



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 16, 2019

Mr. David Gómez
QA Manager
ENSA Equipos Nucleares S.A. S.M.E.
Av. Juan Carlos I, 8,
39600 Maliaño, Cantabria, Spain

SUBJECT: MULTINATIONAL DESIGN EVALUATION PROGRAM VENDOR INSPECTION
REPORT OF ENSA, EQUIPOS NUCLEARES S.A. S.M.E, NO. 99901379/2019-
201, NOTICE OF NONCONFORMANCE

Dear Mr. Gómez:

From October 21 through October 25, 2019, the U.S. Nuclear Regulatory Commission (NRC) staff along with regulators from the United Kingdom Office for Nuclear Regulation (ONR) and from the French L'Autorité de Sûreté Nucléaire (ASN), conducted a Multinational Design Evaluation Program (MDEP) inspection at the ENSA, Equipos Nucleares S.A. S.M.E. (hereafter referred to as ENSA) facility in Cantabria, Spain.

The purpose of multinational inspections is to foster international cooperation amongst nuclear regulatory agencies to leverage the resources and talents of our regulatory peers in other countries. To this end, the NRC actively participates in bilateral and multilateral interactions with our international counterparts to help enhance our vendor oversight capabilities, and to foster more effective and efficient monitoring of the nuclear supply chain.

Consistent with the protocol for conduct of these inspections, described in MDEP Program, vendor inspection cooperation working group (VICWG), VICWG-01, "Witnessed Joint and Multinational Vendor Inspection Protocol," Revision 2, dated March 20, 2014, the NRC led this multinational inspection activity in accordance with the NRC regulatory framework with ONR and ASN participating as inspectors (the MDEP inspection team). The inspection was performed in accordance with NRC inspection procedures and provided an opportunity for our regulatory counterparts to gain inspection experience using the NRC's inspection methodologies.

This report, and the findings herein, are being cited against the regulations of the lead inspection regulatory body, the NRC, which include provisions of selected portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

This technically-focused multinational inspection specifically evaluated ENSA's implementation of the quality assurance (QA) activities associated with fabrication, assembly, and testing of safety-related components being supplied to operating nuclear power plants. The enclosed

report presents the results of the inspection. This inspection report does not constitute NRC endorsement of ENSA's overall QA or 10 CFR Part 21 programs.

Based on the results of this multinational inspection, the MDEP inspection team found that the implementation of your QA program did not meet certain regulatory requirements imposed on you by your customers or NRC licensees' requirements. Specifically, the MDEP inspection team determined that ENSA was not fully implementing its QA program in the area of special processes. The specific finding and references to the pertinent requirements are identified in the enclosures to this letter. In response to the enclosed NON, ENSA should document the results of the extent of condition review for the finding and determine if there are any effects on other safety-related components. Please provide a written statement or explanation within 30 days of this letter in accordance with the instructions specified in the enclosed NON. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," the NRC will make available electronically for public inspection a copy of this letter, its enclosure, and your response through the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information would create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If SGI is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

Docket No.: 99901379

EPID No.: I-2019-201-0062

Enclosure:

1. Notice of Nonconformance
2. Inspection Report No. 99901379/2019-201 and Attachment

SUBJECT: MULTINATIONAL DESIGN EVALUATION PROGRAM VENDOR INSPECTION
 REPORT OF ENSA, EQUIPOS NUCLEARES S.A. S.M.E, NO. 99901379/2019-
 201, NOTICE OF NONCONFORMANCE

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NOTICE OF NONCONFORMANCE

ENSA, Equipos Nucleares S.A. S.M.E.
Av. Juan Carlos I, 8,
39600 Maliaño, Cantabria, Spain

Docket No. 99901379
Report No. 2019-201

Based on the results of a Multinational Design Evaluation Program (MDEP) inspection led by the U.S. Nuclear Regulatory Commission (NRC) conducted at the ENSA, Equipos Nucleares, S.A. S.M.E. (hereafter referred to as ENSA) facility in Cantabria, Spain, from October 21, 2019 through October 25, 2019, it appears that ENSA did not conduct certain activities in accordance with regulatory requirements that were contractually imposed upon ENSA by its customers or NRC licensees:

- A. Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50, states, in part, that "Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements."

ENSA procedure OPR3CS401, "Liquid Penetrant Procedure," Revision 2, dated February 4, 2019, Section 5.6.2, states, in part, to "Observe the surface during the application of the developer to monitor the behavior of indications which tend to bleed-out profusely." Section 3, "Light Conditions," states, in part, that "the examination surface shall be examined under daylight or under artificial light with an illumination of at least 500 lux. During the examination, disturbing reflections and bright spots shall be excluded. The light intensity shall be routinely checked to assure adequate lighting of the examination surface."

Contrary to the above, as of October 25, 2019, ENSA failed to assure that special processes were controlled and accomplished using qualified procedures in accordance with specifications and acceptance criteria. While performing liquid penetrant examination of the weld preparation of the backing plate for 2PR3-10A01 to the surge nozzle, the inspection team observed the ENSA non-destructive examination (NDE) Level II inspector was not aware of the primary area to be inspected as specified on ENSA Drawing OPR3.19862, Revision 0. Specifically, the ENSA NDE Level II inspector did not review the ENSA drawing prior to commencing the inspection to determine the primary area to be inspected and therefore did not question or modify the orientation of the plate so that the primary area was readily accessible and directly observable. As a result, the ENSA Level II inspector had to use mirrors, to prepare and inspect the underside of the plate (the primary area) and did not assure the primary area was examined with an illumination of at least 500 lux, nor was the light intensity routinely checked during the examination to assure adequate lighting.

Proper inspection conditions require direct observation, adequate lighting, drying of plate surface prior to penetrant application, ensuring adequate penetrant application and removal, and developer application. These requirements were indeterminate since these activities were performed on the primary area that was not readily accessible and directly observable.

This issue has been identified as Nonconformance 99901379/2019-201-01.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality Assurance and Vendor Inspection Branch, Division of Reactor Oversight, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance or, if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further noncompliance; and (4) the date when the corrective action will be completed. Where good cause is shown, the NRC will consider extending the response time.

Because your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible from the NRC Web site at <http://www.nrc.gov/readingrm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or Safeguards Information so that the NRC can make it available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information would create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Dated this the 16th day of December 2019.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR OVERSIGHT
QUALITY ASSURANCE VENDOR INSPECTION REPORT**

Docket No.: 99901379

Report No.: 99901379/2019-201

Vendor: ENSA, Equipos Nucleares S.A. S.M.E.
Av. Juan Carlos I, 8,
39600 Maliaño, Cantabria, Spain

Vendor Contact: David Gómez
Quality Assurance Manager
ENSA, EQUIPOS NUCLEARES S.A. S.M.E.
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Nuclear Industry Activity: ENSA's scope of supply includes fabrication, assembly, and testing of safety-related components for nuclear pressure vessels and steam generators being supplied to U.S. operating nuclear power plants.

