <input checked="" type="checkbox"/>
TELEPHONE NO.: 34-91-309-8000 FAX NO.: 34-91-445-0113			ASME NQA-2a, Part 2.7, 1990 <input checked="" type="checkbox"/>
SUPPLIER CONTACT: Marcial Tielas (Lungmen)			ASME SEC. III, 2000 & NQA-1, 1989 + Add. <input checked="" type="checkbox"/>
COMPANY OFFICER/MANAGER: Adolfo Gonzalez	TITLE: General Manager	PHONE: 34-91-309-8002	ANSI N45.2 <input checked="" type="checkbox"/>
QA DIRECTOR/CONTACT: Javier Goicoechea	TITLE: Quality Manager	PHONE: 34-91-309-8016 E-mail: goi@empre.es	
PRODUCT/SERVICE: Supplier of Engineering Services for ASME Code Items and Quality Class S, R and G for the Lungmen Project. Supplier of Engineering Services for ASME Code Items and Quality Class Q and S for the ESBWR Project and ABWR Services.			
QUALITY CLASS: CLASS S & Q <input checked="" type="checkbox"/> CLASS R <input checked="" type="checkbox"/> CLASS G <input checked="" type="checkbox"/> AUDIT No.: Q0710 AUDIT DATES: Oct. 01, 2007			
ASME CODE CERTIFICATION NUMBER(S) AND EXPIRATION DATES: N/A			
ISO CERTIFICATION NUMBER(S) AND EXPIRATION DATES: ISO 9001:2000 Cert. No. ES-0184/1996 Expiration 6/22/09 and ISO 14001 Cert. No. ES-2006/0212 Expiration 6/22/09 issued by IQNet. Also both programs are certified by AENOR, Cert. No. SGI-034/2006 Expiration 5/20/09.			
AUDIT TEAM LEADER: Yu-Chuan Lee		PHONE: (910) 602-4851	FAX:
AUDIT INFORMATION/SCOPE/PO'S/PROCUREMENT SPECIFICATIONS: The Audit Team conducted a performance based audit of Empresarios Agrupados' scope of work for GE Nuclear's Lungmen Project (POs # 431000247 and 431000146) and ESBWR Project (PO# 431005866). The audit was conducted to the GE Nuclear contract/purchase order requirements.			

AUDIT SECTION	SECTION DESCRIPTION	IMPLEMENTATION STATUS	COMMENTS / FINDINGS
1	PROGRAM COMPLIANCE	Satisfactory	
1-A	ORGANIZATION / PROGRAM	Satisfactory	
1-B	NONCONFORMING ITEMS	Unsatisfactory	CAR 43894
1-C	AUDITS	Satisfactory	CAR 43899
1-D	CORRECTIVE ACTION	Satisfactory	
1-E	TRAINING / CERTIFICATION	Satisfactory	
1-F	RECORDS	Unsatisfactory	CAR 43895, CAR 43896
2	DESIGN	Unsatisfactory	CAR 43897, CAR 43898, 43900
3	PROCUREMENT	N/A	No Procurement Activities by "EA"
4	DOCUMENT CONTROL	Satisfactory	
5	MATERIAL CONTROL AND HANDLING, SHIPPING & STORAGE	N/A	Supplying Engineering Services Only
6	FABRICATION/ASSEMBLY/SPECIAL PROCESSES	N/A	Supplying Engineering Services Only
7	INSPECTION AND TEST	N/A	Supplying Engineering Services Only
8	CALIBRATION	N/A	Supplying Engineering Services Only
9	NUCLEAR SAFETY-RELATED REPORTING /10CFR21	Unsatisfactory	CAR 43894
10	ASME	N/A	Non NCA 3800 or NCA 4000 supplier
11	ISO 9001	Satisfactory	

12	SOFTWARE QUALITY ASSURANCE ASME NQA-2A	Satisfactory	
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Supplier QA Manual: 00-MC-X-0001/1 Revision: 6 Date: June 30, 2006

<b>SUPPLIER HISTORY/OPEN CAR'S:</b>
All Previous CARs have been closed

AUDIT TEAM	NAME	TITLE/DISCIPLINE	TELEPHONE NO.
TEAM LEADER	Yu-Chuan Lee	Lead Auditor	(910) 602-4851
TEAM MEMBER	Paul R. Ragan	Auditor	(910) 675-6445
TEAM MEMBER	Kim Yu	Technical Specialist	(408) 925-3895
TEAM MEMBER			

<b>SUPPLIER PERSONNEL CONTACTED:</b>
See Audit Attendance Sheets located in the supplier audit file.

