

April 14, 2016

Mrs. Marikay Speckert
Corporate Quality Manager
Carboline Company
2150 Schuetz Road
St. Louis, MO 63146

SUBJECT: CARBOLINE COMPANY'S NUCLEAR REGULATORY COMMISSION
INSPECTION REPORT NO. 99901462/2016-201

Dear Mrs. Speckert:

From March 14-18, 2016, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Carboline Company's (hereafter referred to as Carboline) facilities in St. Louis, MO and Green Bay, WI. The purpose of this limited-scope routine inspection was to assess Carboline's compliance with provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

This technically-focused inspection specifically evaluated Carboline's implementation of the quality activities associated with the design, manufacturing, and testing of nuclear grade protective coatings being supplied to the Westinghouse Electric Company AP1000 new reactor plants design as well as current operating reactors. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC endorsement of Carboline's overall quality assurance program.

Within the scope of this inspection, no violations or nonconformances were identified.

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 (and if applicable), should not include any personal privacy, proprietary, or Safeguards Information 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 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."

Sincerely,

/RA/

Richard P. McIntyre, Acting Chief
Quality Assurance Vendor Inspection Branch-2
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 99901462

Enclosure:
Inspection Report No. 99901462/2016-201
and Attachment

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."

Sincerely,

/RA/

Richard P. McIntyre, Acting Chief
Quality Assurance Vendor Inspection Branch-2
Division of Construction Inspection
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DATE	04/08/16	04/14/16	

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**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND OPERATIONAL PROGRAMS
VENDOR INSPECTION REPORT**

Docket No.: 99901462

Report No.: 99901462/2016-201

Vendor: Carboline Company
2150 Schuetz Road
St. Louis, MO 63146

Vendor Contact: Marikay Speckert
Corporate Quality Manager
E-mail: mspeckert@carboline.com
Phone: 314-644-1000 x2456

Nuclear Industry Activity: Carboline Company was established in 1947 and has been providing protective coatings for the nuclear industry since the 1970s. Carboline's corporate office and Research and Testing Center are located in St. Louis, MO. Carboline's nuclear coating manufacturing facility is located in Green Bay, WI.

Inspection Dates: March 14-18, 2016

Inspectors: Yamir Diaz-Castillo NRO/DCIP/QVIB-2
Jonathan Ortega-Luciano NRO/DCIP/QVIB-2
Andrea Keim NRO/DCIP/QVIB-3
Gregory Makar NRO/DEIA/MCB

Approved by: Richard P. McIntyre, Acting Chief
Quality Assurance Vendor Inspection Branch-2
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Enclosure

EXECUTIVE SUMMARY

Carboline Company
99901462/2016-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted a vendor inspection at the Carboline Company's (hereafter referred to as Carboline) facilities in St. Louis, MO and Green Bay, WI, to verify that it had implemented an adequate quality assurance (QA) program that complies with the requirements 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." In addition, the NRC inspection also verified that Carboline implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that met NRC's regulatory requirements. The NRC inspection team conducted the inspection from March 14-18, 2016. This was the initial NRC inspection at the Carboline facilities.

This technically-focused inspection specifically evaluated Carboline's implementation of quality activities associated with the design, manufacturing, and testing activities of the nuclear grade protective coatings being supplied to the new and operating reactors.

Specific activities observed by the NRC inspection team included:

- Fillers pre-shift meeting
- Batch makers pre-shift meeting
- Batch mixing of Carboguard 890N, Part A
- Sample collection of Carboguard 890N, Part A
- Weight Per Gallon quality control (QC) test on Carboguard 890N, Part A
- Brookfield Viscosity and Fineness of Grind QC tests on Carboguard 890N, Part A
- Final packing and shipping of Carboguard 890N, Parts A & B to Dubose National Energy

In addition to observing these activities, the NRC inspection team verified that measuring and test equipment (M&TE) was properly identified, marked, calibrated, and used within its calibrated range.

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 NRC inspection team implemented Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," dated July 15, 2015, IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated November 29, 2013, and IP36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated February 13, 2012.