Inspection Dates: October 21-25, 2019

Inspection Team Leader Greg Galletti NRR/DRO/IQVB

Inspectors: Jonathan Ortega-Luciano NRR/DRO/IQVB
John Honcharik NRR/DNRL/NPHP
John Gillespie Office for Nuclear Regulation (ONR)
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Laure Monin Autorité de Sûreté Nucléaire (ASN)
Jérémy Hubert ASN
Isabel Pedraza ASN

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

EXECUTIVE SUMMARY

ENSA, Equipos Nucleares S.A. S.M.E.
99901379/2019-201

From October 21 through October 25, 2019, the U.S. Nuclear Regulatory Commission (NRC) staff along with regulators from the United Kingdom Office for Nuclear Regulation (ONR) and from the French L'Autorité de Sûreté Nucléaire (ASN), conducted a Multinational Design Evaluation Program (MDEP) inspection at the ENSA, Equipos Nucleares S.A. S.M.E. (hereafter referred to as ENSA) facility in Cantabria, Spain.

The purpose of multinational inspections is to foster international cooperation amongst nuclear regulatory agencies to leverage the resources and talents of our regulatory peers in other countries. To this end, the NRC actively participates in bilateral and multilateral interactions with our international counterparts to help enhance our vendor oversight capabilities, and to foster more effective and efficient monitoring of the nuclear industry supply chain.

Consistent with the protocol for conduct of these inspections, described in the MDEP Protocol, VICWG-01, "Witnessed Joint and Multinational Vendor Inspection Protocol," Revision 2, dated March 20, 2014, the NRC lead this multinational inspection in accordance with the NRC regulatory framework with ONR and ASN participating as inspectors (the MDEP inspection team). The multinational inspection was performed in accordance with NRC inspection procedures and provided an opportunity for our regulatory counterparts to gain inspection experience using the NRC's inspection methodologies.

This report, and the findings herein, are being cited against the regulations of the lead inspection regulatory body, the NRC, which include provisions of selected portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

This technically-focused multinational inspection specifically evaluated ENSA's implementation of the quality assurance (QA) activities associated with fabrication, assembly, and testing of safety-related components being supplied to operating nuclear power plants. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC endorsement of ENSA's overall QA or 10 CFR Part 21 programs.

These regulations served as the bases for the NRC inspection:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21

During the course of this inspection, the MDEP inspection team implemented inspection procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017, IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017, and IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting of Defects and Noncompliance," dated May 16, 2019.

With the exception of the nonconformance described below, the MDEP inspection team concluded that ENSA's QA policies and procedures comply with the applicable requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, and that ENSA's personnel are

implementing these policies and procedures effectively. The results of this multinational inspection are summarized below.

10 CFR Part 21

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the implementation of its 10 CFR Part 21 program and determined that ENSA's program was consistent with NRC regulations and was being implemented adequately in accordance with written procedures and instructions. No findings of significance were identified.

Design Control

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the design control program to verify compliance with the regulatory requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. The MDEP inspection team verified that the design and procurement specifications were properly translated into ENSA's specification sheets, drawings, and procedures. The MDEP inspection team focused their review in evaluating the implementation of the process used by ENSA to substantiate design changes used for the Replacement Reactor Vessel Head Closure for Shearon Harris Unit 1. No findings of significance were identified.

Commercial-Grade Dedication

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the implementation of its commercial-grade dedication (CGD) programs to verify compliance with the requirements of Criterion III, "Design Control," Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50.

The MDEP inspection team noted that ENSA's CGD activities related to the Replacement Reactor Vessel Head Closure for Shearon Harris Unit 1 were limited to qualifying commercial calibration service suppliers in accordance with the requirements of the International Standard Organization (ISO)/International Electrotechnical Commission (IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories," in lieu of performing an on-site commercial-grade survey. The MDEP inspection team verified that ENSA implemented this process in accordance with the conditions imposed on the NRC's approval of the International Laboratory Accreditation Cooperation accreditation process as documented in safety evaluation report (SER) dated February 9, 2015 (Agencywide Documents Access Management System Accession (ADAMS) No. ML14322A535). No findings of significance were identified.

Identification and Control of Materials, Parts, and Components

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the identification, and control of materials, parts and components to verify compliance with the requirements of Criterion VIII, "Identification and Control of Materials, Parts, and Components" of Appendix B to 10 CFR Part 50. The MDEP inspection team reviewed the identification and control of items to ensure that only specified and accepted items are used, markings are applied using materials and methods that provide a clear and legible identification and do not adversely affect the function or service life of the item. No findings of significance were identified.

Control of Measuring and Test Equipment

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the implementation of its measuring and test equipment (M&TE) program to determine compliance with the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. The MDEP inspection team observed several mechanical tests in progress and calibration activities, reviewed calibration records and controls, storage and maintenance of calibration equipment, and review of corrective actions associated with prior calibration issues. No findings of significance were identified.

Manufacturing Control and Control of Special Processes

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the fabrication and work control processes to verify compliance with the regulatory requirements of Criterion V, "Instructions, Procedures, and Drawings," Criterion VIII, "Identification and Control of Materials, Parts and Components," Criterion IX, "Control of Special Processes," and Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50, as well as with the requirements of the American Society of Mechanical Engineers Boilers and Pressure Vessel Code (ASME Code), Section III, "Rules for Construction of Nuclear Facility Components" and RCC-M Code, "Design and Construction Rules for the Mechanical Components of PWR Nuclear Islands."

The MDEP inspection team observed non-destructive examination activities conducted in the ENSA shop and determined those activities failed to assure that special processes were controlled and accomplished using qualified procedures in accordance with specifications and acceptance criteria. Specifically, while performing liquid penetrant examination of the weld preparation of the backing plate for 2PR3-10A01 to the surge nozzle, the MDEP inspection team observed the ENSA Level II inspector was not aware that the weld preparation was under the part to be inspected, and ENSA drawing OPR3.19862 Revision 0 was not used as a reference to determine the area of examination. The ENSA Level II inspector did not review the ENSA drawing prior to commencing the inspection to determine the primary area to be inspected; therefore, the part was orientated such that the primary area was under the part. It is noted that the part was specifically moved to a table for ease of access for the inspection.

Therefore, the inspection results were indeterminate since the activities performed on the primary area are questionable under the existing circumstances/conditions. Proper inspection required that the activities include direct observation, lighting, drying prior to penetrant application, penetrant application and removal, and developer application. The MDEP inspection team issued Nonconformance 99901379/2019-201-01 for failure to control and accomplish non-destructive visual examination activities using qualified procedures in accordance with specifications and acceptance criteria.

Nonconforming Materials, Parts, or Components and Corrective Action

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the fabrication and work control processes to verify compliance with the regulatory requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, Corrective Action of Appendix B to 10 CFR Part 50. The MDEP inspection team reviewed corrective actions implemented in response to three nonconformances issued in NRC Inspection Report 99901379/2016-201 and determined that ENSA had taken adequate corrective actions to resolve those nonconformances. Those nonconformances are closed in this report. No findings of significance were identified.

