

Accreditation Program for Quality Control Service Providers of X-ray Medical Equipment - General Requirements and Guidance



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Foreword

The Accreditation Program for Quality Control Service Providers of X-ray medical equipment - General Requirements and Guidance, has been issued by the Middle East Federation of Organizations of Medical Physics (MEFOMP).

Questions or comments concerning this document should be submitted to MEFOMP, Chairman of MEFOMP Accreditation Committee: e-mail: admin@mefomp.com.

Middle East Federation of Organizations of Medical Physics (MEFOMP)
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1. General information

1.1. Purpose and scope

The Accreditation Program for Quality Control Service Providers of X-ray Medical Equipment - General Requirements and Guidance, henceforth refer to as Handbook, describes the framework under which the Quality Control Service Provider (QCSP) Accreditation Program operates as an unbiased third party to accredit QCSPs of medical diagnostic equipment.

This Handbook and the program-specific on-site assessment checklist, constitute the collective body of requirements that must be met by a QCSP seeking MEFOMP accreditation in a specific QCSP Accreditation Program.

This Handbook is for use by accreditation bodies as a basis upon which to judge the competence of a QCSP applying for accreditation.

If a QCSP fulfills the requirements of this Handbook, it meets management system requirements that are necessary for the QCSP to consistently deliver technically valid results.

1.2. Organization of Handbook

This Handbook describes considerations that relate to the accreditation process, including arrangements for granting, maintaining, extending, reducing, suspending and withdrawing accreditation.

1.3. References

The following documents are referenced in the text or notes of this Handbook:

ISO 9001, Quality management systems—Requirements, 2015

ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories, 2017

NIST Handbook 150, National voluntary laboratory accreditation program, Procedures and general requirements, 2006

ACR, American College of Radiology CT Accreditation Program, Testing Instructions, 2018

1.4. Terms and definitions

Acceptance Testing: Acceptance is undertaken by a representative of the purchaser, to verify that the contractor has supplied all the equipment specified and has performed adequate tests to demonstrate that the specified requirements in the contract have been met. Acceptance for the case of X-ray equipment involves numerous test procedures which are performed by the medical physics staff, alone or in collaboration with qualified staff assigned by the contractor (e.g. field service engineers). These procedures are usually described with the general term Quality Control (QC) or Quality Assurance (QA). Any significant discrepancy should be notified formally to the contractor, who should be required to undertake corrective action. Mechanical and electrical safety tests are required by biomedical engineering department in addition to radiation safety tests performed by the radiation protection office.

Accreditation: Formal recognition that a QCSP is competent to carry out QC tests for X-ray medical equipment.

Approved Signatory: An individual who is designated by an accredited QCSP and deemed competent by MEFOMP to sign Quality Control (QC) reports. The Approved Signatory is responsible for the technical content of the QC reports and is the contact person for questions or problems with these reports. Approved Signatories have responsibility, authority and technical capability within the QCSP for the QC reports produced.

APQS: Accreditation Program for Quality control Service provider established and administered under MEFOMP.

Assessment, on-site: Systematic, independent, documented process for determining QCSP competence and for obtaining records, statements of fact or other relevant information by MEFOMP assessors at the QCSPs where quality control services are provided with the objective of determining the extent to which MEFOMP requirements are met.

Authorized Representative: Individual who is authorized by QCSP top management to carry out all necessary actions to fulfill the MEFOMP accreditation requirements. The Authorized Representative reports to MEFOMP changes that may affect the QCSP's capability, scope of accreditation, or compliance with accreditation requirements.

Baseline: The value of a parameter, which is determined at the commissioning of an imaging system, against which the results of subsequent routine QC tests can be compared. At the end of the commissioning, a complete series of QC tests (Status or Constancy test) are performed to establish the baseline values which would be used as benchmarks in the subsequent periodic QC tests or status tests performed after important service intervention on the equipment (e.g. x-ray tube and imaging detector change, software upgrade). Thus, baseline values are used to determine whether there is any change in the performance of the equipment over time. The baseline term also applies to the case where existing equipment, for which there are no commissioning results available, is tested for the first time at the start of a program of routine performance testing.

