

Mandatory Element 2.21 Internal Audits

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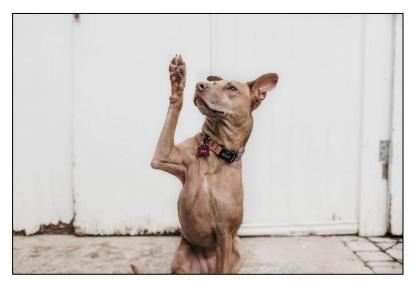
Element 2.21: Internal Quality Audits

- Internal Audit
 - A type of audit performed by the facility to verify compliance and effective implementation of its quality assurance program



Element 2.21: Internal Quality Audits

What is the intent?





The QAC's Intent of 2.21 Internal Quality Audits:

- Facility oversite on their own quality program
 - Including? All 24 elements of Chapter 2
 - When? At least every 365 days
- Documented audit procedure
- Trained/Qualified Personnel
- Documented audit results (checklist, records, etc.)
- Proper root cause investigation and corrective action development
- Follow up





Auditing Internal Audits



• 2.21.1 Does the facility conduct internal audits to verify compliance and effective implementation of their QAP?



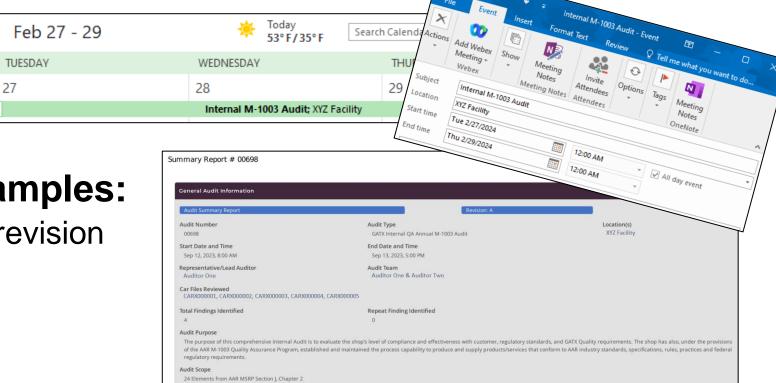
• 2.21.1 Does the facility conduct internal audits to verify compliance and effective implementation of their QAP?

How to Audit?

- Check the records!
- Review Audit Procedure

Objective Evidence Examples:

- Audit procedure current revision
- Calendar meeting
- Audit sign in sheet
- Audit report



• 2.21.2 Does the facility schedule internal audits on the basis of the status and importance of the QAP element? Such that the internal audit encompasses a review of all 24 elements contained in Chapter 2 of this specification annually?



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How to Audit?

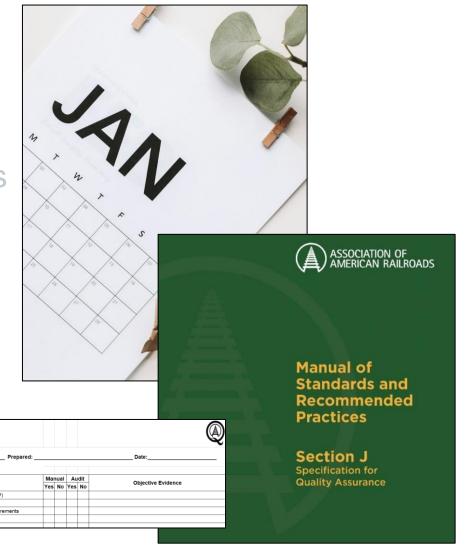
- Review Audit procedure
- Review audit records (checklist, report, etc.)

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Objective of Quality Assurance Program (QAF

Objective Evidence Examples:

- Dated audit reports
- Completed QAPE checklist





• 2.21.3 Are internal audits performed in accordance with documented procedures (using appropriate checklists) by trained personnel who have the organizational freedom to document results?

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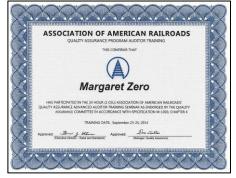
How to Audit?

