



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION II
245 PEACHTREE CENTER AVENUE N.E., SUITE 1200
ATLANTA, GEORGIA 30303-1200

January 30, 2020

Gregory Piefer, Ph.D.
Chief Executive Officer
SHINE Medical Technologies, LLC
101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – NRC INSPECTION REPORT
50-608/2019001

Dear Dr. Piefer:

On December 19, 2019, the U.S. Nuclear Regulatory Commission (NRC) completed an inspection at SHINE Medical Technologies, LLC (SHINE) and discussed the results of this inspection with you and other members of your staff. The results of this inspection are documented in the enclosed report.

The inspections examined a sample of construction activities conducted under your construction permit and operating license application as they relate to safety and compliance with the NRC's rules and regulations and with the conditions of these documents. The inspectors reviewed selected procedures and records, observed activities, and interviewed personnel.

The NRC inspectors did not identify any finding or violation of more than minor significance.

This letter, its enclosure, and your response (if any) will be made available for public inspection and copying at <http://www.nrc.gov/reading-rm/adams.html> and at the NRC Public Document Room in accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding."

Sincerely,

/RA/

Bradley J. Davis, Chief
Construction Inspection Branch 2
Division of Construction Oversight

Docket No. 50-608
Construction Permit No. CPMIF-001

Enclosure: NRC Inspection Report (IR) 50-608/2019001
w/attachment: Supplementary Information

cc w/ encl: (See next page)

Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, LLC
101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

Nathan Schleifer
General Counsel
SHINE Medical Technologies, LLC
101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

Christopher Landers
Director, Office of Conversion
National Nuclear Security Administration, NA 23
U.S. Department of Energy
1000 Independence Ave SW
Washington, DC 20585

Mark Paulson
Supervisor
Radiation Protection Section
Wisconsin Department of Health Services
P.O. Box 2659
Madison, WI 53701-2659

Test, Research and Training Reactor Newsletter
Attention: Amber Johnson
Dept of Materials Science and Engineering
University of Maryland
4418 Stadium Drive
College Park, MD 20742-2115

Mark Freitag
City Manager
P.O. Box 5005
Janesville, WI 53547-5005

Bill McCoy
1326 Putnam Avenue
Janesville, WI 53546

Alfred Lembrich
541 Miller Avenue
Janesville, WI 53548

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – NRC INSPECTION REPORT
 50-608/2019001 DATED: January 30, 2020

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**U.S. NUCLEAR REGULATORY COMMISSION
Inspection Report**

Docket Number: 50-608

Construction
Permit Number. CPMIF-001

Report Numbers: 50-608/2019001

Applicant: SHINE Medical Technologies, LLC

Location: Janesville, WI

Inspection Dates: December 9, 2019 to December 19, 2019

Inspectors: P. Carman, Senior Reactor Inspector
A. Lerch, Construction Inspector
A. Ponko, Senior Construction Inspector

Approved By: Bradley J. Davis, Chief
Construction Inspection Branch 2
Division of Construction Oversight

EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC) monitored the applicant's performance by conducting an inspection at SHINE Medical Technologies, LLC (SHINE). The NRC program for overseeing the construction of non-power utilization facilities is described in Inspection Manual Chapter (IMC) 2550, Non-Power Production and Utilization Facilities (NPUFs) Licensed Under 10 CFR Part 50: Construction Inspection Program (CIP).

List of Findings and Violations

None

Additional Tracking Items

None

REPORT DETAILS

Inspections were conducted using the appropriate portions of the inspection procedures (IPs) in effect at the beginning of the inspection unless otherwise noted. Currently approved IPs with their attached revision histories are located on the public website at <http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html>. The inspectors reviewed selected procedures and records, observed activities, and interviewed personnel to assess applicant performance and compliance with Commission rules and regulations, construction permit conditions, operating license application conditions, site procedures, and standards.

SAFETY-RELATED ITEMS AND SERVICES DURING CONSTRUCTION

Foundations and Buildings (IP 69020, Appendix A)

a. Inspection Scope

The inspectors observed in-progress construction activities and reviewed documents associated with foundation work to verify if:

- foundation work and related quality assurance (QA) activities for Seismic Category I structures was performed in accordance with the Final Safety Analysis Report (FSAR), construction specifications, drawings, and work procedures
- the applicant's system for preparing, reviewing, and maintaining records relative to foundation and building activities was functioning properly
- records reflected work accomplishment consistent with specifications and procedures
- the as-built condition of Seismic Category I buildings met the specified design requirements, specifications, and drawings
- the implementation of the quality assurance program relative to work activities associated with buildings was effective
- deviations from requirements were appropriately resolved

b. Observations and Findings

The inspectors reviewed the preliminary engineering geotechnical report prepared by Golder Associates Inc., and structural calculations, drawings, and specifications prepared by Sargent & Lundy addressing foundation work to verify if the documents conformed to the FSAR and were prepared, reviewed, and approved in accordance with the applicable design control procedures.

The inspectors reviewed the construction specifications governing foundation work to verify if the requirements specified within were consistent with the commitments in the FSAR and the recommendations in the preliminary geotechnical engineering report.

The inspectors reviewed reports to verify if the site-specific soil properties used for the design of below grade walls were bounded by the recommendations in the preliminary geotechnical engineering report. The inspectors also reviewed reports to verify if the net allowable static bearing pressure and minimum average shear wave velocity used in the structural calculations were consistent with Section 3.4.2.6.3.1 of the FSAR and bounded by the recommendations in the preliminary geotechnical report.

The inspectors reviewed a proof-rolling observation report and field density test report for the subgrade supporting the mat slab at -23'-0" to verify if these activities were conducted in accordance with the construction specifications, met the acceptance criteria, and were bounded by the recommendations in the preliminary geotechnical engineering report.

The inspectors reviewed nonconformance report (NCR) 19-004 associated with field density testing to verify if deviations from requirements dispositioned "use-as-is" were properly documented, evaluated, and approved accordance with applicable quality assurance requirements.

No findings of significance were identified.

c. Conclusions

The inspectors observed construction activities and reviewed documents related to foundation work to determine if construction was accomplished in accordance with the construction permit; operating license application conditions; site procedures; and other applicable quality, technical, and regulatory requirements. Specific documents reviewed, and areas inspected included: the geotechnical report; structural calculations, drawings, and specifications for foundation work; soil properties; allowable static bearing pressure; minimum average shear wave velocity; the proof-rolling observation report; and the field density test report. No findings of significance were identified.