The NRC inspection team determined that Carboline is implementing its design control, commercial-grade dedication, supplier oversight, material traceability, inspection, test control, control of M&TE, handling, storage, and shipping, nonconforming material, parts, or components, and corrective actions programs in accordance with the applicable regulatory requirements of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team determined that Carboline is implementing its 10 CFR Part 21 program for evaluating deviations and reporting defects that could create a substantial safety hazard in accordance with regulatory requirements. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspection team reviewed Carboline Company's (hereafter referred to as Carboline) policies and implementing procedures that govern Carboline's 10 CFR Part 21, "Reporting of Defects and Noncompliance," program to verify compliance with the regulatory requirements. In addition, the NRC inspection team evaluated the 10 CFR Part 21 postings and a sample of Carboline's purchase orders (PO) for compliance with the requirements of 10 CFR 21.31, "Procurement Documents." The NRC inspection team also verified that Carboline's nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program.

For a sample of 10 CFR Part 21 evaluations, the NRC inspection team verified that Carboline had effectively implemented the requirements for evaluating deviations and failures to comply. For evaluations that resulted in notifications, the NRC inspection team verified that the notifications were performed in accordance with the requirements of 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation."

The NRC inspection team also discussed the 10 CFR Part 21 program with Carboline's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that Carboline 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 NRC inspection team also determined that Carboline 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 NRC inspection team reviewed Carboline'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 NRC inspection team examined Carboline's standard operating procedures (SOPs) and associated forms for conducting nuclear design work. The NRC inspection team treated formulating new coatings, qualifying existing coatings, and controlling formulation changes as the relevant design work. The NRC inspection team also sampled documents from the most recent design activities to determine if they were consistent with Carboline's design control program.

At Carboline's Research and Development (R&D) Center in St. Louis, MO; the NRC inspection team reviewed an example of an AP1000 Testing Project Request for the chemical resistance testing of combinations of Carboline coatings as an example of defining and documenting the design inputs. The NRC inspection team also examined the contents of a file documenting the addition of nuclear-qualified Carbozinc 11 High Solids Nuclear (HSN) based on the existing Carbozinc 11 HS. This was another project developed for the AP1000. The release of a new product occurs after the completion and approval of the project planning testing, review, and verification. The NRC inspection team confirmed that the file contained the completed Project Design Plan required to load the new formula into Carboline's product line, as well as an email confirmation from Westinghouse Electric Company (WEC) that the coating could be released for use by suppliers of AP1000 components.

At Carboline's manufacturing plant in Green Bay, WI; the NRC inspection team examined how the coating design process in St. Louis is implemented when producing coating material in the plant. Specifically, the NRC inspection team examined the Work in Progress (WIP) tickets for batches of Carbozinc 11 HSN Base and Carboguard 890N Part A. The WIP ticket lists the amounts of all of the ingredients for the batch, the detailed instructions, and the required quality control (QC) tests. The WIPs are generated by Carboline's enterprise resource planning system (Baan) according to the coating formulas developed and maintained by R&D in St. Louis. The NRC inspection team examined the procedures for formula control and examples of documents evaluating and approving changes.

In addition, the NRC inspection team observed mixing of a batch of Carboguard 890N, Part A at the plant. The NRC inspection team observed how the batch maker uses the instructions (WIP ticket) generated by Carboline's Baan system to add the specified amounts of raw materials in the order specified. These instructions are developed by the product owner for that coating in St. Louis under the formula control process. The WIP ticket for mixing a batch in the plant identifies interim and final QC testing requirements.

At both the St. Louis and Green Bay facilities, the NRC inspection team examined the training matrices, QC Inspector Certification forms, and vision examinations for supervisors and laboratory personnel conducting nuclear design and testing work.

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

b. Observations and Findings

Design activities for new nuclear power plant coatings do not occur on a regular basis; the most recent qualification performed by Carboline was for the WEC's AP1000 reactor design. Due to the high cost of qualifying a coating (whether new or existing) for nuclear service, Carboline generally performs this work with a customer who defines the design requirements. However, Carboline controls the product formula. Carboline performs or procures the testing, and both Carboline and the customer have acceptance criteria that must be met.