Oversight of Contracted Activities and Internal Audits

The MDEP inspection team concluded that with the exception of the areas for improvement regarding counterfeit, fraudulent, and suspect item (CSFI) control and internal auditing identified herein, ENSA is implementing its oversight of contracted activities and internal audit program in accordance with the regulatory requirements of Criterion IV, Criterion VII, and Criterion XVIII, respectively, of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and activities observed, the MDEP inspection team determined that ENSA is implementing its policies and procedures associated with oversight of contracted activities and internal audit program. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The Multinational Design Evaluation Program (MDEP) inspection team reviewed the policies and implementing procedures that govern the implementation of its Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," program to determine compliance with regulatory requirements. In addition, the MDEP inspection team evaluated the 10 CFR Part 21 postings and a sample of ENSA, Equipos Nucleares S.A. S.M.E. (hereafter ENSA) purchase orders (POs) for compliance with the requirements of 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation," and 10 CFR 21.31, "Procurement Documents." The MDEP inspection team evaluated whether ENSA's corrective action and nonconformance programs were sufficiently integrated such that identified issues would be appropriately considered for 10 CFR Part 21 evaluation and reportability.

The MDEP inspection team reviewed ENSA's procedure, GP 15.05, "Reporting of Defects and Non-compliances Under 10 CFR 21," Revision 8, dated March 5, 2016, used to perform a 10 CFR Part 21 evaluation and determined that it addressed the requirements for evaluating deviations and failures to comply. The MDEP inspection team reviewed a sample of evaluations performed by ENSA for deviations that resulted in an evaluation. The MDEP inspection team confirmed that ENSA documented the evaluation and notification information in accordance with GP 15.05.

The MDEP inspection team reviewed current nonconformance reports (NCRs) and corrective action reports (CARs) related to U.S. procurements and did not identify any issues requiring evaluation that were not adequately dispositioned.

The MDEP inspection team reviewed training materials that covered topics described in ENSA's Part 21 procedure and verified indoctrination of personnel that perform activities defined in GP 15.05 as having satisfactorily completed the training.

The MDEP inspection team discussed the 10 CFR Part 21 program with ENSA's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the MDEP inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The MDEP inspection team concluded that ENSA is implementing its 10 CFR Part 21 program in accordance with the regulatory requirements of 10 CFR Part 21. Based on the limited sample of documents reviewed, the MDEP inspection team also determined that ENSA is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

2. Design Control

a. Inspection Scope

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the design-control program to verify compliance with the regulatory requirements of Criterion III, "Design Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

The MDEP inspection team verified that the design and procurement specifications were properly translated into ENSA's specification sheets, drawings, and procedures. The MDEP inspection team focused their review in the process used by ENSA to substantiate design changes to the Replacement Reactor Vessel Head Closure for Shearon Harris Unit 1. The MDEP inspection team evaluated a change requested by Framatome to perform additional machining operations for mounting lifting lugs 1 and 3 for loose part monitoring. The change process was evaluated by the MDEP inspection team and concluded that this change was done in accordance with ENSA's policies and procedures.

The MDEP inspection team also discussed the design control program with ENSA's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the MDEP inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The MDEP inspection team concluded that ENSA established its design control program in accordance with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the MDEP inspection team also determined that ENSA is implementing its policies and procedures associated with the design control program. No findings of significance were identified.

3. Commercial-Grade Dedication

a. Inspection Scope

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the implementation of its commercial-grade dedication (CGD) program to verify compliance with the requirements of Criterion III, "Design Control," Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B, to 10 CFR Part 50.

The MDEP inspection team also reviewed ENSA's measures established for the use of accreditation in lieu of performing commercial-grade surveys for procurement of calibration and testing services as part of the CGD process. ENSA's quality assurance (QA) manual allows for the use of the International Laboratory

Accreditation Cooperation (ILAC) accreditation process in lieu of performing commercial-grade surveys for domestic and international calibration and testing services. ENSA currently implements this process as described in the Nuclear Energy Institute (NEI) document No. 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, which was recognized for use by the NRC in a safety evaluation report (SER) dated February 9, 2015 (Agencywide Documents Access Management System (ADAMS) Accession No. ML14322A535).

During this multinational inspection, ENSA was not performing CGD activities. The MDEP inspection team confirmed with ENSA that there were no CGD activities for the last project that was delivered to a US utility (i.e., Replacement Reactor Vessel Head Closure for Shearon Harris Unit 1) other than the dedication of calibration services described above.

The MDEP inspection team also discussed the CGD program with ENSA's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the MDEP inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The MDEP inspection team concluded that ENSA established its CGD program in accordance with the regulatory requirements of Criterion III, IV, and VII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the MDEP inspection team also determined that ENSA is implementing its policies and procedures associated with the CGD program. No findings of significance were identified.

4. Identification and Control of Materials, Parts, and Components

a. Inspection Scope

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the identification and control of materials, parts, and components to verify compliance with the requirements of Criterion VIII, "Identification and Control of Materials, Parts, and Components" of Appendix B to 10 CFR Part 50.

The MDEP inspection team inspected the ENSA warehouse to evaluate receipt inspection of an item, to observe the temporary storage of items, and to verify that a sample of materials had a serial number and a heat number to identify their fabrication process. The MDEP inspection team also checked the records relating to a rejected item selected as a sample from those kept in the quarantine part of the warehouse. The MDEP inspection team confirmed through direct observations and review of records that ENSA staff were controlling rejected and nonconforming items consistent with procedures for nonconforming items.

The MDEP inspection team sampled on-going fabrication and warehouse activities to confirm that items in use in sampled work packages were traceable from receipt of goods by ENSA to the point of use. In the warehouse, the MDEP inspection team found evidence that receipt inspection occurs and includes:

- Visual inspection
- Check against supplier documents
- Information technology (IT) database adequately updated, and
- Item physically numbered with an ENSA number, in indelible ink and/or label attached (Original supplier numbers are retained).

In the fabrication area, the MDEP inspection team found satisfactory evidence that items were adequately controlled and traceability was maintained.

The MDEP inspection team reviewed the identification and control of items to ensure that only specified and accepted items are used, markings are applied using materials and methods that provide a clear and legible identification and do not adversely affect the function or service life of the item. The MDEP inspection team also verified that markings are maintained on the item or in documents traceable to the item. The MDEP inspection team engaged ENSA personnel and reviewed the electronic Q-Pulse functions which control manufacturing route sheets (MRS) and work orders, to ensure traceability and configuration control is maintained.

