

Element New Berlin LLC COMMERCIAL GRADE SURVEY REPORT A-80

Survey Date: September 11, 2024

Facility Surveyed: Element New Berlin, WI

Products/Scope: Services to ABB for composite materials testing.

QA Program: ISO 17025:2017 A2LA Chemical and Mechanical Certified

Quality Assurance Manual - ENB-QM (Quality Manual) rev 21 with effective date of 07/20/23

Survey Team Leader: Jose Aviles, Quality Specialist, ABB ELDS Service

Survey Contact: Mark Harty - Quality Manager

1.0 Introduction

A review of order entry, procurement control, design, development & configuration control, inspection & test, material identification & control and manufacturing processes was performed at the Element New Berlin, WI to determine if they should be maintained on the ABB Nuclear Approved Vendors List (NAVL).

2.0 Survey Scope and Summary

The Element New Berlin Quality Management System (QMS) is based on ISO 17025:2017 and consists of a QMS Manual, Quality Policy, Quality Objectives, Process Interaction Flowchart with procedures and forms necessary to control QMS processes. The Quality Manual is formatted similar to the ISO 17025:2017 standard. The scope of the survey included:

 Order Entry – clear identification and flow-through of customer requirements
Inspection and Test – part configuration verified with positive evidence of performance using trained personnel and use of calibrated M&TE
Material Controls – positive control of both raw material stock and inventory identification

4) Manufacturing Processes - positive evidence of control using qualified procedures and personnel as applicable

The survey resulted in zero (0) Opportunities for Improvement or recommendations.



3.0 Survey Approach

This Survey was performed to the ABB Florence Commercial Grade Checklist current revision. The Auditor acted as the Technical Specialist for this survey. The survey was performance based to the extent possible. ABB ELDS Florence Purchase Orders # ABB ELDS Florence Purchase Orders # 4800130270, 4800154828, were reviewed during this commercial grade survey.

4.0 Investigation of Previous Survey Findings

No previous findings.

5.0 Personnel Contacted:

Name	Title	Opening	Closing	Auditee
Peter Radaj	General Manager	Х	Х	
Todd Menna PhD	Engineering Manager	Х	Х	
Rob Pieper PhD	Senior Polymer Scientist	Х	Х	Х
Brad Loeschmann	Application Sales Engineer	Х	Х	Х
Tom Hirsch	Analytical Laboratory Supervisor	Х	Х	
Nick Hansen	Business Development Manager	Х	Х	
Mark Harty	Quality Manager	Х	Х	Х
Aaron Applebee	Chemist			Х
Elena Moore	Senior Polymer Engineer			X

6.0 Summary

This full scope CG Survey was completed on 09/11/2024. Element New Berlin Quality Procedures Manual reviewed during the survey was revision 21 dated 7/20/2023. Element New Berlin QMS is based on ISO 17025:2017 A2LA Certified under certificate numbers 0098.01 and 0098.02 with expiration date on 9/30/2024. Element is waiting for the accreditation body to provide the new certificate before the expiration of this certificate. Element has been ISO QMS certified on Chemicals and Mechanical under the scope of analysis of metal and metal alloys and organic material characterization of adhesives, composites, elastomers, lubricants and plastics, physical tests welding qualification tests, nondestructive testing on metallic and non-metallic materials and to perform laboratory corrosion and environmental exposure tests. The service purchased by ABB are under the scope of Element New Berlin scope of services.

7.0 Effectiveness

The overall effectiveness of the Element New Berlin QMS is Satisfactory. Best Practices identified during this CG Survey was the evidence and recorded history of basing their standard procedures on 10 CFR 50 appendix B and 10 CFR Part 21even though they do not run a Nuclear Program.

Prepared by:	Jose Aviles Audit Team Leader	Date: 9/11/2024.	
Attachment:	Checklist to follow on separate correspondence		
Copy to:	Rene Henriquez, ABB HUB Quality Manager Mark Harty, Element New Berlin Quality Manager		