In addition to developing new coatings and qualifying existing coatings for nuclear service, design activities include making changes to existing product formulas. The coating formula describes not only the chemical content of the coating, but also the instructions and quality control tests for producing it. To evaluate a recent example, the NRC inspection team examined changes to the formula of an existing nuclear coating, Carbozinc 11 Specification Grade (SG). Carboline made the changes in response to a 10 CFR Part 21 notification about slow cure of a batch of Carbozinc 11 SG. The NRC inspection team examined the documentation describing the investigation and conclusions about the cause of slow cure, the proposed actions to prevent future occurrences, the evaluation and approval of those actions, and verification that the actions were completed and approved by the Vice President of R&D in accordance with Carboline's SOPs.

c. Conclusion

The NRC inspection team concluded that Carboline is implementing 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 NRC inspection team also determined that Carboline 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 NRC inspection team reviewed Carboline's policies and implementing procedures that govern the dedication of commercial-grade items for use in safety-related applications to verify compliance with the applicable regulatory requirements of 10 CFR Part 21, Criterion III, and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of commercial-grade dedication plans, checklists, reports and associated POs, and commercial-grade surveys of several commercial vendors on Carboline's Approved Supplier's List (ASL). The NRC inspection team evaluated the criteria for the selection of critical characteristics and the selection of verification methods to verify effective implementation of Carboline's dedication process.

The NRC inspection team also discussed the commercial-grade dedication program with Carboline's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team evaluated a sample of technical evaluations and concluded that the technical evaluations in the dedication plans appropriately identify the critical characteristics and technical attributes necessary to provide reasonable assurance that the coatings would perform their intended safety function.

During the review of the commercial-grade surveys, the NRC inspection team identified that the survey of Sterigenics, which was contracted to perform gamma radiation services, did not adequately verify the control of sub-suppliers to ensure that the test results and certifications could be accepted. In addition, the NRC inspection team noted that the survey results did not contain sufficient objective evidence relating to some of the critical characteristics. The NRC inspection team evaluated the supplemented documentation collected during the performance of the survey by the lead auditor to verify if Carboline had reasonable assurance that Sterigenics had adequate controls in place to control the critical characteristics. The NRC inspection team concluded that Carboline verified all the critical characteristics listed in the dedication plan.

As a result of this inconsistency, Carboline generated corrective action report (CAR) No. 0965-2016. Carboline will perform an extent of condition and review other commercial-grade surveys to verify if the reports/checklists have sufficient objective evidence that provide reasonable assurance that all the critical characteristics were verified as part of the actions required by this CAR. Commercial-grade surveys that will be reviewed by Carboline include: Sterigenics, Underwriters Laboratories, Intertek, Atlas, US Zinc and Nexeo / Startex. Based on Carboline's technical capacity to manufacture the coatings, the extensive testing that the coatings go through to verify that they meet the required technical specifications, the NRC inspection team has reasonable assurance that the coatings will perform their intended safety function.

c. Conclusion

The NRC inspection team concluded that Carboline is implementing its commercial-grade dedication program in accordance with the regulatory requirements of 10 CFR Part 21, Criterion III and Criterion VII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Carboline is implementing its policies and procedures associated with the commercial-grade dedication program. No findings of significance were identified.

4. Supplier Oversight

a. Inspection Scope

The NRC inspection team reviewed Carboline's policies and implementing procedures that govern the implementation of supplier oversight program to verify compliance with the requirements of Criterion IV, "Procurement Document Control," and Criterion VII of Appendix B to 10 CFR Part 50. Carboline's ASL includes Global Quality Assurance (GQA) as the only supplier of safety-related services. GQA is contracted to perform

Carboline's internal audits at the R&D and manufacturing facilities. The NRC inspection team verified that the POs included, as appropriate: the scope of work, right of access to facilities, and extension of contractual requirements to subcontractors. In addition, the NRC inspection team confirmed that the reviewed safety related POs invoked the requirements of 10 CFR Part 21 and required GQA to conduct safety-related work under its approved QA program.

The rest of the suppliers in Carboline's ASL are of a commercial nature and any products or services contracted from these suppliers are dedicated by Carboline. For more information on Carboline's commercial-grade dedication program please refer to Section 3.0 above.

The NRC inspection team reviewed a sample of training and qualification records of GQA auditors and Carboline lead auditors and inspection personnel and confirmed that auditing and inspection personnel had completed the required training and maintained qualification and certification in accordance with Carboline's policies and procedures.

The NRC inspection team also discussed the supplier oversight program with Carboline's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

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

5. Material Traceability

a. Inspection Scope

The NRC inspection team reviewed Carboline's policies and implementing procedures that govern material traceability to verify compliance with the regulatory requirements of Criterion VIII, "Identification and Control of Material, Parts, and Components," of Appendix B to 10 CFR Part 50.

The NRC inspection team observed that all materials were marked with unique identifiers traceable to procurement records. The NRC inspection team observed that raw material identification was traceable to the batch ticket. Each batch ticket has a unique code number for identification.