Certificate of Accreditation: Document issued by MEFOMP to a QCSP that has been granted MEFOMP accreditation. A Certificate of Accreditation is always issued with a Scope of Accreditation.

Commissioning: Commissioning includes all the setups and measures necessary to prepare the machine for the clinical activity. Therefore, it includes but it is not limited to Acceptance Testing. Commissioning should be performed by a multidisciplinary team, including radiologist, technologist and medical physicist. Clinical examination protocols provided by the manufacturer should be analyzed and adapted to the department needs and clinical practice. Not used protocols that have been replaced with others should be deleted. The extension of this phase depends on the complexity of the equipment and clinical practice. Phantoms and dose measurements can be used to test examination protocols prior their use on patients.

Competence: Ability of a QCSP to conduct tests and perform QC tests in accordance with the specified standards and to produce accurate, proper, fit for purpose, technically valid data and test results.

Customer: Any Health facility that engages the services of a QCSP.

Level of expertise: Staff who undertake equipment tests must be suitably trained. Two levels of expertise are identified:

- **Level A:** Applicable to the more frequent tests which are generally quick and simple pass/fail tests which do not require sophisticated test equipment or detailed analysis. These tests are likely to be undertaken by the radiographic staff of a radiology department. Therefore, the radiographic staff involved with such tests, must receive proper training regarding the way that these tests are performed, the pass/fail limits and the way of documenting/reporting the test results. The course of actions after a fail result must be clearly defined within the context of written rules regarding the management of such cases.
- **Level B:** Applicable to less frequent, more analytical tests requiring greater equipment resources and expertise. These are most likely to be undertaken by medical physics staff or specially trained radiographers but may also be undertaken by service engineers or other staff external to the radiology department, provided that they have the proper degrees/certificates which prove their expertise in this field.

Maintenance: Maintenance and routine performance testing are complementary. Equipment has to be maintained to ensure that it is safe to use and that it is working properly, which means that the performance according to machine specifications, which was demonstrated at commissioning, continues to be achieved during the working life of the equipment. Service contractors should be able to demonstrate that they undertake appropriate tests to regularly check the performance against the specifications. Departments can use the results of their own routine performance testing program to audit the service contract. It is important that engineers should feedback the results of any testing or servicing they undertake, particularly if they could affect the clinical image quality and radiation dose. An additional critical examination/commissioning phase may be necessary when the machine has been subject to modification, maintenance, reinstallation or repair.

Physical parameter: The variable to be measured

Priority: The priority for routine performance tests are denoted as:

- **Priority 1:** represents the recommended minimum standard. Conformance to this standard of testing would be regarded as good practice.
- **Priority 2:** The inclusion of this level of testing would be regarded as best practice. However, it is recognised that the level of implementation of priority 2 tests may be influenced by the equipment characteristics, clinical workload or other factors.

QCSP (Quality Control Service Provider): Organization that performs QC tests of X-ray medical equipment. When a QCSP is part of an organization or corporation that carries out activities additional to quality control, the term QCSP refers only to those parts of that organization or corporation that are involved in the quality control process.

Quality control equipment: All the measuring instruments, measurement standards, reference materials, auxiliary apparatuses and instructions that are necessary to perform a measurement.

Remedial level: A level of performance at which remedial action needs to be initiated. This action will be based on a formal assessment of the equipment's performance and of the risk arising from its continued use. Following this assessment, agreement should be reached on a reasonable timescale for corrective action to be undertaken and on any specific restriction placed on the continued use of the equipment. Additional, more thorough and accurate measurements may be necessary to determine the exact cause of the change in performance. These actions should be recorded.