CORRECTIVE ACTION REPORTS (CAR'S)					
CAR NUMBER	TITLE	DATE OPENED	DATE CLOSED	DATE VERIFIED	COMMENTS
Q0613C1-41531	Program Deficiency	9-7-2006	11/14/2006	10/30/2007	All 4 CARs were improperly closed. CAR 43905 issued for corrective actions
Q0613C2-41532	Design verification	9-7-2006	11/14/2006	10/30/2007	
Q0613C3-41533	Software Error Evaluation	9-7-2006	11/14/2006	10/30/2007	
Q0613C3-41534	Order Entry Review	9-7-2006	11/14/2006	10/30/2007	

**AUDIT SUMMARY**

**ENTRANCE MEETING:**

A pre-audit conference was held on October 3, 2007. During this pre-audit meeting the scope of the audit was discussed and the agenda was reviewed. For the Lungmen Project the scope of this audit was to verify Empresarios Agrupados' (E/A) compliance with applicable requirements of NQA-1 1983, NQA-1 1986 Edition for ASME Code services, NQA-2 Subpart 2.7:1990 for computer programs, ISO-9001:1994 for Class R services, "E/A's" Quality Assurance program and implementing procedures, Lungmen purchase order requirements; and LQAR-1 Rev. 5 for services provided for the Lungmen Project. For the ESBWR Project the scope of this audit was to verify E/A's compliance with applicable provisions of the Supplier's 10CFR50 Appendix B QA program requirements for DCD/COLA safety-related services, NQA-1 1989 Edition plus addenda for ASME Code services, ISO-9001:2000, "E/A's" Quality Assurance program and implementing procedures; NEDO 33260 ESBWR SQAR purchase order requirements. For the STP project the scope of audit was to verify E/A's compliance with applicable provisions of the Supplier's 10CFR50 Appendix B QA program requirements for DCD/COLA safety-related services, NQA-1 1989 Edition plus addenda for ASME Code services, ISO-9001:2000, "E/A's" Quality Assurance program and implementing procedures; NEDO 33282 STP SQAR purchase order requirements. During the meeting E/A personnel presented a general status of all projects for GE Hitachi Nuclear Energy.

**AUDIT CONDUCT:**

The applicable provisions of 10CFR50 Appendix B requirement, NQA-1 & NQA-2 requirements, the applicable elements of ISO-9001 and project specific Supplier Quality Requirements for Engineering Design and Service (SQAR) were sampled to verify EA's implementation and effectiveness. The NIAC Checklist was used for recording and audit documentation aids.

**AUDIT EXIT MEETING:** On October 5, 2007 the audit exit meeting was conducted and the positive observations, concerns and recommendations, and audit findings were discussed and the CAR's presented

**POSITIVE OBSERVATIONS:**

- Personnel were very knowledgeable and supportive to the auditors' requests
- Excellent technical personnel support and responses
- Documentation was well organized and readily available

**RECOMMENDATIONS: CAR 43900**

- During the review of design input list of Doc # 092-134-F-M-01400-LDP issue 1, it was noticed that for evidence that one of the data input items has been used in the flooding analysis per Doc. 26A6007, there is no direct reference of the input document to refer. For example: The reactor building general arrangement item 4 of the data input list was applied. However it informed that evidence is to be seen in design verification.

For changes to design inputs due to update of 'preliminary' information, evidence is seen in updates of the List of Document Input Data from Issue 0 and Issue 1. For the list of documents, one recommendation is to clarify some titles in the Title of Document. For example, item 35 "Re Flooding Analysis" is vague. The problem is that the title only states "Flooding Analysis" but it actually means "GE Replies to EA Comments to Flooding Analysis Rev. XXX"

It is recommended that EA to clean up the list of input data in this table, do not include items that do not apply. For example, letters related to EA Comments to GE on data input issues should not be included in this list.