Structural Concrete (IP 69020, Appendix B)

a. Inspection Scope

The inspectors observed in-progress construction activities and reviewed documents associated with structural concrete work to verify if:

- structural concrete work and related quality assurance activities for Seismic Category I structures was performed in accordance with the FSAR, construction specifications, drawings, and work procedures
- the applicant system for preparing, reviewing, and maintaining records relative to structural concrete activities was functioning properly
- records reflected work accomplishment consistent with specifications and procedures
- the as-built condition of reinforced concrete structures met the specified design requirements, specifications, and drawings
- the implementation of the quality assurance program relative to work activities associated with structural concrete was effective; and deviations from requirements were appropriately resolved

b. Observations and Findings

The inspectors reviewed the structural calculations, drawings, and specifications prepared by Sargent & Lundy addressing the analysis, design, and construction of reinforced concrete components of the Seismic Category I structures to verify if the documents conformed to the FSAR and were prepared, reviewed, and approved in accordance with the applicable design control procedures.

The inspectors reviewed the construction specifications governing structural concrete work to verify if the requirements specified within were consistent with the commitments in the FSAR and adequately addressed the following areas:

- qualification of materials (cement, water, aggregate, and admixtures)
- concrete mix design
- qualification of concrete batch plant
- preplacement activities (concrete forms, rebar and splices, embedded items, cleanliness, and inspection)
- in-process testing of plastic concrete (slump, entrained air, temperature, unit weight, and cast cylinders)
- concrete placement activities and inspection of concrete placement activities
- post-placement activities (adequate curing and identification and repair of defects)
- evaluation and review of concrete test results
- engineering direction
- qualification of quality control (QC) personnel

The inspectors reviewed the concrete mix designs, commercial grade dedication plan, records associated with qualification testing of the materials selected for use in the concrete, and final concrete acceptance test records to verify if the concrete mixes and constituent materials met the requirements of the FSAR, American Concrete Institute (ACI) 349-13, "Code Requirements for Nuclear Safety Related Concrete Structures," and the quality assurance program description (QAPD). Additionally, the inspectors verified if the concrete batch plant was certified by the National Ready Mixed Concrete Association (NRMCA).

The inspectors observed installed bottom reinforcing bars in the -16'-6" slab west of column line G between column lines 1 and 2 to verify if the bar sizes, grade, material, orientation, spacing, and development lengths conformed to the design drawings, construction specifications, and ACI 349-13. The inspectors also observed exterior wall bars in the 3'-0" thick reinforced concrete wall defining the western edge of the carbon delay beds at elevation -23'-0" to verify if the bar sizes, orientation, spacing conformed to the designed drawings and ACI 349-13. Additionally, the inspectors verified if the lap splice length of the exterior vertical bars in this wall met the minimum lengths specified in the concrete general notes on drawing DWG-FSTR-1500 and whether these lengths were calculated in accordance with ACI 349-13.

The inspectors reviewed a certified material test report (CMTR) for reinforcing bars installed in Seismic Category I concrete components to verify if the installed material conformed to American Society for Testing and Materials (ASTM) A706 as required by the construction specification.

The inspectors observed concrete placement activities associated with construction of a portion of the 3'-0" reinforced concrete wall defining the northern edge of the carbon delay beds at elevation -23'-0" to verify if work activities were completed in accordance with the construction specifications, ACI 349-13, and quality assurance requirements. Specifically, the inspectors reviewed the work package and pre-placement inspection checklist to verify if any required inspections had been performed and documented in accordance with applicable procedures and specifications prior to placing concrete. The inspectors also observed in-process material sampling and testing to verify if specified

samples were obtained and tested in accordance with the construction specifications and ACI 349-01. The inspectors reviewed a sample of concrete batch tickets to determine if the concrete mix material type, quantity, and tolerances were in accordance with an approved mix design, the commercial grade dedication plan, and ACI 117-06, "Specifications for Tolerances for Concrete Construction and Materials." The inspectors reviewed the qualification records of the individual taking the samples and performing the testing to verify if he was qualified to do so. Additionally, the inspectors observed the mechanical vibration of plastic concrete to verify if activities associated with the consolidation of concrete were conducted in accordance with the construction specifications and ACI 349-13.

The inspectors reviewed the work packages associated with construction of the foundations and below grade walls to verify if the inspection hold points had been established; the work was appropriately planned, controlled, and sequenced; and records were maintained to reflect the result of inspections and the current state of construction in accordance with QA implementing procedures.

No findings of significance were identified.

c. Conclusions

The inspectors observed construction activities and reviewed documents related to structural concrete to determine if construction was accomplished in accordance with the construction permit; operating license application conditions; site procedures; and other applicable quality, technical, and regulatory requirements. Specific documents reviewed, and areas inspected included: analysis, design, and construction of reinforced concrete components; construction specifications for structural concrete; concrete mix designs; commercial grade dedication plan; qualification testing of the materials; final concrete acceptance test records; reinforcing bars in the -16'-6" slab exterior wall of the carbon delay beds at elevation -23'-0"; CMTRs for reinforcing bars; concrete placement activities associated with the northern edge of the carbon delay beds at elevation -23'-0"; and work packages associated with construction of the foundations. No findings of significance were identified.

QUALITY ASSURANCE PROGRAM

Quality Assurance Program Documents (IP 69021, Appendices A through R)

a. Inspection Scope

The inspectors reviewed QA implementing documents to determine if they demonstrated compliance with the applicant's QAPD requirements and FSAR commitments. Where the applicant has delegated portions of the QA program implementation to other organizations working on behalf of the applicant, the inspectors reviewed applicable documents for those organizations. The inspectors reviewed SHINE and Baker Concrete Construction (Baker) QA implementing documents to determine if they had been developed in accordance with applicable sections of the SHINE QAPD; the Baker QAPD; American National Standards Institute (ANSI)/American Nuclear Society (ANS) 15.8-1995, "Quality Assurance Program Requirements for Research Reactors;" and Chapter 12, "Conduct of Operations," of the FSAR.

b. Observations and Findings

Organization (Appendix A)

The inspectors reviewed QA implementing documents related to organization to determine if they had been developed in accordance with Section 2.1 of the SHINE QAPD, Section 5.1 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to determine if the organizational structure and assignments of responsibilities was defined and documented such that:

- quality is achieved and maintained by those who have been assigned responsibility for performing work
- quality achievement is verified by persons not directly performing the work.

The inspectors reviewed implementing procedure to determine if they contained documentation that persons responsible for ensuring that appropriate controls have been established, and for verifying that activities have been correctly performed, need sufficient authority, access to work areas, and freedom to:

- identify problems
- initiate, recommend, or provide corrective action
- ensure corrective action implementation

No findings of significance were identified.

Quality Assurance Program (Appendix B)

The inspectors reviewed QA implementing documents related to the QA program to determine if they had been developed in accordance with Section 2.2 of the SHINE QAPD, Section 5.2 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to determine if they prescribed that the QA program:

- identify the items and activities to which it applies and the extent of program application for each item and activity
- provide for the appropriate and necessary indoctrination and training of personnel who perform activities that affect quality, to ensure that suitable proficiency is achieved and maintained

No findings of significance were identified.