Routine QC tests: Routine QC tests (also referred to as Constancy or Status tests) comprises those performance tests which are undertaken either regularly or after maintenance or repairs, to detect whether any change in the performance of the equipment has occurred; if so, corrective action can be initiated. Routine performance tests are really a sub-set of the commissioning tests. Generally, routine QC testing will involve both internal and external staff. Internal staff necessarily undertake the frequent tests which are quick to perform and external staff undertake the more time-consuming tests which may require special expertise and instrumentation. As many of these tests have implications for radiation safety, they are usually undertaken under the auspices of the user's radiation protection office. This also provides a measure of independence from the user and the maintenance contractor. These tests may also be undertaken by service engineers or other external agency, which however must have the required level of expertise and be independent from the company in charge of maintenance to avoid any possible bias. A collaborative, multidisciplinary approach to routine performance testing is essential. The routine performance testing is required: a) annually b) after reinstalling a new tube c) after relevant service (generator, detectors, software upgrade etc).

1.5. Confidentiality

To the extent permitted by applicable laws, MEFOMP will protect the confidentiality of all information obtained relating to the application, on-site assessment, proficiency testing, evaluation and accreditation of QCSPs.

2. Establishment of Accreditation Program for Quality control Service provider (APQS)

2.1. Basis for establishment

MEFOMP establishes APQS's in response to legislative or administrative actions or to requests from government agencies and private sector entities.

2.2. APQSS established by request

A request to introduce an APQS must be made in writing to the Chairman of MEFOMP. Each request must include:

- The scope of the APQS in terms of QC tools and testing services proposed for inclusion
- Identification of the medical x-ray equipment for which QC testing will be conducted
- An estimate of the health facilities in which QC services will be conducted

MEFOMP may request clarification of the information submitted in the request.

The Chairman of MEFOMP Accreditation Committee analyzes the request and any supporting information received and after consultation with interested parties through public workshops and other means to ensure open participation, determines if there is need for the accreditation.

2.3. Adding to or modifying an APQS

An APQS may be added to, modified or realigned based on either a written request to MEFOMP or by MEFOMP itself. Any person or organization wishes to add or delete specific tests or type of x-ray equipment that should be required to undergo QC testing, QC equipment required or standards, may submit a request to MEFOMP.

2.4. Termination of a QCSP accreditation

The Chairman of MEFOMP Accreditation Committee may terminate the accreditation of a QCSP, when significant deviations from accreditation requirements have been occurred.

Accreditations previously granted remain effective until their expiration date unless terminated voluntarily by the QCSP or by MEFOMP.

3. Accreditation process

3.1. Application for initial accreditation

General

A QCSP may apply for accreditation to MEFOMP. In order to initiate the accreditation process, the applicant QCSP shall submit a completed application along with a QC manual and relevant associated documentation, agree to conditions for accreditation and pay all required fees.

Required information

An applicant QCSP shall complete an application for accreditation that includes, but is not limited to, the following information:

- The legal name and full address of the QCSP
- The ownership of the QCSP
- The Authorized Representative's name and contact information
- The names, educational titles and certificates, and contact information for QCSP staff nominated to serve as approved signatories of QC reports
- A general description of the QCSP, including its departments and scope of operation
- An organizational chart defining departments of the QCSP and relationships that are relevant to the QCSP covered in the accreditation request
- In addition to the application for accreditation, the QCSP shall provide its policy and related management system documentation to MEFOMP for review

Conditions for accreditation

By signing the application, the QCSP's Authorized Representative commits the QCSP to fulfill the conditions for accreditation. The Authorized Representative should review all documents provided with the application package and become familiar with MEFOMP requirements before signing the application.

Fees for accreditation

MEFOMP is a non-profit organization whose main purpose is the promotion of medical physics in the Middle East Countries through education and training of its members. It provides services to QCSPs under a certain fee to support its operational costs.

The fee may vary depending on the scope(s) and other economical or social factors related to the QCSP. The fees for the initial accreditation will be agreed between the MEFOMP and each QCSP candidate for accreditation, at the application stage taking into consideration these factors. The accreditation renewal fee and fees for modifications (e.g. for scope addition) will be also agreed between MEFOMP and each QCSP following the same basic principles.

Review of application

Upon receipt of a QCSP's application for accreditation, MEFOMP assigns a MEFOMP Code to the applicant QCSP; acknowledges receipt of the application in writing; reviews the information supplied by the QCSP for adequacy; requests further information, if necessary; confirms payment of fees; and specifies the next step(s) in the accreditation process.