- Review Audit procedure
- Observe actual audit or walk through
- Review completed checklists
- Review documented nonconformances

•	Objective	Evidence	Examp	les:
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- Completed checklists
- Auditor training record or certificate
- Other documentation required by their program

Paragraph	Element	Manual		Audit		Objective Evidence	
			No	Yes	No		
2.10.1	Does the facility inspect, test, and identify incoming items as required by the inspection and test plans?	x		x		Reviewed quality procedure QP-123 for inspection requirements at incoming inspection, reviewed completed incoming material inspection logs the inspector completed for acceptance per W-1003 2.5.2.1	
2.10.2	Does the facility check the evidence provided by subcontractors and suppliers as a means of verifying quality per the requirements of paragraph 2.10.1?	x		x		Reviewed incoming material inspection logs WSF-2.10, Rev.D to ensure purchased parts from subcontractors and suppliers were being completed per 2.10, para. 3.2, reviewed five pages of log books and all were completed per precedure	
2.10.3	Does the facility hold incoming items until the required inspection and tests are completed or the necessary inspection and test reports are received and verified (except when items are released under positive recall)?	x		x		At steel plate yard, verified heat numbers of three stock plate areas #H72762R1.0, #H730D9R1.3, #H49365R5.0 at shipping and receiving office reviewed MTRs for three heat numbers all were painted blue for okay to release to production per incoming inspection procedure	



• 2.21.4 Are internal audit results documented and do they include evidence of conformance and/or nonconformance of activities to specified requirements?

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How to Audit?

- Review audit records/reports
- Review objective evidence

Objective Evidence Examples:

 Completed checklist with objective evidence (pictures, notes, etc.)





• 2.21.5 Are the results of audits documented and brought to the attention of the personnel having responsibility in the area audited?

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How to Audit?

- Review documented procedure
- Interview personnel from various departments/areas

Objective Evidence Examples:

- Personnel included on meetings
- Personnel assigned tasks or signing off





• 2.21.6 Do management personnel responsible for audited areas with noted nonconformances take timely corrective action on the deficiencies per paragraph 2.6.2?

[2.6.2?]

• 2.6.2: The facility shall establish and maintain documented procedures for corrective action.

• 2.21.6 Do management personnel responsible for audited areas with noted nonconformances take timely corrective action on the deficiencies per paragraph 2.6.2?

How to Audit?

- Review timing of nonconformance responses
- Interview management personnel

Objective Evidence Examples:

 Nonconformance record - date stamp, sign off





- 2.21.7 Do follow-up actions:
 - Verify and record the implementation and effectiveness of the action(s) taken?



• 2.21.7 Do follow-up actions:

 Verify and record the implementation and effectiveness of the action(s) taken?

How to Audit?

- Review follow up documentation
- Follow up on corrective action

Objective Evidence Examples:

- Nonconformance record
- Observe corrective action implemented







Example of QAPE for 2.21

		Manual		Audit			
Paragraph	Element	Yes	No	Yes	No	Objective Evidence	
2.21	INTERNAL QUALITY AUDITS						
2.21.1	Does the facility conduct internal audits to verify compliance and effective implementation of their QAP?	X		X		Manual: Confirmed this requirement is covered in Section 21.A of XYZ Company's Quality Assurance Manual Audit: Reviewed audit records from past two years to confirm internal M-1003 audits are occurring.	
2.21.2	Does the facility schedule internal audits:						
2.21.2.1	On the basis of the status and importance of the QAP element?	X		X		Manual: Confirmed this requirement is covered in Section 21.A of XYZ Company's Quality Assurance Manual Audit: Yes, last internal M-1003 audit was performed 05/04/2023. The facility utlized the QAPE checklist which is located in their Audit Record Database	
2.21.2.2	Such that the internal audit encompasses a review of all 24 elements contained in Chapter 2 of this specification annually?	X		X		Manual: Confirmed this requirement is covered in Section 21.A of XYZ Company's Quality Assurance Manual Audit: Yes, the audits are scheduled annually. The last internal M-1003 audit was performed 05/02/23-05/04/23 and the one before was performed 05/03/22-05/05/22. The facility audited all 24 elements and utlized the QAPE checklist which is located in their Audit Record Database.	
2.21.3	Are internal audits performed in accordance with documented procedures (using appropriate checklists) by trained personnel who have the organizational freedom to document results?	X		X		Manual: Confirmed this requirement is covered in Section 21.B of XYZ Company's Quality Assurance Manual Audit: The internal M-1003 audit was performed by QA Manager "Auditor One"- see attached for AAR Advanced Auditor Certification. The Audit Procedure (QP-XX) requires use of the QAPE checklist: last year's completed QAPE checklist was reviewed and is attached in the Audit Record Database	

Resources:

AAR Quality Assurance Program Evaluation Checklist (QAPE)

• AAR MSRP Section J, Appendix D: Recommended Practice for

Internal Quality Auditing