Design Control (Appendix C)

The inspectors reviewed QA implementing documents for design control to verify if they were consistent with Section 2.3 of the SHINE QAPD, Section 5.3 of the Baker QAPD, ANSI/ANS-15.8 and the commitments in the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify if the design control measures established assured that:

- a sufficient level of detail is provided to allow the design authority to perform design/engineering work and maintain control of the facility design in accordance with the requirements as specified in the FSAR

- the process for the review and approval of design calculations and analyses is adequately described
- applicable design inputs are identified and documented
- design interfaces are identified and controlled
- the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, are verified for each application
- deviations from the established and documented design inputs, including the reasons for the changes, are documented and controlled
- the final design is relatable to design input by documentation in sufficient detail to permit traceability and verification
- design documents identify assemblies and/or components that are part of the item being designed
- independent reviews are used to verify the adequacy of the design
- design verification is completed prior to reliance upon the component, system, structure, or computer program to perform its function in operations;
- the most current design documents are implemented during construction
- modifications to safety-related structures, systems, or components, or computer codes are based on a defined “as-exists” design
- changes to verified designs are documented, justified, and subject to design control measures commensurate with those applied to the original design

No findings of significance were identified.

Procurement Document Control (Appendix D)

The inspectors reviewed QA implementing documents for procurement document control to verify if they were consistent with Section 2.4 of the SHINE QAPD, Section 5.4 of the Baker QAPD, ANSI/ANS-15.8 and the commitments in the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify if the measures established:

- contained sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the purchaser
- identified the documentation required to be submitted for information, review, or approval by the purchaser
- provided for access to the supplier’s facilities and records for inspection or audit by the purchaser, the designated representative, or other parties authorized by the purchaser
- included purchaser’s requirements for reporting and approving disposition of supplier nonconformances associated with the items or services being procured
- prohibited the supply of substandard or counterfeit parts and materials for safety-related items

No findings of significance were identified.

Procedures, Instructions, and Drawings (Appendix E)

The inspectors reviewed QA implementing documents related to the development of procedures, instructions, and drawings to verify if they had been developed in accordance with Section 2.5 of the SHINE QAPD, Section 5.5 of the Baker QAPD,

ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify if they required procedures to contain:

- performance expectations for actions detailed in the procedures
- qualitative or quantitative acceptance criteria for activities affecting quality
- proper sequence of activities
- instructions that made them available to the proper work organization

No findings of significance were identified.

Document Control (Appendix F)

The inspectors reviewed QA implementing documents for document control to verify if they were consistent with Section 2.6 of the SHINE QAPD, Section 5.6 of the Baker QAPD, ANSI/ANS-15.8 and the commitments in the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify if the document control system was documented and provided for:

- identification of documents to be controlled and their specified distribution
- identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents
- review of documents for adequacy, completeness, and correctness prior to approval and issuance

No findings of significance were identified.

Control of Purchased Items and Services (Appendix G)

The inspectors reviewed QA implementing documents for the control of purchased items and services to verify if they were consistent with Section 2.7 of the SHINE QAPD, Section 5.7 of the Baker QAPD, ANSI/ANS-15.8 and the commitments in the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify if they provided controls to assure that items or services meet the procurement requirements, are accepted prior to use, and ensure:

- appropriate procurement planning
- source evaluation and selection
- evaluation of objective evidence of quality furnished by the supplier
- source inspection
- audit
- assessment and examination of items or services for acceptance upon delivery or completion

No findings of significance were identified.

Identification and Control of Items (Appendix H)

The inspectors reviewed QA implementing documents related to identification and control of items to verify if they had been developed in accordance with Section 2.8 of the SHINE QAPD, Section 5.8 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify if they prescribed that item identification and control processes are capable of:

- identifying items
- legibly marking items upon receipt or fabrication
- providing traceability control
- identifying nonconforming or rejectable material to prevent inadvertent use

No findings of significance were identified.

Control of Special Processes (Appendix I)

The inspectors reviewed QA implementing documents related to the control of special processes to determine if they had been developed in accordance with Section 2.9 of the SHINE QAPD, Section 5.9 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to determine if they required that:

- special processes be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means
- the requirements of applicable codes and standards, including acceptance criteria for the process, be specified or referenced in the procedures or instructions that control the process
- records be maintained as appropriate for the currently qualified personnel, processes, and equipment associated with special processes

No findings of significance were identified.

Inspections (Appendix J)

The inspectors reviewed QA implementing documents related to inspections to determine if they had been developed in accordance with Section 2.10 of the SHINE QAPD, Section 5.10 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to determine if they required that:

- inspections to verify conformance of an item or activity to requirements be planned, documented, and performed
- the inspection program be applied to procurement, construction, modification, and maintenance
- associated quality records be examined for adequacy and completeness
- inspection results be documented
- inspection be performed by persons other than those who performed the work being inspected
- persons be qualified to perform the assigned inspection task

No findings of significance were identified.

Test Control (Appendix K)

The inspectors reviewed QA implementing documents related to test control to determine if they had been developed in accordance with Section 2.11 of the SHINE QAPD, Section 5.11 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to determine if they contained

provisions that formal testing be required to verify conformance of designated structures, systems, and components (SSCs) to specified requirements and demonstrate satisfactory performance, and that test results be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied.

No findings of significance were identified.

Control of Measuring and Test Equipment (Appendix L)

The inspectors reviewed QA implementing documents related to measuring and test equipment (M&TE) to verify if they had been developed in accordance with Section 2.12 of the SHINE QAPD, Section 5.12 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify they contained provisions that M&TE used for activities affecting quality is:

- controlled
- calibrated or adjusted at specified periods
- tagged or segregated when out of calibration
- evaluated for previous performance when found out of calibration

In addition, the inspectors reviewed implementing procedures to verify if they required that calibration records and data produced by M&TE be maintained and be traceable to that piece of M&TE.

No findings of significance were identified.

Handling, Storage, and Shipping (Appendix M)

The inspectors reviewed QA implementing documents for the handling, storage, and shipping of items to verify if they were consistent with Section 2.13 of the SHINE QAPD, Section 5.13 of the Baker QAPD, ANSI/ANS-15.8 and the commitments in the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify if the handling, storage, and shipping of items is performed in accordance with the work or inspection instructions, drawings, specifications, shipping instructions, or other pertinent documents or procedures for conducting the activity, and

- items are shipped, handled, and stored in accordance with item manufacturer's instructions or alternatively as designated in documented procedures
- preventative maintenance requirements established by the item manufacturer are planned and implemented
- system cleaning requirements established in the specifications and/or implementing procedures are planned and implemented.