The MDEP inspection team also discussed the identification and control of materials, parts, and components program with ENSA's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the MDEP inspection team.

b. Observation and Findings

The MDEP inspection team noted one area for potential improvement regarding counterfeit, fraudulent, or suspect item (CFSI) controls. This observation is based, in part, on ONR's Technical Assessment Guide, NS TAST-GD-077, "Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services," (TAG 77), Revision 5, that detail "relevant good practice" to implement adequate quality management arrangements in all matters which may affect safety. Section 6.8 of TAG 77 described the expectation that CFSI programs to be developed and implemented and applies to both Nuclear New Build (NNB) and ENSA through contractual arrangements between the two organizations.

ENSA accepts suppliers' certificates of compliance documentation to verify the technical requirements in the ENSA purchase request. ENSA does not sample these items to confirm physical measurement or to repeat basic mechanical or chemical tests. Such occasional physical checks can prevent against fraud in the documentation. ENSA may wish to consider including such checks in the CFSI controls they have under development as documented in CAR 0102/19.

No findings of significance were identified.

c. Conclusion

The MDEP inspection team concluded that ENSA is identifying and controlling materials, parts, and components in accordance with the regulatory requirements of the Criterion VIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the MDEP inspection team also determined that ENSA is implementing its policies and procedures associated with the identification and control of materials, parts, and components procedures. No findings of significance were identified.

5. Control of Measuring and Test Equipment (M&TE)

a. Inspection Scope

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the M&TE program to verify compliance with the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. The MDEP inspection team observed several mechanical tests in progress and calibration activities including:

- tensile test (project Hinkley Point C – embedded tank)
- charpy impact test (project Hinkley Point C)
- calibration of micrometer 0400-0546
- calibration of drying oven for electrodes and flux 0740-5882

The MDEP inspection team determined that M&TE had the appropriate calibration stickers and current calibration dates, including the calibration due date. The MDEP inspection team also verified that M&TE had been calibrated, adjusted, and maintained at prescribed intervals prior to use. In addition, the calibration records reviewed by the MDEP inspection team indicated the as-found or as-left conditions, accuracy required, calibration results, calibration dates, and the due date for recalibration. The MDEP inspection team also verified that the selected M&TE was calibrated using procedures traceable to known industry standards.

The MDEP inspection team observed storage of MT&E to verify that ENSA properly segregated, documented, and evaluated when M&TE was found out of calibration, lost, or out of service. The MDEP inspection team also reviewed the controls that ENSA has in place for (1) performing evaluations to determine whether previous inspection or test results were affected by M&TE found out of calibration, (2) appropriately notify affected customers, and (3) repair or replace devices consistently found out of calibration.

The MDEP inspection team also verified that when M&TE equipment is received from the calibration service supplier and the calibration certificate states that it was found to be out of calibration, ENSA generates an NCR to identify items that have been accepted using this equipment since the last valid calibration date and to perform an extent of condition review.

The MDEP inspection team also discussed the control of M&TE program with ENSA's management and technical staff. The attachment to this inspection report

lists the documents reviewed and personnel interviewed by the MDEP inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The MDEP inspection team concluded that ENSA is implementing its M&TE program in accordance with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the MDEP inspection team also determined that ENSA is implementing its policies and procedures associated with the M&TE program. No findings of significance were identified.

6. Manufacturing Control and Control of Special Processes

a. Inspection Scope

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern the fabrication and work control processes to verify compliance with the regulatory requirements Criterion VIII, "Identification and Control of Materials, Parts and Components," Criterion IX, "Control of Special Processes," and Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50, as well as with the requirements of the American Society of Mechanical Engineers Boilers and Pressure Vessel Code (ASME Code), Section III, "Rules for Construction of Nuclear Facility Components" and RCC-M Code, "Design and Construction Rules for the Mechanical Components of PWR Nuclear Islands."

The MDEP inspection team reviewed ongoing welding activities. Specifically, inspection point plans (IPPs), welding reports, weld procedure specifications (WPSs), supporting procedure qualification records (PQRs), welder qualifications, filler metal control, and the calibration certificates of the welding equipment were reviewed. For NDE, the MDEP inspection team reviewed liquid penetrant testing (PT) procedures, PT reports, and the calibration certificates of the measuring equipment.

The MDEP inspection team reviewed the ENSA procedures for magnetic particle (MT), PT, and ultrasonic (UT) inspections, and verified that they were consistent with the applicable RCC-M and ASME Code requirements. The MDEP inspection team also reviewed the Level III non-destructive examiner and Level II non-destructive inspector qualification records and confirmed they were qualified in accordance with the requirements in RCC-M and ASME Codes and had sufficient training. The MDEP inspection team also verified that the examinations were performed by qualified personnel and qualified procedures in accordance with the requirements of RCC-M and ASME Code.

The MDEP inspection team also discussed the manufacturing control program with ENSA's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the MDEP inspection team.

b. Observations and Findings

b.1 Welding Process

The MDEP inspection team verified that the WPSs were qualified in accordance with the requirements of RCC-M Code and ASME Code, Sections III and IX using the supporting PQRs and the applicable ENSA procedures.

The MDEP inspection team verified that the applicable welding data; such as weld material and heat/lot number, WPS, inspection procedures used, and that the final inspection results were recorded in accordance with the applicable ENSA procedures and instructions. The welding data was recorded on the associated weld record for each weld joint along with the applicable NDE results. All applicable information, including drawings, procedures, instructions and non-destructive examination tests were included in the electronic version of the welding report.

b.2 Control of Weld Material

The MDEP inspection team observed the weld material storage and issue station and verified that weld material was adequately controlled, including that flux covered weld electrodes were in hermetically sealed containers, kept in baking ovens or portable ovens to control the moisture content within the requirements of the applicable filler metal specification, RCC-M Code, and ASME Code Section III. The MDEP inspection team also verified that calibrated thermocouples/ovens and portable heated weld wire bins were used and had valid calibration documentation in accordance with applicable ENSA procedures. The MDEP inspection team verified that weld material was controlled at all times until its consumption.

b.3 Nondestructive Examination

The MDEP inspection team witnessed PT examination of the weld preparation of the backing plate for 2PR3-10A01 to the surge nozzle for the Hinkley Point C project in accordance with the applicable ENSA procedures. During the PT examination, the MDEP inspection team observed the part being specifically moved to a table for ease of access for the inspection, but with the weld preparation (primary area to be examined) was placed facing downwards to the table. The ENSA Level II inspector did not reference or review the Drawing, OPR3.19862, Revision 0, that was available to determine the primary area to be examined prior to commencing the examination. Therefore, the ENSA Level II inspector was not aware that the weld preparation was under the part. Since the primary area was under the part, the ENSA Level II inspector applied the developer with the aerosol can upside down at times to reach underneath the part, which could result in uneven developer application. The MDEP inspection team noted that the ENSA Procedure OPR3CS401, Section 5.6.2, states, in part, "Observe the surface during the application of the developer to monitor the behavior of indications which tend to bleed-out profusely," and requires the ENSA Level II inspector to observe the primary surface during application of the developer to monitor behavior of any indications and bleed out and to ensure that

correct amount of developer is applied. This was not performed since the primary area was not readily accessible.

