

GAHAR HANDBOOK FOR

DIAGNOSTIC AND THERAPEUTIC RADIOLOGY CENTERS ACCREDITATION STANDARDS



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Diagnostic and Therapeutic Radiology Centers Accreditation Standards - 2022

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A handwritten signature in black ink, belonging to Prof Jeffrey Braithwaite.

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Contents

Foreword.....	9
Introduction.....	10
Scope of this Handbook	11
Purpose	12
Reading and Interpretation of the book.....	13
Used Language and Themes	15
Accreditation Overview.....	17
Applying for a GAHAR survey	20
Look back period	21
Scoring Guide	22
Accreditation Decision Rules.....	23
Acknowledgments	24
Acronyms	26
Section 1: Accreditation Prerequisites and Conditions.....	29
Compliance with GAHAR accreditation prerequisites.....	29
Transparent and ethical relationships.....	31
Section 2: Patient-Centered Standards.....	37
National Safety Requirements.....	41
Patient-Centeredness Culture	44
Establishing patient-centered culture.....	46
Ensuring patient and family empowerment.....	49
Responding to patient's needs	52
Responsiveness to patients' and families' voices.....	53
Access, Continuity, and Transition of Care.....	56
Effective and safe patient flow in the radiology center	58
Ensuring patient comfort	61
Criteria for acceptance of referred patients and appropriate patient request process	64
Ensuring effective, safe patient care provision and radiological examinations	67
Integrated Care Delivery.....	69
Effective screening, assessment, and care.....	71

Sustaining uniform care	73
Safe critical and special diagnostic and care procedures.....	78
Medical Radiological Services	83
Appropriateness and justification of the radiology examination.....	85
Medical imaging procedure manuals	86
Therapeutic radiological procedures	87
Pregnant and Breast-Feeding Patients	89
Release of Patients after Radionuclide procedures	90
Safe and uniform radiation studies and measures.....	91
Interventional Radiology Standards.....	99
Safe and effective invasive procedure care	102
Safe and effective anaesthesia and sedation care	111
Medication Management and Safety	119
Medication Use, Selection, and Procurement.....	122
Section 3: Organization-Centered Standards.....	135
Environmental and Facility Safety	137
Safe, appropriate radiology center structure and infrastructure:.....	140
Effective and safe environment and facility safety plans	141
Safe hazardous materials and waste management plan	143
Effective Safety and security plan.....	145
Safe utility plan	146
Safe emergency preparedness plan	148
Safe radiological medical equipment.....	149
Infection Prevention and Control	155
Efficient structure of the infection prevention and control program	157
Safe and effective infection prevention practices	159
Communicable diseases preventive measures and transmission-based precautions.....	164
Safe injection practices	168
Effective epidemiological surveillance and monitoring.....	171
Organization Governance and Management	173
Effective governing body	175
Effective organization direction and leadership.....	177
Efficient supply chain management.....	181

Efficient financial stewardship	183
Proper contract management and monitoring process.....	184
Safe, ethical, and positive organizational culture.....	185
Effective staff engagement, safety, and health.....	187
Work Force Management.....	190
Efficient workforce planning	192
Effective orientation, training and education programs	195
Equitable staff performance evaluation.....	199
Information Management and Technology	203
Effective document management and recording.....	205
Ensuring confidentiality, integrity, and security of information	208
Effective, safe documents retention process	210
Effective patient medical record management	211
The effective medical record review process.....	212
Effective information technology in healthcare	213
Quality And Performance Improvement	215
Availability of appropriate, effective quality management program.....	216
Efficient risk management program	218
Sustaining improvement	223
Survey Activities and Readiness	225
GLOSSARY	239
References	247

Foreword

As an essential step towards implementing comprehensive healthcare recovery in Egypt, here is the first edition of the Egyptian Accreditation Standards for Radiology services issued by the General Authority for Healthcare Accreditation and Regulation (GAHAR). This edition is a continuation of the efforts started in the last century for improving healthcare services in the country through standardization. The development of these standards is a valuable eventual product of collaborative efforts of representatives from the different health sectors in Egypt, including the Ministry of Health and Population, the private sector, university professors, professional syndicates, and others.

This book of standards handles healthcare delivery from two main perspectives, the patient-centred perspective, and the organisation-centred perspective. Each of the three main sections of this book adopts one of these perspectives and discusses in detail the minimum requirement for accrediting organizations based on them. The first section discusses accreditation prerequisites and conditions. The second section discusses patient-centered standards and adopts Picker's model for patient-centered care to ensure the responsiveness of organizations to patients' needs. The third section discusses organization-centered standards, highlighting many aspects required for workplace suitability to provide safe and efficient healthcare.

While these standards were carefully tailored to steer the current situation of Egyptian healthcare in the direction of Egypt's 2030 Vision, they have been finely compared to international standards and found to meet their basic intent that applies to Egyptian laws, regulations, and culture. It is expected that the standards shall be a catalyst for applying change and improvement in both the culture and practice of healthcare in Egypt.

Introduction

Patient-centered care is healthcare that respects and responds to the preferences, needs, and values of patients and consumers. The widely accepted dimensions of patient-centered care are respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination, family involvement, and access to care. Surveys measuring patients' experience of health care are typically based on these domains. Research demonstrates that patient-centered care improves patient care experience and creates public value for services. When healthcare administrators, providers, patients, and families work in partnership, the quality and safety of health care improve, costs decrease, provider satisfaction increases, and patient care experience is successfully achieved.

Patient-centered care can also positively affect business metrics, such as finances, quality, safety, satisfaction, and market share. Patient-centered care is recognized as a dimension of high-quality healthcare and is identified in the Institute of Medicine report *Crossing the Quality Chasm* as one of the six quality aims for improving care. In recent years, strategies used worldwide to improve overall healthcare quality, such as public reporting and financial incentives, have emerged as policy-level drivers for improving patient-centered care.

Healthcare workers face risks, as well. Although debate continues regarding whether worker wellbeing should be considered part of the patient safety initiatives, many organizations think about it that way, including major players in the healthcare industry worldwide. Three major aspects may affect the worker's wellbeing: safety, stress, and organizational structure.

This book defines the minimum requirements for healthcare organizations to comply with patient safety and centeredness while maintaining a safe, structured, and positive work environment.

Scope of this Handbook

These standards apply to diagnostic and therapeutic radiology centers seeking to be accredited by the General Authority for Healthcare Accreditation and Regulation (GAHAR).

Inclusions:

These standards are applicable to:

- Standalone radiology centers that provide diagnostic, interventional, and therapeutic services.
- Reference Radiology Centers that receive patients direct from outside the facility (only In GAHAR Accredited Facilities)

Exclusions:

These standards are not applicable to:

- Hospital radiology department (Not fulfilling the above criteria).

Purpose

GAHAR standards describe the competent level of care in each phase of the patient care process. They reflect a desired and achievable level of performance against which a radiology center's actual performance is. The main purpose of these standards is to direct and maintain safe healthcare practice through the accreditation standards.

These standards also promote and guide organization management. They assist staff, the management team, and the radiology center as a whole to develop safe staffing practices, delegate tasks to licensed and unlicensed staff members, ensure adequate documentation and even create policies for new technologies.

Compliance with GAHAR standards guarantees radiology center accountability for its decisions and actions. Many standards are patient-centered and safety-focused to promote the best possible outcome and minimize exposure to the risk of harm. These standards encourage the radiology center's staff to persistently enhance their knowledge base through experience, continuing education, and the latest guidelines. These standards can be used to identify areas for improvement in clinical practice and work areas, as well as to improve patient and workplace safety.

Reading and Interpretation of the book

- The General Authority for Healthcare Accreditation and Regulations evaluates organizations' structure, processes, and/or outcomes by setting standards that address these concepts.
- This book is divided into three sections, in addition to the foreword, introduction, Scope of this handbook, Purpose, Use, Acknowledgments, Acronyms, Survey activities and readiness, Glossary, and References.
- Each section is divided into chapters when applicable.
- Each chapter has:
 - An introduction that contains an overall intent.
 - Implementation of guiding documents that need to be checked to achieve full compliance with the standards.
 - Purpose which clarifies the introduction, and each purpose has a standard or more in the chapter.
- A standard is a level of quality or achievement, especially a level that is thought to be acceptable; it is composed of a standard statement, keywords, intent, survey process guide, evidence of compliance, and related standards paragraphs.

Standard Component

- Standard Statement:
 - In this handbook, each standard is written as a standard statement preceded by a code.
 - Each standard is followed by a *non-black-scripted statement* that describes the essential quality dimension(s) addressed by the standard.
- Keywords:
 - To help organizations understand the most important element of the standard statements, as these are words or concepts of great significance. They answer the question of WHAT the standard is intended to measure.
- Intent:
 - Standard intent is meant to help organizations understand the full meaning of the standard.
 - The intent is usually divided into two parts:
 - Normative: that describes the purpose and rationale of the standard and provides an explanation of how the standard fits into the overall program. It answers the question of WHY the standard is required to be met.

- Informative: is meant to help organizations identify the strategy to interpret and execute the standard. It answers the question of HOW the standard is going to be met.
- Some standards require the implementation of minimum components of processes to be documented, implemented, recorded, and/or monitored. These components are usually preceded with the phrase “at least the following”, followed by a numbered/lettered list of requirements. Hence, these elements are considered essential, indivisible parts of compliance with the minimum acceptable standard.
- Evidence of compliance (EOCs):
 - Evidence of compliance of a standard indicates what items will be reviewed and assigned a score during the on-site survey process.
 - The EOCs for each standard identifies the requirements for full compliance with the standard as scoring is done in relation to EOCs.
- Survey process guide:
 - Facilitates and assists the surveyors in the standard rating for the required EOCs.
- Related standards:
 - As healthcare is a complex service, each standard measures a small part of it. To understand what each standard means in the overall context of healthcare standards, other standards need to be considered as well.
- Standards are categorized and grouped into three sets of groups:
 - Chapters, where standards are grouped as per uniform objective.
 - Quality dimensions, where each standard addresses a particular quality dimension, and strategic categorization of standards to analyze their quality characteristics.
 - Documentation requirements, where some standards require certain types of documents

Used Language and Themes

This handbook used certain themes and vocabulary to ensure uniformity and clarity; these are the most important ones that will help radiology centers to interpret the standards:

Process, Policy, Procedure, Program, Plan, Guideline, Protocol

Whenever 'Process' is used in a standard, it indicates a requirement that is necessary to follow.

- 'Process'

A series of actions or steps taken in order to achieve a particular end.

- 'Documented Process'

A document that describes the process and can be in the form of policy, procedure, program, plan, guideline, or protocol.

- Policy:

- A principle of action adopted by an organization.
- It usually answers the question of what the process is.
- It is stricter than guidelines or protocols.
- It does not include objectives that need to be met in a certain timeframe.

- Procedure:

- An established or official way of doing something.
- It usually answers the question of how the process happens.
- It is stricter than guidelines or protocols.
- It does not include objectives that need to be met in a certain timeframe.

- Program:

- A plan of action aimed at accomplishing a clear business objective, with details on what work is to be performed, by whom, when, and what means or resources shall be used.

- Plan:

- A detailed proposal for doing or achieving something.
- It usually answers the question of what is the goal, why, how it is going to be achieved, and when.
- It includes objectives that need to be met in a certain timeframe.

- Guideline:

- A general rule, principle, or piece of advice.
- It usually answers the question of what the process is and how it should happen.
- Usually, it is more narrative than protocol.

- Protocol:
 - A best practice protocol for managing a particular condition, which includes a treatment plan founded on evidence-based strategies and consensus statements.
 - Usually, it has graphs, flow charts, mind maps, and thinking trees.
 - Document versus Record
- Document:
Created by planning what needs to be done.
- Record:
Created when something is done.
- Physician Versus Medical staff member
- Physician:
A professional who practices medicine
- Medical Staff member:
A professional who practices medicine, and other independent practitioners.

Accreditation Overview

This chapter aims to set the rules and requirements to obtain GAHAR accreditation for the radiology centers, which includes, but is not limited to, the following:

1. Compliance with licensure requirements for licensing the radiology centers as mandated by laws and regulations and regulatory ministerial decrees.
2. Compliance with the National Safety Requirements for radiology centers, (herein included), to ensure the safety of the patients, families, visitors, and staff.
3. Compliance with the requirements of the standards according to Accreditation Decision Rules in this handbook.

A. General rules:

- Determining which set of accreditation manuals is applied to the applicant's facility is done by matching the facility's scope of services provided. The Authority must be informed of any change in the field of services provided (adding a new service, canceling an existing service, or increasing the volume of an existing service by more than 15%) in writing to the e-mail reg@gahar.gov.eg. at least one month prior to the actual implementation of this change.
- Facilities that desire to obtain GAHAR's accreditation have to apply starting from the date of entering the governorate under the scope of universal health insurance law implementation, within a maximum period of three years. For facilities in the governorates that have not fallen yet under the scope of the law application, they have to apply within three years from the date of application submission.
- The facility shall ensure the validity of the documents and data provided at all stages of the accreditation process. If there is evidence that the submitted documents are proven to be inaccurate, the facility is at risk of rejection of accreditation.
- The facility is not permitted to use GAHAR's certificate or logo in a misleading manner.
- The accreditation may be withdrawn or at risk of rejection if there is an evidence that the facility has falsified or withheld or intentionally misled the information submitted to GAHAR.
- GAHAR shall inform the facility about the accreditation decision within a period not exceeding 15 working days starting from the date of completion of the survey visit.
- GAHAR has the right to publish the results of survey visit, accreditation suspension, or rejection, according to the requirements of Law No. 2 of 2018.
- The facility has to complete at least 60% of its staffing plan, and to register at least 60% of each category of health professional members before the survey visit,

provided that the remaining registration process has to be completed within three months starting from the date of accreditation.

- In case of a sentinel event or any serious adverse event, GAHAR shall be notified within 7 days of its occurrence, or via email notification using the following link; reg@gahar.gov.eg. The root cause analysis shall be submitted no later than 45 days starting from the date of the occurrence or its notification with the appropriate corrective plan to prevent/reduce its recurrence according to the nature of the event. (Refer to standard no. QPI.05 for more information).

B. Compliance with current relevant laws, regulations, licensures requirements, and their updates as follows;

For Governmental and Non- governmental radiology centers:

- Unit/Center/Facility license.
- Radioactive materials usage license (HOT LAB license).
- Catheterization unit licenses.
- Non-ionizing radiation equipment license (MRI).
- Ionizing radiation equipment license.
- Therapeutic radioactive sources license.
- Hazardous waste handling license.
- Certificate of conformity with the civil protection requirements.
- Elevator license (if any).
- Electric generators license (in accordance with Article 2 and Article 3 of Law No. 55 of 1977 regarding the establishment and management of thermal machines and steam boilers).
- Nuclear Energy License for the Nuclear Medicine Unit.
- An annual survey with an approved certificate for all radiation equipment in the center by the executive office for radiation protection.
- In the nuclear medicine units, the radiation survey in the nuclear medicine department is done once or twice weekly by a radiation safety officer RSO or radiation safety expert RPE and the survey meter used must be calibrated annually.

C. Accreditation may be suspended (for a period not exceeding 6 months) if:

- The facility fails to pass an unannounced survey,
- The facility fails to comply with GAHAR circulars when applicable.
- The facility data in the application form does not match its status upon unannounced evaluation visits.
- Sentinel events related to the safety of patients, healthcare providers, or visitors that had not reported to GAHAR within 7 days of its occurrence.

- The GAHAR has not been notified of any changes in the scope of services provided (e.g. adding a new service, canceling an existing service, or increasing the volume of an existing service by more than 15%) within at least one month before the actual implementation of this change.
- The facility did not register at least 60% of its medical professional members.
- The Radiology center fails to submit corrective action plans in case of the presence of one not met EOC or more,

D. Accreditation may be withdrawn or at risk of rejection if:

- The facility fails to pass follow up surveys in case of conditioned accreditation,
- GAHAR team discovers any falsification, withholding, or intentionally misleading the information submitted during or after the survey visit, or it is proven that the attached and submitted documents are inaccurate.
- The facility prevents GAHAR regulatory team/inspectors from doing their duties, such as refusing or preventing them from obtaining documents and data related to the scope of their duties.
- The facility refuses to meet the auditors' team or GAHAR surveyors in the announced /unannounced evaluation visits.
- A legal document issued by an administrative agency or Supreme Court rules against the facility either by the permanent or temporary closure.
- Moving the facility from its actual place mentioned in the application form, or when the facility is demolished, reconstructed, or rebuilt without any pre-notification to GAHAR.
- Exceeding the period prescribed for suspension of accreditation without correcting the reasons for this suspension.

Applying for a GAHAR survey

A radiology center seeking GAHAR accreditation begins by:

- Applying to join the program via www.gahar.gov.eg or by sending an email to reg@gahar.gov.eg
- GAHAR is going to respond by sending an application template attached to the email. The radiology center will complete the application and upload the required documents.
- Radiology center documents will be reviewed.
- GAHAR will determine survey financial fees, and bank account details will be shared.
- The radiology center will make the payment to the Central Bank of Egypt on the bank account, and it will send the receipt back via email.
- An appointment for the survey visit will be determined for the radiology center.
- GAHAR's surveyor team will evaluate the radiology center according to the GAHAR Handbook for Diagnostic and Therapeutic Radiology center accreditation standards
- The survey report is submitted to the accreditation committee to review and decide based on the decision rules.
- The radiology center is notified of the decision of the accreditation committee. The radiology center has 15 days to submit an appeal. If no appeal is submitted, the chairman of GAHAR approves the decision, and a final certificate is issued.

Look back period

- Surveyors are required to review standards requirements and evaluate organization compliance to them over a lookback period of time.
- Look back period: It is the period before the survey visit to which any radiology center is obliged to comply with the GAHAR accreditation standards. Failure to comply with this rule affects the accreditation decision.
- Look back period varies from one radiology center to another, depending on accreditation status.
- A radiology center seeking accreditation will:
 - Comply with the GAHAR Handbook for Diagnostic and Therapeutic Radiology Center Accreditation Standards as applicable for at least four months before the actual accreditation survey visit.
- A radiology center seeking re-accreditation:
 - For GAHAR accredited radiology centers, compliance with the GAHAR Handbook for Diagnostic and Therapeutic Radiology Center Accreditation Standards from receiving the approval of the previous accreditation till the next accreditation survey visit.

Scoring Guide

During the survey visit, each standard is scored for the evidence of compliance (EOC). These are mathematical rules that depend on the summation and percentage calculation of scores of each applicable EOCs as follows:

- **Met** when the radiology center shows 80% or more compliance with requirements during the required lookback period with a total score of 2.
- **Partially met** when the radiology center shows less than 80% but more than or equal to 50% compliance with requirements during the required lookback period with a total score of 1.
- **Not met** when the radiology center shows less than 50% compliance with requirements during the required lookback period with a total score of 0.
- **Not applicable** when the surveyor determines that, the standard requirements are out of the organization's scope (the score is deleted from the numerator and denominator).
- While most EOCs are independent, stand-alone units of measurement that represent the structure, process, and/or outcome, few EOCs are dependent on each other. Dependence means that compliance with one EOC cannot be achieved (or scored) without ensuring compliance with other EOCs.

Scoring of each standard

- **Met:** when the average score of the applicable EOCs of this standard is 80% or more.
- **Partially met:** when the average score of the applicable EOCs of this standard is less than 80% or but not less than 50%.
- **Not met:** when the average score of the applicable EOCs of this standard is less than 50%.

Scoring of each chapter

Each chapter is scored after calculating the average score of all applicable standards in this chapter.

Accreditation Decision Rules

Radiology center can achieve accreditation by demonstrating compliance with certain accreditation decision rules. These rules mandate achieving certain scores on a standard level, chapter level, and overall level as the accreditation decision is composed of four decisions.

1st Decision: Status of Accreditation for a radiology center (3 years).

- Overall compliance of 80% and more, and
- Each chapter should score not less than 70%, and
- No single whole standard is scored as not met.

2nd Decision: Status of Conditioned Accreditation for a radiology center (2 years).

- Overall compliance of 70% to less than 80%, or
- Each chapter should score not less than 60%, or
- Up to one standard not met per chapter, and
- No single not met NSR standard.

3rd Decision: Status of Conditioned Accreditation for a radiology center (1 year).

- Overall compliance of 60% to less than 70%, or
- Each chapter should score not less than 50%, or
- Up to two standards not met per chapter, and
- No single not met NSR standard.

4th Decision: Rejection of Accreditation

- Overall compliance of less than 60%, or
- One chapter scored less than 50%, or
- More than two standards not met per chapter, or
- A single Not met NSR standard.

Radiology centers having a status of accreditation or conditioned accreditation with elements of non-compliance are requested to:

- Submit a corrective action plan for unmet EOCs and standards within 90 days for 1st decision, 60 days for 2nd decision, and 30 days for 3rd decision to the email reg@gahar.gov.eg.
- Apply and pass the accreditation survey in 2 years for 2nd Decision and 1 year for 3rd Decision.

Acknowledgments

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Acronyms

Code	Meaning
APC	Accreditation Prerequisites and Conditions
NSR	National Safety Requirements
PCC	Patient-Centeredness Culture
ACT	Access, Continuity, and Transition of Care
ICD	Integrated care delivery
MRS	Medical Radiological Services
IRS	Interventional Radiology Standards
MMS	Medication Management and Safety
EFS	Environmental and Facility Safety
IPC	Infection Prevention and Control
OGM	Organization Governance and Management
WFM	Workforce Management
IMT	Information Management and Technology
QPI	Quality and Performance Improvement



SECTION 1

ACCREDITATION PREREQUISITES AND CONDITIONS

Section 1: Accreditation Prerequisites and Conditions

Section Intent

This section aims at providing a clear ethical framework that a radiology center must follow in order to comply with the GAHAR survey process. Scores of these standards are always be met in order to continue the survey process. One partially met or not met evidence of compliance is to be dealt with on the GAHAR accreditation committee level and may result in denial or suspension of accreditation.

Compliance with GAHAR accreditation prerequisites

APC.01 The radiology center ensures full compliance with national regulations and licensure requirements.

Safety

Keywords:

National regulations and licensure requirements.

Intent:

Regulation and licensure requirements are considered a basic requirement to ensure a minimum level of compliance for any radiology center or other facility providing healthcare services and aiming to be enrolled in the Universal Health Insurance system or achieving the accreditation or to be accredited by GAHAR. When the radiology center is applied for accreditation, it is expected to sustain or improve the same level of quality scored during the accreditation visit.

Licensure requirements shall be met by the radiology according to the scope of services provided.

Survey process guide:

- GAHAR surveyor may review facility licenses that match the national laws and regulations.

Evidence of compliance:

1. The radiology center has a clear process of frequent assessment of compliance with the national, applicable regulation requirements.
2. When a gap is identified, the radiology center has developed a corrective action plan describing all necessary measures needed to improve performance and sustain full compliance.
3. The radiology center reports to GAHAR any challenges that affect compliance with the national regulation requirements.

Related standards:

OGM.01 Governing body Structure and clear responsibilities, WFM.01 Staffing plan, EFS.01 Radiology center environment and facility safety structure, IMT.04 Retention of records, data, and information

APC.02 The radiology center ensures safe medical provision through compliance with GAHAR Healthcare Professionals Registration.

Safety

Keywords:

Registration of Healthcare professionals.

Intent:

The Healthcare Professionals Registration process aims at ensuring the competence of healthcare professionals by matching their qualifications and experience to an accredited radiology center's scope of medical services. In return, this process will improve the quality of healthcare services provided to the community. The radiology center is expected to register 100% of all members of the following healthcare professions:

- a) Physicians
- b) Nurses
- c) Nursing technicians
- d) Physicists
- e) Health technicians

The radiology center shall create a process to register all applicable newly hired staff members within 1-3 months.

Survey process guide:

- GAHAR surveyor may review healthcare professional registration records including both the current and new staff.

Evidence of compliance:

1. The radiology center has an approved process for registering all members of the required medical professionals including both current and newly hired members.
2. All contracts/ agreements either full-time, part-time, visiting, or other types of employment contracts with the healthcare professionals mentioned in the intent from (a) to (e) are to be submitted in the GAHAR healthcare professionals' registration process.
3. The radiology center has a process to report to GAHAR, other healthcare authorities, and professional syndicates any findings that affected patient safety such as fake, or falsified credentials.

Related standards:

WFM.02 Job description, WFM.08 Clinical Privileges, WFM.01 Staffing plan

Transparent and ethical relationships

APC.03 The radiology center provides GAHAR with accurate and complete information throughout all phases of the accreditation processes.

Effectiveness

Keywords:

Accurate and complete information.