The NRC inspection team also discussed the material traceability program with Carboline's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusions

The NRC inspection team concluded that Carboline is implementing its material traceability program in accordance with the regulatory requirements of Criterion VIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Carboline is implementing its policies and procedures associated with the material traceability program. No findings of significance were identified.

6. Inspection

a. Inspection Scope

The NRC inspection team reviewed Carboline's policies and implementing procedures that govern the inspection program to verify compliance with the regulatory requirements of Criterion X, "Inspection," of Appendix B to 10 CFR Part 50. The NRC inspection team observed the processing and inspection of Carboguard 890N Part A, batch ticket No. 771477, lot No. 16CN1781B. The NRC inspection team also reviewed a sample of training and qualification records for manufacturing and inspection personnel, and reviewed a sample of completed documentation from other processed batches.

The NRC inspection team verified that inspections are performed by qualified persons other than those who performed or directly supervise the work being inspected. For a sample of inspection documents, the NRC inspection team verified that these documents included appropriate information as required by Carboline's SOPs such as inspection date, observations, results of examinations and tests, and the appropriate signature and/or initials of the QA inspector. The NRC inspection team verified that hold points were indicated and that work did not proceed without appropriate approval.

The NRC inspection team also discussed the inspection program with Carboline's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusions

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

7. Test Control

a. Inspection Scope

The NRC inspection team reviewed Carboline's policies and implementing procedures that govern the test control program to verify compliance with the requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. No testing was performed at Carboline's R&D facility during the inspection.

The NRC inspection team examined a sample of Carboline's SOPs and associated test procedures, including those related to coatings testing under conditions that simulate the temperature, pressure, and water chemistry of a loss-of-coolant accident (LOCA). These tests are called "Design Basis Accidents (DBA) qualification" tests. Specifically, the NRC inspection team reviewed two DBA testing reports and examined the corresponding laboratory notebook for consistency of information and instrument calibration according to the relevant SOP. These tests were part of the work to provide coatings for the AP1000 and were completed by 2012.

At the Green Bay manufacturing facility, Carboline was mixing nuclear coating batches and performing the associated QC tests. The NRC inspection team discussed the QC tests with a technician in the QC laboratory and observed him performing Fineness of Grind, Weight per Gallon, and Brookfield Viscosity tests. The NRC inspection team later examined the completed WIP ticket for the Carbozinc 11 HSN Base, showing that all QC tests were adequately completed. The NRC inspection team also examined a printout showing the QC test results from a batch that had been entered into Baan and examined the updated WIP ticket for the Carboguard 890N, Part A, which showed the additional QC test results and subsequent batch adjustments.

The NRC inspection team also discussed the inspection program with Carboline's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

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

8. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed Carboline'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 NRC inspection team reviewed the calibration records of the M&TE used during the batch mixing, filling, and QC testing at the Green Bay manufacturing plant. The NRC inspection team determined that the M&TE had the appropriate calibration stickers and current calibration dates, including the calibration due date. The NRC inspection team also verified that the M&TE had been calibrated, adjusted, and maintained at prescribed intervals prior to use. In addition, the calibration records reviewed by the NRC inspection team indicated the as-found or as-left conditions, accuracy required, calibration results, calibration dates, and the due date for recalibration. The NRC inspection team also verified that the selected M&TE was calibrated using procedures traceable to known industry standards.

The NRC 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, Carboline generates a nonconformance report (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 NRC inspection team also discussed the M&TE program with Carboline's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that Carboline 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 NRC inspection team also determined that Carboline is implementing its policies and procedures associated with the M&TE program. No findings of significance were identified.

9. Handling, Storage, and Shipping

a. Inspection Scope

The NRC inspection team reviewed Carboline's policies and implementing procedures that govern the handling, storage, and shipping to verify compliance with the requirements of Criterion XIII, "Handling, Storage, and Shipping" of Appendix B to 10 CFR Part 50.

The NRC inspection team performed a walk down of the Green Bay manufacturing and warehouse facilities, including the laboratories in both of these locations, to verify that raw and completed materials, as well as chemicals, are adequately controlled and stored to prevent deterioration before use. Carboline assesses the condition of the raw materials and chemicals in the laboratory areas to ensure that old or deteriorated materials are not available for use.

