QHP202

AUDIT, INSPECTION, AND NON-CONFORMANCE POLICY AND PROCEDURES

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1. POLICY INTRODUCTION

A robust audit and inspection policy, with equally robust non-conformance procedures, are key parts of National Ambulance's commitment to QHSE and continual improvement. These allow the company, clients, shareholders, and regulatory bodies to monitor and verify the effective implementation of the QHSE Policy and correct deficits as they are found. They also provide a mechanism by which the company can be proactive with its improvements and controls, thus creating a safer and more efficient work environment.

This document has been developed in accordance with the principals set out in OSHAD – SF: Management System Elements, V3.1 - Element 8, and ISO 19011:2018- Guidelines for Auditing Management Systems.

This policy is relevant to the "Auditing and Inspections" management system component.

2. SCOPE

This policy applies to all personnel working on behalf of National Ambulance including staff, contractors, and visitors to National Ambulance managed sites. This is applicable for all business operations.

3. ROLES AND RESPONSIBILITIES

There are two distinct areas of responsibility – Clinical Audit under the responsibility of the Medical Director and Non Clinical Audit under the responsibility of the QHSE & BC Manager. Clinical Audit is explained in details in CGP148 Clinical Audit Policy and Procedure.

1. QHSE & BC Manager

- Identify and appoint personnel as Lead Auditor/Inspector in the event of a conflict of interest during an audit
- Ensure Lead auditor/inspector(s) is qualified
- Review investigations and ensure they are done in accordance with the established policy and procedures
- Establish the objectives and intent of the Auditing Program and process
- Understand the technical and business requirements for the activities that are going to be audited
- Establish the Auditing Procedures
- Establish the Roles and Responsibilities for the program
- Ensure that the company has sufficient competent resources to undertake the auditing program
- Ensure the implementation of the Auditing Program
- Ensure adequate records are kept
- Ensure that Senior Managers and other relevant stakeholders are updated on the results of auditing and subsequent Non-Conformances and Corrective Actions
- Monitor, review and improve the Auditing Program

2. Medical Director

- Provide ownership and oversight of Clinical Audits
- Ensure Lead auditor/inspector(s) is qualified
- Review clinical investigations and ensure they are done in accordance with the established policy and procedures
- Establish the objectives and intent of the Clinical Auditing Program and process
- Understand the technical and business requirements for the clinical activities that are going to be audited
- Establish the Clinical Auditing Procedures
- Establish the Roles and Responsibilities for the Clinical Auditing program
- Ensure that the company has sufficient competent resources to undertake the Clinical auditing program
- Ensure the implementation of the Clinical Auditing Program
- Ensure adequate Clinical audit records are kept
- Ensure that Senior Managers and other relevant stakeholders are updated on the results of Clinical audits and subsequent Non-Conformances and Corrective Actions

- Monitor, review and improve the Clinical Auditing Program

3. Managers

- Identify and appoint personnel independent of the activities being audited, as Lead auditor/inspectors
- Review Audit Reports

4. Lead Auditor/ Inspector

- Determine whether the QHP201 Risk Management Policy and Procedure is being followed in accordance with company requirements and within the scope of the specified audit
- Determine that the policy conforms to the international standards
- Lead and conduct an objective/non-biased audit in accordance with the audit specifications
- Determine whether the corrective actions implemented since previous audits conform to policy and are effective in mitigating any negative events
- Report findings and recommendations to the Managers

4. AUDIT AND INSPECTION PROGRAM

4.1. The National Ambulance Audit Program – Clinical and Non Clinical

- Encompasses all aspects of the organization with criteria established for the individual audit executed in order to establish benchmarks, identify non-conformances and hazards, and highlight areas for improvement
- Is the responsibility of the QHSE & BC Manager who may delegate the workload as appropriate. The QHSE & BC Manager ensures audits are appropriately resourced by coordinating with the appropriate individuals and departments. Additional roles and responsibilities are outline in QHP201 Risk Management Policy and Procedure
- Carried out by competent personnel taking into account the details of the specific audits
- Follows the Audit/Inspection Schedule
- Is reported to the Audit Owner as identified on the audit itself and is entered into the appropriate tab on the QHSE Report Register