Intent:

During the accreditation processes, there are many points at which GAHAR requires data and information. When a radiology center is accredited, it lies under GAHAR's scope to be informed of any changes in the radiology center and any reports from external evaluators. Radiology centers may provide information to GAHAR verbally, through direct observation, an interview, application or any other type of communication with a GAHAR employee. Relevant accreditation policies and procedures inform the radiology center of what data and/or information are required and the period for submission. The radiology center is expected to provide timely, accurate and complete information to GAHAR regarding its structure, scope of work, building, governance, licenses, and evaluation reports by external evaluators. GAHAR requires each radiology center whether accredited or just interested to engage in the accreditation process to act with honesty, integrity, and transparency.

Survey process guide:

- GAHAR surveyors may review reports of other accreditation, licensure, inspection, audits, legal affairs, reportable sentinel events, and reportable measures.
- GAHAR surveyors may observe the honesty, integrity, and transparency through the accreditation process

Evidence of compliance:

1. The radiology center has a process to verify all reports for accuracy and completion prior to GAHAR submission, throughout all stages of the accreditation process.
2. The radiology center is aware of their commit to report any structural changes in its scope of work by addition or deletion of medical services by more than 15% within 30 days.
3. The radiology center provides GAHAR access to evaluation results and reports of any evaluating organization.

Related standards:

OGM.01 Governing body Structure and clear responsibilities, QPI.05 Sentinel events, IMT.01 Documentation management system.

APC.04 The radiology center uses the accreditation process to improve safety and effectiveness.

Safety

Keywords:

Accreditation process value.

Intent:

GAHAR accreditation implies that a radiology center is a place that maintains high safety standards. Public bodies, governmental bodies, staff, and third-party payers, will assume credibility in accredited radiology center processes. Thus, GAHAR has the right to obtain any information to confirm standards and accreditation policy compliance and evaluate patient safety and quality concerns at any time during all phases of accreditation. When external bodies other than GAHAR evaluate areas related to safety and quality such as fire safety inspections, Police criminal investigations, court allegations checking, staff working conditions inspections, and evaluation of safety incidents or quality complaints. These evaluations complement accreditation reviews but may have a different focus or emphasis. Creating a safe culture is not an easy task; it requires everyone to be aware of safety issues and able to report them.

The radiology center improves safety by sharing knowledge with GAHAR about any challenges identified through internal or external processes. The radiology center's website, advertising and promotion, brochures, newspapers, and other information made available to the public accurately reflect the scope of services provided that are accredited by GAHAR, as well as the methods of reporting any safety issues which affect the patients or the healthcare professionals or practitioners.

Survey process guide:

- GAHAR surveyors may review any reports or concerns related to safety issues.
- GAHAR surveyors may interview responsible staff and patients to check their awareness of the mechanisms of reporting safety issues to GAHAR.

Evidence of compliance:

1. The radiology center permits GAHAR to perform on-site evaluations of compliance or verification of quality and safety concerns, reports, or any regulatory authority sanctions.
2. The radiology center accurately represents its accreditation status and scope.

3. The radiology center has a process to inform staff and patients on mechanisms to report safety issues to GAHAR.

Related standards

QPI.01 Quality management program, QPI.02 Performance measures, QPI.06 Performance improvement plan, APC.01 National regulations and licensure requirements, PCC.01 Radiology center Advertisement

APC.05 The radiology center maintains professional standards during surveys.

Safety

Keywords:

Professional standards during surveys.

Intent:

Surveyors' aim is to perform their duties and responsibilities and to attain the highest levels of ethical performance by the ethical requirements generally to meet the public interest and maintain the reputation of GAHAR. To achieve these objectives, the survey process must establish credibility, professionalism, quality of service and confidence. The radiology center is expected to maintain professional standards in dealing with surveyors. The radiology center is expected to report to GAHAR if there is a conflict of interest between a surveyor and the radiology center that could affect any of the following:

- a) Integrity
- b) Objectivity
- c) Professional competence
- d) Confidentiality
- e) Respect

The radiology center ensures that there are no immediate risks to surveyors' safety and security. The radiology center respects the confidentiality and sensitivity of the survey process.

Survey process guide:

- GAHAR surveyor may observe all aspects towards the safety, security, confidentiality, privacy, respect, integrity, objectivity, professional competence values and proper ethical management implementation.

Evidence of compliance:

1. Any conflict of interest is directly reported to GAHAR with evidence. (if present).
2. The radiology center maintains professional standards on dealing with surveyors.

3. The radiology center ensures that the environment does not pose any safety or security risks to surveyors during the survey.
4. Social media releases are not allowed without GAHAR's prior approval and notification.

Related standards:

OGM.08 Ethical management, PCC.01 Radiology center Advertisement



SECTION 2

PATIENT-CENTERED STANDARDS

Section 2: Patient-Centered Standards

Patient-centered care represents a paradigm shift in how patients, healthcare professionals, and other participants think about the processes of treatment and healing. It is defined by the Institute of Medicine as the act of providing care that is respectful of, and responsive to, individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions. The rise of patient-centered care paves the way for a healthcare system designed to optimize the benefit and comfort of the most important and vulnerable people in the equation: patients, their families, and their communities.

Over the past two decades, patient-centered care has become internationally recognized as a dimension of the broader concept of high-quality healthcare. In 2001, the semiannual US Institute of Medicine's (IOM), *Crossing the Quality Chasm: A New Health System for the 21st century*, defined good-quality care as safe, effective, patient-centered, timely, efficient, and equitable.

The report sets out several rules to redesign and improve patient-centered care, which include ensuring that care is based on continuous, healing relationships; customizing care based on patients' needs and values; ensuring the patient is the source of control; sharing knowledge and information freely; and maintaining transparency.

The IOM report defined four levels that further define quality care and the role of patient-centered care in each level:

1. The experience level refers to an individual patient's experience of their care. Care should be provided in a way that is respectful, informative, and supportive for the participation of patients and families
2. The clinical micro-system level refers to the service, department, or program level of care. Patients and families should participate in the overall design of the service, department, or program.
3. The radiology center-level refers to the radiology center as a whole. Patients and families should participate as full members of key radiology center committees
4. The environment level refers to the regulatory level of the health system. Patients and families can inform local authorities.

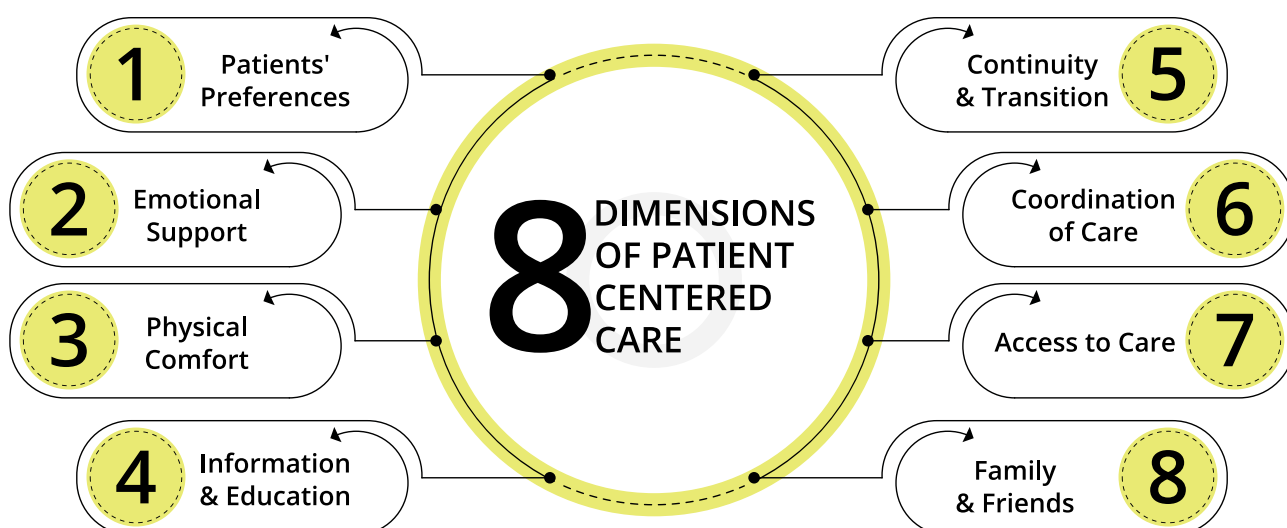
According to Charmel and Frampton, the IOM report reinforces patient-centered care not only as a way of creating a more appealing patient experience but also as a fundamental practice for providing high-quality care in the US.

Practically, many Egyptian radiology centers could readily put patients' medical record and informed consent policies in place, but many find it hard to actively change the way care is delivered, and struggle to involve patients and learn from their experiences.

Key strategies from leading patient-centered care organizations worldwide include demonstrating committed senior leadership; regular monitoring and reporting of patient feedback data; engaging patients and families as partners; resourcing improvements in care delivery and environment; building staff capacity and a supportive work environment; establishing performance accountability; and supporting a learning organization culture.

Internationally, healthcare services use a range of strategies to promote patient-centered care, including staff development, leadership, collecting and reporting patient feedback, redesigning and co-designing service delivery, implementing patient rights bills, and engaging patients and families as partners in improving care.

There are Eight Principles of Patient-Centered Care as defined by Picker's Institute:



1. Patients' Preferences

At every step, patients should be given the needed information to make thoughtful decisions about their care. Those preferences should always be considered when determining the best course of action for that patient. The expertise and authority of healthcare professionals should complement and enhance the patient perspective. Assessment and care should be in a way that maintains patients' dignity and demonstrates sensitivity to their cultural values healthcare professionals need to focus on the person's quality of life, which may be affected by their illness and treatment. Everyone involved is always on the same team, working toward the same goal.

2. Emotional Support

The challenges of treating and healing the body can also take their toll on the mind

and the heart. Practicing patient-centered care means recognizing the patient as a whole person, having a multi-dimensional human experience, eager for knowledge and human connection, who may need extra, specialized help in keeping up the spirit of optimism. It helps to alleviate fear and anxiety the person may be experiencing with respect to their health statute (physical status, treatment, and prognosis), the impact of their illness on themselves and others (family, caregivers, etc.), and the financial impacts of their illness.

3. Physical Comfort

Patients shall summon the courage to face circumstances that are scary, painful, lonely, and difficult. Strong pain relief and a soft pillow can go a long way. Healthcare professionals should work to ensure that the details of patients' environments are working for them, rather than against them. Patients should remain as safe and comfortable as possible through difficult straits, surrounded by people equipped to care for them.

4. Information and Education

Providing complete information to patients regarding their clinical status, progress, and prognosis; the process of care; and information to help ensure their autonomy and their ability to self-manage and to promote their health. When patients are fully informed, given the trust and respect that comes with sharing all relevant facts, they will feel more empowered to take responsibility for the elements of their care that are within their control.

5. Continuity and Transition

A transition from one phase of care to the next should be as seamless as possible. Patients should be well informed about what to expect. Treatment regimens, especially medication regimens, should be clearly defined and understood. And everyone involved should be able to plan and understand what warning signs (and positive indicators) to look out for.

6. Coordination of Care

Every aspect of care depends on every other aspect working as efficiently and effectively as possible. Treatment and patient experience shall be considered as an integrated whole, with different moving parts working in concert to reduce feelings of fear and vulnerability. Healthcare professionals shall cooperate in the interest of the patient's overall wellbeing.

7. Access to Care

To the extent that it is possible, patients should have access to all the care they need, when they need it, in a manner that's convenient and doesn't inflict too much stress. It

should be simple to schedule appointments, stick to medication regimens, and practice self-care.

8. Involvement of Family and Friends

Patient-centered care encourages keeping patients involved and integrated with their families, their communities, and their everyday lives by:

- Accommodating the individuals who provide the person with support during care.
- Respecting the role of the person's advocate in decision-making.
- Supporting family members and friends as caregivers, and recognizing their needs.

National Safety Requirements

Chapter intent:

The World Health Organization (WHO) defines patient safety as the reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of best practices shown to lead to optimal patient outcomes. Healthcare is a complex environment where errors can lead to injury or death. Usually, the safeguards work. However, each layer of defense such as alarms, standardized procedures, and trained health professionals has weak spots.

Advances and commitment to patient safety worldwide have grown since the late 1990s, which leads to a remarkable transformation in the way patient safety is viewed.

When multiple system failures occur, mistakes that would usually be caught slip through, the price we pay when such situations occur is often high, on both human and health-system levels.

Measuring patient safety initiatives and adverse events is essential when monitoring the progress of these strategies, tracking success, and helping to flag issues or identify potential areas for improvement.

As part of the GAHAR accreditation process, radiology centers have to show commitment to patient safety. This requires compliance with each of the National Safety Requirements (NSRs). During surveys, surveyors evaluate that safe and efficient implementation of each of the NSRs is maintained in all relevant practices. The application of the standards should be according to the applicable Egyptian laws and regulations.

Chapter purpose:

1. To address all the National Safety Requirements.
2. To ensure that the organizations provide and maintain the patient safety program effectively.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

- 1) Egyptian Constitution
- 2) Egyptian code of medical ethics 238/2003
- 3) Egyptian code of nursing ethics
- 4) Jeddah Declaration on Patient Safety 2019
- 5) WHO Patient Safety Assessment Manual
- 6) WHO Surgical Safety Checklist
- 7) WHO Patient Safety Friendly Initiatives

8) Law 59 /1960 – Radiation Protection against Ionizing Radiation

9) Law 7 / 2010 - Regulating nuclear and radiological activities

No standards are scored under this chapter; all National Safety Requirements will be scored in their corresponding chapters.

Code	NSR Keyword	Code in this book
GENERAL PATIENT SAFETY		
NSR.01	Patient identification	ACT.02
NSR.02	Fall screening, assessment and prevention	ICD.02
NSR.03	Verbal and telephone orders	ICD.06
NSR.04	Critical findings	ICD.07
NSR.05	Specific radiological hazardous	MRS.01
NSR.06	Hand hygiene	IPC.03
INTERVENTIONAL PROCEDURES		
NSR.07	Site marking and identification.	IRS.03
NSR.08	Pre-invasive procedural verification process	IRS.04
NSR.09	Timeout	IRS.05
MEDICATION MANAGEMENT AND SAFETY		
NSR.10	High-alert medications, look-alike sound-alike medications	MMS.03
ENVIRONMENTAL AND FACILITY SAFETY		
NSR.11	Radiation safety program	MRS.06
NSR.12	Fire and smoke Safety plan	EFS.02
NSR.13	Hazardous materials and waste disposal	EFS.03
NSR.14	Safety and Security plan	EFS.04
NSR.15	Utilities management plan	EFS.05
NSR.16	Medical equipment management plan	EFS.07

Patient-Centeredness Culture

Chapter intent

In patient-centered care, a patient's specific health needs and desired health outcomes are the driving force behind all healthcare decisions and quality measurements. As many patients are unable to evaluate a healthcare professional's level of technical skill or training, criteria for judging a service are non-technical, personal and include aspects like comfort, friendly service, healthcare professional's communication, soft skills, and on-time schedules. This requires that healthcare professionals develop good communication skills and address patient needs effectively and timely.

Patient-centered care also requires that the healthcare professional becomes a patient advocate and strives to provide care that is not only effective but also safe. The goal of patient-centered healthcare is to involve and empower patients and their families to become active participants in their care not only from a clinical perspective, but also from an emotional, mental, spiritual, social, and financial perspective.

Globally, the Universal Declaration of Human Rights article 25 emphasized the human right to a standard of living adequate for the health and well-being of himself and of his family, which includes medical care and the right to security in the event of sickness or disability.

Locally, Egyptian legal and ethical frameworks supported patient-centered care as well. According to the Egyptian constitution, comprehensive quality-standardized healthcare is a right for Egyptians. Egyptian codes of medical, nursing, pharmaceutical, and other healthcare professionals' ethics emphasized multiple aspects of patients' rights and healthcare professionals' obligations towards patients. The Consumer Protection Agency has identified multiple practices and instructions for patients to assume during their healthcare processes. In addition, Egyptian laws clearly describe the mechanism to obtain legal consents. During the past few years, the Egyptian parliament discussed some laws that are pertinent to the rights of some groups of Egyptian society, such as women, children, and handicapped and elderly.

Practically, radiology centers need to ensure infrastructure for uniform patient-centered care policies and procedures. Policies and procedures need to identify mechanisms to establish and sustain patient-centered care culture. Education and techniques to encourage patient-centeredness behaviors are needed.

During the GAHAR survey, surveyors shall be able to measure how organizations define their patient-centeredness culture and work to sustain it through reviewing documents pertinent to this chapter, reviewing the implementation of direct patient management.

Chapter purpose

1. To describe the patient-centeredness culture needed to comply with the chapter requirements.
2. To describe basic patient rights and responsibilities.
3. To emphasis on the techniques and cultural changes that organizations need to address while building a patient-centeredness culture.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates and annexes)

- 1) Egyptian Constitution
- 2) Universal Declaration on Human Rights year 1964
- 3) Cairo Declaration on Human Rights in Islam, 1990
- 4) Law 126/2008 on Egyptian Child
- 5) Law 10/2018 on the rights of handicapped
- 6) Drafted Egyptian law for Elderly care
- 7) Law 181/2018 on Egyptian "Consumer Protection"
- 8) Law 206/2017 on advertisement for healthcare services
- 9) Egyptian code of medical ethics 238/2003
- 10) Egyptian code of nursing ethics (Nursing Syndicate Publications)
- 11) Code of ethics and behavior for civil service staff, 2019, if applicable
- 12) Egyptian Criminal code 58/1937
- 13) Egyptian consent laws
- 14) MOH Ministerial decree number 216 / 1982 Healthcare facilities organization
- 15) MOH Ministerial 186/2001 Patient right to know expected cost of care
- 16) Law 59/1960 – Radiation Protection against Ionizing Radiation
- 17) Law 7/2010 - Regulating nuclear and radiological activities

Establishing patient-centered culture

PCC.01 The radiology center advertisements are clear and comply with applicable laws, regulations, and ethical codes of the healthcare professionals' syndicates.

Patient-Centeredness

Keywords:

Radiology center advertisement.

Intent:

Good advertising helps the community have a better understanding of the available health services. Radiology centers might use banners, brochures, pamphlets, websites, social media pages, call centers, or other media to advertise provided services. Medical syndicates, nursing syndicates, and other syndicates addressed honesty and transparency as high values in their codes of ethics. The radiology center can start complying to this standard by exploring the relevant laws, regulations, and ethical codes and finding out how they apply to the radiology center advertisement/communication process. The radiology center shall develop and implement a policy regarding the advertisement information of the services.

Information shall be accurate, updated, and clearly communicated about types of services, healthcare professionals, cost of services, and working hours.

Survey process guide:

- GAHAR surveyors may observe radiology center advertisements at any time from receiving the application and assigning of surveyors until sending the survey report.
- GAHAR surveyors may review the radiology center policy of the advertisement information of the services.
- GAHAR surveyors may review the application information with the survey visit observations.

Evidence of compliance:

1. The radiology center has an approved policy guiding the process of providing clear, updated, and accurate advertisement of services.
2. Advertisements are done in compliance with laws, regulations, and ethical codes of healthcare professionals' syndicates.
3. Patients and their families receive clear, updated, and accurate information about the radiology center's services, healthcare professionals, and working hours.

Related standards:

OGM.08 Ethical management, PCC.04 informed consent, ACT.01 Safe patient access and registration process, APC.04 Accreditation process value, APC.05 Professional standards during surveys

PCC.02 Patient and family rights are protected and they are empowered to assume their responsibilities.

Patient-centeredness

Keywords:

Patient and family rights and responsibilities.

Intent:

The radiology center is committed to help patients/clients to gain knowledge about their rights and responsibilities. The radiology center shall provide a clear direction to staff regarding their role in protecting patients' and families' rights and informing them about their responsibilities. Patient and family rights shall be defined as per national laws, regulations, and the ethical code of healthcare professionals' syndicates. Patient privacy, particularly during examinations and procedures/treatments, is important. Patients may desire privacy from other staff members, from other patients, or even from accompanying family members, when ever possible provide separate facilities and services for females and males according to their culture needs.

The radiology center ensures that all staff members are aware of, respect, and respond to patient and family rights issues when they interact with and care for patients throughout the radiology center.

The radiology center shall develop and implement a policy and procedures that address at least the following:

I. Patient and family rights to:

- a) Have access to the radiology center services
- b) Receive care that respects the patient's personal values, beliefs, religion, spiritual needs, and personal preferences.
- c) Be treated with dignity, respect, and without discrimination
- d) Protect patient's privacy, dignity, and his information confidentiality
- e) Have a safe and secure service environment
- f) Make a complaint or suggestion
- g) Know the price of services and procedures
- h) Identify, choose or refuse the options for provided care.
- i) Know the name and the title of the healthcare provider.
- j) Have protection from any violation or use.

II. Patient and family responsibilities to:

- I. Provide clear and accurate information on their current disease/condition, past medical history, and administered medications.
- II. Comply with the system and working hours of the radiology center.

- III. Comply with the provided instructions and recommendations.
- IV. Comply with financial obligations according to laws, regulations and the radiology center policy.
- V. Show respect to other patients and healthcare professionals.

Survey process guide:

- GAHAR surveyor may review patient and family rights and responsibilities policy
- GAHAR surveyor may interview staff members to check their awareness of the policy.
- GAHAR surveyor may observe patient rights and responsibilities statements availability in the center.
- GAHAR surveyors may observe how patients receive information about their rights and may check conditions under which patient rights are protected.
- GAHAR surveyor may interview staff members to check their awareness of how to manage violations or predict a violation as one of the patients' and family rights

Evidence of compliance:

1. The radiology center has an approved policy that guides the process of defining patient and family rights and responsibilities, as mentioned in the intent from I) through II).
2. All staff members are aware of the patients' and families' rights and responsibilities.
3. Patient rights and responsibilities statements are posted in the public areas throughout the center.
4. Information about patient rights and responsibilities is provided in written or in another manner, that the patients and their families understand.
5. Patients are aware of their rights and responsibilities.
6. Any violations to patient rights are managed and reported through a defined process.

Related standards:

ACT.01 Safe patient access and registration process, ACT.03 Physical access and comfort, ACT.04 Waiting spaces, PCC.06 Patient and family feedback, PCC.07 Complaints, and suggestions, OGM.06 Billing system, PCC.04 informed consent. ICD.04 Individualized care plan, PCC.03 Patient and family education process.

Ensuring patient and family empowerment

PCC.03 The radiology center ensures that patients' and families' education is provided clearly especially patient preparation instructions.

Patient-Centeredness

Keywords:

Patient and family education process.

Intent:

Some radiology examination requires specific preparation of the patients prior to the examination (e.g. fasting), as this may affect the results of the examination.

The radiology center ensures that examination-specific preparation processes are communicated accurately to patients and/or their family, and that the facility has procedures for managing patients who are inappropriately prepared.

Patient and family education help to understand the care process and empower patients and families taking informed decisions. Multiple disciplines, such as physicians, nurses, and medical technicians, contribute to the process of educating patients and families during care processes. All patient education activities required shall be recorded in the patient's medical record.

Healthcare providers shall inform female patients who are going to undergo a radiological procedure about the importance to notify the radiologist or radiographer in case that she is pregnant or planning to be pregnant during the next three months of the examination and if she is breast-feeding.

The radiology center shall develop and implement a policy and procedures to define the process of patient and family education. The policy shall address at least the following:

- a. Identifying patient and family educational needs especially patient preparation instructions for imaging examinations
- b. Multidisciplinary responsibility to educate patients and families.
- c. Educational methods provided, according to patient and family values and level of learning, and in a language and format that they understand.
- d. Process of recording patient's educational activities.
- e. Means of communication to inform any female patients about the possible radiation hazards in case of pregnancy or breast-feeding

The multidisciplinary responsible team shall identify all the educational needs, which may vary from one patient to another; however, at least the following needs shall be addressed for all patients:

- i. All possible measures to ensure patients are appropriately prepared.
- ii. The current diagnosis and medical condition according to the radiological request
- iii. Plan of care for a patient with interventional or therapeutic radiology services.

Survey process guide:

- GAHAR surveyor may review a policy describing patient and family education process before/after procedures.
- GAHAR surveyor may interview staff members to check their awareness of the patient and family education process
- GAHAR surveyor may review patient and family education records to assess completion.
- GAHAR surveyor may observe the availability of patient education materials.

Evidence of compliance:

1. The radiology center has an approved policy for patient and family education guiding the process of patient and family education that includes at least the points mentioned in the intent from a) through e).
2. All staff members are aware of patients' and families' education process.
3. Patient education activities are recorded in the patient's medical record.
4. All the educational needs are identified and addressed at least items from i) to iii).
5. Patient education materials are available as per the center's policy.
6. Educational material for patients is informed in a manner and a language that they easily understand.

Related standards:

PCC.02 Patient and family rights and responsibilities, IMT.05 Medical record management, IRS.09 Post-procedural care plan, PCC.04 informed consent, MRS.05 Release of patients undergoing treatment with radionuclides, ICD.04 Individualized care plan.