The NRC inspection team observed the filling operation for Carboguard 890N. Cans are already pre-labeled and include the product name, lot number, shelf life information, and storage requirements. In addition, a label indicating "Nuclear" is also attached to the cans. The NRC inspection team also observed the final packing and shipping of Carboguard 890N. In addition, the NRC inspection team verified that the temperature in the storage areas is monitored and recorded as required.

The NRC inspection team also discussed the handling, storage, and shipping program with Carboline's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that Carboline is implementing its handling, storage, and shipping program in accordance with the regulatory requirements of Criterion XIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Carboline is implementing its policies and procedures associated with the handling, storage and shipping. No findings of significance were identified.

10. Nonconforming Materials, Parts, or Components and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed Carboline's policies and implementing procedures that govern the nonconformance and corrective action programs (CAP) 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.

The NRC inspection team reviewed Carboline's Corrective/Preventive Action Requests (CPARs) and nonconformance report (NCR) control logs and selected a sample of NCRs and CPARs to verify that Carboline implemented an adequate program to ensure that nonconforming items and conditions adverse to quality were promptly identified and corrected. The NRC inspection team verified that nonconforming components were properly identified, marked, and segregated when practical, to ensure they were not reintroduced into the manufacturing process. In addition, the NRC inspection team verified that the CPARs provide (1) adequate documentation and description of conditions adverse to quality; (2) an appropriate analysis of the cause of these conditions and the corrective actions taken to prevent recurrence; (3) direction for review and approval by the responsible authority; (4) a description of the current status of the corrective actions; and (5) the follow-up actions taken to verify timely and effective implementation of the corrective actions.

The NRC inspection team also discussed the NCR and CAP process with Carboline's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that Carboline is implementing its nonconforming materials, parts, or components program 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 NRC inspection team also determined that Carboline is implementing its policies and procedures associated with the control of nonconforming materials, parts, or components and corrective actions. No findings of significance were identified.

11. Entrance and Exit Meetings

On March 14, 2016, the NRC inspection team discussed the scope of the inspection with Dwayne Meyer, Carboline's Senior Vice President, Global Innovation & Technology, and other members of Carboline's management and technical staff at St. Louis, MO. On March 18, 2016, the NRC inspection team presented the inspection results and observations during an exit meeting with Marikay Speckert, Carboline's Corporate Quality Manager, and other members of Carboline's management and technical staff at Green Bay, WI. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals whom the NRC inspection team interviewed.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Title	Affiliation	Entrance	Exit	Interviewed
Dwayne Meyer	Senior Vice President Global Innovation & Technology	Carboline	X		X
Mary Roley	Vice President Research and Development	Carboline	X		X
John Kloepper	Technical Director Global Product Development	Carboline	X		X
Marikay Speckert	Corporate Quality Manager	Carboline	X	X	X
Brian Huesgen	Global Process and Quality Manager	Carboline	X		X
Steve Liebhart	Laboratory Manager Tank Linings	Carboline			X
Jesse Hansen	Plant Manager	Carboline		X	X
Ed Widi	Quality Control Supervisor	Carboline		X	X
Shannon Barnaby	Process Excellence Specialist	Carboline		X	X
Craig Delfosse	Level III Quality Control Technician	Carboline			X
Adam Charlier	Batch Maker Level III	Carboline			X
Devon Stone	Receiver Level II	Carboline			X
Jay VanFrachen	Warehouse Manager	Carboline			X
Yamir Diaz-Castillo	Inspection Team Leader	NRC	X	X	
Jonathan Ortega- Luciano	Inspector	NRC	X	X	
Andrea Keim	Inspector	NRC	X	X	
Gregory Makar	Inspector	NRC	X	X	
Richard P. McIntyre	Acting Chief	NRC		X	

INSPECTION PROCEDURES USED

- Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated February 13, 2012
- IP 43002, "Routine Inspections of Nuclear Vendors," July 15, 2015
- IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated November 29, 2013