4.2. The Annual Internal QHSE Management System Audit

- Takes into account applicable legislation, industry benchmarks, and the framework dictated by the QHSE Management System
- Systematically examines the QHSE Management System to determine whether activities and related results conform to planned arrangements. The audit shall determine whether these arrangements are implemented effectively and are suitable in achieving the policies and objectives
- Annual external third party compliance audits are performed by an OSHAD registered auditor
- Follows the Audit/Inspection Schedule
- Is reported internally to the Audit Owner as identified on the audit itself and is entered into the appropriate tab on the QHSE Report Register

4.3. The National Ambulance Inspection Program

- Encompasses all aspects of the organization with criteria established for the individual site
- Is executed in order to identify non-conformances, identify hazards, and highlight areas for improvement
- Is the responsibility of the QHSE & BC Manager who may delegate the workload as appropriate. The QHSE & BC Manager ensures inspections are appropriately resourced by coordinating with the appropriate individuals and departments

- Is carried out by competent personnel taking into account the details of the specific sites
- Follows the Audit/Inspection Schedule
- Is reported to the Audit Owner as identified on the audit itself and is entered into the appropriate tab in the QHF414 QHSE Suggestions, Risk Assessment & Audit Register and entered in task and reporting tracking system

4.3.1. Site Inspections

- Built based on JCI, ISO, DoH and MOI requirements
- Used as a tool either by leadership or individual staff
- Designed to ensure consistency across all sites to meet the required standards, control and mitigate hazard and risks, ensure staff and patient safety, and highlight areas for improvement
- Covers general safety, chemicals, hazard identification, fire safety, and infection control

4.3.2. Ride Alongs

- Conducted by leadership, QHSE, and education
- Looks at activities conducted during the course of the clinician's work
- Designed to ensure consistency across all sites to meet the required standards, control and mitigate hazard and risks, ensure staff and patient safety, and highlight areas for improvement

4.4. Security

- Security is looked at during audits and inspections to safeguard our staff, patients, and assets
- All operational staff are educated about the security measures associated with the ambulances, BLS bags/ALS bags, paper PCRs, store rooms, drug bags, and medication
- NA Head Quarters is located in Al Dar HQ, which has a tight security system to ensure staff security and documents / information confidentiality
- Warehouse is guarded by a security guard due to the nature of the goods held as detailed in PUP302 Warehouse Management Policy

4.5. Non Conformance and Corrective Action Plan

- Corrects non-conformities and takes actions to mitigate their consequences
- Investigates non-conformities according to the Investigation Procedure in QHP203 Hazard Near Miss and Incident Policy and Procedure or complete an Action Plan as appropriate
- Conducts a Root Cause Analysis
- Identifies and implements corrective actions to prevent non-conformities and avoid their reoccurrence if they do happen
- Entered in task and reporting tracking system

4.6. Root Cause Analysis

- Is an approach to determine the origin of a problem, incident, near miss or non conformance.
- Ensures addressing the real problem and not just a symptom of the problem.
- Should be used whenever there is an incident, near miss or non conformance. The level of detail within the RCA depends on the problem and its risk
- Is used to answer the below questions:
    1. Define the problem, gather data and evidence

2. Ask "why" and identify the causes
3. Identify corrective actions that will prevent recurrence of what occurred
4. Identify solutions that will prevent recurrence
5. Implement the recommended root cause corrections
6. Ensure effectiveness by observing the implemented solution

- Ideally, an RCA should be done with a cross functional team but conducted solo by the functional expert is also acceptable if it is also shared with the relevant parties for review or input
- RCA can be done on task and reporting tracking system or by filling and submitting the QHF225 Root Cause Analysis Form to QHSE

4.6.1. The 5 Whys

- The 5 Whys Technique is an iterative interrogative technique with the primary goal to determine the root cause by repeating the question "Why?"
- Ask why until the Root Cause is discovered
- Each answer forms the basis of the next question
- There may be more than 5 Whys or less than 5 Whys

4.7. The Audit Procedure

The audit procedure is outlined below and can be found in Figure 1. This format is to be followed for all audits though the scope of the specific audit will dictate the amount of time and effort required to adequately complete each step. Steps marked with ** below will often be omitted from smaller or focused audits.