No findings of significance were identified.

Inspection, Test, and Operating Status (Appendix N)

The inspectors reviewed QA implementing documents related to inspection, test, and operating status of SSCs to verify if they had been developed in accordance with Section 2.14 of the SHINE QAPD, Section 5.14 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to

verify if they required the status of items be identified and documentation be traceable to the item.

No findings of significance were identified.

Control of Nonconforming Items and Services (Appendix O)

The inspectors reviewed QA implementing documents for the control of nonconforming items and services to verify if they were consistent with Section 2.15 of the SHINE QAPD, Section 5.15 of the Baker QAPD, ANSI/ANS-15.8 and the commitments in the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify if they required that:

- items that do not conform to requirements are controlled to prevent inadvertent installation or use
- controls on nonconforming items provide for identification, documentation, evaluation, segregation from like conforming items when practical, and disposition of nonconforming items
- nonconforming conditions are evaluated as required by 10 CFR Part 21
- nonconforming characteristics are reviewed, and recommended dispositions of nonconforming items proposed and approved, in accordance with documented procedures
- the disposition of nonconforming items is identified and documented
- technical justification for the acceptability of nonconforming items dispositioned “repair” or “use-as-is” is documented
- nonconformance to design requirements of items dispositioned “use-as-is” or “repair” is subject to design control measures commensurate with those applied to the original design
- as-built records are required to reflect any accepted deviations
- repaired or reworked items are reexamined in accordance with applicable procedures and with the original acceptance criteria, unless the nonconforming item disposition has established alternate acceptance criteria

No findings of significance were identified.

Corrective Actions (Appendix P)

The inspectors reviewed QA implementing documents related to corrective actions to verify if they had been developed in accordance with Section 2.16 of the SHINE QAPD, Section 5.16 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify if they contained provisions to:

- promptly identify conditions adverse to quality (CAQs)
- correct CAQs to be in accordance with design requirements
- evaluate CAQs for 10 CFR Part 21 reporting
- investigate and preclude recurrence of significant conditions adverse to quality (SCAQs)

No findings of significance were identified.

Quality Records (Appendix Q)

The inspectors reviewed QA implementing documents related to quality records to verify if they had been developed in accordance with Section 2.17 of the SHINE QAPD, Section 5.17 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to verify if provisions existed to ensure:

- a record system is defined, implemented, and enforced
- records include inspection and test results, results of quality assurance reviews, quality assurance procedures, and engineering reviews and analyses in support of designs or changes and modifications
- records will be maintained for the life of the plant
- records will be stored in a location or locations that prevent damage from moisture, temperature, and pestilence
- records with special processing (such as radiographs) are stored with additional protections
- records are retrievable

No findings of significance were identified.

Assessments (Appendix R)

The inspectors reviewed QA implementing documents related to assessments to determine if they had been developed in accordance with Section 2.18 of the SHINE QAPD, Section 5.18 of the Baker QAPD, ANSI/ANS-15.8, and the FSAR. Specifically, the inspectors reviewed these implementing procedures to determine if they required that:

- periodic assessments of quality-affecting activities are conducted during design, construction, modification, and operations
- assessments are performed in accordance with written procedures or checklists
- assessment results are documented and reviewed by management personnel who have responsibility for the area assessed
- conditions requiring prompt corrective action be reported immediately to the appropriate management

No findings of significance were identified.

c. Conclusions

The inspectors reviewed QA implementing documents to determine if they demonstrated compliance with the SHINE QAPD, the Baker QAPD, ANSI/ANS-15.8, and the FSAR. The inspectors reviewed documents associated with the following QA requirements as described in the SHINE QAPD and ANSI/ANS-15.8: organization; quality assurance program; design control; procurement document control; procedures, instructions, and drawings; document control; control of purchase items and services; identification and control of items; control of special processes; inspections; test control; control of measuring and test equipment; handling, storage, and shipping; inspection, test, and

operating status, control of nonconforming items and services; corrective actions; quality records; and assessments. No findings of significance were identified.

Quality Assurance Program Implementation (IP 69021, Appendices A, B, C, G, and M)

a. Inspection Scope

The inspectors observed construction activities, conducted interviews, and reviewed QA documents to determine if the applicant has effectively implemented its QA program during construction activities. Where the applicant has delegated portions of the QA program implementation to other organizations working on behalf of the applicant, the inspectors observed activities, conducted interviews, and reviewed applicable documents for those organizations. The inspectors observed activities and reviewed documents to determine if they had been implemented in accordance with applicable sections of the SHINE QAPD; the Baker QAPD; implementing procedures, ANSI/ANS-15.8-1995; and Chapter 12, "Conduct of Operations," of the FSAR.

b. Observations and Findings

Organization (Appendix A)

The inspectors interviewed a sample of personnel that perform QA oversight functions to determine if they had an adequate understanding of the QA program in accordance with Section 2.1 of the SHINE QAPD, Section 5.1 of the Baker QAPD, and applicable QA implementing procedures. Specifically, the inspectors interviewed the SHINE QA Manager, the Baker Director of QA, the SHINE Director of Engineering Construction, the SHINE Structural Engineering Manager, and one Baker QC inspector to determine if personnel involved in quality oversight were independent from the organizations performing the work or service. The inspectors conducted interviews to determine if personnel involved in quality oversight had the freedom to identify quality problems; to initiate, recommend, or provide solutions; and verify implementation of solutions.

The inspectors interviewed a sample of personnel that perform activities in support of quality objectives to determine if they had an adequate understanding of the QA program in accordance with Section 2.1 of the SHINE QAPD, Section 5.1 of the Baker QAPD, and applicable QA implementing procedures. Specifically, the inspectors interviewed a SHINE field engineer and a Terracon technician to determine if they understood their roles and responsibilities and were knowledgeable of the SHINE QA program and the activities they were responsible for. The inspectors conducted interviews to determine if personnel were aware of the levels of management to which they would elevate awareness of a quality issue; and determine if they felt they had freedom to: identify problems; initiate, recommend, or provide corrective action; and ensure corrective action implementation.

The inspectors interviewed personnel and reviewed the SHINE and Baker approved supplier lists to determine if delegation of authority was documented in accordance with SHINE QA procedure 2000-01-11, "Supplier Qualification," Revision 3, and Baker QA procedure NQAP SHINE-7.01, "Controlling Purchases of Items and Services," Revision 2.

No findings of significance were identified.

