

**JOINT PROGRAMME OFFICE**

**REPORT ON THE JOINT REGULATORS' TEAM INSPECTION OF  
GENERAL ELECTRIC-HITACHI'S ARRANGEMENTS AS PART OF THE GENERIC  
DESIGN ASSESSMENT  
(QUALITY MANAGEMENT ARRANGEMENTS)**

**NOVEMBER 2007**

<b>REQUESTING PARTY:</b>	GE-Hitachi	<b>FILE REF.:</b>	
<b>SITE:</b>	Wilmington North Carolina USA	<b>CC:</b>	
<b>DATE:</b>	12-15 November 2007		
<b>INSPECTION No.:</b>	02/07		
<b>SUBJECT</b>	Inspection of GEH quality management arrangements in support of GDA process.		
<b>INSPECTION OBJECTIVES:</b>	<p>-To check that GEH has Quality Management Systems that provide organisational and procedural arrangements that adequately support production of the submission.</p> <p>- Through inspection, to establish that GEH has implemented and continue to review arrangements that adequately control their GDA related activities.</p> <p>- To inform the UK Nuclear Regulators' assessment of GEH's submission.</p>		
<b>INSPECTION BACKGROUND:</b>	<p>As part of the GDA process the UK Nuclear Regulators, from HSE's Nuclear Directorate and the Environment Agency, carried out an inspection of the GEH QMS and in particular those arrangements relating to the development of the submission (environmental, safety, security report). Inspectors from the United States Nuclear Regulatory Commission (USNRC) attended the inspection as observers. USNRC asked questions and sought clarification on a number of issues and provided the UK regulators with a very useful insight into the US regulatory process.</p>		
<b>FACILITY/AREA:</b>	GEH Wilmington North Carolina		

## **SUMMARY OF INSPECTION**

### **SUMMARY**

GEH operates a well developed set of quality arrangements which include Engineering Operating Procedures for the design process. The arrangements are directed toward compliance with US legal requirements and compliance with the management system and procedures is mandatory on all employees. Quality management is seen as an integral element in the functioning of the organisation and specific resources are allocated to this function. Currently there is no environmental management system or development toward an integrated management system, which would include environmental aspects. The US Nuclear Regulatory Commission (NRC) has reviewed and accepted the GEH Quality Assurance Programme which was used to develop the Design Control Document (DCD). There have been organisational changes since the regulatory acceptance, all of which have been provided to the USNRC.

GEH has set up a GDA project office in the UK and awarded a contract to Atkins Ltd. to advise on the UK regulatory process, and provide support in the production of GDA submission. This indicates a good level of commitment to the UK project. Atkins Ltd. operates to the quality arrangements of GEH where appropriate.

GEH regards the recruitment and retention of personnel with relevant skills as an essential element in its current and future success. A UK licensing team is currently being recruited to manage licensing aspects of the GDA submission. This will include a lead for the environmental aspects. Retention of key staff and succession planning are the organisation's and line managers' responsibility. There is an ongoing recruitment campaign primarily for technically qualified personnel and in particular those with nuclear skills and experience.

Authorship of chapters of the DCD is carried out in a formalised and controlled manner with proposed changes having to be fully justified and subjected to appropriate levels of challenge. A significant objective of GEH is to establish a standard design. Operational feedback processes are used to inform design changes.

There are a number of points, including the development of Intelligent Customer (IC) capability for environmental aspects, that GEH need to consider resulting from this inspection that will improve the UK regulators' understanding of GEH's arrangements and provide confidence in GEH's ability to deliver its submission within the GDA timescales.

**The UK Regulators' conclusion is that:**

GEH operates an appropriate QMS that provides a suitable framework which controls the content and accuracy of its submission to the Joint Programme Office. Particular strengths are the experience of staff involved in the design process and the depth of technical resource within the company. GEH appears to be committed to the UK market and is developing awareness of the UK regulatory process and is recruiting a lead to deal with environmental requirements. There is some way to go in developing the environmental submission for GDA. However, the UK Regulators have confidence that the production and update of submissions is adequately controlled for this stage of the GDA process and that any comments or queries raised will be properly dealt with. The UK Nuclear Regulators would welcome a paper of principle describing GEH's approach to satisfying the requirements of the GDA process for the next steps.