2. DOCUMENTS REVIEWED

Policies and Procedures

- Carboline Nuclear NQA-1 Quality Assurance Program (QAP) Manual Revision 2, dated April 3, 2014
- Standard Operating Procedure (SOP) CAL-01, "Calibration Control (Monitoring and Measuring Devices)," Revision 9, dated December 26, 2012
- SOP CAL-02, "Calibration Level Identification," Revision 13, dated February 2, 2016
- SOP CAL-03, "Key Process Equipment Validation," Revision 2, dated November 16, 2009
- SOP CAL-04, "LOCA Process Description," Revision 8, dated February 2, 2016
- SOP CAL-13, "Thermometers," Revision 10, dated October 29, 2015
- SOP CAL-17, "Finished Goods Warehouse Temperature Monitoring & Quality Control (QC) Lab Monitoring," Revision 10, dated September 9, 2014
- SOP COR-01, "Corrective Action," Revision 7, dated December 3, 2012
- SOP COR-02, "10CFR21 Reporting," Revision 8, dated February 2, 2016
- SOP COR-03, "Corrective Action: Issue Reports," Revision 6, dated February 2, 2016
- SOP COR-04, "Quality Improvement Requests," Revision 9, dated March 31, 2011
- SOP COR-06, "Control of Nonconforming Product," Revision 10, dated February 2, 2016
- SOP CR-01, "Customer Purchase Order Review," Revision 7, dated March 26, 2014
- SOP CR-05, "Nuclear Testing Request / Evaluation Procedure (Corporate)," Revision 4, dated November 16, 2009
- SOP CR-06, "Orders for Nuclear 'Safety Related' Testing," Revision 2, dated November 16, 2009

- SOP HR-03, "Training Matrix," Revision 5, dated August 9, 2013
- SOP HR-06, "Nuclear Training Program," Revision 9, dated November 16, 2009
- SOP HR-07, "Nuclear Quality Control Inspector Qualification," Revision 3, dated December 26, 2013
- SOP HR-08, "Nuclear Auditor Qualification," Revision 0, dated November 16, 2009
- SOP ID-01, "Product Identification and Traceability," Revision 2, dated November 16, 2009
- SOP LIT-01, "Product Data Sheet (PDS) Control," Revision 7, dated November 7, 2010
- SOP MFG-02, "Batch Numbering Logic," Revision 5, dated August 26, 2013
- SOP MFG-03, "WIP Batch Ticket Issue (Plant)," Revision 9, dated August 14, 2014
- SOP MFG-06, "Batch Making," Revision 9, dated July 10, 2015
- SOP MFG-09, "Retain Samples," Revision 3, dated November 16, 2009
- SOP MFG-10, "Filter Selection and Inspection (Plant)," Revision 5, dated September 15, 2010
- SOP MFG-11, "Filling Operation," Revision 4, dated December 26, 2013
- SOP MFG-13, "First Piece Inspection," Revision 5, dated May 14, 2015
- SOP RCT-01, "Verification of Purchased Product," Revision 6, dated August 27, 2013
- SOP RCT-02, "Raw Material Receipt (Plant)," Revision 8, dated December 3, 2012
- SOP RCT-03, "Incoming Raw Materials Testing," Revision 8, dated September 14, 2011
- SOP RD-01, "Design and Development," Revision 8, dated March 26, 2014
- SOP RD-02, "Formula Control (Corporate)," Revision 3, dated November 16, 2009
- SOP RD-06, "QA Product Listing," Revision 16, February 2, 2016
- SOP RD-07, "Nuclear Product Release (Corporate)," Revision 3, November 16, 2009
- SOP RD-08, "Nuclear Formula Control (Corporate)," Revision 5, May 31, 2011
- SOP RD-11, "Nuclear Software Control Procedure," Revision 0, November 16, 2009
- SOP RD-12 "Nuclear Design and Development," Revision 2, January 18, 2012

- SOP RD-13, "Documentation (edoc) System (Corporate)," Revision 1, July 10, 2014
- SOP RD-14, "Testing Request / Evaluation Procedure," Revision 0, August 6, 2013
- SOP PUR-01, "Purchasing," Revision 10, dated September 14, 2011
- SOP PUR-02, "Purchasing: Material Specifications (Corporate)," Revision 8, dated December 26, 2012
- SOP PUR-03, "Purchasing: Set-up and Monitoring of Subcontractors (Corporate)," Revision 7, dated November 16, 2009
- SOP PUR-04, "Purchasing; Purchase Orders (Plant)," Revision 8, dated October 17, 2011
- SOP PUR-05, "Supplier Information Document," Revision 8, dated July 10, 2015
- SOP PUR-06, "Supplier Performance," Revision 6, dated January 22, 2010
- SOP PUR-07, "Approval of Suppliers of Goods or Services related to Nuclear 'Safety Related' Products," Revision 9, dated December 6, 2012
- SOP PUR-08, "Procedure and Requirements for Performance of Commercial Grade Surveys," Revision 3, dated December 6, 2012
- SOP PUR-09, "Approved Suppliers of Goods and Services for Nuclear 'Safety Related' Products," Revision 19, dated February 2, 2016
- SOP PUR-10, "Procurement of Services related to Nuclear 'Safety Related' Products," Revision 8, dated December 6, 2012
- SOP PUR-12, "Procedure and Requirements for Performance of External Nuclear Suppliers Audits," Revision 1, dated January 28, 2015
- Quality Control Test (QCT) No. 1, "Fineness of Grind," dated September 19, 2012
- QCT No. 14, "Volatile and Non-Volatile Content (For Non-Catalyzed Samples Only)," dated April 22, 2013
- QCT No. 15, "Drawdown and Cure Test," dated December 20, 2012
- QCT No. 17, "Weight Per Gallon Test," dated January 18, 2012
- QCT No. 44, "Brookfield Viscosity," dated August 15, 2012