Since the primary area to be examined was not readily available, due to the incorrect orientation of the part, the ENSA Level II inspector proceeded to use a mirror in order to have visual access to the primary area to be examined. ENSA Procedure OPR3CS401 does not specifically allow or was qualified for the use of aids such as mirrors, since liquid penetrant examination is considered a direct accessible inspection technique. ENSA Drawing OPR3.19862 Revision 0, clearly showed the area of examination and was not readily accessible for examination without the use of aids, such as mirrors.

Therefore, the inspection results are indeterminate since the activities performed on the primary area are questionable under the existing conditions. The activities include direct observation, lighting, drying prior to penetrant application, penetrant application and removal, and developer application. The MDEP inspection team concluded that the examination was not performed in accordance with procedure OPR3CS401 requirements.

Examples of these activities not being performed in accordance with the requirements of procedure OPR3CS401 include: not determining if the weld prep area was dry prior to applying the developer; the primary area to be examined was underneath the piece and was only accessible with a mirror, which is not allowed by procedure OPR3CS401, or qualified as such; the procedure requires the ENSA Level II inspector to monitor during application of the developer, behavior of any indications and bleed out and to ensure that the correct amount of developer is applied, which was not performed since the primary area was not readily accessible. Lastly, it could not be determined if the ENSA Level II inspector met the procedure OPR3CS401 requirements for preventing disturbing reflections and bright spots with the use of the flashlight and mirror under the part.

The MDEP inspection team identified this issue as Nonconformance 99901379/2019-201-01 for ENSA's failure to assure that special processes were controlled and accomplished using qualified procedures in accordance with specifications and acceptance criteria. This could lead to defects propagating from the backing plate into the weld and the base metal of the pressurizer shell.

Although this particular example was associated with on-going work to support the Hinkley Point 3 project in the United Kingdom, these activities, which are programmatic in nature, therefore, are also applicable to U.S. licensees that have imposed Appendix B to 10 CFR Part 50 requirements on ENSA in their procurement documentation

b.4 Qualification and Training of Welding and Nondestructive Examination Personnel

The MDEP inspection team reviewed the associated welder qualification records and confirmed that the welders had completed the required training and had maintained their qualifications in accordance with ENSA procedures. The MDEP inspection team also verified that the applicable procedure for welder qualification met the requirements of RCC-M Code. ENSA had fabricated the

replacement reactor pressure vessel head for Shearon Harris, Unit 1; therefore, the MDEP inspection team also reviewed the associated welder qualification records and confirmed that the welders had completed the required training and had maintained their qualifications in accordance with ENSA procedures and met the requirements of ASME Code, Section III and IX.

b.5 Mechanical Testing

The MDEP inspection team observed tensile testing and charpy impact testing of material in the test laboratory for the Hinkley Point C project. The MDEP inspection team verified that the testing laboratory was accredited to ISO 17025 “General requirements for the competence of testing and calibration laboratories,” (certificate reference 942/LE1853).

The MDEP inspection team verified that the testing operations observed were performed according to ENSA’s procedures by suitably qualified staff.

b.6 Fabrication

During observation of shop fabrication activities, the MDEP inspection team reviewed the functionality of ENSA’s computer system for work control used on the shop floor. The MDEP inspection team reviewed a sample of IPPs and observed a dimension check had to be performed on the IPP BAT7/20AO6 at line 1000. This step involved measuring axis and diameter to compare against the dimensions on the drawing.

However, the line was marked as “not acceptable” on the computer because the required dimensions were not what is on the drawing. These issues were discussed with the ENSA QA Manager and technical staff and CAR 0113/19 was opened during the inspection to address the concern.

c. Conclusion

The MDEP inspection team issued Nonconformance 99901379/2019-201-01 in association with ENSA’s failure to implement the regulatory requirements of Criterion IX, of Appendix B to 10 CFR Part 50. Nonconformance 99901379/2019-201-01 cites ENSA for failing to assure that special processes were controlled and accomplished using qualified procedures in accordance with specifications and acceptance criteria. Specifically, ENSA did not prepare and examine the primary area of the weld preparation on the backing plate used for the pressurizer in accordance with drawing OPR3.19862 Revision 0, and liquid penetrant procedure OPR3CS401.

7. Nonconforming Materials, Parts, or Components and Corrective Actions

a. Inspection Scope

The MDEP inspection team reviewed ENSA’s policies and implementing procedures that govern the control of nonconformances and corrective action to verify compliance with the requirements of Criterion XV, “Nonconforming Materials, Parts, or Components,” and Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50, respectively.

The MDEP inspection team reviewed ENSA's NCR log and reviewed a sample of NCRs to ensure that ENSA implemented an adequate program to assess and control nonconforming items, including appropriate identification, documentation, segregation, evaluation and disposition. Additionally, the MDEP inspection team interviewed ENSA staff to verify there were designated areas to segregate and control nonconforming materials.

The MDEP inspection team reviewed ENSA's corrective action log and reviewed a sample of CARs to ensure that ENSA implemented an adequate program to evaluate conditions adverse to quality and take appropriate steps to correct the deficiencies. In all cases CARs were written, apparent causes identified, corrective actions identified, and verification (objective evidence) of completion of actions were documented. CARs are not closed in the system until at least 3 months have passed since corrective actions have been implemented to assure the corrective actions effectively resolved the issues and prevent recurrence.

The ENSA QA Manager evaluates CARs on an annual basis and develops a comprehensive report for management. This report analyzes all CARs and NCRs based on classifications prescribed within the corrective action and preventative action (CAPA) and NCR systems for each. The results are tabulated and evaluated to determine any significant trends in quality areas or quality processes that need to be addressed.

The MDEP inspection team reviewed the implementation and completion of all corrective actions associated with three nonconformances identified in NRC Inspection Report 99901379/2016-201 (ML16145A514) to verify that ENSA's actions were consistent with the corrective actions described in ENSA's response to the NRC inspection report, and those corrective actions adequately addressed the nonconforming conditions.

The MDEP inspection team also confirmed that all NCRs and CARs require an evaluation for part 21 applicability.

The MDEP inspection team discussed the nonconformances and corrective action programs with ENSA's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the MDEP inspection team.

b. Observations and Findings

b.1 Corrective Action Associated with Nonconformance No. 99901379/2016-201-01

In the April 2016 inspection of ENSA, the NRC issued Nonconformance (NON) 99901379/2016-201-01 for ENSA's failure to establish suitability of application of materials that are essential to the safety-related functions of structures, systems, and components. Specifically, ENSA's Material Inspection Plan (MIP) OBV2MIP001, "Certification Compliance with 10 CFR 50 Appendix B, 10 CFR 21, and Westinghouse Specification A105C01-GEN Revision B, of Carbon Steel forged Flanges SA-105," did not establish and document the sample testing population for the acceptance of material critical characteristics used for the

commercial-grade dedication of the feed water ring (FWR) assembly inspection port slip-on and blind flange SA-105 carbon steel material. In addition, ENSA did not verify that the supplier had quality controls in place to ensure heat traceability of the material.