Quality Assurance Program (Appendix B)

The inspectors selected a sample of training records to determine if personnel performing quality-affecting activities were qualified for the appropriate activities and received required indoctrination and training. The inspectors reviewed training records for one SHINE field engineer, two Baker QC inspectors, one Baker QA/QC manager, and one Terracon technician to determine if training was completed in accordance with SHINE QA procedure 0500-04-01, "Employee Onboarding," Revision 0, and Baker QA procedures NQAP SHINE-2.01, "General Co-Worker Indoctrination and Training," Revision 0, and NQAP SHINE-2.02, "Co-Worker Qualification and Certification," Revision 0.

No findings of significance were identified.

Design Control (Appendix C)

The inspectors reviewed records associated with the owner's acceptance review of technical documents produced by others and the resolution of any comments generated during those reviews to verify if the requirements of SHINE QA Procedure 1200-01-03, "Owner's Acceptance Review," Revision 3, were adequately implemented. Specifically, the inspectors reviewed forms and comments associated with the acceptance of the preliminary geotechnical engineering report prepared by Golder Associates Inc., structural calculations and specifications prepared by Sargent & Lundy, and reinforcing bar shop drawings prepared by CMC Rebar. The inspectors reviewed these records to verify if the design control measures for the acceptance of technical documents prepared by others were adequately implemented and the results documented.

No findings of significance were identified.

Control of Purchased Items and Services (Appendix G)

The inspectors reviewed records associated with the audit, assessment, and qualification of suppliers to verify if the requirements SHINE QA Procedure 2000-01-11, "Supplier Qualification," Revision 3, were adequately implemented. Specifically, the inspectors reviewed records associated with the evaluation of Golder Associates Inc. and Sargent & Lundy. The inspectors reviewed two surveillance records and the supplier assessment report of Golder Associates Inc. The inspectors also reviewed Nuclear Procurement Issues Corporation (NUPIC) audit records and the supplier evaluation form for Sargent & Lundy. The inspectors reviewed these records to verify if the measures established for the control of purchased items and services were adequately implemented and the results documented.

No findings of significance were identified.

Handling, Storage, and Shipping (Appendix M)

The inspectors reviewed the storage conditions of a sample of safety related reinforcing bars to determine if they were marked to ensure traceability to the CMTR and reinforcing bars were not stored directly on the ground in accordance with specification SPEC-FSTR-1001, "Nuclear Safety Related Rebar," Revision 2, and Baker QA procedure

NQAP SHINE-13.01, "Handling, Storage, Cleaning, Packaging, and Shipping of Items,"
Revision 0.

No findings of significance were identified.

c. Conclusions

The inspectors observed construction activities, conducted interviews, and reviewed QA documents to determine if the applicant has effectively implemented its QA program during construction activities. The inspectors conducted these activities for portions of QA implementation associated with the following QA requirements as described in the SHINE QAPD and ANSI/ANS-15.8: organization; quality assurance program; design control; control of purchase items and services; and handling, storage, and shipping. No findings of significance were identified.

EXIT MEETING SUMMARY

On December 19, 2019, the inspectors presented the inspection results to Dr. Gregory Piefer and other members of the applicant staff. The inspectors verified no proprietary information was retained or documented in this report.

SUPPLEMENTARY INFORMATION

KEY POINTS OF CONTACT

J. Arellano, Baker, Project QA/QC Manager
J. Bartelme, SHINE, Director of Licensing
K. Bennett, SHINE, Construction Quality
S. Boggan, SHINE, Structural Field Engineer
J. Costedio, SHINE, VP of Regulatory Affairs & Quality
A. Cowne, SHINE, Director of Engineering Construction
A. Donahue, SHINE, Structural Engineering Manager
J. Fluellen, SHINE, Document Control/Records Management Supervisor
T. Frazee, SHINE, QA Manager-Manufacturing
A. Gonnering, SHINE, Director-Engineering Support
J. Hausfeld, Baker, Corporate Director of Quality Assurance
T. Huerter, SHINE, Nuclear Quality Manager
M. Jorn, Baker, Project Executive
A. McClelland, SHINE, Construction Manager
G. Miller, Baker, Construction Manager
S. Miltenberger, SHINE, Chief Operating Officer
M. Ostrander, Terracon, Technician II
G. Piefer, SHINE, Chief Executive Officer
J. Pierce, SHINE, Field Engineering Manager
T. Radel, SHINE, Director of Process Engineering
J. Riste, SHINE, Senior Licensing Engineer
T. Sobotka, SHINE, Procurement Manager
W. Warren, Baker, Regional QA Director

LIST OF DOCUMENTS REVIEWED

IP 69020

Certified Material Test Reports

ASTM A706 #10 Reinforcing Bar Heat No. 7005134
58191092.0024C, Particle Size Distribution Report, 11/22/2019
58191092.0025A, Aggregate Sample Pick-Up Report, 11/22/2019
58191092.0026, Concrete Compressive Strength Test Report, 12/4/2019

Commercial Grade Dedication Documents

CGDP-SHINE-001 CGD Plan, Commercial Grade Dedication Plan of Ready-Mix Concrete
CGDP SHINE-001, Revision 2
CGDVP-SHINE-001, Commercial Grade Dedication Verification Plan for Ready-Mix Concrete
CGDVP SHINE-001, Revision 3
FRM-1600-01-02-01, Commercial Grade Dedication Request and Technical Evaluation, Ready
Mix Concrete, CGD ID: CGD-2019-0001, 10/21/2019

Corrective Action Documents Resulting from Inspection

IMR 2019000373, QA Procedures Inspection - Ensure 2100-04-01 Includes Acceptance Criteria
as Appropriate, dated 12/10/19
IMR 2019000379, Owner's Acceptance Review of Preliminary Geotechnical Engineering Report
Missing Procedurally Required Signature, dated 12/12/2019

IMR 2019000380, Vendor Calculation Status not Marked as Approved, dated 12/12/2019
IMR 2019000403, CALC-2017-1000 Rev 1 Contains Preliminary Information, dated 12/17/2019
IMR 2019000406, TOAR Checklist for CALC-2017-1000 Incorrectly Filled Out for Questions
Related to Assumptions, Preliminary Information, and Unverified Assumptions, dated
12/17/2019
IMR 2019000409, SHINE OAR Process Improvement, dated 12/18/2019
IMR 2019000411, Note in DWG-FSTR-1501 does not conform to ACI 349 / ACI 318, dated
12/18/2019
IMR 2019000414, CI-SHINE 6.01-2 Controlling of Non-Public SHINE Technology, dated
12/19/2019
IMR 2019000415, Baker IP-SPEC-FSTR-1007 improvements, dated 12/19/2019
IMR 2019000417, Lycon Mix Design Submittal - ASTM C33, dated 12/19/2019

Design Drawings (Sargent & Lundy)