Step One: Define the Audit Scope and Criteria

- A clear scope and criteria need to be documented prior to beginning the audit
- The audit scope should describe the extent and boundaries of the audit, such as physical locations, organizational units, activities and processes to be audited, as well as the time period covered by the audit.
- The audit criteria are used as a reference against which conformity is determined and may include applicable policies, procedures, standards, laws and regulations, management system requirements, contractual requirements or industry/business sector codes of conduct.
- This information must be clearly stated on the audit checklist/form

Step Two: Set the Frequency of the Audit

- Audits are scheduled on yearly, monthly, or weekly basis or as required
- Select the Audit dates and duration based on the complexity of operations, risk level, and location/departments to be audited
- Audit plan is shared with the audit client, and is revisited and reconfirmed in a suitable timeframe before the scheduled date

Step Three: Appoint a Lead auditor/inspector/ Audit Team Leader

Many audits will require multiple auditors to fully capture the information sought.

- The person that is appointed as the Lead Auditor/Inspector should be considered competent and also have the relevant technical knowledge of the task / process being audited

Step Four: Select the Audit Team (**)

- The audit team should be selected taking into account the competencies required by the tasks or activities being audited. The entity should also consider the independence of the audit team members for the tasks or activities

Step Five: Establish Contact with the Auditee

- To provide information on the proposed timing and audit team composition
- To ensure access to relevant documents and records
- To determine applicable site safety rules
- To make arrangements for the audit

Step Six: Conduct Document Review (**)

- Prior to the audit, the auditor should review any relevant documentation
- The document review should provide the auditor with information on the performance of the department, any non-conformances that were raised and other ongoing issues

Step Seven: Prepare the Audit Plan (**)

- An audit plan should be prepared for the audit that will facilitate the scheduling and coordination of auditing activities
- The plan should be agreed with the auditee prior to the on-site auditing starts
- Assign work to the Audit Team members

Step Eight: Prepare Auditing Documentation

- The auditor should ensure that all documentation required for the audit is available and reflects the agreed scope and criteria of the audit. In most cases this will simply be the audit checklist/form

Step Nine: Perform the Audit

- During the audit, information relevant to the audit scope and criteria, including information relating to interfaces between functions, activities and processes, is collected by appropriate sampling and verified. Only information that is verifiable may be audit evidence and should be recorded
- Each relevant procedure should be examined and supporting documentation should be made available as required by the procedure. The documentation should be examined to ensure it meets agreed standards
- Following the examination of the procedure and supporting documentation, there may be further scope to test the implementation of the procedure by viewing the actual practices. Compare what the procedure requires against what actually happens on site
- In general while conducting the audit, the auditors will need to interview various personnel on site. A good approach on interviewing is for the audit team to pose the same question to the supervisor and members of his team individually.
- The audit team should ask open-ended questions as interviews and observations during the site visits. This will provide evidence of strengths and weaknesses in the system

Step Ten: Prepare Audit Conclusions

- Following completion of the audit, the audit team should review the entire audit findings and agree on levels of non-conformity for any areas where non-compliance to the system has been identified
- The audit team should also agree on any follow up requirements

Step Eleven: Hold Closing Meeting

- On completion of the audit, a close out meeting should be held. The close out meeting can be a formal meeting that is recorded or an informal meeting that just communicates the results of the audit with the auditee. The Lead Auditor/Inspector should present an overview of the audit findings and also any major non-conformances that have been identified.