PCC.04 The radiology center has a defined process to obtain informed consent for certain medical processes.

Patient-Centeredness

Keywords:

Informed consent.

Intent:

One of the main pillars to ensure patients' involvement in their care decisions is by obtaining informed consent. It is also a way to ensure patient decision-making about their own care by discussing available methods of treatment, care, or examinations. To give consent, a patient should be informed about many factors related to the planned care, procedure, or examination. These factors are required to make an informed decision. Informed consent is a process of getting permission before performing a healthcare intervention on a person, or for disclosing personal information. The informed consent shall include the likelihood of success and the risk of not doing the procedure or

intervention, benefits, and alternatives for performing that particular medical process. The radiology center identifies and respects the patient preferences and choices. The Radiology center shall develop and implement a policy and procedures to describe how and where informed consent is used. The policy includes at least the following:

- a) The list of situations/settings when informed consent is needed, this list includes:
 - i. Invasive procedures.
 - ii. Anaesthesia, moderate and deep sedation.
 - iii. High-risk procedures or treatments, including but not limited to (radiation, therapy, and chemotherapy.....)
 - iv. Research, if applicable.
 - v. Photographic and promotional activities, for in which the consent could be for a specific time or purpose
- b) Certain situations when consent can be given by someone other than the patient, and mechanisms for obtaining and recording it according to applicable laws and regulations and approved radiology center policies. Specific informed refusal consent shall be used to document the refusal process. In case of refusing or discontinuing a step or steps in the medical care process, the patient informed refusal consent should be used to document the refusal process.
- c) Consent forms availability in all applicable, relevant locations.
- d) The validity requirements for informed consent.

Survey process guide:

- GAHAR surveyor may review a policy describing the process of obtaining informed consent.
- GAHAR surveyor may review patients' consents to assess completion.
- GAHAR surveyor may observe the distribution and availability of consent forms in areas where they are needed the most.

Evidence of compliance:

1. The radiology center has an approved policy guiding the process of informed consent that includes all elements mentioned in the intent from (a) through (d).
2. The informed consent forms are available in all relevant areas as per the center's policy.
3. Informed consent is obtained in a manner and language that the patient understands.
4. Informed consent is recorded and kept in the patient's medical record.
5. The most responsible physician obtaining the informed consent signs the form with the patient.
6. All relevant staff members are aware of the consent process.

Related standards:

PCC.02 Patient and family rights and responsibilities, PCC.03 Patient and family education process, MRS.04 Pregnant and lactating patients, IMT.02 Standardized codes, symbols and Abbreviations, ICD.05 High-risk patients and procedures/ services, IRS.01 provision of invasive procedure.

Responding to patient's needs

PCC.05 The radiology center responsibility towards patient's belongings is defined.

Patient-Centeredness

Keywords:

Patient's belonging.

Intent:

Patient belongings may include clothes, dentures, hearing aids, eyeglasses, or valuables such as jewelry, electronic devices, cash, and credit/debit cards. The radiology center shall develop and implement a policy and procedures to manage lost, found situations and patient's belongings security during emergency situations. The radiology center policy shall address at least the following:

Identify the staff who is responsible for managing the patient's property.

Identify procedures to manage patient's property.

Define lost and found process, lost and found items shall be recorded, protected, and returned when possible.

Clear process to follow when items are not returned within a defined timeframe.

Survey process guide:

- GAHAR surveyor may review a policy that guides radiology center responsibilities for patient's belongings.
- GAHAR surveyor may interview staff members to check their awareness of the radiology center policy.
- GAHAR surveyor may observe posters, brochures, or other means of communication that remind patients of securing their belongings.
- GAHAR surveyor may review security records, other records, and cabinets where patient belongings are kept and recorded.

Evidence of compliance:

1. The radiology center has an approved policy guiding the radiology center's responsibilities towards patients' belongings and addresses items from a) through d) in the intent.
2. Staff members are aware of the radiology center's patient belongings policy.
3. Records of lost and found items are available and match the cabinet's contents.

Related standards:

PCC.02 Patient and family rights and responsibilities, EFS.04 safety and Security plan/s.

Responsiveness to patients' and families' voices

PCC.06 The radiology center improves its provided services based on measured patient and family feedback.

Patient-Centeredness

Keywords:

Patient and family feedback.

Intent:

Patient feedback could include concerns, compliments, and formal complaint or through surveys,

that may help the radiology center to identify ways of improving performance. Radiology centers can solicit feedback from patients in a variety of ways: phone surveys, written surveys, focus groups, or personal interviews. Many radiology centers shall use written surveys, which tend to be the most cost-effective and reliable approach. The radiology center shall develop and implement a policy and procedures to guide the process of managing patient feedback.

The radiology center shall define if the process addresses the measurement of patient experience or patient satisfaction. For patient experience, the radiology center shall assess whether something that should happen in a healthcare setting (such as clear communication with a healthcare professional) actually happened or for how long it happened. While for patient satisfaction, the radiology center shall measure whether a patient's expectations about a health encounter were met. Two people who receive the exact same care, but who have different expectations for how that care is supposed to be delivered, can give different satisfaction ratings because of their different expectations. Measuring alone is not enough. Radiology centers need to analyze and interpret information obtained from measured feedback and identify potential improvement projects.

Survey process guide:

- GAHAR surveyor may review the policy of patient and family feedback.
- GAHAR surveyor may review the process of using patient and family feedback for performance improvement

Evidence of compliance:

1. The radiology center has an approved policy guiding the process of patient and family feedback measurement.

2. There is evidence that the radiology center has received, analyzed, and interpreted feedback from patients and families.
3. There is evidence that interpreted feedback has been shared with concerned staff members.
4. There is evidence that patient and family feedback is used to improve the quality of service.

Related standards:

PCC.02 Patient and family rights and responsibilities, PCC.07 Complaints, and suggestions, QPI.02 Performance measures, QPI.06 Performance improvement plan.

PCC.07 Patients and families are able to make oral, written complaints or suggestions through a defined process.

Patient-Centeredness

Keywords:

Complaints and suggestions.

Intent:

While radiology centers should be able to proactively measure and use patients' feedback, patients and families may also want to give oral or anonymous complaints or suggestions about their care and to have those complaints or suggestions reviewed and acted upon. The radiology center shall develop and implement a policy and procedures to create a uniform system for dealing with different complaints and suggestions from patients and/or their families so to make it easily to follow up, monitor, and learn from practices. Radiology center policy shall address at least the following:

- a) Mechanisms to inform patients and families of communication channels to voice their complaints and suggestions.
- b) Tracking processes for patient and family complaints and suggestions.
- c) Responsibility for responding to patient complaints and suggestions.
- d) The time frame for giving feedback to patients and families about voiced complaints and informing the patient of progress and outcome.

Survey process guide:

- GAHAR surveyor may review the policy of managing patient complaints and suggestions.
- GAHAR surveyor may interview staff to check their proper awareness.

Evidence of compliance:

1. The radiology center has an approved policy guiding the process of managing patients' complaints and suggestions as mentioned in the intent from a) through d).

2. Staff is aware of the complaints and suggestions process.
3. The radiology center allows the complaining process to be publicly available.
4. Complaints and suggestions are investigated and analyzed by the radiology center.
5. Patients and families receive feedback about their complaints or suggestions within approved timeframes and according to the level of urgency of the complaint.

Related standards:

PCC.02 Patient and family rights and responsibilities, PCC.06 Patient and family feedback, QPI.02 Performance measures, QPI.06 Performance improvement plan.

Access, Continuity, and Transition of Care

Chapter intent

Access is the process by which a patient can start receiving healthcare services. Facilitating access to healthcare is concerned with helping people reach appropriate healthcare services in order to preserve or improve their health. Access is a complex concept, and at least four aspects require evaluation: availability, affordability, acceptability, and physical accessibility.

Continuity of care becomes increasingly important for patients as the community ages and develops multiple morbidities and complex problems or includes more patients who become socially or psychologically vulnerable.

Globally, the WHO presented the global framework for access to care, announcing that all people have equal access to quality health services that are co-produced in a way that meets their life course needs, are coordinated across the continuum of care, and are comprehensive, safe, effective, timely, efficient, and acceptable; and all careers are motivated, skilled and operate in a supportive environment.

Locally, the Egyptian constitution focuses on the importance of granting access to healthcare services to all Egyptians. The medical code of ethics defined the framework of doctors' responsibilities towards patients. In addition, the Egyptian government has announced a major initiative to transform the healthcare industry in Egypt, where payers and healthcare professionals shall be separated, and a body of accreditation shall measure the quality of provided services. All this shall be under the umbrella of the Universal Health Insurance, where eligibility criteria are set for patient access, and referral mechanisms are established.

Practically, radiology centers need to consider all aspects of access to services. Establishing organization policies on patient flows and studying flow bottlenecks help organizations to better use available resources and safely handle patient journeys. During the GAHAR survey, the surveyor is going to assess the smooth flow of patients from/to the radiology center and assess the process and its implementation. In addition, the surveyor will be interviewing staff and reviewing documents related to the standards to assure that equity, effectiveness, and efficient process are in place.

Chapter purpose:

1. To ensure that organizations provide and maintain equitable, effective access to patient care services in a safe and efficient way.
2. To develop a process to avoid risks that may arise when patients need to be physically transported from one place to another which may entail a risk of mishandling and missing some information.
3. To document clear information, upon release outside the radiology center.

Implementation guiding documents

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

- 1) Egyptian constitution
- 2) Universal Health Insurance Law 2/2018
- 3) Transition of care, WHO, 2016
- 4) Law 10/2018 on the rights of handicapped
- 5) Egyptian code of building for handicapped
- 6) Nursing Syndicate Publications – Nursing Guidelines
- 7) MOH Ministerial decree number 216 / 1982 Healthcare facilities organization
- 8) Publications of Central Administration of Emergency and Critical Care, the Egyptian ministry of health, and population
- 9) Law 59 / 1960 – Radiation Protection against Ionizing Radiation
- 10) Law 7 / 2010 - Regulating nuclear and radiological activities

Effective and safe patient flow in the radiology center

ACT.01 The radiology center ensures safe patient access and an efficient registration process.

Patient- centeredness

Keywords:

Safe patient access and registration process.

Intent:

Patient access can have a direct impact on the quality of care provided, and one of the most important aspects of efficient patient access is the good communication between patients and healthcare providers. The availability of services must be considered, removal of any obstacles that may prevent access of patients to satisfy the different perspectives; the health needs, and the physical and cultural conditions of various groups of patients in the community.

As reception/registration staff are often the first persons whom patients encounter, simple criteria are useful to identify patients who may need immediate assistance and when the medical staff should be notified. When there is a delay in care or treatment, or there are known long waiting periods for diagnostic and/or therapeutic services that require the patient to be placed on a waiting list, the patient is informed of the reasons for the delay or wait and informed of available alternatives

Pre-set criteria need to be available for those responsible for granting access to patients. In order to improve accessibility to the radiology center services, patients and families should be well informed about the available services.

The radiology center shall develop and implement a policy and procedures to guide the process of granting patient access and registration process. The policy addresses at least the following:

- a) A process to identify barriers to access, and proper measures to manage.
- b) A clearly defined scheduling and queuing process for patients that include appropriate identification, clear, sufficient information exchange, safety, and comfort.
- c) A standardized process for registering patients based on the scope of services
- d) Criteria need to prioritize patients with urgent needs.
- e) Patients are referred and/or transferred to other healthcare organizations when healthcare needs are not matching with the radiology center scope of service, with the involvement of the patient and family opinion and preferences when appropriate,.

Survey process guide:

- GAHAR surveyor may review the policy that describes the actual radiology center's access process.
- GAHAR surveyor may interview related staff members and patients to assess their awareness of patient access and the registration process.

Evidence of compliance:

1. The radiology center has an approved policy that grants patients access and registration process which addresses all elements mentioned in the intent from a) through e).
2. Patients are made aware of available services, including operating hours, types of services, cost of each service, and access path.
3. There is a standardized process in place for registering patients based on the scope of services provided and patient clinical needs.
4. When there will be a delay in care and/or treatment, the patient is informed of the reasons for the delay or wait.
5. Patients are referred and/or transferred to other healthcare organizations when healthcare needs are not matching with the radiology center scope of service.

Related standards:

PCC.01 radiology center advertisement, PCC.02 Patient and family rights and responsibilities, MRS.05 Release of patients undergoing treatment with radionuclides, IRS.01 provision of invasive procedure, ACT.08 acceptance of referred patient, ACT.03 Physical access and comfort.

ACT.02 NSR.01 Accurate patient identification through at least two unique identifiers to identify the patient and all elements during care provision.

Safety

Keywords:

Patient identification.

Intent:

Providing care or performing interventions on the wrong patient are significant errors, which may have grave consequences.

Using two identifiers for each patient is the key driver in minimizing such preventable errors, which is especially important with the administration of high alert medications, contrast media and radiopharmaceuticals or performing high risk or invasive procedures. The radiology center shall develop and implement a policy and procedures to guide the process of patient identification.

The policy shall address at least the following:

- a) Two unique identifiers (personal).
- b) Occasions when verification of patient identification is required.
- c) Special situations when patient identification may not follow the same process. such as for unidentified patients, disasters and others.

Survey process guide:

- GAHAR surveyor may review the patient identification policy
- GAHAR surveyor may review a sample of medical records and check correct patient identification on each sheet as per the center's policy.
- GAHAR surveyor may interview the healthcare professionals, to check their awareness.

Evidence of compliance:

1. The radiology center has an approved policy of patient identification that addresses all elements mentioned in the intent from a) through c).
2. All healthcare professionals are aware of the radiology center patient identification policy
3. Patient identification occurs according to the policy.
4. The patient's identifiers are recorded in each form of the patient's medical record.
5. The radiology center measures and monitors staff compliance with the patient identification process and corrective actions are taken based upon.

Related standards:

IMT.05 Medical record management, MMS.04 Medication ordering, preparation, and administration, IRS.01 provision of invasive procedure, IRS.04 Pre-invasive procedural verification process, IRS.05 Timeout, IRS.07 Human tissue biopsy and specimen, IRS.10 Anesthesia and sedation services, IRS.03 Site marking and identification, ACT.07 Radiology request, QPI.02 Performance measures.

ACT.03 The radiology center works in collaboration with other community stakeholders to provide physical comfort and easy physical access.

Patient-Centeredness

Keywords:

Physical access and comfort.

Intent:

Community members often encounter barriers to healthcare that limit their ability to obtain the care they need. In order to have sufficient access, necessary and appropriate healthcare services should be available and obtainable in a defined timeframe manner.

Even when an adequate supply of healthcare services exists in the community, there are other factors to consider in terms of healthcare access. For instance, to have good healthcare access, a patient should also have the means to reach and use services, such as transportation to services that may be located at a distance. Radiology centers aiming at achieving accreditation may work with authorities or community members to ensure the availability of public transportation access, ramps and paths for wheelchairs and trollies, and adequate access pathways.

Survey process guide:

- GAHAR surveyor may observe the accessibility of the way to the radiology center, identifying potential blockages of access such as the absence of nearby public transportation, the presence of a physical barrier like a canal, or even the absence of clear signs to direct the patient's journey in the radiology center.
- GAHAR surveyor may observe the availability of measures such as ramps, wheelchairs, and trollies
- GAHAR surveyor may observe the radiology center's services are accessible for patients, especially those with disabilities

Evidence of compliance:

1. The radiology center has a defined process that guides safe physical access through multiple means of transportation, either private, public, or both.
2. The radiology center's services are accessible for patients, especially those with disabilities.
3. Measures as ramps, wheelchairs and trollies are available for served patients.
4. Barriers to access the radiology center services are identified and proper corrective actions are taken.

Related standards:

PCC.02 Patient and family rights and responsibilities, ACT.01 Safe patient access and registration process, ACT.04 Waiting spaces, QPI.02 Performance measures, EFS.01 Radiology center environment and facility safety.

Ensuring patient comfort

ACT.04 Waiting spaces in the radiology center are available for various services.

Patient-Centeredness

Keywords:

Waiting spaces.

Intent:

Waiting spaces are a major pain point in the patient experience. Not only emotions such

as anxiety, fear, confusion, frustration, or annoyance are high when a patient is waiting for a medical service, but it is more frustrating to be combined with uncomfortable seating, lacking basic human needs, and overcrowding. The radiology center shall ensure that waiting spaces are comfortable and suitable for the patient's and family's needs.

Survey process guide:

- GAHAR surveyor may observe waiting spaces and assess the suitability for patients' needs

Evidence of compliance:

1. There are waiting spaces that are suitable to accommodate the expected number of patients and families
2. Waiting spaces are lit, ventilated, clean, and safe.
3. Waiting spaces provide access to satisfy basic human needs such as toilets and potable water.
4. Patients receive information on how long they may wait.

Related standards:

PCC.02 Patient and family rights and responsibilities, ACT.01 Safe patient access and registration process, EFS.04 Safety and security plan/s, EFS.01 Radiology center environment and facility safety.

ACT.05 Appropriate and clear wayfinding signage are used to help patients and families to reach their destination inside the radiology center.

Safety

Keywords:

Wayfinding signage.

Intent:

Wayfinding systems aim to help radiology center to reduce their patients' stress by providing easy-to-follow signage and legible directions to their destinations. Wayfinding signage is important for the prospective patients as they need to find their way and its design should be suitable for all types of patients, good lighting is very important. Signage needs to be readable in different lighting conditions and in different weather (if the signage is used outdoors). In some settings, reliance on text-based signs is minimized, and systems rely heavily on non-text signs such as colors and symbols

Survey process guide:

- The GAHAR surveyor may observe wayfinding signs' readability, clarity and acceptability. Wayfinding signs may include all those signs encountered by patients during their journey in the radiology center.

Evidence of compliance:

1. Clear, readable, illuminated wayfinding signs are used in all relevant places and areas during working hours to reduce patient and family confusion.
2. When color-coded signage is used, clear instructions on what each color means should be available.
3. The staff is fully aware of the wayfinding signage used.

Related standards:

ACT.03 Physical access and comfort, ACT.01 Safe patient access and registration process, PCC.02 Patient and family rights and responsibilities, EFS.02 Fire and smoke safety plan, EFS.01 Radiology center environment and facility safety.

ACT.06 The radiology center ensures timely, safe patient transportation services.

Safety

Keywords:

Transportation of patient.

Intent:

Transportation in this standard refers to the act of lifting, maneuvering, positioning, and moving patients from one point to another point under the custody of radiology center staff members.

Evidence-based research has shown that safe patient handling interventions can significantly reduce overexertion injuries by replacing manual patient handling with safer methods. The radiology center should coordinate patient transportation between different departments and services. The radiology center should be able to meet patient needs within an appropriate timeframe, especially in critical conditions. Patient transportation should be facilitated and coordinated within the available services and resources. The radiology center shall develop and implement a policy and procedures for managing patient transportation. The policy addresses at least the following:

- a) Safe patient handling to and from examination bed, trolley, wheelchair, and other transportation means.
- b) Staff safety while lifting and handling patients.
- c) Coordination mechanism to ensure safe patient transportation
- d) Identification of responsible staff members for the transportation of patients.

Survey process guide:

- GAHAR surveyor may review the policy describing patient transportation
- GAHAR surveyor may observe the mechanisms of lifting, handling, and/or transporting patients.

- GAHAR surveyor may observe equipment used for lifting, handling, and/or transporting patients.
- GAHAR surveyor may also interview healthcare professionals to check their awareness of the process.

Evidence of compliance:

1. The radiology center has an approved policy that addresses all elements mentioned in the intent from (a) through (d).
2. All staff members involved in the transportation of patients are aware of the radiology center's policy.
3. Staff responsible for monitoring the patient during transportation are qualified according to the type of patient being transferred.
4. Requirements for transporting patients in critical conditions are identified, used, and timely recorded in the patient's medical record.

Related standards:

ACT.03 Physical access and comfort, ACT.08 acceptance of referred patient, MRS.05 Release of patients undergoing treatment with radionuclides.

Criteria for acceptance of referred patients and appropriate patient request process

ACT.07 Radiological services are done only when requested and justified.

Effectiveness

Keywords:

Radiology request.

Intent:

A request form is an essential tool for communicating patient data and clinical indications from the referring physicians to radiologic departments and reduction of unnecessary radiation doses to the patient. The Royal College of Radiologists has periodically issued guidelines regarding the completion of radiology request forms, one of which states: Requests should be completed accurately and legibly to avoid any misinterpretation. The clinician is required to state the reason for referral as this helps radiologists to better understand the patient's condition so that the required expertise may be utilized to proffer the necessary information to aid appropriate patient management. Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure.

The justification of medical exposure if needed for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, and recorded in the patient medical record. The radiology center shall develop and implement a policy to describe the accurate, legible request, that includes at least the following:

- a) The patient identification
- b) The minimum requirements of the request which include at least the following;
 - i. Provisional diagnosis
 - ii. Study requested;
 - iii. Date of the request;
 - iv. Referring medical practitioner's signature and contact details;
 - v. Pregnancy status
 - vi. Clinical complaint
 - vii. The urgency of the radiological procedure;
 - viii. Relevant information from the patient's previous radiological procedures.
- c) Measures to be done when the request is not complete, inaccurate, illegible, or not documented in patients' medical records.
- d) Action in case of there's no written request.
- e) The communication methods between the radiologist and the referring physician.

Survey process guide:

- GAHAR surveyor may review the policy of radiological request.
- GAHAR surveyor may review the processes of contacting referring physicians and changing radiology requests if required.
- GAHAR surveyor may review a sample of requests to check the completeness of request and appropriateness of authorizations.

Evidence of Compliance:

1. The radiology center has an approved policy including items mentioned in the intent from a) through e).
2. The staff is aware of the components of the radiological request.
3. Actions are taken when a radiological request is not referred from a medical practitioner.
4. The radiological request is complete, accurate, legible, and documented in the patient's medical record.

Related standards:

ACT.02 Patient identification, MRS.01 Specific radiological hazards, MRS.04 Pregnant and lactating patients, PCC.02 Patient and family rights and responsibilities, ACT.08 acceptance of referred patient, ACT.01 Safe patient access and registration process.

ACT.08 The radiology center identifies eligibility criteria for acceptance of referred patients.

Safety

Keywords:

Acceptance of referred patients.

Intent:

For radiology centers, effective management of the referred patient is an integral way of ensuring that patients receive optimal care at the right time and at the appropriate level, as well as cementing professional relationships throughout the healthcare community. Performing and recording referral feedback ensures continuity of care and completes the cycle of referral. The radiology center shall develop and implement a policy and procedures to guarantee the appropriate acceptance of referred patients within an approved timeframe, which is based on identified patients' needs, and preferences and guided by clinical guidelines/protocols.

The policy shall address at least the following:

- a) Eligibility criteria of acceptance of referred patients.
- b) Communication means with referral agencies, other levels of health service, and other organizations.
- c) The time frame for performing and sending the referral feedback.
- d) Measures taken in case of incompliance with the eligibility criteria.

Survey process guide:

- GAHAR surveyor may review the radiology center policy describing the processes for acceptance of referred patients.
- GAHAR surveyor may also interview healthcare professionals to check their awareness of the policy.

Evidence of compliance:

1. The radiology center has an approved policy for acceptance of referred patients that addresses all elements mentioned in the intent from a) through d).
2. All staff members involved in the acceptance of referred patients are aware of the process.
3. The referral sheet is recorded in the patient's medical record.
4. The referral feedback is reviewed, signed, and recorded in the patient's medical record.

Related standards:

ACT.06 Transportation of patient, ACT.01 Safe patient access and registration process, ACT.07 Radiology request.

Ensuring effective, safe patient care provision and radiological examinations

ACT.09 The radiology center ensure that radiological examination results are reported effectively within a defined time frame.

Timelines

Keywords:

Reporting of radiology examination results.

Intent:

The written radiological report is the most important means of communication between the radiologist and referring medical doctor. It is part of the patient's permanent health record and interprets the investigation in the clinical context. The appropriate construction, clarity, and clinical focus of a radiological report are essential to high-quality patient care.

Reporting imaging examinations within the planned and targeted time frame is crucial for the proper decision-making. All imaging reports must be checked and signed with an electronic or other signature. The radiology center shall develop and implement a reporting policy that addresses at least the following:

- a) Timeframes for reporting various types of medical imaging, especially in urgent and critical findings.
- b) Methods of interpretation and means of communication.
- c) Qualifications are required for those who are authorized for interpretation and reporting.

The radiology center shall ensure the validity, and legibility of the radiological report, a copy of the report shall be kept in the patient medical file, and the content of the radiological report shall address at least the following:

- I. The radiology center's name
- II. Patient identifiers on each page
- III. time of examination
- IV. Type of the examinations
- V. Results of the examinations
- VI. Time of reporting.
- VII. Name and signature of the reporting physician.