3.2. Activities prior to on-site assessment

Assignment of assessor(s)

MEFOMP selects assessors on the basis of their professional and academic achievements, experience in the field of quality control, training, technical knowledge and communications skills.

MEFOMP assigns qualified assessors to evaluate all information collected from an applicant QCSP and to conduct the assessment on its behalf at the QCSP and any other sites where activities to be covered by the accreditation are performed.

Document review

The MEFOMP assessor may identify nonconformities in the documentation. Nonconformities are discussed with the Authorized Representative and the QCSP is given the opportunity to address them prior to the on-site assessment. Based on the document review, MEFOMP may require that the QCSP address the nonconformities before the on-site assessment is scheduled. In such cases, the assessor will provide a list of the nonconformities to the QCSP in writing. Where the management system documentation requires significant revision, MEFOMP

may require that the QCSP improve its documentation and submit it for further review prior to proceeding with the accreditation process.

Scheduling of on-site assessment

The QCSP is contacted by the assessor to schedule a mutually acceptable date for the on-site assessment. An assessment normally takes two to five days, depending on the proposed scope of accreditation. Every effort is made to conduct an assessment with as little disruption as possible to the normal operations of the QCSP.

If a QCSP requires a change of its established assessment date, it shall contact the assessor(s) and MEFOMP. The QCSP is responsible for any costs associated with the date change.

Following initial accreditation, an on-site assessment will be conducted during the renewal of accreditation procedure (every three years).

3.3. On-site assessment

Conduct of on-site assessment

Assessors use checklists provided by MEFOMP so that each QCSP receives an assessment comparable to that received by others.

At the beginning of the assessment, an opening meeting is conducted with management and QCSP personnel to explain the purpose of the on-site assessment and to discuss the schedule for the assessment activities.

During the assessment, the assessor examines the management system, reviews quality and technical records, examines quality control tools and calibration certificates, interviews staff, observes demonstrations of preparation of reports and archiving system, and examines tests, remedial actions and QC reports.

In order to conduct an appropriate assessment of competence, the assessor requires access to QCSP records for all staff members who routinely perform or affect the quality of the QC testing for which accreditation is sought. This includes resumes, job descriptions of key personnel, training and continuous professional development (CPD), and competency evaluations. The assessor should not be given information that violates individual privacy, such as salary and medical information. The staff information may be kept in the QCSP's official personnel folders or in separate folders that contain only the information that the MEFOMP assessor needs to review.

At the conclusion of the assessment, the assessor conducts a closing meeting to discuss observations and any nonconformities with the Authorized Representative and other responsible QCSP staff.

On-site assessment report

At the closing meeting of the on-site assessment, the assessor submits a written report on the compliance of the QCSP with the accreditation requirements. The report shall include as a minimum:

- a) date(s) of assessment
- b) the names of the assessor(s) responsible for the report
- c) the assessed scope of accreditation
- d) comments and/or nonconformities cited by the assessor(s) on the compliance of the QCSP with the accreditation requirements
- e) a copy of completed checklists

The Authorized Representative signs the report to acknowledge that the assessor has discussed its content and agrees to respond to MEFOMP regarding resolution of any nonconformities within 60 days.

The assessor forwards the original report to MEFOMP and leaves a copy with the QCSP.

Nonconformity notification and resolution

A QCSP is informed of any nonconformities observed during the on-site assessment, which should be described and documented in the on-site assessment report.

A QCSP shall respond in writing to MEFOMP within 60 days of the date of the on-site assessment report, addressing all documented nonconformities. The response shall be signed by the Authorized Representative and shall include documentation that the specified nonconformities have either been corrected or will be corrected as described in a plan of corrective actions. A corrective action plan must include a list of actions, expected completion dates and names of persons responsible for discharging each of these actions.

All nonconformities shall be satisfactorily resolved before initial accreditation may be granted. Should resolution take longer than 60 days, the QCSP may submit a corrective action plan in its initial response and

provide evidence of resolution when the planned actions have been completed. At that time, MEFOMP will continue with the accreditation process.

