American Global Standards Confidential Audit Report
ISO 9001:2015

Organization:	CORTEC BIOTECHNOLOGY CAMPUS A Division Cortec Corporation				
Location:	2420 Trailmate Drive Sarasota, Florida 34243				
Type of Audit:	QMS				
Standard:	ISO 9001: 2015				
Audit Dates:	February 11, 2020				
Management Rep. / E-mail:	Debbie Hannan; Email: dhannan@cortecvci.com				
AGS Representative:	Jeff Porter : QMS & EMS Auditor				
Technical Expert / Trainee:	N/A				
Scope of Certification:	Design & Manufacturing of Corrosion Protection Systems, Metal Cleaning & Treating Chemicals Packaging Products, Process & Polymer Additives & Concrete Protection Products				
Industry scope:	EAC: -- SIC:				
No. of add'i sites / branches:	0				
No. of add'i sites audited:	0				
Results of the evaluation of the management documents and audits:	Y	The requirements of the standard on which the audit has been based have been satisfied, certificate award recommended			
	Y	Continuation of validity recommended.			
	n/a	Certificate expansion recommended.			
	N	Re-audit required (see Audit Nonconformities)			
	N	Submit new / additional documents.			
	N	Certificate suspension / withdrawal recommended.			
Environmental Aspect Complexity *(only for ISO 14001)*		Limited		Moderate	
		Low		High	
Re-Audit date: (corrective action)	N/A				
Audit Frequency	Annual				
Accreditation:	AIAO-BAR				

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1. Objective:

The objective of this audit was to:

- Determine the extent of conformity of the management system with the standard(s);
- Evaluate the capability of the management system to ensure compliance with relevant statutory, regulatory and contractual requirements, as applicable;
- Evaluate the effectiveness of the management system in meeting its specified objectives;
- Evaluate the operational control of processes, including internal audits and management review;
- Evaluate the management's responsibility for the company's policies
- Evaluate the links between the standard requirements and the management system requirements.
- Identify areas for potential improvement of the management system.

2. Company Information

2.1 General:

The audit team reviewed and accepted the following clause exclusions to the standard:

*** 8.1 Operational control & planning; 8.2 Requirements for products & services; 8.3 Design & development of products & services; 8.4 Control of externally provided processes, products & services; 8.5.3 Property belonging to customers or external providers; 9.1.2 Customer Satisfaction; 9.1.3 Analysis & Evaluation;**

3. Audit execution

The practical implementation of the standard was evaluated and compared with the organization's management system manual and supporting documents. The audit was conducted through discussions and interviews with personnel in various functions within organization.

The audit covered relevant documentation and processes / areas of the organization in order to obtain an overall understanding of the degree of management system implementation. Although performed to reasonable depth, not every detail of the complete management system could be checked.

The processes and their associated areas of the organization were verified in accordance with the agreed audit plan, if applicable. Particular questions were used in support of the audit plan and audit question list.

Assessment of the audit results was made using the following categories:
Nonconformities (N): Corrective action is required before the decision to issue/continue certification.

Opportunities for Improvement (I): These are improvement possibilities of the management system. The overall requirements of the Standard are met.

Positive remarks (P): Comments made when a requirement was seen to be particularly well established and effective.

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4. The following processes / clauses were audited:

Processes:	4.1	4.2	4.3	4.4	5.1	5.2	5.3	6.1	6.2	7.1	7.2	7.3	7.4	7.5	8.1	8.2	8.3	8.4	8.5	8.6	8.7	9.1	9.2	9.3	10.1	10.2	10.3
Internal Audits	X	X	X	X	X	X	X	X	X	X	X	X	X	X	-	-	-	-	X*	X	X	X*	X	X	X	X	X
Management Review	X	X	X	X	X	X	X	X	X	X	X	X	X	X	-	-	-	-	X*	X	X	X*	X	X	X	X	X
Documented Main Processes:	X	X	X	X	X	X	X	X	X	X	X	X	X	X	-	-	-	-	X*	X	X	X*	X	X	X	X	X
Support Proc.			See Document ID list																								
Internal Audits	X	X	X	X	X	X	X	X	X	X	X	X	X	X	-	-	-	-	X*	X	X	X*	X	X	X	X	X
Corrective Action	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Preventive Action	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