All radiological examinations shall be reported by a qualified, licensed, competent radiologist.

Privileges for interpretation and reporting of different examination results are determined based on assessed competencies. Radiology consultants are responsible to report different plain x-ray studies, CT scan and MRI studies, while Nuclear Medicine consultants should report different conventional gamma camera studies and PET/CT and PET/MRI studies.

Survey process guide:

- GAHAR surveyor may review the policy and procedures of radiology reporting.
- GAHAR surveyor may observe radiological report components and completeness.
- GAHAR surveyor may review a sample of reports to assess whether reports are thorough and timely
- GAHAR surveyor may interview the assigned radiologists for reporting of radiology procedures regarding the policy of radiology reporting

Evidence of Compliance:

1. The radiology center has an approved policy for the reporting process that covers the items mentioned in the intent from a) through c).
2. The radiological report covers the items mentioned in the intent from I) through VII).
3. Radiologists assigned for reporting are privileged, qualified, and licensed regarding each type of provided radiology services.
4. Radiologists assigned for reporting are aware of the radiology center policy.
5. Radiology examinations are reported, with respect of urgency, within the approved time frame as per center policy.

Related standards:

ACT.02 Patient identification, IRS.06 invasive procedure report, IRS.07 Human tissue biopsy and specimen, IRS.08 Implantable Devices, WFM.08 Clinical Privileges, ACT.08 Acceptance of referred patient.

Integrated Care Delivery

Chapter intent:

Screening is a strategy used in a population to identify the possible presence of an as-yet-undiagnosed disease in patients without signs or symptoms by performing a high-level evaluation of patients to determine whether a further deeper assessment is required. It is a crucial step to save resources and time.

Assessment is aimed to protect numerous patient safety issues in the radiology standalone centers such as; protection from direct harm arising from the techniques and technologies we use; ensuring the physical and psychological well-being of patients while under our care; maintaining the highest possible quality of service provision; Assessment is not only protecting patients, but also it protects the healthcare providers to ensure they can deliver safe services. The purpose of radiological assessment is to identify the location, nature and extent of the injury before determining the type of procedure or radiological examinations required.

Individualized care plans are developed by the radiology center after the collection of patients' needs. Literature shows that this concept helps to coordinate care, to improve healthcare service utilization, and to reduce costs. It also improves patient satisfaction and engagement.

The Egyptian government has announced a major initiative to transform the healthcare industry in Egypt, where payers and providers shall be separated, and a body of accreditation shall measure the quality of provided services. All this shall be under the umbrella of the Universal Health Insurance, where defined eligibility criteria are set for patients, and access and referral mechanisms shall be developed.

Chapter purpose:

1. To emphasize, the uniformity of care through the description of simple screening, assessment, and care provided to the patient at the first point of contact with the radiology center.
2. To describe the basic screening, assessment, reassessment, and care processes.
3. To highlight the need for special forms of assessments and care processes based on the patient's needs or patient's risks.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

- 1) Egyptian Constitution.
- 2) Drafted Egyptian law for Elderly care.

- 3) Egyptian code of medical ethics 238/2003 (Medical Syndicate Publications).
- 4) Egyptian code of nursing ethics (Nursing Syndicate Publications).
- 5) Law 71/2009 on the care of psychiatric patients.
- 6) Law 126/2008 on Egyptian Child.
- 7) Law 10/2018 on the rights of handicapped.
- 8) Publications of Central Administration of Emergency and Critical Care, the Egyptian ministry of health and population.
- 9) Requirements of inspection per MOHP law and regulation .
- 10) National cancer treatment guidelines, High committee of cancer. The Egyptian ministry of health and population.
- 11) Law 51/1981 for healthcare organizations.
- 12) Managing victims of social abuse guidelines – ministry of health, UNFPA.
- 13) Law 59/1960 – Radiation Protection against Ionizing Radiation.
- 14) Law 7/2010 - Regulating nuclear and radiological activities.

Effective screening, assessment, and care

ICD.01 The radiology center ensures that a comprehensive, effective patient screening and assessment process is implemented.

Effectiveness

Keywords:

Screening and assessment.

Intent:

Screening is a set of standardized rules or tests applied to patient groups which help to the appropriateness and the presence of the demanded services and help also to determine the need for a further nutritional, functional and special needs assessment. The initial assessment is considered the basis of all medical care decisions, it aids in the determination of the severity of a condition, and it helps in prioritizing initial clinical interventions. Initial assessment should be standardized, comprehensive, detailed, and completed within a specific time span to achieve high-quality care that fulfills patient needs.

The radiology center shall develop a patient screening and assessment policy and procedure, which shall include at least the following:

- I. For screening
 - a) Define screening criteria according to the radiology center's scope of service
 - b) Determine who is responsible to perform the screenings
 - c) Timeframe to complete and document the screening
- II. For assessment
 - i. The scope and content of the assessment required
 - ii. The specific assessments are done by a competent staff member.
 - iii. The timeframe for completing the assessment

Survey process guide:

- GAHAR surveyor may review the radiology center policy that guides the screening and/or assessment process.
- GAHAR surveyor may review a patient's medical record to evaluate documents of screening and/or assessment.
- GAHAR surveyor may interview staff members to check their awareness of the policy.

Evidence of compliance:

1. The radiology center has an approved screening and assessment policy including elements in the intent from I) through II).
2. The staff who perform the screening and assessment process are qualified and aware of how to apply it.

3. All screenings and assessments are completed and recorded within an approved timeframe as per the center's policy.
4. All the screenings and assessment records are kept in the patient medical record.

Related standards:

ICD.02 Fall screening, assessment, and prevention, MMS.06 Radiopharmaceutical, ICD.04 Individualized care plan, ICD.05 High-risk patients and procedures/ services, IRS.02 Assessment before invasive procedures, IRS.11 Pre- anesthesia assessment, Pre-sedation assessment, IMT.01 Documentation management system.

ICD.02 NSR.02 Patient's risk of falling is screened, assessed, and managed safely.

Safety

Keywords:

Fall screening, assessment, and prevention.

Intent:

All patients are liable to fall; however, some are more prone. Identifying the more prone is usually done through a screening process that offers further assessment which helps to determine the tailored preventative measures against falling. Effective preventive measures to minimize falling are those tailored to each patient and directed towards the risks being identified from risk assessment.

The radiology center shall develop and implement a policy and procedures to guide the fall screening and prevention process. The policy shall address at least the following:

- a) Patient risk screening at the first point of care.
- b) Timeframe to complete the fall screening.
- c) Fall risk assessment.
- d) General measures required to reduce the risk of falling such as call systems, lighting, corridor bars, bathroom bars, bedside rails, wheelchairs, and trolleys with locks.
- e) Tailored preventive measures for patients with a high risk of fall, for example; Fixation measures and continuous visualization for patients during examinations.

Survey process guide:

- GAHAR surveyor may review the policy describing screening and prevention of patient fall.
- GAHAR surveyor may review a sample of medical records to check the completeness of the patient fall screening and assessment forms.
- GAHAR surveyor may interview healthcare providers, to assess their knowledge about patient fall screening and assessment processes.
- GAHAR surveyor may observe general measures for patient fall prevention.

Evidence of compliance:

1. The radiology center has an approved policy and procedures for fall screening, assessment and prevention that addresses items a) through e) of the intent.
2. Staff is aware of the fall screening, assessment and prevention policy.
3. Patients at high risk of fall are identified and educated on fall prevention measures.
4. All fall risk screenings are completed and timely documented in the patient's medical record according to the center's policy.
5. Fall preventive general measures are implemented all over the center.
6. Tailored preventive measures for high-risk patients are implemented and recorded.

Related standards:

ICD.01 screening and assessment, ICD.04 Individualized care plan, ICD.05 High-risk patients and procedures/ services, QPI.02 Performance measures, PCC.03 Patient and family education process, IMT.01 Documentation management system.

Sustaining uniform care

ICD.03 The clinical practice guidelines development process is defined.

Effectiveness

Keywords:

Clinical practice guidelines.

Intent:

Clinical guidelines serve as a framework for clinical decisions and supporting best practices. Clinical practice guidelines are also statements that include recommendations intended to optimize patient care. Promoting uptake and use of clinical guidelines at the point of care delivery represents a final transition hurdle to move scientific findings into practice. Characteristics of the intended users and context of practice are as important as guideline attributes for promoting adaptation and adoption of clinical guidelines recommendations.

The radiology center shall develop and implement a policy and procedure for clinical guidelines adaptation and adoption. The policy shall address at least the following:

- a) Selection criteria of clinical practice guidelines.
- b) How clinical practice guidelines/protocols implementation are monitored and evaluated.
- c) Staff training required to apply the selected guidelines, pathways, or protocols.
- d) Periodic update of clinical practice guidelines based on changes in the evidence and evaluation of processes and outcomes.

Survey process guide:

- GAHAR surveyor may review the radiology center policy followed by interviewing staff members to check their awareness of the policy.
- GAHAR surveyor may review medical records to check the implementation of clinical practice guidelines.
- GAHAR surveyor may review a staff member file to check training records.

Evidence of compliance:

1. The radiology center has an approved policy that guides clinical guidelines adaptation and adoption which addresses all the elements mentioned in the intent from a) through d).
2. Related staff are trained on the implementation of the relevant approved clinical guidelines.
3. Compliance to clinical guidelines is linked to staff performance evaluation and appraisal processes.

Related standards:

ICD.05 High-risk patients and procedures/ services, MRS.01 Specific radiological hazards, MRS.06 Radiation Safety Program, IRS.10 Anesthesia and sedation services, IRS.13 Continuous monitoring during anesthesia and sedation, QPI.02 Performance measures, WFM.07 Staff performance and competency.

ICD.04 An individualized care plan with desired outcomes and goals is developed.

Effectiveness

Keywords:

Individualized care plan.

Intent:

A care plan is developed for every patient that will undergo either radiation therapy or intervention procedure by the responsible physician, radiotherapist consultant, and/or specialist based on a referral report, history, assessment, patient and/or family participation, and should be updated if needed.

The plan is based on recommendations and final diagnosis of the patients' treating physician and evidence-based guidelines or pathways, and has to specify the goals of the plan, predicted level of care to be done, proposed duration and frequency required to reach the desired goals and outcomes. A responsible consultant or specialist develops and signs the individualized plan of care.

The radiology center shall develop and implement a policy to describe the required items needed to develop an individualized radiology care plan that shall include at least

the following components:

- a) Identified needs, procedures, and desired outcomes with timeframes.
- b) Participation of patients and/or their families in the care plan.
- c) Any changes in the patient's condition.
- d) Any problem other than the patient's primary problem.
- e) Progress of patient in achieving the desired goals.
- f) Requirement for periodic reassessments of the care plan.

Survey process guide:

- GAHAR surveyor may review the care plan policy.
- GAHAR surveyor may review medical records and check the content and completeness of the care plan form.
- GAHAR surveyor may interview staff to assess their awareness of the policy.
- GAHAR surveyor may interview patients and their families to check their participation in the care plan.

Evidence of compliance:

1. The radiology center has an approved policy and procedures to ensure that each patient has an Individualized care plan that includes items from a) through f) in the intent.
2. The staff is aware of the policy and the components of the individualized care plan.
3. A responsible consultant or specialist develops, updates, and signs the individualized care plan in a timely manner.
4. The individualized care plan is recorded on the patient's medical record.

Related standards:

ICD.02 Fall screening, assessment, and prevention, IRS.02 Assessment before invasive procedures, IRS.09 Post- procedural care plan, IRS.12 Anesthesia care plan, IRS.14 Post- anesthesia care, ICD.01 screening and assessment, ICD.05 High-risk patients and procedures/ services, PCC.03 Patient and family education process, IMT.01 Documentation management system.

ICD.05 The radiology center has identified high-risk patients and procedures/ services.

Safety

Keywords:

High-risk patients and procedures/ services.

Intent:

The radiology center needs to make sure that evidence-based clinical guidelines are available and used to define the early assessment and recognition of high-risk patients. When providing care for any of the high-risk patients identified below, the radiology centers shall establish and implement guidelines and procedures for the services provided for the patients served.

The radiology center shall develop and implement a policy to identify high-risk patients and procedures/services.

a) Identify high risk patients.

The high-risk patients include at least the following:

- i. Female patients either, breastfeeding or pregnant.
- ii. Patients with a communicable disease.
- iii. Immunosuppressed patients (eg. Diabetic patients...).
- iv. Patients receiving chemotherapy.
- v. Vulnerable patient populations, including elderly, disabled and immobilized patients, dependent children, and patients at risk for abuse and/or neglect.
- vi. Psychiatric patients.
- vii. Patients at high risk of fall.

b) Identify high-risk procedures/services include at least the following:

Interventional procedures, stress examinations, and the administration of moderate sedation or general anesthesia, etc.

c) measures to reduce and/or prevent identified risks.

Survey process guide:

- GAHAR surveyor may review a policy to identify high-risk patients and services/ procedures.
- GAHAR surveyor may interview responsible staff to assess their awareness of the process of identifying high-risk patients, and assessment forms.

Evidence of compliance:

1. The radiology center has an approved policy for identify high-risk patients and services/procedures, which includes at least items a) and c) in the intent.
2. Staff is educated and trained on how to apply the policy.
3. Measures to reduce and/or prevent identified risks are implemented.

Related standards:

PCC.04 informed consent, MRS.04 Pregnant and lactating patients, ICD.01 screening and assessment, ICD.02 Fall screening and prevention, ICD.03 Clinical practice guidelines, IRS.01 provision of invasive procedures, IPC.06 communicable diseases preventive measures, EFS.04 safety and Security plan, WFM.06 Continuous education, and training program, IMT.01 Documentation management system, IRS.10 Anesthesia and sedation services, QPI.03 Risk management plan/program.

ICD.06 NSR.03 Verbal or telephone orders are communicated safely and effectively throughout the radiology center.

Safety

Keywords:

Verbal and telephone orders.

Intent:

Miscommunication is the most common root cause of adverse events. Writing down and reading back the complete order, by the person receiving the information, minimizes miscommunication and reduces errors from ambiguous speech, unfamiliar terminologies, or unclear pronunciation. This also provides an opportunity for verification.

The radiology center shall develop and implement a policy and procedures for receiving verbal and telephone communication. The policy shall address at least the following:

- a) Process of recording verbal orders.
- b) Process of recording telephone orders.
- c) Read-back by the recipient.
- d) Confirmation by the individual giving the order.

Survey process guide:

- GAHAR surveyor may review the policy of receiving verbal or telephone orders to check whether it clearly describes the process of recording, and read back by the recipient.
- GAHAR surveyor may review recordings in used registers and/or patient's medical record.
- GAHAR surveyor may interview healthcare professionals to assess their knowledge and compliance with radiology center policy.

Evidence of compliance:

1. The radiology center has an approved policy to guide verbal communications that addresses at least all elements mentioned in the intent from a) through d).
2. Healthcare professionals are aware of how to apply the policy.

3. All verbal orders and telephone orders are recorded in the patient's medical record within a pre-defined timeframe.
4. The radiology center measures and monitors staff compliance with verbal and telephone order process and corrective actions are taken based upon.

Related standards:

ICD.07 Critical findings, IMT.05 Medical record management, QPI.02 Performance measures.

Safe critical and special diagnostic and care procedures

ICD.07 NSR.04 Critical findings are communicated in a safely, accurately and timely manner throughout the radiology center.

Safety

Keywords:

Critical findings.

Intent:

Patient safety and quality of care can be compromised when there are delays in communicating the critical findings to the requestor. Miscommunication is the most common root cause of adverse events. Writing down and reading back the results, by the person receiving the information, minimizes miscommunication and reduces errors from unambiguous speech, unfamiliar terminologies, or unclear pronunciation. This also provides an opportunity for verification. The medical imaging service shall define the critical findings for specific tests/ studies or examinations. The process includes instructions for immediate notification with results that exceed the critical findings for the authorized physician responsible for the patient. The radiology center shall develop and implement a policy and procedures to guide the process of identifying and reporting critical findings. The policy shall address at least the following:

- a) Lists of critical findings.
- b) Critical findings reporting process including timeframe and "read-back" by the recipient.
- c) The process of recording includes:
 - i. The mean of notification.
 - ii. Date and time of notification.
 - iii. Identification of the notifying responsible staff member.
 - iv. Identification of the notified person.
 - v. The reported critical findings.
- d) Measures to be taken in case of difficulties in notifying the requesting physician.

Survey process guide:

- GAHAR surveyor may review the policy of critical findings to check whether it clearly describes the process of recording and read-back by the recipient.
- GAHAR surveyor may review recording used registers and/or patient's medical record.
- GAHAR surveyor may interview healthcare professionals to assess their knowledge and compliance with the radiology center policy.

Evidence of compliance:

1. The radiology center has an approved policy to guide critical findings communications that addresses at least all elements mentioned in the intent from a) through d).
2. Healthcare professionals are aware of the elements of the policy.
3. A list of critical findings is available for relevant staff.
4. critical findings are reported to the requesting physician as per the center policy.
5. All critical findings are recorded in the patient's medical record within a predefined timeframe including all elements in the intent from i) through v).
6. The radiology center measures and monitors staff compliance with Critical findings reporting process and corrective actions are taken based upon.

Related standards:

IMT.05 Medical record management, ACT.09 Reporting of radiology examination results, QPI.02 Performance measures.

ICD.08 Response to medical emergencies and cardio-pulmonary arrest in the radiology center is managed effectively.

Safety

Keywords:

Medical emergencies and cardiopulmonary resuscitation.

Intent:

Any occupant within a radiology center is liable to suffer from a medical emergency requiring a rapid and efficient response. Time and skills are essential elements for an emergency service to ensure satisfactory outcomes. Therefore, trained staff members, at least on basic life support, should be available during working hours ready to respond to any emergencies. The radiology center shall develop and implement a policy and procedures to ensure the safe management of medical emergencies and cardio-pulmonary arrests. The policy shall address at least the following:

- a) Defined criteria of recognition of emergencies and cardio-pulmonary arrest including adults and pediatrics.

- b) Basic cardiopulmonary resuscitation training at least every two years for all staff that provides direct patient care.
- c) Identify staff who are responsible to respond immediately.
- d) Mechanisms to call staff members to respond; including the code(s) that may be used for calling for an emergency.
- e) The time frame of response.
- f) The response is uniform at all working times.
- g) Recording of response and management.

Survey process guide:

- GAHAR surveyor may review the policy for medical emergencies and cardio-pulmonary arrest.
- GAHAR surveyor may review the evidence of staff training concerning recognition and communication of medical emergencies or cardio-pulmonary arrest.
- GAHAR surveyor may observe compliance with the policy for medical emergencies and cardio-pulmonary arrest.

Evidence of compliance:

1. The radiology center has an approved policy of medical emergencies and cardio-pulmonary arrest that addresses all the elements mentioned in the intent from a) through g).
2. All staff members involved in medical emergencies and cardiopulmonary resuscitation are aware of the radiology center policy.
3. Qualified individuals are responsible for the management of medical emergencies and cardio-pulmonary arrests.
4. Management of medical emergencies and cardio-pulmonary arrests occurs according to the policy.
5. Management of medical emergencies and cardio-pulmonary arrests are recorded in the patient's medical record.

Related standards:

ICD.03 Clinical practice guidelines, WFM.06 Continuous education, and training program, MMS.02 Medications storage and labelling, ICD.09 Emergency equipment and supplies, WFM.08 Clinical Privileges.

ICD.09 Emergency equipment and supplies are available and functioning.

Safety

Keywords:

Emergency equipment and supplies.

Intent:

Adequate and functioning equipment, presence of supplies, and quick access to emergency medications is critical and a cornerstone for resuscitating patients in emergency conditions as required by laws, regulations, and guidelines.

Their availability all the time ensures successful resuscitation. The radiology center shall develop and implement a policy and procedures to ensure a safe process of the management of emergency equipment and supplies. The policy shall address at least the following:

- a) Identification of required emergency equipment and supplies list according to laws, regulations, and standards of practice that include at least an automatic external defibrillator, sphygmomanometer, stethoscope, and bag valve masks in different sizes and different sizes of airways.
- b) Emergency equipment and supplies are available and protected from abuse, loss, or theft.
- c) Emergency equipment and supplies are age-appropriate.
- d) Emergency supplies are replaced immediately after use or when expired or damaged.
- e) Emergency equipment and supplies are checked daily for their availability and readiness.

Survey process guide:

- GAHAR surveyor may review the radiology center policy regarding the management of emergency equipment and supplies.
- GAHAR surveyor may interview staff members to check their awareness of the policy.
- GAHAR surveyor may check emergency equipment and supplies to assess continuous maintenance and checking.

Evidence of compliance:

1. The radiology center has an approved policy of management of emergency equipment and supplies that addresses all the elements mentioned in the intent from a) through e).
2. All staff members involved in the management of life-threatening conditions are aware of the radiology center policy.
3. Emergency equipment and supplies are available, secure, and age-appropriate.

4. Emergency equipment and supplies are checked daily.
5. Emergency supplies are replaced after use.

Related standards:

ICD.08 Medical emergencies and cardiopulmonary resuscitation, MRS.02 Technical medical imaging procedures, EFS.08 Calibration of equipment.

Medical Radiological Services

Chapter Intent:

Patients seek medical help for the determination and treatment of various health problems. Sometimes a combination of the patient's history and a clinical examination by a physician is enough to decide whether medical treatment is needed, and what treatment should be given. However, often radiology examination is required to confirm a clinically suspected diagnosis or to obtain more accurate information. As the radiology examination exposes patients to radiation risk, it is mandatory to choose wisely the appropriate examination that gives the required clinical information with the least risk to the patient.

Appropriate clinical information is essential for a good quality radiology practice. While it is the responsibility of the referring medical practitioner to ensure that the request contains the necessary information, the radiology center should have a written policy and procedure for the verification of the requested data and a justification of examination selection.

There should be a process in place to ensure that information regarding examinations, indications, advantages, benefits, and limitations, risks, are readily available to the referring medical practitioners to allow appropriate selection and justification of an examination. The process should include regular updating of available information. The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS) were published as Nuclear technology review, International Atomic Energy Agency, 2014. The BSS represents the culmination of efforts over the past decades toward the harmonization of radiation protection and safety standards internationally and is jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the IAEA, the International Labour Office (ILO), the OECD Nuclear Energy Agency (OECD/ NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO). The purpose of the standards is to establish basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure. The standards can only be implemented through an effective radiation safety infrastructure according to applicable laws and regulations, an efficient regulatory system, supporting experts and services, and a 'safety culture' shared by all those with responsibilities for protection, including both management and workers.

Chapter purpose:

The main objective of this chapter is

1. To ensure appropriate justification of the radiology examination.
2. To have a Medical imaging procedure manual.
3. To have a Therapeutic radiological procedure.
4. To implement a Radiation safety program.
5. To determine the Diagnostic reference level.

Implementation guiding documents

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

- 1) Egyptian Constitution
- 2) Egyptian code of medical ethics 238/2003 (Medical Syndicate Publications)
- 3) Egyptian code of nursing ethics (Nursing Syndicate Publications)
- 4) Law 59 /1960 – Radiation Protection against Ionizing Radiation
- 5) Law 7 /2010 - Regulating nuclear and radiological activities
- 6) MOHP Ministerial decree number 513 / 2016 for the licensing and control of magnetic resonance imaging devices.
- 7) Law 192/2001 for Hazardous waste management

Appropriateness and justification of the radiology examination

MRS.01 NSR.05 Any specific radiological hazards to the patient's health conditions are early identified and managed according to evidence-based guidelines and/or protocols.

Safety

Keywords:

Specific radiological hazards.

Intent:

Patients subjected to radiology examination may have clinical conditions contraindicated for specific radiology examinations that may lead the examination to be hazardous to the patient's health condition.

The radiology center shall adopt and implement evidence-based guidelines/protocols that identify the patient health conditions that may be contraindicated for specific radiology examinations and methods of how to select the examination or the alternative diagnostic investigations. The radiology center shall inform the patient about the alternative diagnostic investigations and the center has to respect his/her preferences. The radiology center shall develop and implement a policy of specific radiological hazard early identification. The proper selection of examination and the alternative diagnostic examination shall address at least the following:

- a) Contrast media contraindications;
- b) Renal impairment;
- c) Pacemakers and aneurysmal clips
- d) Anti-coagulant therapy;
- e) Pregnancy status.

Survey process guide:

- GAHAR surveyor may review the policy for specific radiological hazard early identification.
- GAHAR surveyor may review the adopted specific radiological hazards guidelines.
- GAHAR surveyor may interview staff to assess their awareness and compliance with the adopted specific radiological hazards' guidelines\protocol.