Step Twelve: Prepare Audit Report

The Audit Team prepares a full audit report that provides a complete, accurate, concise and clear record of the audit, and should include or refer to the following:

- The audit scope, particularly identification of the organizational and functional units or processes audited and the time period covered
- Identification of the audit client
- Identification of audit team leader and members
- The dates and places where the on-site audit activities were conducted
- The audit criteria
- The audit findings. An Action Plan is completed for any findings requiring correction and all non-conformances require a Root Cause Analysis. This is completed and tracked as outlined in the QHP201 Risk Management Policy and Procedure
- The audit conclusions

The final two points above are the most significant of those listed. In many cases, the majority of this information will be provided if the audit checklist/form is completely and accurately completed.

Step Thirteen: Approving and Distributing the Report

- All completed audits are logged into the QHF414 QHSE Suggestions, Risk Assessment & Audit Register. Each audit checklist/form identifies the owner of that specific audit. Upon completion, that owner must receive and acknowledge the audit.
- The distribution of the audit findings is also designated on the individual audit and the Lead Auditor/Inspector/Audit Team Leader ensures this is done at the conclusion of the audit. The findings are added in task and reporting tracking system under the QHSE Audit Findings.

Step Fourteen: Verify Corrective Actions Implementation

- An Action Plan, Root Cause Analysis, and corrective and preventative actions have to be completed by the audit client for any non-conformances
- These corrective actions should be revisited to determine whether they were implemented or not
- The non-conformances will remain open until the corrective actions provided are deemed to be implemented and satisfactory

4.8. The Inspection Procedure

The inspection procedure is nearly identical to the audit procedure. This format is to be followed for all inspections though the scope of the specific inspection will dictate the amount of time and effort required to adequately complete each step. Steps marked with ** below will often be omitted from smaller or focused inspections.

Step One: Define the Inspection Scope and Criteria

- A clear scope and criteria need to be documented prior to beginning the inspection
- The inspection scope should describe the extent and boundaries of the inspection, such as physical locations, organizational units, activities and processes to be inspected, as well as the time period covered by the inspection.
- The inspection criteria are used as a reference against which conformity is determined and may include applicable policies, procedures, standards, laws and regulations, management system requirements, contractual requirements or industry/business sector codes of conduct.
- This information must be clearly stated on the inspection checklist/form

Step Two: Set the Frequency of the Inspection

- Inspections are scheduled on yearly, monthly, or weekly basis or as required
- Select the inspection dates and duration based on the complexity of operations, risk level, and location/departments to be inspected
- Inspection plan is shared with the inspection client, and is revisited and reconfirmed in a suitable timeframe before the scheduled date

Step Three: Appoint an Inspection Team Leader/Lead Inspector

Many inspections will require multiple inspectors to fully capture the information sought.

- The person that is appointed as the Lead Inspector should be considered competent and also have the relevant technical knowledge of the task / process being inspected

Step Four: Select the Inspection Team (**)

- The inspection team should be selected taking into account the competencies required by the tasks or activities being inspected. The entity should also consider the independence of the inspection team members for the tasks or activities.

Step Five: Establish Contact with those responsible for the area/asset being inspected

- To provide information on the proposed timing and inspection team composition
- To ensure access to relevant documents and records
- To determine applicable site safety rules
- To make arrangements for the inspection

Step Six: Conduct Document Review (**)

- Prior to the inspection, the inspector should review any relevant documentation
- The document review should provide the inspector with information on the performance of the target of the inspection, any non-conformances that were raised and other ongoing issues.