4. Changes since the last audit:

Since the last audit, the following significant changes were introduced:

- Quality Manual System reviewed & approved.
- All Polices & Procedures reviewed & approved.
- Changes/Improvements that could affect the QMS: Context of the organization, PFMEA Suppliers, PFMEA Contractors & QMS Record Matrix.
- Internal Audit Reports: There were no CAs opened in 2019, reviewed 2018 CAPA Report. Customer Satisfaction is monitored & measured by Cortec CHQ. Supplier Approval & Review are also done through Cortec CHQ. Outputs from the Management Review were positive & provided risks & opportunities for more improvement. There haven't been any changes since last audit. This process conforms to the standard & CBCs requirements.
- Quality Assurance: On time shipments 100% - Corporate goal is 100%. Total shipments 66 – No late shipments. No Product Returns to report.
- All Corrective Actions for 2019 have been reviewed & closed.
- Training: Confined Space Awareness; Blood Borne Pathogens; AWAIR; HAZCOM; Fire Prevention & Safety Training; Emergency Action Plan;
- No Customer Complaints to report.

* Organization must notify the AGS Lead Auditor of all future significant changes made to the approved management system.

5. Summary

The audit team was able to verify the effectiveness of the management system in the audited areas by reviewing selected management system documents and records.

- Management Meeting Minutes dated January 22, 2020
- Internal Audit Reports dated December 09, 2019 thru January 07, 2020
- Reviewed & Approved on February 11, 2020
- ISO 9001:2015 Certificate Expires on February 26, 2020

Departments audited are listed on the audit plan.

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6. Audit results

	yes	no	n/a
1. Correction and Corrective Action for Nonconformities identified during this audit were submitted and found to be acceptable.	X		
2. The audit team evaluated the corrective action taken for all Nonconformities from the previous audit.	X		
3. The effectiveness of the management system was assessed by Internal Audits and the results were supplied to Management Review.	X		
4. The auditors determined that the management system is effective in ensuring that agreed requirements for any product or service supplied are met.	X		
5. Documentation contains a statement for Quality Policy, measurable goals and documented methods for their achievement.	X		
6. A central Management Review was carried out at least once annually.	X		
7. The central Management Review addresses the internal audit results from all locations. (multiple-site only).			X
8. The AGS auditors evaluated internal audit records for all locations under the scope of the certification. (multiple-site only).			X
9. A single quality management system exists for all locations. The management system is managed centrally. (multiple-site only).			X
10. The organization has a method of collecting customer feedback, including customer complaints. The data is evaluated and corrective / preventive measures are taken.	X		
11. Minor nonconformities from the last audit were checked and the measures taken were seen to be effective.	X		
12. The auditors checked the use of the certification and AGS mark. (e.g., in marketing literature / internet). All uses are acceptable.	X		
13. The auditor(s) was/were convinced of the qualification and professional experience of those employees who were interviewed / whose records were supplied during the audit.	X		

	yes	no	n/a
14. The authority and position of these employees were clearly defined.	X		
15. The organization provides resources for the improvement and maintenance of the management system as well as for increased customer satisfaction.	X		
16. The organization ensures continual improvement of the management system and customer satisfaction by measuring, analyses and actions.	X		
17. The organization's internal audit program can be relied upon to ensure that the management system is effective and that requirements are being met.	X		
18. If a Repeat Audit, information over the past 3 years indicates positive trends and improvement in the management system's effectiveness.	X		
19. When responding to AGS nonconformities the organization considered correction and corrective action for all sites and not just the site where the nonconformity was identified. (multiple-site only).			X

Note: If any answer is "no", enter details below in Section 7 Action List

Action List

Clause Number	Process	N/C Type Maj./Min.		Description of non-conformity MUST include: Requirement, Nonconformity Statement, and Objective Evidence	C/A Due Date(s)	Cause Analysis of the company Correction and Corrective Action (may reference attached internal corrective action)	N/C Corrected	C/A Plan Accepted	C/A Implemented
None Required				Requirement: Description of N/C: Supporting Audit Evidence:					
				Requirement: Description of N/C: Supporting Audit Evidence:					

Date: February 11, 2020 **AGS Representative: Jeff Porter** **Client Management Rep: Debbie Hannan**