DWG-FSTR-1500, "CONCRETE GENERAL NOTES SHEET 1, REVISION 2
DWG-FSTR-1501, "CONCRETE GENERAL NOTES SHEET 2," REVISION 3
DWG-FSTR-1502, "NORTH AND SOUTH REINFORCEMENT PLAN AT ELEVATION 0'-0","
REVISION 2
DWG-FSTR-1503, "EAST AND WEST REINFORCEMENT PLAN AT ELEVATION 0'-0","
REVISION 2
DWG-FSTR-1504, "REINFORCEMENT PLAN EL -12'-0", -16'-0" AND -23'-0"," REVISION 1
DWG-FSTR-1505, "DRAWING KEY PLAN," REVISION 3
DWG-FSTR-1506, "I.U. CELL AREA NORTH PLAN ELEVATION 0'-0"," REVISION 2
DWG-FSTR-1507, "I.U. CELL AREA SOUTH PLAN ELEVATION 0'-0"," REVISION 2
DWG-FSTR-1508, "PRODUCTION AREA NORTH PLAN ELEVATION 0'-0"," REVISION 3
DWG-FSTR-1509, "PRODUCTION AREA SOUTH PLAN ELEVATION 0'-0"," REVISION 5
DWG-FSTR-1510, "CONTROL ROOM NORTH PLAN ELEVATION 0'-0"," REVISION 1
DWG-FSTR-1511, "CONTROL ROOM SOUTH PLAN ELEVATION 0'-0"," REVISION 1
DWG-FSTR-1512, "ADMIN & SERVICE AREA – EAST FOUNDATION PLAN ELEVATION 0'-0","
REVISION 1
DWG-FSTR-1513, "ADMIN & SERVICE AREA – WEST FOUNDATION PLAN ELEVATION 0'-0","
REVISION 1
DWG-FSTR-1514, "PRODUCTION AREA NORTH PLAN ELEVATION -12'-0" AND -16'-0","
REVISION 2
DWG-FSTR-1515, "PRODUCTION AREA SOUTH PLAN ELEVATION -12'-0", -16'-0" AND -23'-
0"," REVISION 2
DWG-FSTR-1516, "I.U. CELL AREA NORTH PLAN ELEVATION 18'-7"," REVISION 2
DWG-FSTR-1517, "I.U. CELL AREA SOUTH PLAN ELEVATION 18'-7"," REVISION 2
DWG-FSTR-1518, "BUILDING SECTIONS SECTIONS 1 AND 2," REVISION 2
DWG-FSTR-1519, "BUILDING SECTIONS SECTIONS 3 AND 4," REVISION 3
DWG-FSTR-1520, "BUILDING SECTIONS SECTIONS 5 AND 6," REVISION 2
DWG-FSTR-1521, "BUILDING SECTIONS SECTIONS 7 AND 8," REVISION 2
DWG-FSTR-1522, "BUILDING SECTIONS SECTIONS 9 AND 17," REVISION 1
DWG-FSTR-1523, "BUILDING SECTIONS SECTION 10," REVISION 4
DWG-FSTR-1524, "FOUNDATION SECTIONS SECTIONS 11 AND 12," REVISION 1
DWG-FSTR-1525, "FOUNDATION SECTIONS SECTIONS 13 AND 14," REVISION 3
DWG-FSTR-1526, "FOUNDATION SECTIONS SECTIONS 15 AND 16," REVISION 2
DWG-FSTR-1527, "FOUNDATION SECTIONS AND DETAILS," (SHEET 1 OF 2), REVISION 4
DWG-FSTR-1527, "FOUNDATION SECTIONS AND DETAILS," (SHEET 2 OF 2), REVISION 4
DWG-FSTR-1528, "FOUNDATION SECTIONS AND DETAILS," REVISION 1
DWG-FSTR-1529, "FOUNDATION SECTIONS AND DETAILS," REVISION 1

DWG-FSTR-1530, "PRECAST VAULT PLANS AND SECTIONS," REVISION 0
DWG-FSTR-1531, "PRECAST VAULT PLANS AND SECTIONS," REVISION 0
DWG-FSTR-1530, "PRECAST VAULT SECTIONS AND DETAILS," REVISION 0
DWG-FSTR-1540, "MAT FOUNDATION PLANS, SECTIONS AND DETAILS," REVISION 2
DWG-FSTR-1541, "MAT FOUNDATION PLANS, SECTIONS AND DETAILS," REVISION 0
DWG-FSTR-1543, "CONCRETE WALL SECTIONS AND DETAILS," REVISION 1
DWG-FSTR-1544, "CONCRETE WALL AND SLAB SECTIONS AND DETAILS," REVISION 1
DWG-FSTR-1545, "CONCRETE SLAB PLAN, SECTIONS AND DETAILS," REVISION 2

Inspection/Test Reports

Baker Concrete Preplacement Inspection Report, Report No. 10.01-3a-001
Form 10.01-2, Concrete Batch Plant Inspection, WP-FSTR-PF-CON-BGFND-001-002,
12/13/2019
Form 10.01-3b, Concrete Placing Inspection, WP-FSTR-PF-CON-BGFND-001-002, 12/14/2019
Lycan Concrete Batch Ticket 1820536, WP-FSTR-PF-CON-BGFND-001-002, 11/22/2019
Lycan Concrete Batch Ticket 1820626, WP-FSTR-PF-CON-BGFND-001-002, 11/22/2019
Lycan Concrete Batch Ticket 1820668, WP-FSTR-PF-CON-BGFND-001-002, 11/22/2019
Lycan Concrete Batch Ticket 1826517, WP-FSTR-PF-CON-BGWALLS-001-002, 12/19/2019
Lycan Concrete Batch Ticket 1826559, WP-FSTR-PF-CON-BGWALLS-001-002, 12/19/2019
Terracon Field Density Test Report, Report No. 58191092.0012
Terracon Proof Rolling Observation Report No. 58191092.0013

Miscellaneous

RFI 2019-0045, dated 10/30/2019

Nonconformance Reports

NCR 19-0004, Native Soil bearing capacity, Revision 1
NCR 19-0005, Concrete Strength Specimens for foundation, Revision 1

Shop Drawings (CMC Rebar)

R-1.1, "EL. -23'-0" FOUNDATION PLAN," REVISION 2
R-1.2, "EL. -23'-0" COB WALLS REINFORCEMENT PLAN," REVISION 2
R-1.3, "EL. -23'-0" COB WALLS REINFORCEMENT PLAN," REVISION 2
R-1.5, "EL. -23'-0" COB WALLS REINFORCEMENT PLAN," REVISION 2
R-1.7, "SLAB REINFORCEMENT PLAN EL. -16'-0", -16'-6" & -12'-6" BOTTOM BARS,"
REVISION 2
R-1.8, "SLAB REINFORCEMENT PLAN EL. -16'-0", -16'-6" & -12'-6" BOTTOM BARS,"
REVISION 2
R-1.9, "SLAB REINFORCEMENT PLAN EL. -16'-0", -16'-6" & -12'-6" TOP BARS," REVISION 2
R-1.10, "SLAB REINFORCEMENT PLAN EL. -16'-0", -16'-6" & -12'-6" TOP BARS," REVISION
2
R-1.11, "SLAB REINFORCEMENT PLAN EL. -16'-0", -16'-6" & -12'-6" STANDEE/EDGE
BARS," REVISION 3
R-1.12, "SLAB REINFORCEMENT PLAN EL. -16'-0", -16'-6" & -12'-6" WALL DOWELS,"
REVISION 2
R-1.13, "SLAB EL. -16'-0", -16'-6" & -12'-6" SECTIONS," REVISION 3