Design Documents

- Nuclear Quality Assurance Product Evaluation Form (blank), Form No. 4, dated July 26, 2011
- Testing Project Request (blank), Form No. 78, dated February 14, 2014
- Testing Project Request, Project No. 05190, "Chemical Resistance Testing of Systems for the AP1000 Nuclear Reactor," dated July 15, 2009
- Carboline e-document No. 00078269, "Change in a Raw Material for Carbozinc 11 HSN and other Inorganic Zinc Products," dated August 25, 2009
- Carboline e-document No. 00081070, "Change in Pigment for Certain Coatings," dated April 19, 2001 and the associated Nuclear QA Product Evaluation Record evaluating pigment change, dated April 20, 2011.
- Carboline e-document No. 00086290, "Specific Actions taken to Address Carbozinc 11 SG Poor Cure, dated February 27, 2015 and the associated Nuclear QA Product Evaluation Record, dated March 2, 2015
- Design File STP 126-08 for Carbozinc 11 HSN
- Carboline's Internal Memo from John Ladage to Marikay Speckert, "Carbozinc 11 SG Poor Cure Issue Final Status Update for Issue Report #4274," dated March 3, 2016
- Work in Progress Ticket for Carbozinc 11 HSN Base, Lot No. 16CN1477B, dated March 15, 2016
- Work in Progress Ticket for Carboguard 890N Part A, Lot No. 16CN1481B, dated March 17, 2016
- Carboline Manual Receipt Acknowledgment Form, E. Widi, dated March 16, 2016

Commercial Grade-Dedication Documents

- Survey of Anter Laboratories, Inc., Pittsburg, PA, dated June 24, 2009
- Survey of Underwriter Laboratories, Inc. (UL) in Northbrook, IL, dated August 10, 2011
- Survey of Intertek Plastic Technology Laboratory (PTL), Pittsfield, MA, dated June 17, 2011
- Survey of Atlas Weathering Service Group, DSET Laboratories in New River, AZ, dated June 6, 2011
- Survey of Startex Inc./ST Laboratories, LLC., dated August 27, 2013
- Survey of NEXEO Solutions Inc. (formerly Startex Inc.), dated October 23, 2015

- Survey of US Zinc, dated April 14, 2014
- Commercial Dedication Plan for ASTM E84 Testing Services: Supplier Underwriters Laboratories Inc. (UL) in Northbrook, IL, Revision 0 dated November 29, 2011
- Commercial Dedication Plan for ASTM E1269 Testing Service: Supplier Intertek Plastic Technologies Laboratory, Pittsfield, MA, Revision 0 dated November 29, 2011
- Commercial Dedication Plan for ASTM E408 Testing Service Supplier: Atlas Weathering Service Group, DSET Laboratory in New River, AZ, Revision 0 dated November 29, 2011
- Commercial Dedication Plan for Gamma Radiation Services Supplier: Sterigenics, Rockaway, NJ & University of Massachusetts, Lowell, Revision 1 dated October 9, 2013
- Commercial Dedication Plan for ASTM E1530 Testing Service Supplier: Intertek Plastic Technology Laboratory (PTL), Pittsfield, MA, Revision 0 dated November 29, 2011
- Commercial Grade Dedication Plan for Carboline Thinners (2, 21, 26, 33) Suppliers: NEXEO Solution Inc., Conroe, TX, dated October 30, 2014
- Commercial Grade Dedication Plan for Carboline Zinc Fillers and Zinc Fillet Type 3 Supplier: US Zinc, Houston Texas, Revision 5 dated March 11, 2016
- Quality Control Test #127 Approval to Receive and Use Zinc Filler, dated June 17, 2015
- Annual Review of Nuclear Supplier: Sterigenics, dated November 5, 2014
- Annual Review of Nuclear Supplier: Sterigenics, dated November 7, 2013
- Annual Review of Nuclear Supplier: Sterigenics, dated November 7, 2012
- Annual Review of Nuclear Supplier: NEXEO Solution Inc., dated December 21, 2015