The MDEP inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions including CAR 0086/16, Revision 00, dated April 28, 2016, NCR OBV2/057, Revision 00, dated May 10, 2016, and audit reports AR 13-16, and 21-14. The corrective actions required the affected items to be dedicated for their intended use. This activity was documented in WEC BV2-RSG-CDI-001, revision 01, which was incorporated into ENSA Base Material Receiving Reports IR/153/173/184. The basis for sampling used in the dedication was consistent with commonly accepted industry practices as described in EPRI TR-017281-R1. In addition, the sub-supplier's written procedures were verified on site by ENSA to ensure traceability of the process for identifying source materials in a manner that provides traceability to the Certified Material Test Reports (CMTR's). ENSA also verified that no other material was identified which was procured as nuclear safety-related from non-Appendix B supplier. A stand-down with ENSA engineering and QA personnel was completed on July 8, 2016, as indicated by registration records. The discussion included an explanation of the issue identified and the actions taken to avoid recurrence.

Based on the review, the MDEP inspection team closed Nonconformance 99901379/2016-201-01.

b.2 Corrective Action Associated with Nonconformance No. 99901379/2016-201-02

In the April 2016 inspection of ENSA, the NRC issued NON 99901379/2016-201-02 for ENSA's failure to assure that special processes were controlled and accomplished using qualified procedures in accordance with specifications and acceptance criteria. Specifically, ENSA used several open flame gas burners that were installed underneath the secondary side of the steam generators to facilitate final drying and vacuuming after the secondary side hydrostatic pressure test, without a qualified procedure for this activity.

The MDEP inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions including CAR 0087/16, Revision 00, dated April 28, 2016, Technical Report IT 2016/11, Revision 00, dated July 13, 2016, "Heating process regarding vacuum and drying of the steam generator secondary side," and Lesson Learned dated July 29, 2016. The corrective actions including an evaluation of conditions that could result in deformation, changes to material properties, and dimensional tolerances of the affected steam generators, confirmed that the conditions present during drying process did not have an adverse effect on these characteristics. The Lessons Learned described the issue, corrective actions, affected component type (generator), and reference to ENSA Specification 0BV2FS503, "Draining and Drying of the Secondary Side," Revision 1, dated September 30, 2015. Future use of the process will require the quality engineer to review the Lessons Learned database for applicability based on part type and incorporate proposed revisions into project specifications. A stand-down with

ENSA personnel was completed on July 13, 2016 as indicated by registration records. The discussion included an explanation of the issue identified and the actions taken to avoid recurrence.

Based on the review, the MDEP inspection team closed Nonconformance 99901379/2016-201-02.

b.3 Corrective Action Associated with Inspection Report No. 99901379/2016-201-03

In the April 2016 inspection of ENSA, the NRC issued NON 99901379/2016-201-03 for ENSA's failure to establish adequate measures to obtain objective evidence of quality furnished by the contractor or subcontractor. Specifically, ENSA did not provide adequate documented objective evidence in their external audit reports of material and service suppliers to provide reasonable assurance that the suppliers had implemented an Appendix B to 10 CFR Part 50 and 10 CFR Part 21 programs for the supply of safety-related basic components.

The MDEP inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions including CAR 0088/16, Revision 00, dated April 28, 2016, ENSA's supplier audit checklist, and indoctrination records. The corrective actions required revision of ENSA's supplier audit checklist to strengthen the criteria to be checked, preparation of a package for suppliers to better understand and describe the Appendix B and Part 21 processes in their policies and procedures, a review supplier Part 21 programs to verify satisfactory compliance with regulation, and training provided to the ENSA lead auditor personnel on Part 21 requirements to be evaluated during supplier audits.

Based on the review, the MDEP inspection team closed Nonconformance 99901379/2016-201-03.

c. Conclusion

The MDEP inspection team concluded that ENSA is implementing its Nonconforming Materials, Parts, or Components and Corrective Action programs in accordance with the regulatory requirements of Criterion XV and Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the MDEP inspection team also determined that ENSA is implementing its policies and procedures associated with these programs.

The MDEP inspection team also reviewed ENSA's corrective actions associated with three non-conformances identified in the NRC's inspection of ENSA in April 2016. The MDEP inspection team verified implementation of those corrective actions to be adequate and complete to address those concerns. Therefore, NON's 99901379/2016-201-01, 99901379/2016-201-02, and 99901379/2016-201-03 are closed. No findings of significance were identified.

8. Oversight of Contracted Activities and Internal Audits

a. Inspection Scope

The MDEP inspection team reviewed ENSA's policies and implementing procedures that govern its oversight of contracted activities and internal audit program to verify compliance with the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50.

The MDEP inspection team also considered the technical and administrative controls described in ONR's Technical Assessment Guide, NS TAST-GD-077, "Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services," (TAG 77), Revision 5, that detailed "relevant good practice" to implement adequate quality management arrangements in all matters which may affect safety. Section 6.8 of TAG 77 described the expectation that CFSI programs would be developed and implemented and applied to both Nuclear New Build (NNB) and ENSA through contractual arrangements between the two organizations.

Additionally, the MDEP inspection team considered ENSA's accreditation to ISO 9001 in reviewing aspects of the area of auditing. ISO 9001:2015, Section 9.2.2 on audits, states, in part, that "The organization shall plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits."

a.1 Internal Audits

The MDEP inspection team reviewed ENSA's procedures that govern the internal audits to verify compliance with the requirements according to their QA Manual and to verify the compliance with Appendix B of 10 CFR Part 50.

The MDEP inspection team reviewed a sample of internal audit reports to understand the internal audit process and to verify the implementation of the internal audit program. ENSA conducts audits of quality processes following the content of the QA manual. The MDEP inspection team verified that ENSA had prepared and approved plans that identify the audit scope and applicable checklist criteria before the initiation of the audit activity. The MDEP inspection team observed evidence that the internal audits were comprehensive against ENSA's quality plan and each area was audited every year.

The MDEP inspection team reviewed a sample of training and qualification records of quality personnel involved in internal audits. The evidence showed that personnel undertake training in quality and undergo an examination regularly in quality aspects. There were records to demonstrate tracking of the number of audits per auditor, and that lead auditors met the requirement for experience of five audits before becoming a lead auditor, as required by ENSA's policy. The MDEP inspection team confirmed that audit personnel had completed the required training and maintained qualification and certification in accordance with ENSA's policies.

a.2 Oversight of Contracted Activities

From a sample of supplier audit records, the MDEP inspection team verified that supplier audits were performed using approved checklists and procedures. The MDEP inspection team verified that ENSA auditors followed an appropriate checklist to evaluate the suppliers QA programs, internal QA processes, and the components they produce for ENSA. This evidence shows that ENSA has a system for review of supplier QA controls.