Specifications

SPEC-FSTR-1001, Nuclear Safety Related Rebar, Revision 2
SPEC-FSTR-1003, Safety Related Earthwork Inspection and Testing, Revision 0
SPEC-FSTR-1004, Safety Related Excavation and Backfill for Foundations, Revision 0

SPEC-FSTR-1006, Safety Related Concrete Procurement Including Mix Design, Revision 3
SPEC-FSTR-1006, Safety Related Concrete Procurement Including Mix Design, Revision 4
SPEC-FSTR-1007, Nuclear Safety Related Installation of Structural Concrete, Revision 1

Structural Calculations (Sargent & Lundy)

Calculation No. 2017-1000, SHINE Facility Structural Design, Revision 1
Calculation No. 2017-1001, Evaluation of Aircraft Impact, Revision 1
Calculation No. 2018-06920, Soil Structure Interaction Analysis of SHINE Medical Isotope Production Facility for Design Seismic Event, Revision 1

Training and Qualification Records

Terracon Inspection Experience and Education Form for employee M.O.

Work Packages

WP-FSTR-PF-CON-BGFND-001, Production Facility FSTR QL-1 Mass Concrete Foundations Below Grade Foundations at Elevations (-)23'-0"
WP-FSTR-PF-CON-BGFND-002, Production Facility FSTR QL-1 Mass Concrete Foundations Below Grade Foundations at Elevations (-)16'-6", (-)16'-0", (-)12'-6", and (-)11'-0"
WP-FSTR-PF-CON-BGWALLS-001, Production Facility FSTR QL-1 Below Grade Walls

IP 69021

Audits, Assessments & Surveillances

Golder Associates Inc., Project Work Plan, dated 10/18/2011
Surveillance Report No. Golder 1, associated with Observation of Site Activities, dated 10/26/2011
Surveillance Report No. Golder 2, associated with Observation of Vertical Seismic Profiling (VSP) field testing, dated 11/29/2011
Assessment Report ASMT-2011-003 associated with Golder Associates Duluth Office conducted 10/3/2011-10/4/2011, dated 12/14/2011
SHINE Letter to Golder Associates Inc.: Assessment Report (ASMT-2015-004), dated 3/18/2016
Duke Energy NUPIC Audit of Sargent & Lundy, LLC; NUPIC Audit No. 24182, dated 5/26/2016
Duke Energy NUPIC Audit 24182 Supplier Audit Finding Report Closure Responses, dated August 31, 2016
Supplier Evaluation Form QUAL-2016-0002 associated with Sargent & Lundy, Revision 0, dated 11/26/2017
Sargent & Lundy Letter to SHINE: Response to QUAL-2016-0002, dated 2/27/2017
SHINE Letter to Sargent & Lundy: Supplier Qualification (QUAL-2016-0002), dated 1/23/2017

Corrective Action Documents

IMR 2019000122, Manufacturing Sciences Corp. - Finding No. EXAS-2019-0003-01 – Supplier Assessments Activities Not Being Conducted, dated 6/10/19
IMR 2019000166, Identification of single failure criterion deficiencies, dated 8/20/19
IMR 2019000231, Change Order K-2019-0003-CO 1 and CO 2 executed without Quality Review, dated 9/20/19
IMR 2019000240, Overdue Closure of IMRs, dated 9/30/19
IMR 2019000272, Apparent Trend in Implementation of SHINE Procurement Process, dated 10/23/19
IMR 2019000321, The process of controlling and the distribution of shop drawings, dated 11/18/19

Corrective Action Documents Resulting from Inspection

IMR 2019000373, QA Procedures Inspection - Ensure 2100-04-01 Includes Acceptance Criteria as Appropriate, 12/10/19

Miscellaneous

ATCH 2000-11-01-01, SHINE Quality Records Retention Schedule, Revision 0

Owner's Acceptance Review Documents:

- FRM 1200-01-03-01, Technical Document Owner's Acceptance Review Form associated with Various Concrete Drawings including DWG-FSTR-1527, "Foundation Sections and Details (Sheets 1 & 2)," Rev. 4, dated 11/19/2019.
- FRM 1200-01-03-02, "Owner's Acceptance Comment Resolution Form associated with Various Concrete Drawings including DWG-FSTR-1527, "Foundation Sections and Details (Sheets 1 & 2), Rev. 4," dated 11/19/2019
- FRM 1200-01-03-01, Technical Document Owner's Acceptance Review Form associated with Various Rebar Shop Drawings including R1.1 and R1.8, Rev. 2, dated 10/31/2019.
- FRM 1200-01-03-02, Owner's Acceptance Comment Resolution Form associated with Various Rebar Shop Drawings including R1.1 and R1.8, Rev. 2, dated 10/31/2019
- FRM 1200-01-03-01, Technical Document Owner's Acceptance Review Form associated with Construction Specification SPEC-FSTR-1001, "Nuclear Safety Related Rebar," Rev. 2, dated 11/20/2019
- FRM 1200-01-03-01, Technical Document Owner's Acceptance Review Form associated with Various Construction Specifications SPEC-FSTR-1003, "Safety Related Earthwork Inspection and Testing," Rev. 0, dated 3/16/2019
- FRM 1200-01-03-02, Owner's Acceptance Comment Resolution Form associated with Construction Specification SPEC-FSTR-1003, "Safety Related Earthwork Inspection and Testing," Rev. 0, dated 3/16/2019
- FRM 1200-01-03-01, Technical Document Owner's Acceptance Review Form associated with Construction Specification SPEC-FSTR-1007, "Safety Related Concrete Procurement Including Mix Design," Rev. 1, dated 11/21/2019
- FRM 2200-03-02, Technical Document Owner's Acceptance Review Checklist associated with Preliminary Geotechnical Engineering Report – Golder Report 6, dated 8/29/2012.
- FRM 2200-03-03, Owner's Acceptance Comment Resolution Form associated Preliminary Geotechnical Engineering Report – Golder Report 6, dated 8/9/2012
- FRM 1200-01-03-01, Technical Document Owner's Acceptance Review Form associated with Structural Calculation CALC-2017-1000, "SHINE Facility Structural Design," Rev 1, dated 7/15/2019
- FRM 2100-01-02-02, Record Correction Notice associated with Technical Document Owner's Acceptance Review of Concrete Drawings, DWG-FSTR-1103, dated 7/3/2019