### **GE Organisational Overview**

1. GEH operates as 3 business units, New Plants, Fuel, and Nuclear Services. Since the merger with Hitachi, all GEH Nuclear Energy staff are GE-Hitachi employees. GE and Hitachi worked together on the ABWR and have built around 40 plants together. The merger has expanded the manufacturing and construction capability significantly on ESBWR. GEH is the Design Authority for ESBWR. The relocation to Wilmington from San Jose in 2003 presented GEH with challenges particularly relating to retention of expertise. The inspection team were assured that this aspect had been managed effectively.
2. GEH has significant technical personnel resources. Many of these individuals are experienced within the nuclear industry and in BWR technology specifically. There is obvious pride in ownership of design information and knowledge of the safety documentation. The company is continuing to recruit to meet the significant demand of an industry that is experiencing renewed worldwide interest in nuclear power. Problems of singleton expertise or intelligent customer issues (with the exception of environmental aspects) are unlikely in the short term and if continuing recruitment is successful in the longer term also. Significant additional resources are available in the GEH Nuclear Services and Fuel Business Units.
3. GEH gave the inspection team a very interesting verbal history of the development of the ESBWR which included elements of optioneering and considerations for plant simplification and more reliance on passive systems. It was noted that this presentation, which had not been written down, could provide a good basis for the demonstration of the application of BAT and ALARP principles. It was our understanding that GEH considered that the main responsibility for environment rests with the operator, however, examples were discussed where developments in design result in lower levels of radioactive waste and contamination of plant. Additionally it wasn't apparent that the decommissioning strategy was regarded as an integral part of the design process. GEH need to develop a better understanding of the UK regulatory requirements for environmental issues.

4. GEH utilise a number of processes to attract new staff (both graduate and experienced). Strategies are in place to attract, train and retain technical resources particularly those identified as key or scarce. Individual managers are held responsible for retaining such resource and are held to account if any are lost to the company.
5. The selection and use of contractors is carried out to established procedures. Procurement includes the use of an approved suppliers list based on document reviews, audit and surveillance activities. It was made very clear that the ownership of technical information required to enable contractors to carry out their function is retained within GEH. Such that with the adequate resources in technical disciplines, there are no issues relating to intelligent customer other than for environment aspects. The specification, monitoring and acceptance of contracted work is controlled by GEH personnel. For specialist support GEH have a number of divisions, eg Nuclear Fuel that can provide technical resource and guidance if required.
6. The adoption of Design Acceptance Criteria (DACs) and attendant Inspection, Test, Analyses and Acceptance Criteria (ITAACs) could possibly make it difficult for the UK regulators to carry out assessment to a satisfactory level. It is recognised that the regulatory position in the US is not aligned with the UK GDA process and as such there needs to be further discussions, on a number of points, between USNRC and the UK regulators to fully understand the issues. For example the difference is evident for the environmental requirements to satisfy the UK GDA process.
7. GEH employs a number of ways of obtaining Operational Experience Feedback (OEF) pertinent to the operation of BWRs. Involvement with operators around the world, and the close working relationships with suppliers and customers, coupled with the significant experience of key GEH staff provide a comprehensive overview of incidents and suggested modifications. However, these information streams do not appear to be documented but the use of OEF does appear to be co-ordinated.

#### **QA Arrangements Overview**

8. GEH's QMS satisfies 10 CFR 50 Appendix B. Its top tier QA Manual sets out its quality programme description and how it complies with Appendix B criteria. The programme has also been developed to meet the requirements of ASME NQA 1 and more recently ISO 9001. A UK Project specific quality plan is being developed which will identify the organisational and procedural arrangements applicable to the project. The inspection team pointed out that it would also be beneficial to show a clear governance process for the UK Project which would show high level oversight and direction to the design process. GEH does not have an environmental management system (EMS). It is our understanding that it is not GEH's intention to move toward

an integrated management system that takes account of environmental aspects.