The MDEP inspection team reviewed a sample of CARs created NNB's external audit of May 2019. The corrective actions created are still pending and await the creation of a CFSI general procedure and training for the staff.

The MDEP inspection team also reviewed CARs from two other audits and the disposition of these to ensure that findings were adequately resolved before 3 months had elapsed, as required by the ENSA QA manual. The MDEP inspection team confirmed these corrective actions had been resolved in a timely manner.

The MDEP inspection team also discussed the oversight of contracted activities and internal audit programs with ENSA's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the MDEP inspection team.

b. Observations and findings

b.1 Internal Audits

The MDEP inspection team noted that the internal audits typically cover the quality processes, and do not evaluate the technical aspects of the processes to a significant depth. The MDEP inspection team reviewed two internal audits regarding ENSA's equipment calibration and ENSA's specifications and procedures. For both audits, the scope covered only programmatic aspects and not the technical details of the processes reviewed. For example, the equipment calibration audit documented examination of the calibration program procedures, but the instruments were not technically checked again to see whether they were calibrated properly, nor were any specific technical procedures for calibration of specific equipment reviewed or documented.

The MDEP inspection team also noted that ENSA did not use the results of previous audits to inform their plan for future audits, either to make those audits more in depth or to change their focus. The audit plan remains annual, covering the sections of the QA Manual, irrespective of outcomes.

These issues were discussed with the ENSA QA Manager and technical staff. The MDEP inspection team determined these issues to be minor items because the issues did not specifically violate any regulatory requirements associated with auditing, and the MDEP inspection team verified, through direct inspection that calibration activities were being controlled and implemented in accordance with regulatory requirements.

b.2 Oversight of Contracted Activities

The MDEP inspection team noted an area for improvement in the management of CFSI. Presently, although there is some mention of CFSI management in one of ENSA's General Procedures, there is no dedicated section of their QA manual related to CFSI, consistent with the guidance in TAG 77. A supplier audit of ENSA performed by NNB Hinkley Point C Ltd., in May 2019 had observed this shortfall and recommended improvements. ENSA created a corrective action, CAR 0102/19 to develop dedicated CFSI plans and training for ENSA's quality auditors. This CAR is ongoing and scheduled to be completed by December 31, 2019. This issue was determined to be minor because ENSA did initiate a timely corrective action when the issue was identified, and the corrective actions are currently being implemented.

c. Conclusion

The MDEP inspection team concluded that with the exception of the areas for improvement regarding CSFI control and internal auditing identified herein, ENSA is implementing its oversight of contracted activities and internal audit program in accordance with the regulatory requirements of Criterion IV, Criterion VII, and Criterion XVIII, respectively, of Appendix B to 10 CFR Part 50.

Based on the limited sample of documents reviewed and activities observed, the MDEP inspection team determined that ENSA is implementing its policies and procedures associated with oversight of contracted activities and internal audit program. No findings of significance were identified.

9. Entrance and Exit Meetings

On October 21, 2019, the MDEP inspection team discussed the scope of the inspection with Mr. David Gomez, QA Manager, and other members of ENSA's management and technical staff. On October 25, 2019, the MDEP inspection team presented the inspection results and observations during an exit meeting with Mr. Rafael Triviño, Senior Director-Manager, and other members of ENSA's management and technical staff. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals whom the MDEP inspection team interviewed.

ATTACHMENT

1. Entrance/Exit Meeting Attendees and Persons Interviewed

Name	Title	Affiliation	Entrance	Exit	Interviewed
Greg Galletti	Inspection Team Leader	NRC	X	X	
Jonathan Ortega	Inspector	NRC	X	X	
John Honcharik	Inspector	NRC	X	X	
Russ Booler	Inspector	ONR	X	X	
John Gillespie	Inspector	ONR	X	X	
Laure Monin	Inspector	ASN	X	X	
Jérémy Hubert	Inspector	ASN	X	X	
Isabel Pedraza	Interpreter	ASN	X	X	
Rafael Triviño	Senior Director-Manager	ENSA		X	
Manuel Sánchez	Vice President Administration and Resources	ENSA		X	
David Gómez	Quality Assurance Manager	ENSA	X	X	X
Angel Muñoz Bustillo	Calibration Lab Manager-Level III	ENSA			X
Arturo Fernandez	Project Manager for the Shearon Harris Project	ENSA	X	X	X
Pierre Foucher	Resident Inspector	Westinghouse France (WEF)	X	X	X
Frédéric Lafosse	Procurement Engineering Leader	WEF	X	X	X
Jorge Elices	Test Technical Manager	ENSA			X
Pablo Mier	Test Technician	ENSA			X
Inmaculada Fernandez	System Evaluation and Control Engineer	ENSA	X	X	X
Pablo Gomez	Supply Control Engineer	ENSA			X
Laura Airas	Logistics Manager	ENSA			X
Miguel DeDios Gonzalez	Warehouse Operative	ENSA			X
Pablo Alvarez	Procurements Department Mgr.	ENSA			X

Name	Title	Affiliation	Entrance	Exit	Interviewed
David Gil	Quality Engineer	ENSA	X	X	X
Susana Santidrian	Quality Engineer	ENSA	X	X	X
Jose Luis Barreda	Welding Department Manager	ENSA			X
Diego Garcia Alonso	QC Level 2	ENSA		X	X
Antonio Gabeza Fernandez	QC Level 3 Specialist	ENSA		X	X
Javier Sanchez Pereda	Quality Control Manager	ENSA		X	X
Victor Gonzalez	Quality Engineer	ENSA	X	X	X
Hector Puebla	QC Inspector	ENSA			X
Francisco Alonso	QC Inspector	ENSA			X
James Haithcox	NDE Inspector	ENSA			X
Rafael Gonzalez Garmendia	0AT7 Project Engineer				X
Ismael Fernández	Methods Manager				X
110338	Welder	ENSA			X
109355	Welder	ENSA			X
114033	Welder	ENSA			X
197665	Welder	ENSA			X

2. INSPECTION PROCEDURES USED

- Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated May 19, 2019
- IP 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017
- IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
99901379/2016-201-01	CLOSED	NON	Criterion III
99901379/2016-201-02	CLOSED	NON	Criterion IX
99901379/2016-201-03	CLOSED	NON	Criterion VII

99901379/2019-201-01	OPENED	NON	Criterion IX
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4. DOCUMENTS REVIEWED

