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| **Approved by: Managing Director**  آرم پايش سلامت  **PSA**  **Document Title :** Internal Audit Procedure  **Document Code:QSP-PSA-8.6**   |  | | --- | | **The online version of this document is the latest version; all printed material is uncontrolled. It is the reader’s responsibility to check that printed copies are the current version.** |  |  |  |  | | --- | --- | --- | | **Date of Approval** | **Description of changes** | **Version number** | | **April** | **First edit** | **#1** | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |

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| Code: **QSP-PSA-8.6**  February 2019  **1-Objective and Scope**  **The purpose of this procedure is to provide an independent and systematic review to ensure that activities related to the quality management system and its results are effectively implemented with planned arrangements, and to achieve goals and policy are appropriate, as well as ensuring the effectiveness of corrective and preventive actions following these audits.**  **The scope of the procedure is the internal audit of the entire quality management system, based on the ISO / IEC 9001 standard and the standard ISO / IEC17065 in the corporation, and subsequent corrective and preventive actions.**  **2- Definition:**  **Audit is a systematic, independent and written process for the collection of audit evidence and its objective assessment, in order to determine the extent to which audit criteria are met.**  **3-Records**  **1-3-** **Corporate Quality Management Standard ISO/IEC 9001**  **2-3 ISO/IEC 17065**  **4-Method**  **Responsibility**  **-The P M is responsible for planning, organizing, directing and controlling the internal audit,with external company**  **-The request for corrective action is on the senior auditor, it is the responsibility of each auditor to determine any nonconforming and to prepare the relevant reports. In this regard, the auditors have full discretion to receive all required document copies from related unit.**  **All personnel of the corporation are responsible for cooperation with internal auditors.**  **-Follow-up of the effectiveness of corrective actions is the responsibility of the management representative.**  **1-4- Planning**  **Internal audit in the Corporation is organized and planned by the annual P M according to the annual planning of the audit .**  **2-4 Planned audits**  **An annual audit will be conducted and will be prepared by the P M of Audit for any audit and will be approved by the CEO. The program includes an internal audit plan in which individuals and requirements that are to be audited are identified with regard to the importance of the activities and results found in previous audits, along with the timing of audits, individuals and Activities that are audited should be communicated to the auditor at least a week before by the technical director on the audit history, scope, and sources that the auditors need. In planning, the type and scope of the audit are also specified.**  **The senior auditor with the opinion and approval of the technical director, based on activities to be audited, as well as the standard demands, organize audits and determines what activities each auditor should audit, it should be noted that the PM himself is selected as auditor.**  **3-4 Super Audit**  **PM Based on Management Review, Customer Complaints, Acute Problems and Audit Results of the previous period can audit the entire management system, or part of it, outside the specified audit period, to plan and execute this audit, such as period audits It will be.**  **4-4 audit method**  **Auditors must obtain credible indications or evidence to demonstrate that the management system is designed and implemented in a manner that is in accordance with the implementation procedures, the requirements of ISO 9001 and customer requirements, and is sufficiently effective.** **It should be noted that the audit is conducted on the basis of interview, observation and test in a random manner.** **The audit team, based on the documentation, also verifies the accuracy of equipment and manpower in accordance with the requirements of ISO 9001 and ISO , and during the audit, the representative of the audited entity under the title of the audit team is to facilitate the audit Process and explain observations.**  **4-5 Senior audit**  **He has been selected by the technical manager as a senior who, in addition to his academic ability and personal qualities, should have the necessary experience.**  **Gradually, with the opinion and approval of the technical director, they will be selected from those who have completed the internal audit period. The technical director and senior auditor, on the basis of the set planning, elects auditors from among persons who are not directly responsible for the field of audit. The technical director must ensure that the audit team has been selected and selected among those who have received the necessary training and have individual abilities (realism, judgment), and it should be noted that these auditors can use the auditors Qualify from outside.**  **6-4 Reports and Documents**  **The auditors record the reports of each audit in the form of an internal audit report system with the F-L-50 code, and will be given to the technical director in the end to provide a basis for tracking possible noncompliance. If any non-compliance is detected during the audit, all relevant evidence is carefully checked and full details of the noncompliance or defect are recorded in the form of the necessary steps to resolve internal audit noncompliance with the FL-47 code so that they can take action Corrected After completing the form, the necessary actions are taken to resolve internal audit inconsistencies with the F-L-47 code. The form is signed by the auditor and the person responsible for the audited entity. Then, the responsible audited or audited entity is required to determine the root causes of the noncomliance found. After determining the root causes of the lack of conformity, appropriate corrective action is taken to remove the root causes of the lack of conformity by the accredited or audited entity and recorded in the form, and finally, together with evidence, carry out corrective action to address the root causes Non-conformance shall be sent to the technical director in order to determine the effectiveness of the corrective action. If the corrective action is effective, the form will be archived to the management representative. It should be noted that if the corrective action is not carried out, the technical director, in accordance with the procedure of corrective action and preventive action, requests the corrective action to remove the root causes of non-compliance.**  **7-4- Audit reports**  **The technical director, after conducting the audit, provides an analytical report for use in subsequent audit programs and plans at the management review meetings.**  **Note: If the findings of the audit make any doubts about the effectiveness of the operation or the availability or validity of the results of the performance, the corrective action will be determined by the technical director and timely adopted, if the investigation indicates that the company's performance may be affected. They are communicated to the customer by the management representative in writing.**  **5.** The PSA shall have a written procedure to confirm annually that every auditor and all PSA personnel involved with  conformity assessment services are qualified and competent as described in Annex B and registered with the ASC as required.  a) This procedure shall include:  i. Regular performance evaluation of PSA personnel involved in the ASC conformity assessment activities  ii. Regular calibration sessions to ensure consistent practice among auditors and other PSA personnel.  b) The CAB shall keep records of all training and calibration sessions including a record of the individuals that participated  **6-Form**  **1) Internal audit checklist PSA**  **2)** **Audit Planning Form**  **3)** **Annual audit scheduling**  **4)** **The form of action required to resolve internal audit nonconformance**  **6) Internal quality audit report form**  **7) Internal audit checklist ASC**  **8) Internal audit checklist MSC** |