9. The structure of the QMS includes level 1 GEH Nuclear Energy QMS documents that are applied across the company and these are supported by Level 2 Engineering Operational Procedures (EOPs). The EOPs appear to be well controlled by identified owners who ensure that the procedures remain current and relevant to the business objectives and that changes are controlled. Responsibilities of those carrying out the processes covered by the EOPs are detailed. The EOPs cover aspects such as document control, design changes and auditing and corrective actions. These appeared to provide sufficient controls to give confidence in the effectiveness of the arrangements. Weekly sessions are being held to develop awareness of GEH procedures for new employees or those affected by the merger with Hitachi now working on ESBWR. There are a number of Level 1 and Level 2 procedures that are applicable to the UK Project.
10. Authorship of chapters of the DCD is carried out in a formalised and controlled manner with proposed changes having to be fully justified and subjected to appropriate levels of challenge. GEH recognised the need to increase awareness of chapter authors with regard to the UK regulatory framework such that the development of the safety, security and environment report aligns with UK regulators' guidance and requirements.
11. There are established interfaces between design and safety analysis personnel and these appeared to be working effectively. It was difficult, however, to identify a single data list that contains agreed design parameters, which could be used as the basis of ongoing design and safety, security and environmental assessment. This is particularly important where contractors are used for either or both functions.
12. Internal auditing and review is established as part of the QMS and closeout of issues identified is adequately managed. Quality system development is ongoing and there are initiatives to support continuous improvement including changes to the existing corrective action management process. Significant work is underway across GEH in an attempt to improve existing culture and embrace Institute of Nuclear Power Operations (INPO) learning organisation models.

## **Conclusions**

13. GEH operates an adequate QMS that has been developed to meet the requirements of national, international and regulatory requirements. However, there is as yet no fully developed quality plan for the UK Project and the level of governance applied to the project is not transparent.
14. GEH has established a UK Project Office and contracted with Atkins Ltd. to provide, amongst other things, an insight into the UK regulatory process.

This indicates a good degree of commitment to the project as does the recruitment of a UK licensing team to support the GDA process. This work has some way to go to ensure that key personnel such as chapter leads are aware of the UK regulatory process.

15. The key elements of document and design change control, recruitment, ongoing training, key staff retention and the control of contractors are well established within the management system.
16. There is an internal audit system which will benefit from an improving corrective action management process and a culture change initiative.
17. With respect to environmental management issues there is evidence of the reduction of radioactive waste volumes and levels of waste activity which have been initiated by designers. It was our understanding that the decommissioning strategy is not seen by GEH as an integral part of the design process. Additionally, it would appear that there is little intelligent customer capability for environmental aspects within the engineering organisation.
18. The gathering and use of OEF is evident albeit that this process is not documented.
19. There are clear and effective interfaces between the design and safety analysis functions however there is no single documented data list for design and safety analysis.
20. GEH rely, rightly, on very experienced, knowledgeable and dedicated staff that have worked closely on the development of the ESBWR and its predecessors but it has not yet documented the evolution of the design to its current status such that the formal application of BAT and ALARP principles is evident.

### **Recommendations**

21. Recommendation 1: GEH should consider completion of its quality plan and programme for the UK project with clearly defined responsibilities and a strategy for the design process.
22. Recommendation 2: GEH should consider documenting a history of the development of the ESBWR design including the application of BAT and ALARP principles leading to the current design.
23. Recommendation 3: GEH should consider the development of a single data list to be used for design and safety analysis.
24. Recommendation 4: GEH should consider documenting suitable arrangements for the capture of OEF and other sources of feedback.

25. Recommendation 5: GEH should consider establishing a clear governance process to provide high level oversight and direction to the design process.

26. Recommendation 6: GEH should consider implementing a programme to improve awareness and understanding for chapter leads of the need to make the case for safety within the UK framework.

27. Recommendation 7: GEH should consider making the Decommissioning Strategy an integral part of the design process, and not as a stand alone issue.

28. Recommendation 8: GEH should consider showing the approval status of GDA submission documents. This would provide clarity for the assessors in the UK with regard to the status of documents.

29. Recommendation 9: GEH should consider developing an intelligent customer capability for environmental aspects.

On this last point whilst recognition is made of the proposed recruitment of an environmental lead for the UK to sit within the licensing group of GEH there is a concern that there seems to be no such presence within GEH currently. There is some way to go on the development of the environment safety case submission. Additionally the UK Nuclear Regulators would welcome a paper in principle describing GEH's approach to satisfying the requirements of the GDA process for the next Steps.