**AUDIT CONCERNS: CAR 43899**

- EA procedure 00-A-X-1170-I does not require that completed audit checklists be treated as QA records and treated as such with appropriate control and storage.

**AUDIT FINDING:**

- **Finding 1 – CAR-43894**  
GE Hitachi Purchase Order /Contract and the project specific Supplier Quality Requirement for Engineering Design and Services document require Supplier to have procedures and process for 10CFR21 – Reporting of nonconformance and significant safety related impacts. On the contrary, Empresarios Agrupados (EA) International do not have such procedure and practice established. EA Quality Document System Instruction 00-Y-X-10106 Rev. 5 dated 2005-02-037: Disposition and Control of Non-Conformities Section 3.1.1 requires notification to customer on any 10CFR21 applicable non-conformance. But it does not address all Part 21 requirements. EA has no mechanism to evaluate, determine and no process to notify US NRC and Customer on 10CFR21 compliance.
- **Finding 2 – CAR 43895**  
EA procedure 00-Y-X-10115-I identifies the requirements for project-specific training records. ESBWR Project Training record 209-001-RF-Z-7369 does not have an Issue (Revision) number listed as required.
- **Finding 3 – CAR 43896**  
GEH PO 431008457, Revision 0 for staff augmentation support relating to ABWR STP COLA submittal identifies 11 EA engineers that shall work under GEH QA Program. PO states that the identified names in the PO cannot be taken off the project or assigned to any other tasks without GE's written approval. At least one of the engineers identified on the PO had been taken off the project and there was no documented evidence that EA had received written approval from GE. EA should notify GE of any changes to the personnel being supplier in support of the subject PO.

- **Finding 4 – CAR 43897**

In Document 092-134-F-M-01400-LDP issue 1 items 31, 32 shows input data has been transmitted by emails and not by Project Letter, contrary to the ESBWR Design Cert & COL Activities Quality Plan 092-1134-PCP-Z-00001. In sheet 2 of 6 it specifically stated that official transmission of information and documents via Project Letter. Also ESBWR Project Instruction EPI-20-01 rev. 4 section 4.2 states "When the correspondence is electronic (e-Mail) and includes technical content, only a transmittal letter is to be sent by email."

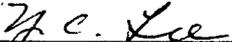
- **Finding 5 – CAR 43898**

GEH document NEDO-33260 rev. 2 Section 4 and EA ESBWR Quality Plan doc. 092-134-PCP-Z-00001 issue 9 dated June 30, 2007 specifies Attached –T identifies Design and Service technical and quality requirements and changes to be made via official transmission of information and documents via Project Letter.

In PO 431006971-2 transmitted 2-21-07, Table 1 identifies the input requirements for each Line Item. For Line item 19 Top Level Documentation, Table 1 stated "See Documents associated with Line item 15". Enquiring the EA Project Manager, whether or not all the documents of Line item 15 are required for Line item 19, the Project Manager is uncertain. It was responded that part of the documents associated with Line item 15 are applied to Line item 19. Confirmation of which of the documents are requirements for Line item 19 should be performed via an evaluation by EA and the results communicated by project letter to GEH. After confirmation, the PO and Att. T needs to be revised accordingly. The revised Att. T resulting in a revised PO should be transmitted to EA in a timely manner.

#### AUDIT CONCLUSIONS:

During the course of this audit, the Audit Team found that Empresarios Agrupados is satisfactorily implementing their Quality Assurance Program as defined in their Quality Assurance Manual 00-MC-X-0001 Rev. 6 dated June 30-2006 and implementing quality instructions manual 00-Y-X-10000. Based on the results of this audit, Empresarios Agrupados ASL status should be conditionally approved. Especially for Empresarios Agrupado shall did not have a 10CFR21 program established, it shall notify every Non-Conformance Report to GEH QA within 48 hours effective November 1, 2007 till the 10CFR 21 program is implemented. Then upon all the forthcoming satisfactory closure of the issued CARs and resolution of the Concerns above, Empresarios Agrupados ASL status will be fully restored as approved supplier of Engineering Services for GE Hitachi including the Lungmen Project, ESBWR Project and STP Services.

  
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Yu-Chuan Lee  
GEH NPP QA Lead Auditor  
October 31, 2007