Evidence of Compliance:

1. The radiology center has an approved policy for specific radiological hazard early identification that addresses all items in the intent from a) through e).
2. The staff is aware of how to apply the policy.
3. Identified specific radiological hazards to the patient's health conditions are managed according to the adopted guidelines/protocols.

4. Any patient health conditions that may be contraindicated for specific radiology examinations are documented in the patient medical record.

Related standards

ICD.03 Clinical practice guidelines, MRS.04 Pregnant and lactating patients, ICD.05 High-risk patients and procedures/ services, IMT.05 Medical record management.

Medical imaging procedure manuals

MRS.02 The radiology center ensures the validity of the medical imaging studies using a standardized, effective process.

Effectiveness

Keywords:

Technical medical imaging procedures.

Intent:

Radiology service encompasses different techniques, modalities, and processes to analyze services. Furthermore, radiology service is important in the diagnosis and follow-up of the disease. A prepared procedure manual provides a reference for the medical imaging service quality assurance program. The procedure manual may be used to document how studies are performed, train new staff members, remind staff members of how to perform infrequently ordered studies, troubleshoot the technical problem, and measure acceptable performance when evaluating staff.

The radiology center shall develop technical procedures for all study types. The technical medical imaging procedures should be written according to evidence-based best practice clinical imaging guidelines in accordance with the manufacturers' recommendation and available in an accessible location. It could be in a paper-based, or electronic, format.

The radiology center shall develop and implement a documented procedure manual for medical imaging to ensure the safety and usability of modalities. For each modality, procedure manuals shall address at least the following:

- a) Scope and general overview.
- b) Pre-examination, examination, and post-examination procedures.
- c) Equipment description.
- d) Maintenance procedures.
- e) Quality control.
- f) Safety procedures.

Survey process guide:

- GAHAR surveyor may review the written procedure manual for each modality.
- GAHAR surveyor may interview staff members to check their awareness.

- GAHAR surveyor may observe the availability of the written procedure manual for each modality in all the relevant areas.

Evidence of compliance:

1. The radiology center has a documented procedure manual for each modality according to the manufacturers' recommendations.
2. Modality procedure manuals are readily available and accessible for the radiology center staff members.
3. Each modality procedure manual includes all the required elements from a) through f) in the intent.
4. Staff is aware and trained of the contents of procedure manuals in use.
5. Staff compliance with technical standards procedure manuals is monitored, tracked, and acted upon.

Related standards:

MRS.06 Radiation Safety Program, EFS.09 Quality assurance and control program, EFS.02 Fire and smoke safety plan, EFS.08 Calibration of equipment, WFM.06 Continuous education and training program, QPI.03 Performance measures.

Therapeutic radiological procedures

MRS.03 The radiology center establishes optimization measures to achieve the required therapeutic effect using the effective radiation dose to the targeted organ with less radiation hazards

Safety

Keywords:

Effective therapeutic radiation dose.

Intent:

Radiation therapy (also called radiotherapy) is a cancer treatment that uses high doses of radiation and uses beams of intense energy to kill cancer cells and shrink tumors. Radiation therapy most often uses X-rays, but electrons, protons, or other types of energy also can be used. Optimization measures to achieve the required therapeutic effect using the effective radiation dose shall be documented and readily used.

For radiation therapeutic procedures, the radiation oncologist, in cooperation with the medical physicist and the radiographer ensures that for each patient the surrounding volumes other than the planning target volume (PTV) are kept as low as reasonably achievable (ALARA), in accordance with the administration of the prescribed dose to the planning target volume within the required tolerance limits.

There are three basic principles of radiation protection: justification, optimization,

and dose limitation. Justification involves an appreciation for the benefits and risks of using radiation for procedures or treatments. Any amount of radiation exposure will increase the risk of stochastic effects, namely the chances of developing malignancy following radiation exposure. For these reasons, the radiology center shall implement the protection practices under the ALARA principle.

The radiation therapy dose shall be primarily localized in the target organ(s) thus, the hazards for the other critical organs are kept as low as reasonably achievable (ALARA). The Dose-volume histogram (DVH) is a histogram relating radiation dose to tissue volume in radiation therapy planning. DVHs are most commonly used as a plan evaluation tool in radiation therapy.

Survey process guide:

- GAHAR surveyor may review the patient radiation therapy medical record.
- GAHAR surveyor may review records of the planning, the dose-volume histogram (DVH) of the planning quality control (QC) records in high/advanced technology procedures, and patient therapeutic radiation doses.
- GAHAR surveyor may interview relevant staff about the therapeutic radiation dose planning process.

Evidence of Compliance:

1. All clinical data are documented in the patient radiation therapy medical record.
2. The radiology center has records for both therapeutic radiological planning and for the dose-volume histogram (DVH) of the planning.
3. The radiology center has records for the calculation of the therapeutic radiation dose.
4. Quality control records are available for high/advanced technology procedures.
5. Relevant staff is aware of the therapeutic radiation dose planning process.

Related standards:

MRS.06 Radiation Safety Program, MRS.09 Personal radiation dosimeter monitoring device, ICD.05 High-risk patients and procedures/ services, EFS.09 Quality assurance and control program, IMT.01 Documentation management system, MRS.07 Diagnostic Reference Levels (DRLs).

Pregnant and Breast-Feeding Patients

MRS.04 The radiology center has a clearly defined process for medical imaging during pregnancy and lactation.

Safety

Keywords:

Pregnant and lactating patients.

Intent:

The burden of the risk of fetal radiation exposure should be carefully weighed against the advantages of rapidly obtaining a critical diagnosis and using a specific technique imaging study. In general, pregnant patients are less aware than expected of the radiation risks to the fetus. Exposure of the pregnant female to radiation, especially in the first trimester, may cause harmful effects on the embryo and in some cases may lead to induced abortion.

Modalities that do not use ionizing radiation, such as ultrasonography and magnetic resonance imaging, should be the preferred examinations for evaluating an acute condition in a pregnant patient. However, no examination should be denied when a significant clinical diagnosis is contemplated.

The reasons for approval shall be documented by the radiologist with written consent signed by the patient. The radiologist and radiographer shall inform and educate the patient about the potential risks of the exposure.

The radiology center shall ensure that there are arrangements in place, for establishing that a female patient is not currently breastfeeding before the performance of any radiological procedure involving the administration of a radiopharmaceutical, that may cause harm to a breastfed infant so that this information can be considered in the justification for the radiological procedure and in the optimization of protection and safety.

The radiology center shall develop and implement a policy for medical imaging during pregnancy and lactation to decrease the risk of radiological hazards for both the patient and the embryo.

Survey process guide:

- GAHAR surveyor may observe the availability of special pregnancy and lactation consent.
- GAHAR surveyor may review the policy for medical imaging during pregnancy and lactation.
- GAHAR surveyor may interview staff to check their awareness of the policy.
- GAHAR surveyor may review the justification of imaging pregnant patients in the request form.

Evidence of Compliance:

1. The radiology center has an approved policy for medical imaging during pregnancy and lactation.
2. The staff is aware of how to apply the policy.
3. The reasons for approval to expose a pregnant female to radiation are documented by the radiologist.
4. The reasons for approval to expose a lactating female to nuclear medicine procedure are documented by the responsible physician.

Related standards:

PCC.03 patient and family education process, PCC.04 informed consent, MRS.01 Specific radiological hazards, ICD.05 High-risk patients and procedures/ services, MRS.05 Release of patients undergoing treatment with radionuclides.

Release of Patients after Radionuclide procedures

MRS.05 The radiology center ensures the provision of all possible safety measures for the release of patients after radionuclide therapy in particular for family members and the general public.

Safety

Keywords:

Release of patients undergoing treatment with radionuclides.

Intent:

From a radiation safety perspective, the radiation is limited to the patient, with minimal exposure to the public, radiation exposure to family, caregivers, and the public should be kept as low as reasonably achievable (ALARA), especially for children and pregnant women.

The radiology center shall develop and implement a policy and procedure for the release of patients after radionuclide therapy and ensure the presence of an Isolated waiting area for patients after the radionuclide procedure, determination of patient flow and separate exits would be preferable.

The radiation safety officer shall ensure that the patient undergoing treatment with radionuclides is not released from the facility until it has been determined that:

- a) Exposures to persons in the public, particularly family members, are always kept as low as reasonably achievable (ALARA) and after surveying the patient by the radiation survey meter.
- b) The patient or the legal guardian of the patient is provided with:
 - I. Written instructions on how to minimize the exposure doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable (ALARA).

- II. Written instructions on how to avoid the spread of radioactive contamination such as vomiting, and bleeding).
- III. Information about the potential radiation risks.

Survey process guide:

- GAHAR surveyor may review the policy of nuclear medicine release of patients after radionuclide therapy.
- GAHAR surveyor may observe and examine the waiting area for patients after the radionuclide therapy and check the isolation, patient flow, and exits.
- GAHAR surveyor may observe the availability of written awareness information and its communication to the patients and their legal guardians.
- GAHAR surveyor may observe the availability of the survey meter.

Evidence of Compliance:

1. The radiology center has an approved policy for the release of patients after radionuclide therapy.
2. The radiation safety officer validates the accurate dose limits for the general public as per center policy.
3. There are written instructions provided to the patient or to the legal guardian of the patient, to minimize the exposure doses to persons in contact.

Related standards:

MRS.02 Technical medical imaging procedures, MRS.04 Pregnant and lactating patients, PCC.03 Patient and family education process, MMS.06 Radiopharmaceutical

Safe and uniform radiation studies and measures

MRS.06 NSR.11 The radiology center establishes an effective radiation safety program.

Safety

Keywords:

Radiation Safety Program.

Intent:

The programs ensure all activities with ionizing and non-ionizing radiation are conducted in a safe manner and in compliance with the law and regulations, and applicable standards and guidelines.

The program is administered by the Radiation Safety Officer and is designed to protect staff, patients and the public from potential exposure to radiation from radioactive sources and radiation-emitting devices. Furthermore, the radiation safety program controls the release of radioactive materials into the environment. The program shall

maintain that all radiological equipment are used safely.

The radiology center shall develop and implement a radiation safety program that addresses all components of the radiology center services, The Radiology Centre monitors staff health by performing regular biannual CBC analysis and collecting their thermos-luminescent dosimeter (TLD) and/or badge film reports. When CBC results exceed the borderline further investigations are ordered.

The program shall address at least the following:

- a) Availability and applicability of the staff self-monitoring tools.
- b) Availability applicability of the suitable personal protective equipment.
- c) Patients' radiation safety precautions.
- d) Methods of measuring and monitoring the radiation exposure doses for patients who receive CT or in catheter units, and that doses are not exceeding the international references of the International Atomic Energy Agency (IAEA).
- e) Radiation equipment protective maintenance and calibration.
- f) MRI safety program, which includes pre-exposure screening for metals, metallic implants, devices and use of MRI compatible devices.
- g) Nuclear medicine and PET CT radiation protection and safety measures that include at least the following;
 - i. Safe waste disposal and isolated sewage for radioactive materials according to national law and regulations.
 - ii. Safe hot lab for radioisotope processing.
 - iii. Isolated waiting area for injected patients.
 - iv. Each area in the nuclear medicine unit is labeled and isolated.
 - v. The Survey meter and dose calibrator must be calibrated.

Survey process guide:

- GAHAR surveyor may review the radiation safety program to check the approved level of exposure according to local laws and regulations, shielding methods, and safety requirements.
- GAHAR surveyor may review environmental radiation measures, thermos-luminescent dosimeter (TLD), and/or badge films of the staff results, CBC results, and lead aprons inspection.
- GAHAR surveyor may interview staff to check their awareness.
- GAHAR surveyor may observe the implemented radiation safety measures.

Evidence of Compliance:

1. The radiology center has an approved radiation safety program that addresses all elements mentioned in the intent from a) through g).

2. Staff members involved in medical imaging are aware of the radiation safety program and receive ongoing education and training for new procedures and equipment.
3. Exposure radiation doses are measured and monitored for exposed patients and comply with the International Atomic Energy Agency (IAEA) level for the same patient dimensions and population.
4. Environmental radiation safety measures, personal monitoring devices' staff results, and the regular CBC results are available and documented.
5. Nuclear medicine safety measures are implemented by addressing the elements from i) through v) in the intent.

Related standards:

EFS.01 Radiology center environment and facility safety structure, MRS.02 technical medical imaging procedures, EFS.03 Hazardous materials, and waste disposal, MRS.03 Effective therapeutic radiation dose, ICD.03 Clinical practice guidelines, MRS.09 Personal radiation dosimeter monitoring device, IPC.04 Standard precautions measure, ICD.05 High-risk patients and procedures/ services, EFS.02 Fire and smoke safety plan, QPI.03 Risk management plan/program, MRS.07 Diagnostic Reference Levels (DRLs).

MRS.07 The radiology center ensures that the Diagnostic Reference Levels (DRLs) are established and readily used.

Safety

Keywords:

Diagnostic Reference Levels (DRLs).

Intent:

Diagnostic reference levels (DRLs) are a practical tool to promote the optimization of patient protection in diagnostic radiology, diagnostic nuclear medicine, or image-guided interventional procedures that requires the implementation of examination-specific protocols tailored to patient age, size, region of imaging, and clinical indication in order to ensure that patient doses are as low as reasonably achievable (ALARA) for the clinical purpose of the examination.

Recent studies highlight the presence of substantial variations in dose between some healthcare facilities for the same examination or procedure and similar patient groups (adults or children of defined sizes). Such studies indicate the need for dose standardization and reduction in dose variation without compromising the clinical purpose of each examination or procedure.

The diagnostic reference level is measured in CT dose index (CTDI) (measured in mGy) and Dose length product (DLP) (measured in mGy*cm)with respect to the

following parameters:

- a) Imaging procedure (equipment, use of contrast media, site, and laterality).
- b) Patient body dimensions.
- c) Patient age group (adults and children of defined sizes).
- d) Clinical indication.

The examinations or procedures included should represent at least the most frequent examinations performed at the national level, hence the dose assessment is workable, with priority given to those that result in the highest patient radiation dose and include the most commonly used digital equipment as Digital Mammogram, Computed Tomography and Catheterization Lab.

Each healthcare facility shall choose three of its main, common imagining studies (brain -chest –pelvic –abdomen-joints- coronary – computed tomography, Angio .etc) to collect data about DRL's limits at least for 10% of the total studies.

The DRLs shall be collected, tracked, and analyzed by the radiology center, it shall be integrated into the overall center's improvement plan.

Survey process guide:

- GAHAR surveyor may review the presence of the DRLs documents and their accessibility for the radiology staff.
- GAHAR surveyor may interview the responsible staff to check their awareness of how to record the DRLs.

Evidence of Compliance:

1. The radiology center collects diagnostic reference levels for at least 10% of the total three main studies.
2. The radiology center collects the data of diagnostic reference level at least the items mentioned in the intent from a) through d).
3. The diagnostic reference level list is available and accessible for all the relevant radiology center staff.
4. The radiology center staff is aware of how to apply the diagnostic reference level.

Related standards

MRS.03 Therapeutic radiological dose, EFS.07 Medical equipment management plan, QPI.02 Performance measures, QPI.06 Performance improvement plan.

MRS.08 The Radiology center ensures safe, appropriate use of Personal Protective Equipment by all staff to prevent and mitigate serious job-related illness or injury.

Safety

Keywords:

Personal Protective Equipment (PPE).

Intent:

The use of protective equipment is one of the important methods of protection from radiation occupational hazards. Personal protective equipment includes aprons, thyroid shields, gas masks, gloves, and eyeglasses.

Nuclear medicine units shall use other protective measures as the use of shielding equipment such as syringe cases, syringe shield lead eyeglasses, and ring dosimeters. The radiology center shall ensure the availability of personal protective equipment to protect all workers inside the center.

And it is recommended to be easily accessible and available when needed especially in the radiology procedure room; such as fluoroscopy, c-arm, catheters, hot lab interventional and image-guided interventional procedures.

A lead apron is one of the personal protective equipment, which is made of radioactive shield material, worn to drastically minimize the dosage of radiation that the wearer absorbs.

The radiology center shall ensure that the lead aprons are certified by an authorized body and comply with its requirements for the manufacturing materials and body coverings they provide.

The apron shall be calibrated regularly to ensure the accuracy and validity of the lead-equivalent value and it shall be inspected annually for any possible leaks, cracks, creases, or ruptures to ensure adequate protection. The apron shall cover the body from the throat to about 10 cm of the knee and coverage should be frontal and back. Lead aprons shall be checked fluoroscopically under proper imaging tests at least on an annual basis for their shielding integrity.

The radiology center shall strictly follow the lead apron manufacturer's recommendation regarding the proper handling and storage of the apron. When it is not in use, aprons must be stored on hangers to prevent cracks in the protective lead. Aprons should be hung by the shoulder or on an approved apron hanger. Aprons should never be folded or creased, to avoid damaging the lead.

Survey process guide:

- GAHAR surveyor may observe the presence of aprons, thyroid shields, gas masks, syringe case and syringe shield and that all staff is equipped with.
- GAHAR surveyor may review the certificate of the protective aprons, its lead

equivalency, and the aprons' annual inspection records.

- GAHAR surveyor may observe the stored aprons for cracks, creases, or ruptures and check their coverage area.

Evidence of Compliance:

1. There is personal protective equipment for all staff who is working in different radiological procedures.
2. All staff is aware of how to use their personal protective equipment.
3. All lead aprons are certified from an authorized body and calibrated regularly to validate their lead equivalent value accuracy.
4. Records of the annual integrity testing under proper imaging tests for all lead aprons are available.
5. Lead apron are stored and hanged as per the manufacturer's recommendation.

Related standards

MRS.06 Radiation Safety Program, MRS.09 Personal radiation dosimeter monitoring device, EFS.03 Hazardous materials, and waste disposal, IPC.04 Standard precautions measures, WFM.06 Continuous education, and training program, ICD.05 High-risk patients and procedures/ services, OGM.10 Staff health program, QPI.03 Risk management plan/program.

MRS.09 The personal radiation dosimeter and monitoring devices are available, regularly maintained and calibrated.

Safety

Keywords:

Personal radiation dosimeter monitoring device.

Intent:

Personal monitoring is the measurement of radiation doses received by individual workers. Personal monitoring is used to verify the effectiveness of radiation control practices in the workplace. It is also used to detect changes in the workplace, Confirm or supplement static workplace monitoring, and identify work. practices that minimize doses and provide information in the event of accidental exposure.

According to the International Atomic Energy Agency (IAEA), occupational radiation exposure must be monitored through the use of personal monitoring devices, such as; film badges, Thermo-luminescent dosimeters (TLD), pocket dosimeters, pen dosimeters and nuclear emulsion neutron dosimeters (NTA).

In the radiology center, personnel exposed to radiation must wear personal monitors at all times while working. The number of personal monitoring devices must be exactly equal to the number of employees exposed to radiation.

The proper place to wear the device is near the chest or the waist area.

Dosimeter results shall be recorded and kept in compliance with regulatory requirements. The radiology center shall specify the retention period(s). The purpose of Dose records is:

- a) Demonstrate compliance with regulatory requirements, showing that controls are used to keep doses as low as reasonably achievable and that dose limits are not exceeded.
- b) Regular monitoring to alert the worker when practices or equipment deteriorate.
- c) Allow workers to compare procedures and identify the best practical means of working which result in the lowest doses.
- d) Provide long-term medical and legal assurance for the worker in the event that the worker contracts a radiation-linked disease in later life.

Dose records shall contain the results of all special assessments. Each worker should have only one dose record, which should be summarized when employment is terminated. Each new record should contain the summary so that the final record contains the worker's entire dose history.

When not being used, the personal monitoring device shall be stored away from any radiation source. If the employee is working in more than one radiology center, it is preferred to have two different personal monitoring devices, one to measure the cumulative dose at his current workplace and the other to measure the whole cumulative dose at all workplaces.

Survey process guide:

- GAHAR surveyor may interview the staff members about the proper use of the personal monitoring devices.
- GAHAR surveyor may observe that the staff members wearing the personal monitoring devices.
- GAHAR surveyor may review its calibration records.
- GAHAR surveyor may observe the storage of the personal monitoring devices in a low radiation background area in the radiology center.

Evidence of Compliance:

1. All the staff members dealing with radiation are wearing personal monitoring devices during working hours.
2. All staff monitoring devices are kept and stored away from any radiation source when it is not being used.
3. The personal monitoring equipment's calibration records are available, documented, and updated.
4. Actions are taken when radiation doses are higher than the approved limit.

Related standards

EFS.08 Calibration of equipment, MRS.08 Personal Protective Equipment (PPE), OGM.10 Staff health program, MRS.06 Radiation Safety Program, ICD.05 High-risk patients and procedures/ services.

Interventional Radiology Standards

Chapter Intent:

Interventional Radiology using innovative, evolving and often complex techniques have revolutionized patient care in a wide range of diseases. It has produced major improvements in safe, patient-centered care and utilization of imaging guidance at its heart.

Interventional Radiology is increasingly recognized as a vital component of medical services providing lifesaving care and even become now a separate subspecialty of Radiology.

Many surgical procedures have been replaced or enhanced by the provision of interventional radiology services as well as allowing new treatments for patients that were not previously feasible. The provision of interventional radiology services, however, remains variable with many medical centers or hospitals having limited or, in some cases, no direct access to interventional radiology services.

Interventional Radiology procedures are minimally invasive, often targeted treatments performed under imaging guidance and it plays a vital role in both elective and emergency patient care.

Interventional Radiology encompasses a large range of procedures and techniques:

- ▶ Interventional cardiac techniques.
- ▶ Vascular diseases and embolism.
- ▶ Hemorrhage control.
- ▶ Renal medicine and dialysis support.
- ▶ Venous access.
- ▶ Interventional oncology: including ultrasound-guided techniques such as cryoablation, microwave ablation, radiofrequency ablation, and irreversible electroporation.
- ▶ High-Intensity Focused Ultrasound (HIFU).
- ▶ Gastro-Intestinal and hepatobiliary disease.
- ▶ Gynecology and obstetrics.
- ▶ Uro -Intervention.
- ▶ Pediatric intervention.
- ▶ Neuro-Intervention.
- ▶ Image-guided drainage and aspiration.

Access to robust 24/7 interventional radiology services coverage should be a priority. Medical facilities that undertake acute medical and surgical care should have access to interventional radiology services either onsite or through agreements to transfer

patients to a site where the services are available. Interventional radiology units should define the procedures they undertake both within working hours and out of working hours to ensure that the patients' access to appropriate treatment is maintained. Formal pathways are required for the arrangements between medical centers/hospitals to transfer acute patients requiring emergency interventional radiology.

The purpose of this chapter is to inform service providers, clinicians and regulatory authorities of the requirements for the provision of a safe and sustainable interventional radiology service.

GAHAR surveyors shall survey all areas where invasive procedures, anesthesia, or sedation are taking place; to ensure patient safety, staff competency, and effective utilization of these areas.

Chapter purpose:

1. To ensure that organizations provide/maintain safe, timeliness, patient-centeredness, and effective invasive procedural, anesthesia care, and sedation services.
2. To describe processes before, during, and after the invasive procedure.
3. To define anesthesia leadership, followed by pre-anesthesia, during anesthesia, and post-anesthesia required processes.
4. To describe sedation care including pre-sedation, during sedation, and post-sedation care.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

- 1) Egyptian Constitution.
- 2) Law 51/1981 for healthcare organizations.
- 3) MOHP Ministerial Decree 216 for operation procedures.
- 4) MOHP Ministerial decree 236/2004 on anaesthesia service requirements.
- 5) MOHP Ministerial Decree 153/2004 on minimum requirements for anaesthesia services.
- 6) MOHP Ministerial decree 244/2001 on competencies of surgeons.
- 7) MOHP Ministerial decree 34/2001 on surgery and anaesthesia services.
- 8) Patient Safety during operation procedure committee recommendations, 2003.
- 9) Egyptian code of medical ethics 238/2003 (Medical Syndicate Publications).
- 10) MOHP Ministerial decree 284/1985 on requirements for OR.
- 11) Egyptian code of nursing ethics (Nursing Syndicate Publications).
- 12) Emergency Department unified protocol, Egyptian ministry of health and population curative and critical sector.
- 13) Requirements of inspection per MOHP law and regulation.

- 14) ICD-10-PCS.
- 15) WHO Surgical Safety checklist.
- 16) Law 59 / 1960 – Radiation Protection against Ionizing Radiation.
- 17) Law 7 / 2010 - Regulating nuclear and radiological activities.

Safe and effective invasive procedure care

IRS.01 Provision of invasive procedure services is effective, safe, and appropriate to patient's needs.

Safety

Keywords:

Provision of invasive procedures.