Step Seven: Prepare the Inspection Plan (**)

- An inspection plan should be prepared for the inspection that will facilitate the scheduling and coordination of inspecting activities.
- The plan should be agreed with the responsible party prior to the on-site inspection starts
- Assign work to the Inspection Team members

Step Eight: Prepare Inspection Documentation

- The inspector should ensure that all documentation required for the inspection is available and reflects the agreed scope and criteria of the inspection. In most cases this will simply be the inspection checklist/form

Step Nine: Perform Inspection

- During the inspection, information relevant to the inspection scope and criteria, including information relating to interfaces between functions, activities and processes, is collected by appropriate sampling and verified. Only information that is verifiable may be inspection evidence and should be recorded.
- Each relevant procedure should be examined and supporting documentation should be made available as required by the procedure. The documentation should be examined to ensure it meets agreed standards.
- Following the examination of the procedure and supporting documentation, there may be further scope to test the implementation of the procedure by viewing the actual practices. Compare what the procedure requires against what actually happens on site.
- In general while conducting the inspection, the inspectors will need to interview various personnel on site and look at assets. A good approach on interviewing is for the inspection team to pose the same question to the supervisor and members of his team individually.
- The inspection team should ask open-ended questions as interviews and observations during the site visits will provide evidence of strengths and weaknesses in the system

Step Ten: Prepare Inspection Conclusions

- Following completion of the inspection, the inspection team should review the entire inspection findings and agree on levels of non-conformity for any areas where non-compliance to the system has been identified.
- The inspection team should also agree on any follow up requirements

Step Eleven: Hold Closing Meeting

- On completion of the inspection, a close out meeting should be held. The close out meeting can be a formal meeting that is recorded or an informal meeting that just communicates the results of the inspection with the responsible person. The Lead Inspector should present an overview of the inspection findings and also any major non-conformances that have been identified.

Step Twelve: Prepare Inspection Report

The Inspection Team prepares a full inspection report that provides a clear complete, accurate, concise and clear record of the inspection, and should include or refer to the following:

- The inspection scope, particularly identification of the organizational and functional units or processes inspected and the time period covered
- Identification of the inspection client
- identification of inspection team leader and members
- The dates and places where the on-site inspection activities were conducted
- The inspection criteria

- The inspection findings. An Action Plan is completed for any findings requiring correction and all non-conformances require a Root Cause Analysis. This is completed and tracked as outlined in the QHP201 Risk Management Policy and Procedure
- The inspection conclusions

The final two points above are the most significant of those listed. In many cases, the majority of this information will be provided if the inspection checklist/form is completely and accurately completed.

Step Thirteen: Approving and Distributing the Report

- Inspection checklist/form identifies the owner of that specific inspection. Upon completion, that owner must receive and acknowledge the inspection.
- The distribution of the inspection findings is also designated on the individual inspection and the Lead Inspector/Inspection Team Leader ensures this is done at the conclusion of the inspection.

Step Fourteen: Verify Corrective Actions Implementation

- An Action Plan, Root Cause Analysis, and corrective and preventative actions have to be completed by the inspection client for any non-conformances
- These corrective actions should be revisited to determine whether they were implemented or not
- The non-conformances will remain open until the corrective actions provided are deemed to be implemented and satisfactory