Once accreditation has been granted, nonconformities affecting the outcome of QC tests, such as out-of-date calibration certificates of equipment, shall be addressed and corrected within the 60-day limit. Evidence shall be supplied which clearly demonstrates that the actions taken have fully resolved the nonconformities, thereby removing any concern as to the reliability of the QC tests results conducted by the QCSP. Should resolution take longer than 60 days, the QCSP's accreditation may be subject to adverse action. In those cases where nonconformities do not directly affect the results of QC tests, such as those related to record-keeping, MEFOMP, at its discretion, may accept a plan of corrective action as satisfactory resolution.

When this occurs, QCSP is expected to submit sufficient objective evidence to demonstrate that the nonconformities have been resolved according to the plan, within 2-months from the accreditation date.

When responding to nonconformities, a QCSP shall reference each nonconformity by the item number shown on the on-site assessment checklist forms.

3.4. Accreditation decision

The Chairman of MEFOMP Accreditation Committee is responsible for all MEFOMP accreditation actions, including granting, renewing, suspending and terminating any MEFOMP accreditation.

The accreditation decision is based on MEFOMP review of information gathered during the accreditation process and a determination of whether or not all requirements for accreditation have been fulfilled.

The evaluation process considers the QCSP's record as a whole, including:

- a) information provided on the application
- b) results of management system documentation review
- c) on-site assessment reports
- d) actions taken by the QCSP to correct nonconformities

Based on this evaluation, MEFOMP determines whether or not a QCSP should be accredited. If the evaluation reveals nonconformities beyond those identified in the assessment process, MEFOMP will inform the QCSP in writing of the nonconformities, and the QCSP shall respond as specified in *Nonconformity notification and resolution* section. All nonconformities must be resolved to MEFOMP's satisfaction before accreditation can be granted.

3.5. Granting accreditation

Initial accreditation is granted when a QCSP has met all MEFOMP requirements. The renewal period is three years; accreditation expires and is renewable on the assigned date.

Renewal dates may be reassigned to provide benefits to the QCSP and/or MEFOMP. If a renewal date is changed, the QCSP will be notified in writing of the change and any related adjustment in fees.

When accreditation is granted, MEFOMP provides to the QCSP a Certificate of Accreditation and a Scope of Accreditation, which includes:

- a) the name and address of the QCSP that has been accredited
- b) the scope of the accreditation, including the QC tests for all or specific types of diagnostic X-ray medical equipment (like CT, Mammography,) for which accreditation has been granted
- c) the effective and the expiration dates of the accreditation

3.6. Renewal of accreditation

The validity of the initial accreditation is three years.

Each accredited QCSP receives a renewal application before the expiration date of its accreditation to allow sufficient time to complete the renewal process.

Renewed accreditation will also have a validity of three years.

Fees for renewal are charged according to the services required. Both the application and fees must be received by MEFOMP prior to expiration of the QCSP's current accreditation to avoid a lapse in accreditation.

3.7. Monitoring visits

In addition to regularly scheduled assessments, monitoring visits may be conducted by MEFOMP at any time during which a QCSP holds a valid accreditation. These visits may occur either because of a certain reason or on

a random selection basis. While most monitoring visits will be scheduled in advance with the QCSP, MEFOMP may conduct unannounced monitoring visits. No fees are charged to the QCSP for monitoring visits.

The scope of a monitoring visit may range from checking a few designated items to a complete review. The assessors may review QC reports; verify reported changes in the QCSP's personnel, QC instruments or procedures of QC tests when appropriate.

3.8. Changes to scope of accreditation

A QCSP may request in writing changes to its scope of accreditation. If the QCSP requests additions to its scope, it must meet all MEFOMP requirements for the additional new types of X-ray equipment or additional tests or adoption of new remedial levels. A QCSP may also request deletions from its scope of accreditation. The deletions may be temporary or permanent.