- Equipos Nucleares, S.A., S.M.E. Quality Assurance Manual, Revision 50, dated May 28, 2018
- General Procedure (GP) 02.09, "Training, qualification and certification of personnel," Revision 29
- GP 06.01, "Preparation and Control of Laboratory Procedures" Revision 17, dated 4 November 2013.
- GP 08.03, "Suppliers audits," Revision 21
- GP 08.20, "Commercial Grade Dedication Program," Revision 05
- GP 10.1, "Reception of welding material," Revision 32
- GP 10.08, "Storage, handling and delivery of welding material," Revision 27
- GP 15.01, "Handling of non-conforming conditions," Revision 42
- GP 15.05, "Reporting of Defects and Noncompliances Under 10 CFR 21," Revision 8
- GP.05.17, "Issue of Welding Procedure Qualifications and Welding Procedure Specifications," Revision 19
- GP.06.01, "Preparation and control of laboratory procedures," Revision 17
- GP.12.01, "Training, Qualification and Certification of N.D.E. Personnel," Revision 48
- GP.12.09, "Formation et qualification du personnel"
- GP.14.01, "Periodical Calibration of Measuring and Testing Instruments," Revision 64
- GP 17.01, "Internal audit," Revision 17
- Exhibit 15.04: NDC-2011-01, "Notification of Defects and Non-Compliance Under 10 CFR 21," Revision 1, dated March 23, 2011
- Exhibit 15.05: EVAL-2011-01, "Notification of Defects and Non-Compliance Under 10 CFR 21," Revision 1, dated March 23, 2011
- Exhibit 15.07: "Posting 10CFR21"
- Accreditation certificate, ISO 17025 942/LE1853, dated February 24, 2017
- Accreditation certificate, ISO 17025 22/LC10.014, dated July 28, 2017
- WPP-OTL0845, "Testing and Sampling Plan," Revision 00
- WPQ-19.022.0124.0182, "Weld Procedure Qualification Record" Revision 00
- WPQ-19.022.0124.0124, "Weld Procedure Qualification Record" Revision 00
- WPS 0PR3WT217, "Longitudinal Welds Between Gr. 1.1 and Gr. 1.2 Materials (111 & 121 processes), UK EPR Pressurizer Hinkley C Stainless Steel Cladding on GR 3 SMAW/SAW," Revision 3, dated October 8, 2019
 - PQR-RC056
 - PQR- RC057
 - PQR- RC058
 - PQR- RC059
 - PQR- RC0122
- WPS OND2 WT210, Replacement Steam Generator Model 1300MW GV/ND SMAW/SAW," Revision 1
 - PQR-RC018
 - PQR- RC027PF/PC
- WPS OUS2WT255, "Buttering Inconel by 141 Process Auto GTAW," Revision 1, dated March 7, 2019
 - PQR-RC181
- WPS OSR9WT201, "Longitudinal Welds Between Gr. 1.1 and Gr. 1.2 Materials (111

&121 processes),” Revision 0, dated June 6, 2018

- PQR-032
- PQR-029
- OPR3FS501, “In-Process Cleaning Requirements,” Revision 1, dated April 5, 2019
- OPR3U010, “Backing Plate CMTR,” dated August 8, 2019
- OPR3CS401, “Liquid Penetrant Procedure,” Revision 2, dated February 4 2019
- IPP 1PR3/10A02, “Lower Head Cladding,”
- IPP 2PR3/10A01, Temporary Attachment Backing plate
- Welding Report WR-FUS2/005, “Buttering Cladding”
- Welding Report 1SR9/009 “AREVA Reactor Pressure Vessel Support Ring”
- Welding Report WR-1SR9/004, “AREVA Reactor Pressure Vessel Support Ring”
- Welding Report 6ND2/118, “Steam Generator to Channel Head”
- Inspection Report OPR3/017 for backing plate

Welder Qualifications

- 109595 – RCC-M Code
- 110338 – RCC-M Code
- 109595 – RCC-M Code
- 110338 – RCC-M Code
- 106674 – RCC-M Code
- 106674 – RCC-M Code
- 110338 – RCC-M Code
- 197665 – RCC-M Code
- 109355 – RCC-M Code
- 114033 – RCC-M Code
- 108688 – ASME Code
- 110890 – ASME Code
- 111112 – ASME Code
- 113787 – ASME Code
- 120209 – ASME Code
- 111039 – ASME Code

Design Documents

- Drawing OPR3-19862, Revision 00, “Backing Nozzle Cover Surge Nozzle for Interior Bottom Cladding,” Revision 1, Dated August 8, 2019
- Drawing OSR93000, Revision 1, “Reactor Pressure Vessel Support Ring Lower Part Assembly,” dated June 29, 2018
- Drawing OND2.3300, “Steam Generator to Channel Head,” Revision 6, dated October 8, 2019

Calibration Records:

- Certificate 36748 Welding Machine
- Certificate 39155 Welding Machine
- Certificate 1100-609-6230 Voltimeter
- Certificate Instrument 0400-019-60610 Drop Weight
- Certificate Instrument 1100-6709-6230 Welding Machine
- Certificate Instrument 740-5195 Welding Machine Master Tig
- Certificate Instrument 0740-5126-6167 Weld Metal Canister

Review of CARs:

- CAR 0085-16
- CAR 0086-16
- CAR 0088-16
- CAR 0087-17
- CAR 0056/18
- CAR 0079/19
- CAR 0105/19
- CAR 0068/19
- CAR 0064/19
- CAR 0102/19
- CAR 0018/19

Audit Reports

- Internal Audit Report (IAR) 04-19
- IAR 12-18, "Calibration audit,"
- Supplier Audit (AR), AR-01-09 to Le CREUSOT
- Source Inspection, IO-OAT7-006-01, "Source Inspection Report of Le Creusot"
- AR 01-19 "INDUSTREEL FRANCE LE CREUSOT"
- Database of ENSA's approved suppliers
- ENSA Management Report, "Sistema de Gestión de la Calidad Revisión por la Dirección 2018," Revision 1, Dated May 2, 2018

Purchase Orders

- Purchase order (PO) B006, "LE CREUSOT Contract OAT7 (Hinkley Point C)"
- PO 0CB8/093 – Contract MR B18149
- PO 1CZZ8/010 – Contract MR B14901
- PO OAT7/028 – Contract MR OAT7/049

Non-Conformance Reports

- Non-Conformance Report (NCR) 1JT1/015, "RRVH Hole for Vent Pipe with Diameter Out of Tolerance," Revision 0,
- NCR 1JT1/018, "J-Groove Buttering with PT Indications," Revision 1
- NCR 1JT1/019, "Thermal Sleeves Tubes Heat Treatment Temperature Deviation (Ir-1jt1/025)," Revision 1
- NCR 1JT1/027, "Cancelled NCR - Placeholder for Potential Repairs In J-Groove Welds," Revision 1
- NCR 1JT1/032, "CETNA 'Go Gage' Control Not Satisfactory," Revision 0
- NDC-2011-01, "Notification of defects and noncompliance under 10 CFR 21," Revision 1
- EVAL-2011-01, "Evaluation of defects and noncompliance under 10 CFR 21," Revision 1
- DGR- NRC- 2019-01, "Response to NCR Observation during Liquid Penetrant (PT) inspection in ENSA workshop," dated October 25, 2019