5. RELEVANT LEGISTLATION

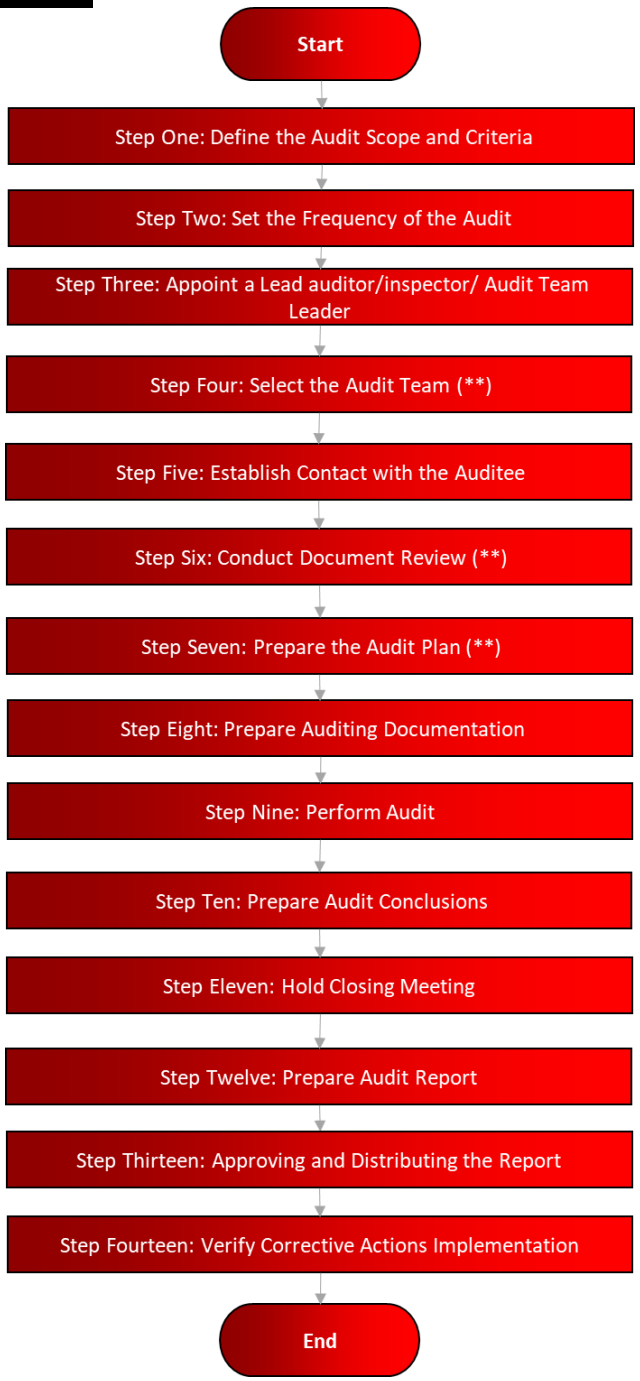
International, federal or local legislation and circulars relevant to this Policy. Full detail on this legislation can be found in QHP109 Legal Register.

Code, Name of Legislation	Jurisdiction
in OSHAD – SF: Management System Elements, V3.1 - Element 8, and ISO 19011:2018- Guidelines for Auditing Management Systems	Abu Dhabi

6. KEY PROCESSES

6.1. AUDIT PROCESS

The Audit Process
QHSE



6.2. INSPECTION PROCESS

The Inspection Process
QHSE

7. RELATED POLICIES AND FORMS

List related policies and procedures to the created/updated policy.

Policy & Procedure /Form
CGP148 Clinical Audit Policy and Procedure
QHP201 Risk Management Policy and Procedure
QHP203 Hazard Near Miss and Incident Policy and Procedure
QHF225 Root Cause Analysis Form

8. FEEDBACK

Any feedback or suggestions for improvement to this Policy, Processes or Procedures can be submitted to ghse@nationalambulance.ae

9. DOCUMENT CONTROL AND OWNERSHIP

A review and update of this document will take place as necessary, when changes occur that identify the need to revise this Policy such as changes in roles and responsibilities, release of new legislative or technical guidance, or identification of a new policy area.

This document ownership for editing is identified as:

- QHSE & BC Manager

Change Brief

Version No.	Date	Change
2.0	27-6-2013	A Process for Action Plan with ASANA
3.0	18/7/2013	Addition of role of Chief Medical Advisor
4.0	January 2016	Due to review, no changes
5.0	November 2019	Add Step Two: Schedule the Inspection, Add Step Fourteen: Verify Corrective Actions Implementation, add Step Fourteen: Verify Corrective Actions Implementation, removal of DPE, addition of QHF414 QHSE Suggestions, Risk Assessment & Audit Register and task and reporting tracking system use, add 4.3.1. Site Inspections, add 4.3.2. Ride Along, add 4.4 Security, add RCA Change Asana to Task and Reporting Tracking System

CEO Approval

Board Member Verification