3.9. Suspension of accreditation

If it is determined that an accredited QCSP does no longer comply with the conditions for accreditation, MEFOMP may suspend the QCSP's accreditation. That determination may be made by MEFOMP (e.g. based on evidence obtained during the renewal assessment process or during a monitoring visit) or by the QCSP itself (e.g. by notifying MEFOMP of a major change). Suspension can be for all or part of a QCSP's accreditation. Depending on the nature of the issues involved, MEFOMP may also consider terminating accreditation.

If a QCSP's accreditation is suspended, MEFOMP notifies the QCSP of that action, stating the reasons for and conditions of the suspension and specifying the action(s) the QCSP must take to have its accreditation reinstated. A reassessment of the QCSP may also be required for reinstatement.

3.10. Voluntary termination of accreditation

QCSP may at any time terminate its participation and responsibilities as an accredited QCSP by informing MEFOMP in writing of its desire to do so.

4. Management requirements for accreditation

4.1. Organization

The QCSP or the organization of which it is part, shall be an entity that can be held legally responsible.

It is the responsibility of the QCSP to carry out its quality control activities, so as to meet the requirements of MEFOMP accreditation and the regulatory authorities, and satisfy the needs of the customers.

If the QCSP is part of an organization performing activities other than QC testing, the responsibilities of key personnel in the organization which have an involvement or influence on the quality control activities of the QCSP shall be defined in order to identify potential conflicts of interest.

The QCSP shall:

- have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results
- define the organization and management structure of the QCSP, its place in any parent organization, and the relationships between quality management and support services
- specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the QC tests
- provide adequate supervision of QC testing staff, by persons familiar with methods and procedures, purpose of each test and with the assessment of the quality control results
- have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of QCSP operations
- appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on QCSP policy or resources

4.2. Management system

- The QCSP shall establish, implement and maintain a management system appropriate to the scope of its activities. The QCSP shall document its policies, systems, programs, procedures and instructions to the

- extent necessary to assure the quality of the QC test results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.
- The QCSP's management system policies related to quality, including a quality policy statement, shall be defined in a "quality manual" document. The overall objectives shall be established and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:
 - a) the QCSP management's commitment to good professional practice and to the quality of its testing in servicing its customers
 - b) the purpose of the management system related to quality
 - c) a requirement that all personnel concerned with quality control activities within the QCSP familiarize themselves with the quality documentation and implement the policies and procedures in their work, and
 - d) the QCSP management's commitment to comply with this Handbook and to continually improve the effectiveness of the management system.
 - Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness.
 - The quality manual shall include or refer to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.
 - Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

4.3. Document control

General

The QCSP shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test methods, as well as software, specifications of tools, instructions and manuals.

In this context "document" could be policy statements, procedures, specifications, calibration certificates, tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

Document approval and issue

All documents issued and distributed to QCSP personnel as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

The procedure(s) adopted shall ensure that:

- a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the QCSP are performed
- b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements
- c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use
- d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

Management system documents generated by the QCSP shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document and the issuing authority(ies).

Document changes

Changes to documents shall be reviewed and approved using the same procedures as for the original document. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

If the QCSP's document control system allows for the amendment of documents by hand pending the reissue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally reissued as soon as practicable.

4.4. Complaints

The QCSP shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the QCSP.

4.5. Improvement

The QCSP shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.6. Corrective action

General

The QCSP shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when a faults or departures from the policies and procedures in the management system or technical aspects, have been identified.

Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

NOTE: Cause analysis is the key and sometimes the most difficult part of the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include for example: limitation of the measuring device or a fault in its use like selection of incorrect filter setting, a fault in the equipment or its calibration, but also problems associated with staff skills and training.

Selection and implementation of corrective actions

Where corrective action is needed, the QCSP shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to a degree appropriate to the magnitude of the problem and associated risk.

The QCSP shall document and implement any required changes resulting from corrective action investigations.

Monitoring of corrective actions

The QCSP shall monitor the results to ensure that the corrective actions taken have been effective.

4.7. Control of records

General

The QCSP shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews, as well as, records of corrective and preventive actions.

All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

NOTE: Records may be in any media, such as hard copy or electronic media.

All records shall be held secure and in confidence.