Procedures (Baker)

- NQAP SHINE-1.01, Organization, Revision 0
- NQAP SHINE-2.01, General Co-Worker Indoctrination and Training, Revision 0
- NQAP SHINE-2.02, Co-Worker Qualification and Certification, Revision 0
- NQAP SHINE-2.03, Quality Assurance Program Description Procedure, Revision 0
- NQAP SHINE-3.01, Design Interface, Revision 1
- NQAP SHINE-4.01, Controlling Procurement Documents, Revision 2
- NQAP SHINE-5.01, Controlling Instructions and Procedures, Revision 1
- NQAP SHINE-6.01, Controlling Documents, Revision 1
- NQAP SHINE-7.01, Controlling Purchases of Items and Services, Revision 2

NQAP SHINE-7.02, Commercial Grade Dedication (CGD) of Items for Safety Related Applications, Revision 1
NQAP SHINE-8.01, Identifying and Marking Material, Revision 0
NQAP SHINE-9.01, Controlling Special Processes, Revision 1
NQAP SHINE-10.01, Performing Inspections, Revision 0
NQAP SHINE-11.01, Controlling Tests, Revision 0
NQAP SHINE-12.01, Controlling Measuring and Test Equipment, Revision 0
NQAP SHINE-13.01, Handling, Storage, Cleaning, Packaging, and Shipping of Items, Revision 0
NQAP SHINE-14.01, Identifying the Inspection, Test, and Operating Status of Items, Revision 0
NQAP SHINE-15.01, Controlling Nonconforming Items, Revision 0
NQAP SHINE-16.01, Corrective Action Program, Revision 0
NQAP SHINE-16.02, Reporting Potential 10 CFR 21 and 10 CFR 50.55 (e) Issues to the SHINE, Revision 1
NQAP SHINE-17.01, Controlling Quality Assurance Records, Revision 1

Procedures (SHINE)

0500-04-01, Employee Onboarding, Revision 0
1200-01-01, Design Packages, Revision 1
1200-01-02, Calculations, Revision 8
1200-01-03, Owner's Acceptance Review, Revision 3
1200-01-04, Technical Reports, Revision 4
1200-01-06, Engineering Change Control, Revision 2
1200-01-07, Classification of Structures, Systems, and Components, Revision 5
1200-01-08, Drawings, Revision 3
1200-01-10, Design Criteria Documents, Revision 4
1200-01-13, Engineering Software Control and Quality Assurance, Revision 2
1200-01-15, Specifications for Structures, Systems, and Components (SSCs), Revision 3
1200-09-01, Configuration Management, Revision 1
1200-09-04, Design Control Program, Revision 0
1600-01-01, Procurement, Revision 8
1600-01-02, Commercial Grade Dedication, Revision 1
1600-01-03, Request for Quotation (RFQ), Revision 2
2000-01-03, Documentation Practices, Revision 0
2000-01-08, Assessments, Revision 4
2000-01-11, Supplier Qualification, Revision 0
2000-01-11, Supplier Qualification, Revision 3
2000-01-12, Signatures and Review/Approval Process, Revision 3
2000-01-13, Quality Assurance Surveillances, Revision 0
2000-01-14, Control of Nonconforming Items, Revision 2
2000-11-01, SHINE Quality Records Retention Policy, Revision 0
2018-01-01, Assessments, Revision 0
2100-01-01, Document Control, Revision 2
2100-01-02, Records Management, Revision 0
2100-04-01, Procedure Writer's Guide, Revision 0
2200-01-01, Issues Management, Revision 5
2200-01-03, 10 CFR Part 21 and 10 CFR 50.55(e) Reporting, Revision 1
2200-01-05, Condition Evaluation, Revision 0
2200-01-06, Apparent Cause Evaluation, Revision 0
2200-01-07, Root Cause Evaluation, Revision 0
2900-01-01, Training, Revision 5

Procurement Documents:

Contract Number: K-2019-0050, "Main Agreement between SHINE and Baker Concrete Construction, Inc. for construction of the SHINE Production," dated 9/30/2019
Contract Number: K-2019-0050-AMD-0001, "Amendment to the Main Agreement (K-2019-0050) for construction services by Baker Concrete Construction, Inc. to complete the superstructure of the production facility," dated 9/30/2019
Change Notice No: K-2019-0050-AMD-0001-CN-0001, dated 10/15/2019
Change Notice No: K-2019-0050-AMD-0001-CN-0002, dated 10/14/2019
Change Notice No: K-2019-0050-AMD-0001-CN-0003, dated 10/22/2019
Change Notice No: K-2019-0050-AMD-0001-CN-0004, dated 10/23/2019
Purchase Order No. PO 4460 between SHINE and Baker Concrete Construction, Inc. for work associated with Contract Number: K-2019-0050-AMD-0001, dated 10/01/2019

Quality Assurance Program Documents

2000-09-01, SHINE Quality Assurance Program Description (QAPD), Revision 14
Baker Quality Assurance Program Description for the SHINE Medical Technologies Facility, Revision 0

Specifications

SPEC-FSTR-1001, Nuclear Safety Related Rebar, Revision 2

Training and Qualification Records

Co-worker No. 22312
Co-worker No. 177622
Co-worker No. 243744
SHINE Onboarding Plan for employee S.B.
Terracon Inspection Experience and Education Form for employee M.O.

LIST OF ACRONYMS

ACI	American Concrete Institute
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
CAQ	Condition Adverse to Quality
CIP	Construction Inspection Program
CMTR	Certified Material Test Report
FSAR	Final Safety Analysis Report
IMC	Inspection Manual Chapter
IP	Inspection Procedure
M&TE	Measuring and Test Equipment
NCR	Nonconformance Report
NPUFs	Non-Power Production and Utilization Facilities
NRC	Nuclear Regulatory Commission
NRMCA	National Ready Mixed Concrete Association
NUPIC	Nuclear Procurement Issues Corporation
QA	Quality Assurance
QAPD	Quality Assurance Program Description
QC	Quality Control
SCAQ	Significant Condition Adverse to Quality

SSC Structure, System, and Component

LIST OF INSPECTION PROCEDURES USED

IP 69020 Inspection of Safety-Related Items (and Services) During Construction of Non-Power Production and Utilization Facilities
IP 69021 Inspections of Quality Assurance Program Implementation During Construction of Non-Power Production and Utilization Facilities

LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Type</u>	<u>Status</u>	<u>Description</u>
None			