Intent:

The radiology center is required to provide invasive procedure services all over the center safely by providing the required resources as obliged by the national laws and regulations. All units designed to provide invasive procedure services have appropriate spacing, ventilation, infrastructure including medical gases, appropriate equipment, medical supplies, and medication. The radiology center shall develop a process to clearly define and grant the clinical privileges to staff who are authorized to perform those types of invasive procedures. The radiology center shall record the time needed during the different patient flow steps inside the unit and provide the analysis of any punctuality that may arise. All these measures will help the radiology center to plan efficiently in providing invasive procedure services.

Survey process guide:

- GAHAR surveyor may observe the place, infrastructure, supplies, medications, and equipment available.
- GAHAR surveyor may review the qualifications and privileges of staff who are permitted to perform invasive procedures.

Evidence of compliance:

1. The procedural units are designed and equipped with the required equipment, medical supplies, and medication as obliged by the national laws and regulations.
2. Punctuality of the procedural unit is maintained and recorded starting with patient calls until room cleaning after the procedure.
3. Staff who are permitted to perform invasive procedure services are qualified and privileged in the center to perform those types of invasive procedures.

Related standards:

ACT.02 Patient identification, ICD.05 High-risk patients and procedures/ services, PCC.04 informed consent, WFM.08 Clinical Privileges, ICD.03 Clinical practice guidelines, QPI.04 Incident reporting system, IRS.02 Assessment before invasive procedures, IRS.03 Site marking and identification, IRS.04 Pre-invasive procedural verification process, IRS.05 Timeout.

IRS.02 Patient assessment is performed by the responsible physician before the invasive procedure.

Safety

Keywords:

Assessment before invasive procedures.

Intent:

Completed patient assessment before the invasive procedure is required and shall include reviewing the examination request or referral form for ensuring the diagnosis, revealing any associated risk factors, and planning for the proper management of all identified risk factors.

Accordingly, a completed patient assessment is needed before all invasive procedures, to determine the precautions needed and to inform the patient and family about the expected outcomes.

Patient reassessment should be performed if an invasive procedure is postponed or canceled to maintain the validity of the patient assessment.

The radiology center is required to perform a complete patient assessment before any invasive procedure and document it in the patient's medical record for the medico-legal issues and for proper communication between staff followed by developing the patient's plan of care that includes at least the following:

- a) Patient needs and condition.
- b) Pre-invasive diagnosis.
- c) Plan for the invasive procedure.

Survey process guide:

- GAHAR surveyor may review the patient record to ensure compliance with a complete assessment of the patient, availability of results of requested investigations and risk classification before the invasive procedure, and appropriate management of the risk factors.

Evidence of compliance:

1. A complete pre-invasive procedure assessment is performed and documented for all patients planned for an invasive procedure, with documentation of any identified risks for the patient's conditions.
2. Actions taken for the management of any associated risk factors are documented in the patient medical record before the invasive procedure.
3. Invasive procedure' plan of care is performed and timely documented in the medical record.
4. In life-threatening emergencies, a brief assessment and surgical care planning are performed and timely documented in the patient's medical record.

Related standards:

IRS.01 provision of invasive procedures, ICD.01 screening and assessment, IRS.11 Pre-anesthesia assessment, Pre- sedation assessment, ICD.04 Individualized care plan.

IRS.03 NSR.07 The radiology center uses an easily noticeable mark for invasive procedures site identification that is consistent throughout the center.

Safety

Keywords:

Site marking and identification.

Intent:

Visible and clear site marking is an error reduction strategy that should be performed by the responsible physician who will perform the invasive procedure with the involvement of the patient if the patient is an adult and fully conscious or the patient's family in other situations. The site marking in each organization should be unified, detectable, and placed on the nearest site to the site of the planned invasive procedure.

When performing an invasive procedure, healthcare professionals should verify the right patient, the right type of procedure, the right site, and the right side. The site is marked in all cases including laterality, and multiple structures.

Survey process guide:

- GAHAR surveyor may interview staff to check their awareness of the site marking process.
- GAHAR surveyor may observe the use of an easily noticeable mark for invasive procedure site marking that is consistent throughout the center.

Evidence of compliance:

1. Invasive procedure' unified site marking is done by the responsible physician who will perform the procedure.
2. The patient is actively involved in the site marking process with the exception of some circumstances.
3. The mark is visible after the patient is prepped, draped, and prepared for the invasive procedure.

Related standards:

ACT.02 Patient identification, IRS.01 provision of invasive procedures, IRS.05 Timeout, PCC.03 Patient and family education process, IRS.04 Pre-invasive procedural verification process, WFM.08 Clinical Privileges.

IRS.04 NSR.08 The radiology center has a pre-invasive verification process to ensure patient safety, availability and appropriateness of care before calling for the patient for the invasive procedure.

Safety

Keywords:

Pre-invasive procedural verification process.

Intent:

Ensuring the availability of all needed items as results of the requested investigation or special prosthesis should be done as a pre-invasive verification process to ensure patient safety and appropriateness of care. Ensuring the availability and functioning of needed equipment minimizes the risk of errors by preventing the use of malfunctioning equipment or the cancellation of invasive procedures. Implementing regular checkups is a quality improvement process that should be guided by designed checklists performed by trained staff.

The radiology center is required to ensure the availability and functioning of equipment needed for the invasive procedure before starting the procedure. This equipment and tools could be differed according to the type of invasive procedure.

The radiology center shall develop and implement a policy for the pre-invasive procedural verification process of the availability of all needed or requested documents and other items before the patient goes for the invasive procedure.

Survey process guide:

- GAHAR surveyor may review the policy of pre-invasive procedural verification.
- GAHAR surveyor may observe the availability and functioning of all needed documents and equipment.
- GAHAR surveyor may interview responsible staff to check their awareness of the Pre-invasive procedural verification policy.

Evidence of compliance:

1. The radiology center has an approved policy for pre-invasive procedural verification to ensure the availability of all needed documents and the functioning of equipment.
2. Pre-invasive procedural verification of all needed documents and equipment is checked and documented before each invasive procedure.
3. Responsible staff is aware of the pre-invasive procedural verification process.

Related standards:

ACT.02 Patient identification, IRS.01 provision of invasive procedures, IRS.03 Site marking and identification, IRS.05 Timeout, IRS.06 invasive procedure report, MRS.03 Effective therapeutic radiation dose.

IRS.05 NSR.09 The Time-out is safely performed, just before starting the invasive procedure.

Safety

Keywords:

Timeout.

Intent:

Time-out for verification of the correct patient, invasive procedure, and correct site and side of invasive procedure is a single process that has been proved to reduce wrong-site procedures. When performing the invasive procedure, healthcare professionals should verify the right patient, the right type of invasive procedure, right site, right side, and the patient received the prophylactic antibiotic if applicable.

The radiology center shall develop and implement a policy and procedures to ensure correct patient, correct invasive procedure, and correct site and side and apply the time out process just before the start of the invasive procedure.

Survey process guide:

- GAHAR surveyor may review the policy of the timeout.
- GAHAR surveyor may interview the relevant staff to check their awareness of the policy.
- GAHAR surveyor may review the document used to record the time-out process.
- GAHAR surveyor may observe the time-out process.

Evidence of compliance:

1. The radiology center has an approved policy to ensure the correct patient, procedure, body part, and site.
2. Relevant staff is fully aware of the Time-out process.
3. The performing physician is involved in the time out process.
4. When an invasive procedure is performed outside the procedural unit, the time-out process is implemented.

Related standards:

ACT.02 Patient identification, IRS.01 provision of invasive procedures, IRS.03 Site marking and identification, QPI.04 Incident reporting system, IRS.04 Pre-invasive procedural verification process.

IRS.06 Invasive procedure details are recorded in a report immediately after the procedure and before the patient leaves the procedural unit.

Safety

Keywords:

Invasive procedure report.

Intent:

Immediate reporting of the procedure has a significant role in the continuity of care. Planning post-procedural care depends on findings and special events that occurred during the procedure, as failure to report these events markedly compromises patient care.

The radiology center is requested to immediately report the procedure details before the patient leaves the procedural unit.

Recording the names of all staff involved in the procedure has a medico-legal aspect and communication aspect and any similarity or discrepancy in the patient diagnoses before and after the procedure should be documented and clarified.

Details of the procedure should be clearly stated, including the incision site, if applicable, step by step of the invasive technique, and ended by how the skin closure or ending the procedure is done.

Use of any prosthesis or implantable devices should be stated in the report, including any special precautions when dealing with or removing it.

The occurrence of complications during the procedure should be recorded with the action taken to manage them. Any specimen removed from the body shall be stated clearly in the procedure report.

The radiology center shall ensure that the invasive procedure report addresses at least the following:

- a) Time of start and time of the end of the procedure.
- b) Name of all staff involved in the procedure, including anesthesia.
- c) Pre-procedure and post-procedure diagnoses.
- d) The procedure performed with details.
- e) The details of any used implantable device or prosthesis including the batch number
- f) The occurrence of complications or not.
- g) Any removed specimen or not.
- h) Signature of the performing physician.

Survey process guide:

- GAHAR surveyor may review patients' medical records to check the completeness of all components needed in the procedure report.

Evidence of compliance:

1. The procedure report is readily available for all patients who underwent a procedure before leaving the procedural unit.
2. The report includes at least all items from a) through h) in the intent.
3. The report is kept in the patient's medical record.

Related standards:

IRS.01 provisions of invasive procedures services, IRS.08 Implantable Devices, IRS.07 Human tissue biopsy and specimen, IRS.10 Anesthesia and sedation services.

IRS.07 The radiology center ensures safe handling of human tissue biopsy and specimen with a clear pathway for the pathological examinations.

Effectiveness

Keywords:

Human tissue biopsy and specimen.

Intent:

A biopsy is the removal of tissue in order to examine it for disease. Biopsies can be safely performed with imaging guidance such as Ultrasound, Computed tomography (CT), and Magnetic resonance imaging (MRI). These types of imaging studies are used to determine exactly where to place the needle in order to perform the biopsy.

The radiology center shall provide and ensure that patients planning for biopsy receive detailed instructions about preparation for the biopsy procedure, based on the type of biopsy being performed. Patients' regular medications shall be reviewed prior to the biopsy. After the tissue is collected, it is sent to the laboratory for pathological, histopathological, or immune-histochemical examinations and analysis. Specimens and tissue biopsies shall be submitted in the correct manner using the appropriate transport material in a leak-proof container. It is the radiology center and caregiver's responsibility to understand the correct specimen and transport requirements prior to collecting specimens. All patient specimens and tissue biopsies shall be placed in biohazard bags for transport to the laboratory or when it is allowed to be given to the patient and his family. The biopsy transportation methods shall be documented in the patient medical record.

The radiology center shall develop and implement a policy to guide the safe handling of specimens and tissue biopsies, determining the criteria for the accurate, legible labeling of tissue biopsies and specimens. The label shall contain at least the following legible information:

- a) Patient full name.
- b) Patient medical record number.

- c) Collection date and time.
- d) Specimen, tissue biopsy type, and/or source.
- e) The test required (note any special handling required).
- f) Ordering physician.

Survey process guide:

- GAHAR surveyor may review the policy of the safe handling of specimens and tissue biopsies
- GAHAR surveyor may interview staff to check their awareness of the policy.
- GAHAR surveyor may review patients' medical records and the invasive procedure report to check the documentation of the specimen /biopsy transportation methods and who received it.

Evidence of compliance:

1. There is an approved policy to guide the safe handling of specimens and tissue biopsies that addresses the criteria of the accurate, legible labeling including items from a) to f) in the intent.
2. The staff is aware of how to apply the policy.
3. The specimen and tissue biopsy transportation methods are documented in the patient medical record and the invasive procedure report.

Related standards:

ACT.02 Patient identification, IRS.01 provision of invasive procedures, IRS.06 invasive procedure report.

IRS.08 radiology center requires special considerations for invasive procedures involving implantable devices.

Safety

Keywords:

Implantable Devices.

Intent:

The implantable device is a medical device that is permanently placed into the body to continuously assist, restore, or replace a function or structure of the body throughout the useful life of the device.

Examples include stents, coils, and applicators of brachytherapy.

There are many considerations while using implantable devices, which include the special instructions for use, sterility, manufactural consideration, and malfunction. The radiology center is required to track the implantable device from its primary source to discover any unstable, contaminated, defective, or imitation product.

Every patient who has an implantable device should be easily identified, and easily reachable within a defined time frame to be ready for any device recall.

Survey process guide:

- GAHAR surveyor may review the list of implantable devices and may inquire about the process for the retrospective tracing of any implantable device.
- GAHAR surveyor may review the patient medical record and the invasive report to ensure the proper documentation of the implantable device, including the batch number.
- GAHAR surveyor may review a process for the recall of a patient who has an implantable device in a defined time- frame after receiving the notification of a recall.

Evidence of compliance:

1. There is a list of implantable devices used in the radiology center.
2. There is a process for the retrospective tracing of any implantable device.
3. The medical record and the invasive procedure report include the details of any used implantable device, including the batch number.
4. There is a process for the recall of a patient who has an implantable device when necessary.

Related standards:

IRS.06 invasive procedure report, IRS.01 provision of invasive procedures, ICD.05 High-risk patients and procedures/ services.

IRS.09 Post-procedural care plan is determined and recorded before the patient leaves the procedural unit.

effectiveness

Keywords:

Post-procedural care plan.

Intent:

The post-procedural care plan is the main factor in determining procedure outcomes. Creating the Post-procedural care plan shall start immediately after the procedure before the patient leaves the procedural unit to prevent any delay, wrong, unnecessary, or missing care.

The post-procedural care plan is developed by the physician who performed the procedure and includes at least the following:

- a) The recent level of care,
- b) Patient position,
- c) Patient activity,

- d) Required further monitoring,
- e) Diet,
- f) Medications, intravenous fluids,
- g) Follow up instructions.

Survey process guide:

- GAHAR surveyor may review medical records for the post-procedural care plan.
- GAHAR surveyor may observe the implementation of the physician orders related to the post-procedural care plan.

Evidence of compliance:

1. There is a post-procedural care plan for all patients performing the procedure that includes items from a) through g) in the intent.
2. The post-procedural care plan is documented in the patient's record before leaving the procedure room.
3. The post-procedural care plan is implemented by the physician who performed the procedure.

Related standards:

PCC.03 Patient and family education process, ICD.04 Individualized care plan, IRS.01 provision of invasive procedures.

Safe and effective anaesthesia and sedation care

IRS.10 Anesthesia and sedation services are provided according to applicable laws and regulations and clinical guideline under the direction of a qualified anesthesiologist.

Safety

Keywords:

Anesthesia and sedation Services.

Intent:

The provision of anesthesia and sedation is a complex, high risk and problem-prone service; hence

Anesthesia and sedation services are provided based on the applicable professional practice standards for providing anesthesia and sedation care and shall meet all applicable national laws and regulations. For the safe perform of anesthesia and sedation, a minimum setup shall be available, which includes equipment, medications, medical supplies, and medical gases.

According to the national laws and regulations, Anesthesia services shall performed by a qualified anesthesia physician with the uniform provision of the service all over

the radiology center. Sedation techniques shall be provided according to the scope of service of the radiology center and type of invasive procedures provided. All individuals privileged to perform sedation are trained for at least on the following items:

- a) Proper use and administration of sedation techniques and methods.
- b) Management of complications that could occur by providing sedation and the process followed, if any.
- c) Monitoring requirements.

Procedural sedation shall be provided by a qualified individual trained in advanced life support (appropriate for the age of patient), use of emergency medical equipment and supplies.

The radiology center is required to appoint a qualified anesthesiologist to lead the anesthesia and sedation services with a specific, detailed job description.

The job description shall clearly determine his responsibility that includes at least the following:

- I. Determine the resources required including staffing, equipment, medications and medical supplies.
- II. Develop all required policies, procedures, applicable guidelines and protocols.
- III. Supervise all activities related to anesthesia and sedation services.
- IV. Evaluate the outcome of anesthesia and sedation services.
- V. Perform anesthesia staff ongoing performance evaluation.

Survey process guide:

- GAHAR surveyor may observe the radiology center units where anesthesia and sedation services are performed to observe the structure of the place, available equipment, medications, and medical supplies.
- GAHAR surveyor may review guidelines/protocols guiding the provision of the services.
- GAHAR surveyor may review the credentials and qualifications of the staff who perform these services.

Evidence of compliance:

1. The provision of anesthesia and sedation services meets the applicable professional practice guidelines, national laws, and regulations.
2. Anesthesia services are standardized and uniformly implemented throughout the radiology center.
3. The qualified individual (anesthesiologist) (s) is assigned to oversee and manage the anesthesia and sedation services.
4. A clear, specific job description for the anesthesia and sedation leader is available in the leader's staff file, which includes items from I) through V) in the intent.

5. Procedural sedation is performed by a qualified individual with advanced life support training (appropriate for the age of the patient).
6. All individuals privileged to perform sedation are trained for items from a) through c) in the intent.

Related standards:

ACT.02 Patient identification, ICD.03 Clinical practice guidelines, ICD.05 High-risk patients and procedures/ services, IRS.11 Pre- anesthesia assessment_ Pre-sedation assessment, IRS.12 Anesthesia care plan, IRS.13 Continuous monitoring during anesthesia and sedation, IRS.14 Post anesthesia care WFM.07 Staff performance and competency, WFM.02 Job description, WFM.08 Clinical Privileges.

IRS.11 The radiology center performs a thorough patient assessment before providing anesthesia or sedation services.

Safety

Keywords:

Pre- anesthesia assessment, Pre- sedation assessment.

Intent:

Anesthesia services usually start with a pre-anesthesia assessment that is performed by a qualified anesthesiologist. Pre-anesthesia assessment determines the patient's condition, risk scoring for receiving anesthesia, and required interventions/care before, during, and after receiving anesthesia.

The radiology center shall develop a policy for pre-anesthesia, pre-induction assessment and pre-sedation assessment that clearly identifies when and how those assessments are performed.

The pre-anesthesia assessment shall be completed prior to the invasive procedure or shortly before the invasive procedure. The pre-induction assessment is separate from the pre-anesthesia assessment, as it determines the physiological stability and readiness of the patient for anesthesia and occurs immediately prior to the induction of anesthesia.

In case of emergency, the pre-anesthesia assessment and pre-induction assessment shall be performed immediately, simultaneously, but are documented independently. A third type of assessment is required to be performed by the radiology center, a pre- sedation assessment, which is required when the patient is planned to undergo a sedation process. A pre-sedation assessment of the patient shall be done to:

- a) Identify any airway problems.
- b) Evaluate at-risk patients
- c) Plan the type of sedation and the level of sedation the patient will need based on the procedure being performed;

- d) Safely administer sedation;
- e) Interpret findings from patient monitoring during procedural sedation and recovery.

Survey process guide:

- GAHAR surveyor may review the radiology center policy for pre-anesthesia assessment and Pre- sedation assessment.
- GAHAR surveyor may observe a patient who received anesthesia to evaluate the process of pre-anesthesia assessment.
- GAHAR surveyor may observe a patient who received anesthesia to evaluate the process of pre-sedation assessment.

Evidence of compliance:

1. The radiology center has an approved policy of pre-anesthesia, pre-induction assessment and pre- sedation that clearly identifies when and how those assessments are performed.
2. Pre-anesthesia assessment is performed for each patient to evaluate risk scoring for receiving anesthesia.
3. The pre-anesthesia assessment and pre-induction assessment are recorded separately in the patient's medical record.
4. Pre-induction assessment is performed for each patient immediately before induction of anesthesia.
5. There is a pre-sedation assessment performed and documented by a qualified individual and includes at least a) through e) in the intent.
6. Relevant staff is educated and fully aware of how to apply the policy.

Related standards:

ICD.01 screening and assessment, IRS.02 Assessment before invasive procedures, IRS.10 Anesthesia and sedation services, IRS.12 Anesthesia plan, IRS.13 Continuous monitoring during anesthesia and sedation, IRS.14 Post anesthesia care.

IRS.12 The radiology center ensures performing anesthesia plan for each patient.

Effectiveness

Keywords:

Anesthesia care plan.

Intent:

Anesthesia care shall be planned and documented in the medical record. The plan includes at least the following:

- a) Information from the complete patient assessments and identifies the appropriate

- anesthesia to be used,
- b) The method of administration,
 - c) Other medications and fluids needed,
 - d) Monitoring procedures,
 - e) Anticipated post-anesthesia outcome.
 - f) The anesthesia agent, and anesthetic technique.
 - g) Signature and the full name of the participating anesthesia team shall be documented in the medical file.

Survey process guide:

- GAHAR surveyor may review samples of patients' medical records to check for anesthesia care plan complete documentation.
- GAHAR surveyor may interview the relevant staff to check their awareness of the anesthesia care plan.

Evidence of compliance:

1. Each patient's anesthesia care plan is performed and documented in the patient's medical record.
2. The anesthesia care plan includes all items from a) through g) in the intent.
3. The anesthesiologist, anesthesia assistants and all participated team are identified in the patient's medical record.

Related standards:

IRS.10 Anesthesia and sedation services, IRS.11 Pre- anesthesia assessment_ Pre-sedation assessment, IRS.14 Post anesthesia care.

IRS.13 The radiology center performs continuous monitoring of the patient's physiological status during anesthesia and sedation.

Safety

Keywords:

Continuous monitoring during anesthesia and sedation.

Intent:

Administering anesthesia and sedation are associated with changes in the patient physiologic status that could be very rapid. Accordingly, the patient physiologic status is required to be continuously monitored starting before receiving the anesthesia or sedation to determine the baseline of patient condition, which is used in determining the patient criteria of discharge from the post-anesthesia care unit. Continuous monitoring allows the anesthesiologist for on-time intervention for any changes in the patient's condition. The type and frequency of anesthesia\ sedation monitoring is determined

according to, at least the following:

- a) Patient's condition and age,
- b) Pre-anesthesia assessment, pre-sedation assessment
- c) Anesthesia, sedation plan of care
- d) Type of anesthesia or sedation used
- e) Type and duration of invasive procedure performed
- f) The applicable, approved clinical practice guidelines.

Survey process guide:

- GAHAR surveyor may observe a patient while receiving the anesthesia and/or sedation service to evaluate the process of patient monitoring and the staff involved in this process.
- GAHAR surveyor may review samples of patients' medical records to check for anesthesia and/or sedation monitoring documentation.

Evidence of compliance:

1. The frequency and type of monitoring during anesthesia and sedation is determined according to item a) through f) in the intent.
2. Monitoring of the patient's physiological status is consistent with the radiology center clinical practice guidelines.
3. The results of monitoring are documented in the patient's medical record.
4. A qualified anesthesiologist performs the anesthesia monitoring.

Related standards:

ICD.01 screening and assessment, ICD.03 Clinical practice guidelines, IRS.01 provision of invasive procedures, IRS.10 Anesthesia and sedation services, ICD.04 Individualized care plan, WFM.02 Job description, WFM.08 Clinical Privileges, IMT.05 Medical record management.

IRS.14 Post anesthesia care, monitoring, and discharge are done by a competent individual.

Safety

Keywords:

Post- anesthesia care.

Intent:

Post-anesthesia care includes monitoring of the patient physiologic status that allows the anesthesiologist to do an on-time intervention for any changes in the patient's condition and determine patient's criteria for discharge from the post-anesthesia care unit.

Administration of any medications, IV fluids, ordered and administered should be recorded in the patient's medical record.

The radiology center is required to record any special or unusual events that occurred inside the post-anesthesia care unit with the management provided, the time of receiving the patient, and the time of discharge from the post-anesthesia care unit. The radiology center shall develop and implement policy of post-anesthesia care and monitoring that describe the process of post-anesthesia care, assign responsibility and describe the documentation requirements.

The patient is discharged, by a fully qualified anesthesiologist for managing the anesthesia services. A qualified individual monitor and document at least the following:

- a) The patient's physiologic status
- b) Time of receiving the patient
- c) Used type of anesthesia.
- d) Administered medications with dose, route, and time of administration.
- e) Fluid management includes intake and output.
- f) The occurrence of any unusual event.
- g) The patient condition before leaving according to defined criteria
- h) Time of discharge from the post-anesthesia care unit.
- i) Signature of the physician who order patient discharge.

Post anesthesia care unit is necessary to be equipped by at least a monitoring equipment, a crash cart with a defibrillator, a source of oxygen supply, recommended medications, and medical supplies. The radiology center shall ensure the availability of this equipment while the patient is present in the unit.

Survey process guide:

- GAHAR surveyor may review the post-anesthesia care and monitoring policy.
- GAHAR surveyor may observe the process of post-anesthesia care and monitoring process .
- GAHAR surveyor may review a sample of patients' medical records to check for post-anesthesia care plan documentation.
- GAHAR surveyor may interview the relevant staff to check their awareness of the policy and process.

Evidence of compliance:

1. The radiology center has an approved policy of post-anesthesia care and monitoring that clearly describes the process of post-anesthesia care, assign responsibility and describe the documentation requirements.
2. Post-anesthesia care plan documented in the patient's medical record including items from a) through i) in the intent.