The QCSP shall have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records.

Technical records

The QCSP shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each QC report, for a defined period.

The records of QC tests shall contain sufficient information to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the tests, the performance of each procedure and checking of results.

When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data (e.g. creation of a copy file marked as corrected version of the original file).

4.8. Internal audits

The QCSP shall periodically and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this Handbook. The internal audit program shall address all elements of the management system, including the quality control activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

NOTE: The cycle for internal auditing should normally be completed in one year.

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the QCSP's results, the QCSP shall take timely corrective action and shall notify customers in writing if investigations confirm that the QCSP QC test results may have been affected.

The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

4.9. Management reviews

In accordance with a predetermined schedule and procedure, the QCSP's top management shall periodically conduct a review of the QCSP's management system and quality control activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

- the suitability of policies and procedures
- reports from managerial and supervisory personnel
- the outcome of recent internal audits
- corrective and preventive actions
- assessments by external bodies
- changes in the volume and type of the work
- customer feedback
- complaints
- recommendations for improvement
- other relevant factors, such as quality control activities, resources and staff training

NOTE: A typical period for conducting a management review is once every 12 months.

Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

5. Technical requirements for accreditation

5.1. General

Many factors determine the correctness and reliability of the QC tests performed by a QCSP. These factors include contributions from:

- Human factors
- Equipment
- Conditions of storage of measuring equipment
- QC procedures and validation methods

5.2. Personnel

The QCSP management shall ensure the competence of all who operate specific equipment, perform QC tests, evaluate results, and sign QC reports. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required by relevant state regulations/requirements.

The qualification of the personnel responsible for the QC tests should preferably be:

Medical Physicist

The medical physicist is required to be qualified in the field of Radiology. Therefore, he/she must be familiar with the principles of imaging physics and of radiation protection; laws and regulations pertaining to the performance of the equipment being tested; the function, clinical uses and performance specifications of the imaging equipment; calibration processes and limitations of the instruments used for performance testing. These qualifications must be proven from degrees (BSc, MSc) in this scientific area from recognized educational institutions and/or official professional licenses/certificates from Middle East or other countries or international organizations (e.g. IMPCB) which certify qualification in medical physics after written exams.

- The medical physicist should be available for consultation regarding patient dosimetry issues within a reasonable period of time.
- The medical physicist is responsible for the conduct of all surveys of the medical x-ray equipment.
- The medical physicist may be **assisted** by properly trained individuals in obtaining data, in accordance with applicable regulations. Their training in the techniques of performing tests, the function and limitations of the imaging equipment and test instruments, the reasons for performing the tests and the importance of the test results, must be approved by the medical physicist. Any assisting individual must be under the direct supervision* of the medical physicist during the surveys.
- The medical physicist **must be present** during the surveys; review, interpret and approve all data, and provide a report of the conclusions **with his/her signature**.

**Direct supervision means that the medical physicist must be present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure. Direct supervision does not require the medical physicist being present the whole time in the room where the testing procedure is being performed.*

Assistant Physicist

The Assistant Physicist is an individual that assists the medical physicist during the QC test procedures.

- The Assistant Physicist operates under the supervision of a Medical Physicist.
- Must be familiar with the principles of imaging physics and of radiation protection; laws and regulations pertaining to the performance of the equipment being tested; the function, clinical uses, and performance specifications of the imaging equipment and limitations of the instruments used for performance testing.

5.3. Test and calibration methods and method validation

General

The QCSP shall have instructions on the use and operation of all relevant equipment. All instructions, standards, manuals and reference data relevant to the work of the QCSP shall be kept up to date and shall be made readily available to personnel.

NOTE: International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the QC tests do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a QCSP. It may be necessary to provide additional documentation for optional steps in the method or additional details.

Selection of methods

The QCSP shall use suitable procedures and which are appropriate for the tests. Methods published in international, regional or national standards shall preferably be used. The QCSP shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so.

The QCSP shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.

Control of data

Calculations and data processing shall be subject to appropriate checks in a systematic manner.