Calibration, Inspection and Test Reports

- For the following measuring and testing equipment, the NRC inspection team verified that the calibration was current and reviewed the associated Certificates of Calibration
 - Oven ID No. 36
 - Timer ID No. 2927
 - Hygrometer SN P4984
 - Micrometer ID No. K120394
 - Refractometer ID No. 02
 - Density Cup ID Nos. 2383, C
 - Gel Timers ID Nos. 2928, 6819
 - Stopwatches ID No. 0614, RD21, and RD9
 - Fineness of grind scraper, ID No. 090711-3
 - Thermometers ID Nos. E15, 3110479, WB10, and LHB4921
 - Viscometer ID Nos. 8544379, 855620, and 855619
 - Fineness of grind gage, ID Nos. 032107-1 and G8495-6
 - Digital Pressure Indicators ID No. 4844047 and 4846765
 - Scales ID Nos. 11, 12, 19, 20, 21, 23, 40, 44, 46, 48, 50 and 51
- QC Test Results Printout, Carbozinc 11 HSN Base, Lot 16CN1477B, dated March 16, 2016
- Testing Department Abstract Report, "Irradiation/DBA qualification Testing for AP1000," Testing Project No. 05147, Report No. 2, dated October 22, 2010
- Testing Department Abstract Report, "DBA Testing for AP1000," Testing Project No. 05398, Report No. 1, dated December 11, 2012
- Laboratory Notebook Entries for Testing Project No. 05398, Lab Notebook No. 647, for April 2007 to September 2014

Purchase Orders

- Purchase Order (PO) No. 947641 to NEXEO Solutions Inc. for Thinners 33 and 2, dated March 1, 2016
- PO No. 947680 to US Zinc Corporation for Zinc Filler II, dated March 7, 2016
- PO Nos. 09232013, 07162014, and 09162015 to Global Quality Assurance, Inc., for Carboline's 2013, 2014, and 2015 Internal Audits
- PO Nos. 0923152, 1103151, 0105161, 0202161, to TIC-MS for Calibration Services, dated October 2, 2015, November 3, 2015, January 12, 2016, and February 2, 2016, respectively
- PO No. 4872-09 to Badger Scales for Calibration Services, dated February 11, 2016
- PO No. 1203131 to Precision Gage for Calibration Services, dated December 2, 2013

- PO Nos. 0402152BEV, 0105161BEV, 0815153BEV, and to TIC-MS Inc., for Calibration Services, dated April 2, 2015, August 12, 2015, and January 12, 2016, respectively
- Sales Order Packing Slip of Carboguard 890N for Dubose National Energy, PO No. 99759-62, dated March 17, 2016
- QA PO Review Checklist and Attachments for Carbozinc 11 HSN for PO No. 3080-01-416 to Williams Specialty Services
- QA PO Review Checklist and Attachments for Carboguard 890N for PO No. 99759-62 to Dubose National Energy

Personnel Training and Qualification Records

- Marikay Speckert, Lead Auditor Certification, dated November 25, 2015
- Craig Delfosse, Nuclear Inspector Level III, dated June 22, 2015
- Shannon Barnaby, Quality Control Technician Level III, dated July 7, 2015
- Susan Reilly, Quality Control Technician Level II, dated October 11, 2013
- Thomas Witek, Batchmaker Level III, dated July 7, 2015
- Zane Krueger, Batchmaker Level III, dated July 16, 2015

Nonconformance Reports

0893-2015, 0918-2015, 0921-2015, 0938-2016

Corrective/Preventive Action Request

0809-2015, 0814-2015, 0819-2015, 0924-2016, 0914-2015, 0906-2015, 0897-2015, and 0896-2015

Opened during the inspection: 0956-2016, 0962-2016, 0964-2016, and 0965-2016

Issue Reports

1324, 1771, 2205, 2230, 3432, 3475, 3666, 3679, 4274, and 4685