3. The time of patient arrival at and discharge from the post anesthesia care unit are documented in the patient's medical record by a competent individual .
4. The post-anesthesia care unit is equipped with the required resources and equipment in accordance to the applicable laws and regulations.

Related standards:

ACT.06 Transportation of patient, ICD.04 Individualized care plan, IRS.10 Anesthesia and sedation services, IRS.13 Continuous monitoring during anesthesia and sedation, IMT.05 Medical record management, WFM.07 Staff performance and competency.

Medication Management and Safety

Chapter intent

Getting the most from medications for both patients and society is becoming increasingly important as more people are taking more medications. Medications are offered by health services throughout the world. Medications prevent, treat, or manage many illnesses or conditions and are the most common interventions in healthcare.

Medication is defined as any prescription medications including narcotics; herbal remedies; vitamins; nutraceuticals, over-the-counter medications; vaccines; biological, diagnostic and contrast agent used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood products; medication containing products, and intravenous solutions with or without electrolytes and/or medications. The definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases unless explicitly stated. Medication management is one of the major responsibilities in any healthcare organization. It is a complex process that involves different phases, including planning, procurement, storage, prescribing, transcribing, ordering, dispensing, administration, monitoring of the medications, and evaluation of the program. Evidence suggests that, at each phase of the cycle, errors do occur adversely influencing patients' safety, which is a priority in today's practice. However, with substantial and increasing medication use comes a growing risk of harm.

Additionally, medication errors are one of the most commonly occurring errors in healthcare organizations, and they can occur at any step along the pathway of medication management. It is further stated that morbidity from medication errors results in high financial costs for healthcare institutions and adversely affects the patient's quality of life. Preventing medication errors is a major priority in the health system, and many international organizations such as the World Health Organization (WHO) have launched medication safety as part of their global patient safety initiatives.

Chapter purpose

1. To highlight the principle for medication management and use in radiology centers promoting safe, quality use of medications, and medication management.
2. To provide a framework for an effective and safe medication management and use program.
3. To evaluate the continuity of medication management processes from planning to monitoring and evaluation with a special focus on the identification of risk points to improve patients' outcomes and safety.

4. To advocate a partnership and systems approach to achieve safe and quality use of medications and medication management in the radiology centers.

Implementation guiding documents

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

- 1) The American Society of Radiologic Technology (ASRT) Practice Standards for Medical Imaging and Radiation Therapy, (2019).
- 2) The decision of the Minister of Health and Population number 496– the year 2012.
- 3) The decision of the Minister of Health and Population number 368- the year 2012 for developing a pharmacovigilance center.
- 4) European Association of Nuclear Medicine Practice Guideline/Society of Nuclear Medicine and Molecular Imaging Procedure Standard 2019 for radionuclide imaging of pheochromocytoma and paraganglioma (2019).
- 5) Institute for Safe Medication Practices. ISMP Medication Safety Tools and Resources. Accessed Dec 6, 2017. <https://www.ismp.org/tools/>.
- 6) Law 127/1955 on practicing the profession of pharmacy.
- 7) Law 182/1960 on narcotics.
- 8) Law 151/2019 on the establishment of Egyptian Drug Authority.
- 9) Prime Minister's Decree 777/2020 about the EDA executive bylaws.
- 10) Rational Drug Use Publication No: 1, year 2019 of The Egyptian Crash cart and emergency drug list.
- 11) The Egyptian Guidelines of Medication Management Standards first edition (2018).
- 12) The Egyptian Drug Authority Decree No. 271, year 2021 on the regulation of Drug storage requirements for pharmaceutical institutions.
- 13) The Egyptian Drug Authority Decree No. 340, year 2021 on the re-regulation of handling of the pharmaceutical substances and products affecting the mental state.
- 14) The Minister of Finance Decree No. 89, year 1998 on the regulation of tenders and auctions law promulgated, and its implementing regulations.
- 15) The Minister of Health and Population decree number 104, year 2003 on the regulation of expiry drugs.
- 16) The Minister of Finance Decree No. 182, year 2018 on the regulation of tenders and auctions law promulgated, and its implementing regulations.
- 17) The Minister of Health and Population Decree No. 380, year 2009 on the re-regulation of the health requirements for pharmaceutical institutions.
- 18) The Minister of Health and Population Decree Number 172, year 2011 on the re-regulation of handling of the pharmaceutical substances and products affecting the mental state.

- 19) The Minister of Health and Population Decree No. 475, year 2019 on the re-regulation of handling of the pharmaceutical substances and products affecting the mental state.
- 20) Standards for the Provision of Nuclear Medicine, Imaging, Therapy and Assay Services. Ministry of Health, Singapore, (2019).

Medication Use, Selection, and Procurement

MMS.01 Medications available for use are managed, selected, listed, and procured based on approved criteria.

Effectiveness

Keywords

Medication management.

Intent

Medication management remains a primary concern in any healthcare setting and is often an important component in the palliative, symptomatic, and curative treatment of many diseases and conditions. The unsafe use of medication is not the only safety problem in any healthcare system, but it is certainly one of the most significant issues. Ensuring a safer medication management program at an organizational level, is a major challenge.

All medication management processes (selections, procurement, prescribing, preparation, administration, monitoring and evaluation) in the radiology centers are conducted and implemented according to the Egyptian laws and regulations (The Egyptian Drug Authority (EDA), Egyptian Nuclear and Radiological Regulation Authority (ENRRA) and the Egyptian Ministry of Health (MOH)).

The radiology center shall develop an inventory medication list of all the medications it stocks. The medications shall be selected from the EDA and other national authorizing bodies legally approved medications based on the patient's needs. The list shall include (but is not limited to):

- a) Name(s) of medication(s).
- b) Strength(s)/concentration(s) of medication(s).
- c) Dosage form(s) of the medication(s).
- d) Indication.
- e) Expiration date.

The procurement and distribution system covers the processes: to select the most cost-effective essential medications to treat/diagnose commonly encountered diseases; to quantify the needs; to pre-select potential suppliers; to manage procurement and delivery; to ensure good product quality, and to monitor and evaluate the performance of suppliers and the procurement system.

The process for evaluating new suppliers can include checking the licensure, providing formal visit(s), reference checks with past clients and agencies, test purchases in small quantities and informal local information gathering.

The radiology center shall have a process to investigate if the medications are contaminated, defective, or counterfeit and trace them back to determine the cause of

the problem, and notify the manufacturer and/or distributor when something is discovered while checking the supply on receiving step. In addition, the radiology center shall define a procedure to inform healthcare providers and physicians about non-available medications and products and respective substitutes.

Survey process guide

- GAHAR surveyors may review the medication management program and the credential(s) and job description(s) of the healthcare professional(s) responsible for the program.
- GAHAR surveyors may review the updated list of medications available in the center.

Evidence of Compliance

1. The radiology center has an updated (at least annually) program that clearly describes the medication use and management which is under the direct supervision of qualified healthcare professional(s).
2. The radiology center has an approved and documented process addressing the criteria for appropriate selection and procurement of medications in accordance to the organization's mission, patient needs and safety.
3. The radiology center has an approved and updated list of the medications, which covers at least items from a) through e) in the intent.
4. The radiology center has an approved and documented process to ensure the integrity and the quality of selected medications when procured.

Related standards

MMS.02 Medications storage and labelling, MMS.06 Radiopharmaceutical, OGM.05 Supply chain management.

MMS.02 Medications are safely and securely stored in a manner to maintain its quality.

Safety

Keywords:

Medications storage and labeling.

Intent

Well-designed and appropriate storage of medications can reduce waste, incorrect medication dispensing and handling. The radiology center maintains proper medication storage conditions (temperature, light, and humidity) in medication storage areas to protect their stability 24 hours a day, and 7 days a week according to the manufacturer/marketing authorization holder requirements. The stability/effectiveness of any medication depends on storing it at the correct temperature, for example, those

medications requiring refrigeration.

There should be clear evidence that the radiology center ensures the storage of medications in a manner to maintain their quality and integrity. In addition, the radiology center limits access to medication storage areas with the level of security required to protect it against loss or theft depending on the types of medications stored including multi-dosing medications

When patient emergencies occur, quick access to appropriate emergency medications is critical and may be lifesaving. The radiology center has a well-implemented policy and procedures that ensure the availability the location of emergency medications and the medications to be supplied in these locations.

Medications or other solutions in unlabeled containers are unidentifiable. Errors, sometimes tragic, have resulted from medications and other solutions removed from their original containers and placed into unlabeled containers. This unsafe practice neglects basic principles of safe medication management.

The labeling of all medications, medication containers, and other solutions is a risk-reduction activity consistent with safe medication management. This practice addresses a recognized risk point in the administration of medications. Medications, medication containers, other solutions, and the components used in their preparation are clearly labeled (if not apparent on the original packages or boxes) with the followings:

- a) Name of medication.
- b) Concentration/strength.
- c) Expiration date /beyond date.
- d) Batch number.
- e) Any applicable warning(s).

Survey process guide

- GAHAR surveyor may review the evidence (e.g., checklists, temperature log) ensuring the compliance with proper medication storage conditions.
- GAHAR surveyor may observe that all medications including emergency medications are stored as per manufacturer/marketing authorization holder recommendations and all are clearly labeled including the handling of multi-dose containers (If available).
- GAHAR surveyor may interview the healthcare professionals about the action(s) taken when there is an electric outage.

Evidence of compliance

1. Medications are safely and securely stored under manufacturer/marketing authorization holder recommendations and kept clean and organized all the time.
2. Emergency medications are available, accessible, and secured at all time.
3. The radiology center has a clear process to deal with an electric power outage to

ensure the integrity of the affected medications before use.

4. The radiology center has a process for the handling of multi-dose medications (if available) to ensure their stability and safety.
5. Medications, medication containers, other solutions, and the components used in their preparation are clearly labeled (if not apparent on the original packages or boxes) with elements from a) to e) in the intent.

Related standards

MMS.01 Medication management, MMS.03 High-alert medications, Look-alike Sound-alike medications, LASA, ICD.09 Emergency equipment and supplies, EFS.05 Utilities management plan, ICD.08 Medical emergencies and cardiopulmonary resuscitation.

MMS.03 NSR.10 High alert medications and look-alike sound-alike medications are managed in a way assures that risk is minimized.

Safety

Keywords:

High-alert medications, Look-alike Sound-alike medications.

Intent:

High-alert medications are those medications bearing a heightened risk of causing significant patient harm when they are used incorrectly. Examples of high-alert medications include (but are not limited to): parenteral contrast media, anesthesia medications, narcotic, inotropic agents, adrenergic agonists, concentrated electrolytes, and look-alike/sound-alike medications.

The radiology center shall develop its own list of high alert medications based on its own data and both national and internationally recognized organizations (e.g, Institute of Safe Medication Practice (ISMP) and the World Health Organization (WHO)) and it has to be updated annually. In addition, the radiology center has strategies in place to prevent the inadvertent use and administration of these medications.

Look-alike/sound-alike (LASA) medications are those visually similar in physical appearance or packaging and names of medications that have spelling similarities and/or similar phonetics. Any confusion between these medications may lead to harmful errors. The Institute for Safe Medication Practices (ISMP) maintains an ongoing list of LASA medication names to highlight medications that may require special safeguards or strategies to help prevent healthcare providers from accidentally mistaking one medication for another. Another strategy that the ISMP recommends for reducing LASA medication name errors is to include both the brand name and nonproprietary name, dosage form, strength, directions, and the indication for use, which can be helpful in differentiating LASA medication names. Other recommendations aimed at minimizing

name confusion include conducting a periodic analysis of new product names; physically separating and segregating these medications in medication storage areas prevents confusion and promotes safety. The radiology center shall develop its own list of look-alike sound-alike medications and has to be updated annually.

The radiology center needs to establish risk management strategies to minimize adverse events with LASA medications, enhance patient safety and protect against inadvertent administration.

Survey process guide

- GAHAR surveyor may review the updated lists of high alert medications and LASA medications.
- GAHAR surveyor may observe the different strategies implemented to ensure safe management of high alert medications and LASA medications.
- GAHAR surveyor may interview staff to check their awareness of the management of high alert medications and LASA medications.

Evidence of Compliance

1. The radiology center has an annually updated list(s) of high alert medications.
2. The radiology center has an annually updated list of look-alike sound-alike medications.
3. The radiology center has a uniform process for the safe storage and administration of high alert medications), including separation, and labeling.
4. The radiology center has a defined process for the safe handling of look-alike sound-alike medications including separation and labeling.
5. Responsible staff members are aware of the strategies implemented when managing high alert medications, and look-alike sound-alike medication.

Related standards

MMS.02 Medications storage and labeling, MMS.04 Medication ordering preparation, and administration.

MMS.04 Medications are safely ordered, prescribed, prepared, and administered.

Safety

Keywords:

Medication ordering preparation, and administration.

Intent:

Treating a patient by medication(s) requires specific knowledge and experience.

The radiology center is responsible for identifying those individuals by experience and who are permitted by licensure, certification, laws, or regulations to prescribe or order

medications.

The radiology center shall develop and implement a policy and procedures to guide the processes of ordering, and prescribing of medications (for example if hydrocortisone is prescribed in allergy reaction, route of administration, dose, conc is documented).

Abbreviations avoidance prevents misunderstanding, miscommunications and administration of incorrect prescriptions.

All medication orders must be reviewed before administration. Each prescription shall be reviewed for the appropriateness of the medication(s) for the right patient and for the right clinical needs.

A safe, clean, and organized working environment provides the basis for good medication preparation practice. This includes qualified/trained staff, appropriate physical surroundings, adequate shelving and storage areas, proper work surfaces, suitable equipment, and necessary packaging materials.

Healthcare professionals who prepare medications are requested to use techniques to ensure accuracy (e.g., double-checking calculations), and avoid contamination, including using clean or aseptic technique as appropriate; maintaining clean, and uncluttered areas for product preparation. Also, healthcare professionals preparing compounded sterile products or preparing medications using multi-dose vials are trained on the principles of medication preparation and aseptic technique.

Prepared medications are labeled in a standardized manner. This requirement applies to any medication that is prepared but not administered immediately (this requirement does not apply to a medication prepared and administered immediately in emergency situations). At a minimum, labels (if not apparent from the container) shall include at least the following:

- a) Medication name
- b) Strength/concentration
- c) Beyond use date
- d) Directions for use and any special/cautionary instructions
- e) Date and time of preparation and the diluent for all compounded intravenous (IV) admixtures, and parenteral solutions (if available).

Also, medication preparation and administration within the radiology center follow standardized processes to ensure appropriateness, effectiveness, and safety of medication based on medication prescription or order. Medication preparation, and administration to manage a patient requires specific knowledge and experience. The safe administration of medications shall include at least the following:

- i. Right patient
- ii. Right medication
- iii. Right time and frequency of administration

- iv. Right dosage amount and regimen
- v. Right route of administration
- vi. Right reasons/indication of medication therapy.
- vii. Review if the patient is allergic to any medication in the prescription or order.
- viii. Provision of information about the medications that they are going to be given and the patients are given the chance to ask questions.

The radiology center educates patients and/or their families about the safe and effective use of medication(s) prescribed and to be administered including (if needed) any potential significant adverse reactions, or other concerns about administering medication.

Survey Process Guide:

- GAHAR surveyor may review the ordering and prescribing policy and the review number of patient records to assess compliance with prescribing policy.
- GAHAR surveyor may interview authorized healthcare professionals involved in the medication review for appropriateness of this process, and may observe the process.
- GAHAR surveyor may observe the process of preparing/compounding medication order and observe the labeling of the prepared products.
- GAHAR surveyor may observe the medication administration process.

Evidence of Compliance:

1. The radiology center has an approved list of those individuals responsible, permitted by law and regulation, qualification, training, experience, and job description to order/prescribe medications.
2. The radiology center has an approved policy for safe and complete medication ordering and prescribing.
3. A qualified healthcare professional prepares and/or administers medications and admixtures, with or without supervision.
4. The radiology center has a process to guide the preparation and compounding of sterile preparations.
5. All medications prepared in the radiology center are correctly labeled in a standardized manner with at least the elements from a) through e) in the intent.
6. The radiology center has a process that covers elements from i) through viii) in the intent to ensure safe medication administration.

Related standards:

MMS.03 High-alert medications, Look-alike Sound-alike medications, MMS.02 Medications storage and labeling, ACT.02 Patient identification, PCC.03 Patient and family education process, WFM.02 Job description, WFM.08 Clinical Privileges.

MMS.05 Medication errors, near misses, and adverse drug reactions are monitored, detected, reported, and acted upon.

Safety

Keywords:

Medication errors, near misses and adverse drug reactions.

Intent:

Each radiology center shall have a medication error and near-miss detecting and reporting system.

This system focuses on preventing and managing medication errors and near misses, or any other safety issues including but not limited to overdose, toxicity, misuse, abuse, occupational exposure, medication exposure during pregnancy, and lactation). Medication errors and near misses are particularly important given the large and growing global volume of medication use. Medication errors can occur at a number of different stages of the medication prescription and use process. Although serious errors are relatively rare, the absolute number is sizeable, with the potential for considerable adverse health consequences.

Monitoring medication effects includes observing and documenting any adverse effects. This is done using a standardized format (The Egyptian National Forms) for reporting and educating staff on the process and the importance of reporting. Reporting to the authorized institutions is done within approved timeframe. It is important that, the radiology center develops and implements a policy to identify and report on medication errors, near misses and adverse drug events. Definitions and processes are developed through a collaborative process that includes all those involved in the different steps in medication management.

The reporting process shall be part of the radiology center quality improvement and patient safety program. Medication errors, near misses, and adverse drug events shall be identified and reported.

Survey process guide

- GAHAR surveyor may interview healthcare professionals involved in medication management processes to inquire about detection, analysis, reporting and actions of medication errors and near misses.
- GAHAR surveyor may review the process of reporting adverse drug event.

Evidence of compliance

1. Effect(s) of medication(s) including actual or potential medication adverse effects on patients is/are monitored and documented in patient's record including the action(s) to be taken in response.

2. The radiology center has a clear definition for medication error(s), and near miss(es) and implements a process for acting on and reporting of medication errors, and near misses in a manner consistent with the national guidelines.
3. Adverse drug events (ADEs) are reported in a manner consistent with the national guidelines using standardized national format.

Related standards:

MMS.01 Medication management, QPI.04 Incident reporting system, QPI.05 Sentinel event, MMS.04 Medication ordering preparation, and administration, QPI.02 Performance measures, QPI.03 Risk management plan/program

MMS.06 Radiopharmaceuticals are safely handled, ordered, prepared and administered.

Safety

Keywords:

Radiopharmaceutical.

Intent:

Radiopharmaceuticals" refer to a group of pharmaceutical drugs that are radioactive and can be used as diagnostic and/or therapeutic agents for medical care. The nature of nuclear medicine practice requires quality assurance measures cover radiation protection, instrumentation maintenance, and radiopharmaceutical preparation, handling, and delivery, in addition to the management of all the other aspects of patient care. Hot Laboratories for the handling of radiopharmaceuticals must meet the relevant requirements, protocols, applicable laws, and regulation.

The radiology center shall develop and implement a policy that describes the process of radiopharmaceuticals management including at least the following:

- a) The presence of hot lab that complies with the general requirements, laws and regulation
- b) Those individuals, by law and regulation, qualification, training, experience, and job description, are authorized to order, prepare and administer radiopharmaceuticals
- c) Procurement,
- d) receipt,
- e) storage,
- f) ordering,
- g) preparation, use and administration and
- h) disposal.

Patients' screening before radiopharmaceuticals administration shall be done by a qualified individual for validating the patients' needs and highlighting any further

assessment or risk may be required. The screening shall include drug and food allergies, drug and food interactions, pregnancy and breastfeeding status.

Accurate patient details and complete records are important. The medical records shall include at least the following:

- i. patient's Identifications
- ii. gender,
- iii. date of birth,
- iv. name of radiopharmaceutical material used,
- v. dose activity measured,
- vi. time of measurement,
- vii. person(s) ordering, administering, and checking, and
- viii. date and time of administration.

Patient receiving radiopharmaceuticals shall be monitored for any potential adverse reactions that may happen. The radiology center shall develop a process for monitoring and reporting adverse reactions to the relevant clinician, to the supplier of the radiopharmaceuticals and to the national regulatory/advisory body according to national arrangements if applicable. The responsible staff shall be aware of the radiopharmaceutical's management process.

The radiology center shall comply with OSHA needle-stick prevention guidelines without compromising radiation protection or procedural efficiency. Syringe shield, outer shield, and any other radiation safety accessories shall be implemented.

The radiology center shall provide secured and well-controlled area for procurement, receipt, use, preparation, administration, storage, and disposal of radiopharmaceuticals including any radioactive waste.

A full, complete order (prescription) is required before dispensing or administering radiopharmaceuticals. The prescription shall be done by an authorized nuclear medicine physician and specifying the quantities in mega Becquerel (MBq) or millicurie (mCi).

Survey process guide

- GAHAR surveyor may review the process of procurement, receipt, use, storage, and disposal of radiopharmaceuticals and may observe their specified area.
- GAHAR surveyor may interview responsible staff to check their awareness of ordering, preparing, administering and monitoring radiopharmaceuticals.

Evidence of compliance

1. The radiology center has an approved policy for radiopharmaceutical management that include the items from a) through h) in the intent.
2. All radiopharmaceuticals ordering and administration are done according to documented order (prescription) by an authorized nuclear medicine physician.

3. All radiopharmaceuticals, Syringes shields and outer shields of the containers are labeled and securely stored in the hot lab within limited access area.
4. Responsible staff is aware of monitoring and reporting of adverse reactions to radiopharmaceuticals (ARRP).
5. The radiology center has a documented guidelines and formula used for the preparation of radiopharmaceuticals.

Related standards:

MMS.01 Medication management, ICD.01 screening and assessment, MRS.04 Pregnant and lactating patients, MRS.05 Release of patients undergoing treatment with radionuclides, EFS.03 Hazardous materials and waste disposal, MMS.02 Medications storage and labelling.



SECTION 3

ORGANIZATION-CENTERED STANDARDS

Section 3: Organization-Centered Standards

While in the previous section, Patient centered care and safety was the focus. Yet, Patients are not the only customers of healthcare systems. Healthcare professionals face risks, as well. Although debate continues regarding whether workers' wellbeing should be considered as part of the patient safety initiatives, many organizations think about it that way, including major players in the healthcare industry worldwide. Three major aspects may affect workers' wellbeing; Safety, Stress, and radiology center Structure. Regarding Safety, according to the United States Department of Labor, Occupational Safety and Health Administration (OSHA), the radiology center is one of the most hazardous places to work. Healthcare professionals experience some of the highest rates of non-fatal illness and injury surpassing both the construction and manufacturing industries. In fact, healthcare accounts for nearly as many serious violent injuries as all other industries combined. Many more assaults or threats go unreported. Workplace violence comes at a high cost; however, it can be prevented.

On the other hand, being exposed to stress for too long may lower a person's efficiency and could trigger negative consequences on one's health or family and social life. Nevertheless, not every manifestation of stress is always a workplace stress. Workplace stress may be caused by various factors. Some professions are inherently more stressful than others. Some studies showed that healthcare professions are among the first six most stressful ones. Not all health professionals develop the same level of stress, and not all of them develop signs of professional burnout either.

Radiology center structure provides guidance to all staff by laying out the official reporting relationships that govern the workflow of the company. A formal outline of a radiology center structure makes it easier to add new positions in the radiology center, as well, providing a flexible and ready means for growth. Organization management needs to be according to a clear ethical framework that is responsive to community needs. Organizations have an obligation to act for the benefit of the community at large. Workers, as community members, need to be engaged in assessing community needs and responding to them, in addition, to being protected from safety and stress hazards while working in the radiology center.

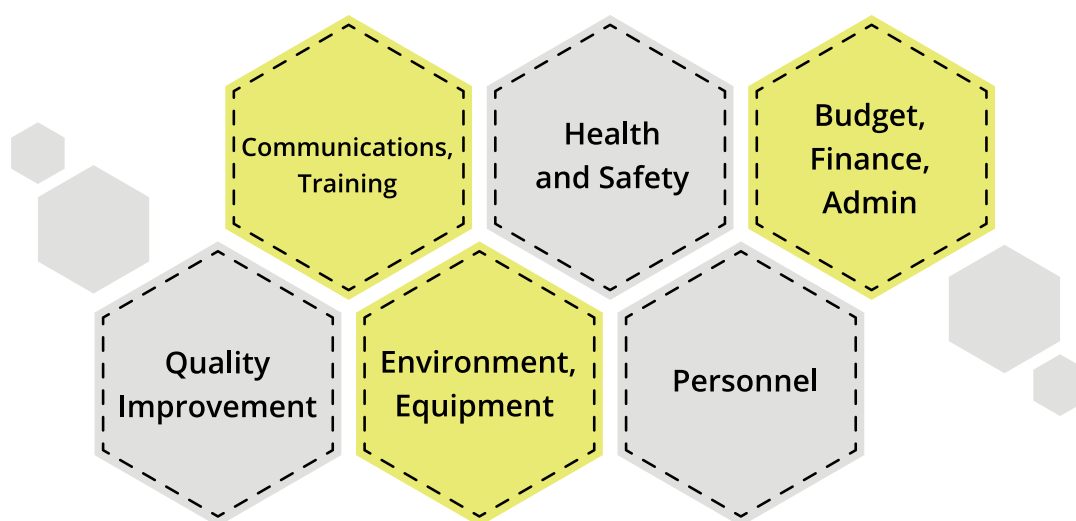
Nevertheless, both the radiology center and the staff bear the responsibility to keep themselves safe. For example, while management provides personal protective equipment (PPE), such as lead aprons which protect the staff from radiation hazardous, it is the staff's responsibility to wear the PPE when performing work that management has identified as requiring it.

