

Functional Area Audited	Functional Area Manager	Audit Date(s)

Auditee Name	Auditee Title / Position	Auditee Phone	Auditee Email

Audit Type / Reason	Comments
<input type="checkbox"/> Routine Audit per Plan <input type="checkbox"/> Follow-up / Verification Audit <input type="checkbox"/> Special Cause Audit	

Audit Reference Standard (Quality Management System)	
Standard(s) To Be Applied	Exemptions / Exceptions

Audit Team	
Name	Audit Role/Function

Audit Scope	
Process or ISO Clause to be Audited	Process Owner

Insert new rows as needed to add additional information

Background and General Comments
<i>[historical information, process information, past audit results or issues, etc.]</i>

Audit Findings
<p>The findings of the audit, listed by the requirement within the appropriate standard follow below.</p> <p><b>Nonconformance (NC):</b> Those items that are considered not compliant within the defined intent of the quality system and/or applicable regulatory or contractual requirements. Additionally, the implementation of the quality system requirements is not consistent with the intent or is not effective. Nonconformances are divided into two categories, major and minor, as follows:</p> <ul style="list-style-type: none"> <li>• <b>Minor Nonconformance</b> - Findings reveal process deficiency in which an isolated observed incident related to product, documentation or process that can be solved with efforts in the area which has been audited.</li> <li>• <b>Major Nonconformance</b>- Findings indicate absence, total breakdown or failure to implement an element of the required standard or regulation. A number of related minor nonconformances when considered together constitute an unacceptable failure of the quality management system.</li> </ul> <p><b>Opportunity for Improvement (OFI):</b> observations which are not direct violations of regulatory standards or contractual elements but are suggested areas of continuous improvement identified by the auditor.</p> <p><b>Area of Compliance:</b> Requirement and organizational processes are effectively fulfilled. Process(es) are adequately implemented and objective evidence supports this conclusion.</p>

1	<input type="checkbox"/> Compliance	<input type="checkbox"/> Minor NC	<input type="checkbox"/> Major NC	<input type="checkbox"/> Opportunity For Improvement
[ISO clause and/or internal requirement associated with finding]				

2	<input type="checkbox"/> Compliance	<input type="checkbox"/> Minor NC	<input type="checkbox"/> Major NC	<input type="checkbox"/> Opportunity For Improvement
[ISO clause and/or internal requirement associated with finding]				

*Copy / paste the tables above to add additional findings*

**Audit Summary & Comments**

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**Audit Approvals**

\_\_\_\_\_  
[Auditor Name]  
Lead Auditor

\_\_\_\_\_  
Date

\_\_\_\_\_  
[Manager Name]  
[Manager Title]

\_\_\_\_\_  
Date