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the QCSP shall ensure that:

- a) Computer software developed by the QCSP is documented in sufficient detail and is suitably validated as being adequate for use by the QCSP Approved Signatory or other experienced Medical Physicist of the QCSP personnel.
- b) Procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing
- c) Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of a QC tests.

5.4. Equipment

The QCSP shall be furnished with all tools needed to assess image quality, all phantoms needed to measure the radiation doses and appropriate tools to measure parameters of the exposure.

Equipment and its software used for testing, shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests concerned.

Equipment shall be operated by authorized QCSP personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the authorized QCSP personnel.

Records shall be maintained of each item of equipment and its software significant to the tests performed. These records shall include at least the following:

- a) the manufacturer's name, model and serial number or other unique identification
- b) the manufacturer's instructions
- c) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration.
- d) in case that some of the instruments have been cross calibrated to an instrument calibrated in Secondary Standards Dosimetry Laboratory, the records of measurements and the results should be maintained and presented in such a way so that is clear that this equipment is reliable for use.
- e) the current location (storage place)

Equipment that has been subjected to mishandling, gives suspect results or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.

Whenever practicable, all equipment requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

When, for whatever reason, equipment goes outside the direct control of the QCSP, the QCSP shall ensure that the function and calibration status of the equipment is checked and shown to be satisfied before the equipment is returned to service.

Where calibrations give rise to a set of correction factors, the QCSP shall have procedures to ensure that relevant computer software or spreadsheets are correctly updated to account for these new calibration or correction factors.

Test equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test results.

Remedial levels

The QCSP shall have a procedure for the reviewing of its acceptance and rejection criteria for results (remedial levels). These criteria should be in line with the relevant requirements issued by international or national organizations.

5.5. Reporting the results

General

The results of each test or series of tests carried out by the QCSP shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods.

The results shall be reported, usually in a QC report or an acceptance test certificate and shall include all the information necessary for the interpretation of the test results and all information required by the method used.

The QC reports or acceptance test certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this Handbook are met.

QC reports and acceptance test certificates

Each QC report or acceptance test certificate shall include at least the following information unless the laboratory has valid reasons for not doing so:

- a) A title (e.g., "QC report" or "Acceptance Test Certificate")
- b) The name and address of the QCSP
- c) The name and address of the customer
- d) Unique identification of the QC report or acceptance tests certificate and on each page an identification in order to ensure that the page is recognized as a part of the QC report or acceptance tests certificate
- e) Soft (or hard) copies of QC report or acceptance tests certificates should also include the page number and total number of pages.
- f) Name of procedure
- g) QC equipment and software used
- h) Information on specific test geometric and other conditions (like focus to dosimeter distance, phantom thickness, exposure parameters, etc.)
- i) Nominal and measured values and/or analysis/computation result (calculated values)
- j) Result after comparison with baseline and remedial levels (acceptable / rejected)
- k) Comments/recommendations
- l) The name(s), title(s) and signature(s) or equivalent identification of person(s) authorized to sign the QC report or acceptance tests certificate. Note that MEFOMP defines the person who authorizes the QC report or acceptance tests certificate, as the Approved Signatory.
- m) In the case of non-conformity, the indication of the maximum time requested for corrective action is taken or the request of an immediate suspension of the equipment operation
- n) Where relevant, a statement should be included to clarify that the results relate only to the items and parameters tested.

Opinions and interpretations

When opinions and interpretations are included, the QCSP shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

Format of reports and certificates

The format shall be designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.

Attention should be given to the layout of the QC tests report or Acceptance tests certificate, especially with regard to the presentation of the QC tests or acceptance tests data and ease of assimilation by the reader.

The headings should be standardized as far as possible.

ANNEX I

Records of Assessment On-site:

- ☒ Record of qualifications of employees
- ☒ Record of occupational exposure for employees
- ☒ Record of measurement equipment specifications and user manual
- ☒ Record of measurement equipment calibration certificates
- ☒ Record of user manual of QC procedures
- ☒ Record acceptance and rejection criteria
- ☒ Record of acceptance test reports
- ☒ Record of annual test reports