One of the tools used to design this section is called Health-WISE, which is an action tool

developed by the International Labor Organization (ILO) in collaboration with the WHO. This tool emerged from traditional thinking about patient safety and improvement more generally.

It describes a process and structure that may lead to improved safety in a variety of healthcare settings. The aim of HealthWISE is to provide healthcare institutions with a cost-effective tool to improve work conditions, performance, occupational health and safety for health workers, and the quality of health services provided. HealthWISE puts the health workforce in focus and addresses topics that are key to delivering high quality of care.

As organization, management is responsible for providing an efficient radiology center structure. Leaders are identified and responsive to the radiology center needs, Leaders work collaboratively to run the radiology center towards preset approved strategic directions. An established structure includes defining capacity and roles of the radiology center workforce, providing sufficient orientation and education, and continuous monitoring and evaluation. Hence, strong information management and technology are needed to record data and information, in addition to a strong quality management program that can capture and interpret data and information.



Elements for safe Healthcare Workplace

Environmental and Facility Safety

Chapter intent:

Environmental and Facility Safety (EFS) in the radiology centers aim at minimizing potential risks for patients, visitors, staff, and buildings through compliance with local laws, regulations, fire, and building codes for providing a safe and secure work environment.

The emitted radiation from using radiation generators (devices, sources, and materials) for diagnostic and therapeutic purposes can affect the work environment in the radiology facility and its surrounding area, as well as affect the safety of all humans in both areas.

From an environmental standpoint, it involves creating a systematic approach to compliance with environmental regulations, such as managing waste and maintaining a safe environmental condition.

From a safety standpoint, it involves creating organized efforts and procedures for identifying workplace hazards and reducing accidents and exposure to harmful radiation and substances. It also includes training of staff members in accident prevention, accident response, emergency preparedness, and the use of protective clothing, equipment, and safe radiology practices.

Nationally, the Ministry of Health and Population has issued the Radiology Facility Standards Guideline which includes structural requirements and design codes for basic radiology facilities. International Atomic Energy Agency (IAEA) issues periodical updates for the Basic Safety Standards including structural and environmental standards for radiation safety in the medical field (diagnostic radiology, radiotherapy, and nuclear medicine). The radiology center shall identify and understand all relevant EFS regulations to implement the required measures.

National initiatives include but are not limited to (Organization building codes, licensure requirements for the whole organization and the individual functions/machine/equipment /units inside the organization, Civil defense laws, Environmental laws, and Radiology laws).

GAHAR surveyor is going to meet the concerned staff in EFS and discuss the different standards of the chapter and review the documents, trace the activities and functions and measure the facility's awareness about safety. A facility tour is an important tool used by surveyors to measure environmental safety risks in a radiology center.

Chapter purpose:

The main objective is to ensure that organization can identify the safety issues and provide a safe and effective program to handle and maintain environmental safety. The chapter discusses the following:

- **Fire safety:**
Prevention, early detection, response, and safe evacuation in case of fire.
- **Hazardous materials:**
Safe handling, storage, transportation, and use of hazardous materials, and waste disposal.
- **Safety:**
Providing a safe work environment for all occupants, ensuring that the radiology center buildings, construction areas, and equipment do not pose a hazard or risk to patients, staff, and visitors.
- **Security:**
Protection of all occupants' properties from loss, theft, destruction, tampering, or unauthorized access or use.
- **Medical equipment:**
Selection, inspection, testing, maintenance, and safe use of medical equipment.
- **Utility systems:**
Ensuring efficiency and effectiveness of all utilities through regular inspection, maintenance, testing, and repair of essential utilities to minimize the risks of operating failures.
- **Disaster preparedness:**
Responding to the disasters and emergencies that have the potential of occurring within the geographical area of the radiology center with an evaluation of the structural integrity of the patient care environment.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

- 1) Egyptian building codes for healthcare organizations.
- 2) Egyptian civil defense laws.
- 3) Law 192/2001 for Hazardous waste management .
- 4) Presidential decree number 3185/2016.
- 5) MOHP Ministerial decree 284/1985 on requirements for OR.
- 6) MOHP Ministerial decree 306/2002 on medication storage spaces.
- 7) Egyptian Guideline for Medical Device Vigilance System.
- 8) National strategy in disasters management.

- 9) National Law for Environment.
- 10) Atomic Energy Commission rules.
- 11) WHO Early Warning Alert and Response Network in emergencies.
- 12) WHO International Health Regulation.
- 13) Guidance in environmental safety book.
- 14) Core Medical equipment -WHO.
- 15) Law 59 /1960 – Radiation Protection against Ionizing Radiation.
- 16) Law 7 /2010 - Regulating nuclear and radiological activities.
- 17) MOHP Ministerial decree number 513 / 2016 for the licensing and control of magnetic resonance imaging devices.
- 18) The Green Pyramid Rating System (GPRS).

Safe, appropriate radiology center structure and infrastructure:

EFS.01 The radiology center facilities comply with applicable laws and regulations.

Safety

Keywords:

Radiology center environment and facility safety structure

Intent:

Radiology centers contain hazardous chemicals, drugs, and infectious matter, among other threatening items. For this reason, governmental authorities enforce laws and regulations to ensure protection against these exposures. In addition, there are also dangers from fire and smoke that can be particularly perilous for vulnerable radiology center patients. The radiology center shall develop and maintain an environmental and facility safety program, the program shall include at least the following:

- a) The exact space required to provide the diagnostic and therapeutic services according to applicable laws, regulations, and the center's scope of service.
- b) Valid and current permits, licenses and radiology center design drawings.
- c) Presence of qualified environmental safety personnel whose skills and qualifications are matching the requirements of the radiology center's scope of services, laws, and regulations.
- d) Review methodology of the aggregated essential data, incident reports, drill reports, safety plan measures, actions taken, and following up to ensure full compliance with all safety requirements.

A comprehensive report shall be submitted to the center leaders and all stakeholders, on a regular way, at least quarterly with appropriate feedback and actions taken. If an external authority or agency, such as civil defense, reported an observation during its inspection, the center's leaders are responsible for providing a corrective action plan for any non-compliance within the required timeframe.

Survey process guide:

- GAHAR surveyor may review the radiology center environment and facility safety program
- GAHAR surveyor may observe compliance with laws and regulations and matching of allocated spaces to services and functions.

Evidence of compliance:

1. The radiology center leaders maintain full compliance with the applicable environmental safety laws and regulations.
2. The radiology center maintains the basic requirement for the development of an environment and facility safety program that included at least items from a) through d).

3. There is a qualified staff member(s) overseeing the environment and facility safety program.
4. Evidence of environment and facility safety regular external inspections are recorded and monitored.
5. The radiology center's leaders ensure compliance with external inspection reports and correction of observations within the required timeframe.

Related standards:

APC.01 National regulations and licensure requirements, MRS.02 Technical medical imaging procedures, EFS.06 Emergency preparedness plan, EFS.03 Hazardous materials and waste disposal, OGM.01 Governing body Structure and clear responsibilities.

Effective and safe environment and facility safety plans

EFS.02 NSR.12. The fire and smoke safety plan address prevention, early detection, response, and safe evacuation in case of fire or other internal emergencies.

Safety

Keywords:

Fire and smoke safety plan.

Intent:

One of the critical considerations in the safety design for the radiology center is the prevention of fire, particularly concerning the combustibility of construction and furnishing materials and the spread of fire and smoke. In the event of either accidental or malicious fires, suppression equipment needs to be readily accessible to combat these fires. Staff members of the radiology center need to have work knowledge of how to use the equipment and to avoid panic. Moving all patients, visitors, and staff out of dangerous and/or damaged facilities as safe as possible is always the goal of an evacuation.

The radiology center shall develop a fire and smoke safety plan that addresses at least the following:

- a) An ongoing risk assessment that shall have the following features:
 - i. Assesses compliance with civil defense regulations.
 - ii. Includes fire and smoke separation, high-risk areas for example stores, oxygen supply storage areas, electrical control panels, medical records room, garbage room, etc.
 - iii. Addresses the safety of all occupants including patients, families, full-time staff, part-time staff, visitors, suppliers, contractors, and others.
 - iv. Addresses evacuation for fire and non-fire emergencies.
 - v. A special risk assessment is performed during renovation and construction.

- b) Early detection of fire and smoke system, including the central control panel connected to all areas in the radiology center according to its functionality, and ensure continuous monitoring 24/7.
- c) Measures of smoking prevention.
- d) Fire suppression systems such as water systems, and automated or manual fire extinguishers.
- e) Listing of firefighting and alarm systems includes maintenance testing and inspection schedule.
- f) Availability of safe, unobstructed fire exits, with clear signage to assembly areas and emergency lights, in addition to other related signage like how to activate the fire alarm using a fire extinguisher and hose reel.
- g) Inspection of all firefighting and alarm systems should be in place, and results are recorded with the needed corrective actions.
- h) Safe storage and handling of highly flammable materials.
- i) The radiology center should perform proper annual training and orientation of all staff practically to make sure that everyone in the radiology center can:
 - Demonstrate RACE and PASS.
 - Safely evacuate all occupants (eg. evacuation pathway, clear signage, trained staff, safe and clear exits, assembly points. etc....).
- j) Fire drills details include, but are not limited to, the following:
 - i. Dates and timings.
 - ii. Staff who participated in the drill.
 - iii. Involved areas.
 - iv. Shifts.
 - v. Drill evaluation and corrective action plan.
- k) Documentation of all results in a proper way and repetition according to the training plan.
- l) The plan is evaluated annually and, if needed, according to related performance measures results or major incidents including corrective action.

Survey process guide:

- GAHAR surveyor may review the fire safety plan, facility fire safety inspections, and fire system maintenance.
- GAHAR surveyor may observe that fire alarm; firefighting and smoke containment systems are working effectively and complying with civil defense requirements.
- GAHAR surveyor may review the plan of testing (drills) and staff training (all staff should be trained on fire safety).

Evidence of compliance:

1. The radiology center has a fire and smoke safety plan that includes all elements from a) through l) in the intent.
2. The radiology center fire alarm, firefighting, and smoke containment system are available, functioning, and comply with civil defense requirements.
3. Inspection, testing, and maintenance of fire alarm, firefighting, and smoke containment systems are performed and recorded.
4. The fire and smoke safety plan is evaluated annually with aggregation and analysis of necessary data.
5. The radiology center has a safe evacuation process for all occupants in case of fire and/or other internal emergencies.

Related standards:

MRS.01 Specific radiological hazards, EFS.01 Radiology center environment and facility safety structure, EFS.06 Emergency preparedness plan, QPI.03 Risk management plan/program, EFS.04 safety and Security plan, ACT.05 Wayfinding signage, APC.01 National regulations and licensure requirements.

Safe hazardous materials and waste management plan

EFS.03 NSR.13 The radiology center has a plan for handling, storage, usage, and transportation of hazardous materials and waste disposal.

Safety

Keywords:

Hazardous materials and waste disposal.

Intent:

Hazardous materials are substances, which, if released or misused, can pose a threat to the environment, life, or health. Industry, agriculture, medicine, research. Hazardous materials come in the form of flammable and combustible substances, and radioactive materials. These substances are often released because of transportation accidents or chemical accidents in healthcare organizations. Because the effects of hazardous materials can be devastating and far-reaching, it is important that radiology center plans their safe use and establish a safe working environment.

Healthcare waste includes infectious, chemical, expired pharmaceuticals, and sharps. These items can be pathogenic and environmentally unsafe. Others as radioactive waste need special precautions/procedures and separate sewage under applicable laws and regulations.

Other waste items generated through healthcare but not hazardous include medication boxes, the packaging of medical items and food, and food residuals.

The radiology center should identify and control hazardous material and waste all over the radiology center to ensure that staff, patients, relatives, vendors, and the environment are safe.

Hazardous material and waste are categorized into the following categories according to the WHO classification:

- i. Infectious
- ii. Pharmaceutical
- iii. Radioactive
- iv. Genotoxic /cytotoxic
- v. Chemical
- vi. Heavy metals
- vii. Pressurized containers
- viii. Sharps

Hazardous materials and waste management plan shall ensure full compliance with laws and regulations, availability of required licenses, and/or permits.

The plan shall include, but is not limited to, the following:

- a) A current and updated inventory of hazardous materials used in the radiology center, the inventory should include the material name, hazard type, location, usage, consumption rate, and responsibility.
- b) Material safety data sheet (MSDS) should be available and includes information such as physical data, hazardous material type (flammable, cytotoxic, corrosive, carcinogenic, radioactive, etc.), safe storage, handling, and spill management and exposures, first aid, and disposal.
- c) Appropriate labeling of hazardous materials.
- d) Procedure for safe usage, handling, storage, and spillage of hazardous materials.
- e) Appropriate segregation, labeling, handling, storage, transportation, and disposal of all categories of hazardous waste.
- f) Availability of required protective equipment and spill kits.
- g) Investigation and documentation of different incidents such as spills and exposure.
- h) Staff training and orientation.
- i) The plan is evaluated and updated annually and/or when required.

Survey process guide:

- GAHAR surveyor may review the hazardous material and waste disposal plan, hazardous material, and waste inventories, as well as Material Safety Data Sheet (MSDS)
- GAHAR surveyor may observe hazardous material labeling and storage in addition to waste collection segregation storage and final disposal.

Evidence of compliance:

1. The radiology center has hazardous material and waste management plan that addresses all elements from a) through i) in the intent.
2. The radiology center ensures staff safety when handling hazardous materials/or waste.
3. The radiology center implements safe usage, handling, storage, and labeling of hazardous materials as per the center plan.
4. The radiology center has a process for spill management, investigation, and recording and documentation of different incidents related to hazardous materials.
5. The plan is evaluated and updated annually with aggregation and analysis of necessary data.

Related standards:

MRS.06 Radiation Safety Program, MMS.06 Radiopharmaceutical, IPC.02 infection prevention and control program, WFM.06 Continuous education and training program, MRS.05 Release of patients undergoing treatment with radionuclides, MRS.08 Personal protective equipment (PPE), EFS.04 safety and Security plan, IPC.05 Environmental and equipment cleaning activities, IPC.04 Standard precautions measures, EFS.05 Utility management plan, APC.01 National regulations and licensure requirements.

Effective Safety and security plan

EFS.04 NSR.14 The radiology center develops and implements a safety and security plan/s.

safety

Keywords:

Safety and security plan/s.

Intent:

Safety is defined as the degree to which the radiology center's buildings, grounds, and equipment do not pose a hazard to patients, their families, and staff. Effective planning requires knowledge on how to prevent accidents and injuries to maintain safe conditions for all occupants to reduce and control risks.

Proactive risk assessment through periodic inspection should be documented to help the radiology center design and carry out improvements.

The radiology center is required to develop and implement safety and security plan/s with continuous monitoring and analysis of data for ongoing performance measurement, identify gaps and do corrective actions.

An authorized staff is responsible for inspecting buildings to identify maintenance and safety issues, such as clogged drains, leaky ceilings, and faulty electrical switches.

Security and safety plan/s shall include, but are not limited to, the following:

- a) Surveillance rounds across all areas and services are performed at least twice annually at least annually.
- b) Methods of Prohibiting staff in technical areas from eating, drinking, smoking, applying cosmetics, and manipulating contact lenses.
- c) Security risk assessment, such as radioactive security programs, CCTV (closed-circuit television) cameras to keep staff, patients, and visitors safe, and monitoring of remote and isolated areas. In addition, children should be protected from abduction; radiology centers may use a range of different security measures.
- d) Vulnerable patients such as the elderly, infants, those with mental disorders, and the handicapped should be protected from harms
- e) Reporting of environment and facility surveillance rounds results to the concerned stakeholders and leadership.
- f) The plan is evaluated annually and, if needed, according to related performance measures results or major incidents including corrective action.

Survey process guide:

- GAHAR surveyor may review safety and security plan/s to make sure that they include all the required elements.
- GAHAR surveyor may observe staff in work areas and waste collection areas to check the usage of suitable personal protective equipment (PPE).
- GAHAR surveyor may interview staff to assess staff awareness of environmental safety requirements.

Evidence of compliance:

1. The radiology center has an approved safety and security plan/s that includes items a) through f) in the intent.
2. The radiology center has a process for regular, current, accurate facility surveillance and inspection documentation at least on an annual basis.
3. The safety and security plan/s is monitored with the collection, aggregation, and analysis of data to identify areas for improvement.
4. Staff is aware of safety and security plan/s and their requirements.

Related standards:

PCC.05 Patient belongings, ICD.05 High-risk patients and procedures/ services, EFS.02 Fire and smoke safety plan, EFS.03 Hazardous materials and waste disposal, IPC.07 Equipment disinfection, sterilization, ACT.01 Safe patient access and registration process, QPI.03 Risk management plan/program.

Safe utility plan

EFS.05 NSR.15 Essential utilities plan addresses regular inspection, maintenance, testing, and repair.

Effectiveness

Keywords:

Utility management plan.

Intent:

Some of the most important utilities include mechanical (e.g., heating, ventilation, and cooling); electrical (i.e., normal power and emergency power); domestic hot and cold water; other plumbing systems; waste; technology systems, including the myriad communications and data-transfer systems; vertical transportation utilities; fuel systems; access control, duress alarm and surveillance systems; medical gases, air, and vacuum systems; and pneumatic tube systems. The radiology center has competent staff members to oversee utility systems.

The radiology center shall have a utility management plan to ensure the efficiency and effectiveness of all utilities. The plan shall include at least the following:

- a) Identify the Critical utility systems and the related backup system, for example, building maintenance, electricity, water supply, medical gases, heating, ventilation, air conditioning, communication systems, sewage, fuel sources, fire alarm, and elevators.
- b) The layout of the utility systems.
- c) Staff training on utility plan.
- d) Regular inspection, testing, and corrective maintenance of utilities.
- e) Preventive maintenance plan, according to the manufacturer's recommendations.
- f) The radiology center shall perform regular, accurate data aggregation, and analysis, for example, frequency of failure, and preventive maintenance compliance for proper monitoring, updating, and improvement of the different systems.

Survey process guide:

- GAHAR surveyor may review the utility management plan to confirm the availability of all required systems, regular inspection, maintenance, and backup utilities.
- GAHAR surveyor may review inspection documents, preventive maintenance schedules, contracts, and equipment, as well as testing results of generators, tanks, and/or another key systems.

Evidence of compliance:

1. The radiology center has a plan for utility management that includes items a) through f) in the intent.
2. The staff is aware of the utility systems plan requirements.

3. Records are maintained for utility systems inventory, testing, periodic preventive maintenance, and malfunction history.
4. Critical utility systems are identified and backup availability is ensured.
5. The plan is evaluated and updated annually with aggregation and analysis of necessary data.

Related standards:

MMS.02 Medications storage and labeling, EFS.03 Hazardous materials and waste disposal, EFS.02 Fire and smoke safety plan, EFS.06 Emergency preparedness plan, WFM.06 Continuous education and training program, EFS.07 Medical equipment management plan.

Safe emergency preparedness plan

EFS.06 Emergency preparedness plan addresses responding to potential external disasters.

Safety

Keywords:

Emergency preparedness plan.

Intent:

The last few decades have witnessed an increased frequency of disasters causing tremendous human casualties, in terms of loss of life and disability in addition to huge economic losses. Although these may not be totally preventable, but their impact can be minimized by effective planning. Other emergencies like road, rail, and air accidents, industrial accidents, explosions, and terrorist attacks have an inherent potential to convert into mass casualty incident. Preparedness measures are taken before a disaster can greatly increase the ability to control it. The radiology center shall have a risk assessment tool to prioritize potential emergencies based on probability and impact. The emergency preparedness plan shall be reviewed and evaluated regularly (at least annually) with aggregation and analysis of necessary data and include at least the following:

- a) Risk assessment of potential external disasters, which may affect the building and/or activities.
- b) Degree of preparedness according to the level of risk.
- c) Communication strategies: internal communication may be in the form of a clear call tree that includes staff titles and contact numbers, and external communication channels may include civil defense and /or ambulance services.
- d) Clear duties and responsibilities for radiology leaders and staff.
- e) Identification of required resources, supplies, and equipment such as utilities and

medical equipment.

- f) Drill schedule for external disaster. The radiology center shall have a drill scheduled for external emergencies at least annually and ensure the attendance of staff; proper evaluation and recording of the drill includes, but is not limited to:
 - i. The scenario of the drill.
 - ii. Observations on: Code announcement, timing, staff attendance, response, and communication.
 - iii. Clear corrective actions, if needed.
 - iv. Debriefing.

Survey process guide:

- GAHAR surveyor may review the external disaster preparedness plan and its records to confirm that it covered all the identified risks.
- GAHAR surveyor may review preparations in terms of equipment, supplies, staff, and others.

Evidence of compliance:

1. The radiology center has an emergency preparedness plan that includes items a) through f) in the intent.
2. Staff training on the emergency preparedness plan is performed and evaluated.
3. The radiology center performs at least one drill for external disaster annually that includes items from i) through iv) in point f) from the intent.

Related standards:

EFS.02 Fire and smoke safety plan, EFS.05 Utilities management plan, QPI.03 Risk management plan/program, OGM.01 Governing body Structure and clear responsibilities, WFM.06 Continuous education and training program.

Safe radiological medical equipment

EFS.07 NSR.16 Medical equipment plan ensures safe selection, inspection, testing, maintenance, and safe use of medical equipment.

Safety

Keywords:

Medical Equipment management plan.

Intent:

Medical equipment is critical to the diagnosis and treatment of patients. In radiology centers, a trained qualified individual/(s) shall oversee and manage the medical equipment management plan. He is responsible for the entire bio-medical inventory, dealing with medical equipment hazards, and monitoring the extensive array of devices.

Poor maintenance lead to inappropriate results which seriously affect both patient and staff safety in addition to frequent downtime, delayed and inadequate services .

This is why it is crucial to establish some basic equipment safety and service guidelines. Alarms are intended to induce immediate appropriate action from staff members to either check device malfunction or initiate action that will revert the situation. This can be ensured when all the staff members become fully aware of alarm settings (values and volume) and their significance and are trained on the required actions to be taken when triggered.

The radiology center develops a plan for medical equipment management that addresses at least the following:

- a) Developing criteria for selecting new medical equipment.
- b) Acceptance test of new medical equipment upon procurement.
- c) Periodic Quality control test according to WHO protocol or manufacturer's recommendation
- d) Training of staff on safe usage of medical equipment upon hiring on the installation of new equipment, and on a predefined regular basis by a qualified person/ company.
- e) Training of staff on safe handling of the specialized equipment.
- f) Inventory of medical equipment including availability, criticality, and functionality.
- g) Identification of critical medical equipment and critical alarming system that should be available for the operator even though the provision of back- up such as life-saving equipment, ventilator, and DC shock.
- h) Periodic preventive maintenance according to the manufacturer's recommendations which usually recommends using tagging systems by tagging dates and due dates of periodic preventive maintenance or labeling malfunctioned equipment.
- i) Calibration of medical equipment according to the manufacturer's recommendations and/or its usage.
- j) Malfunction and repair of medical equipment and critical alarming system.
- k) Dealing with equipment adverse incidents, including actions taken, backup system, and reporting.
- l) Records are maintained including Updating, retiring, and/or replacing medical equipment in a planned and systematic way. These records are implemented for at least the following:
 - i. equipment with critical alarms inventory,
 - ii. user training,
 - iii. equipment identification cards
 - iv. company emergency contact
 - v. testing on installation

- vi. periodic preventive maintenance
- vii. calibration
- viii. malfunction history.

Survey process guide:

- GAHAR surveyor may review the medical equipment maintenance plan to ensure availability of all required documents, inventory of medical equipment, preventive maintenance schedule, calibration schedule, and staff training records.
- GAHAR surveyor may observe the functionality of the medical equipment.
- GAHAR surveyor may review the completeness of some medical equipment records.

Evidence of compliance:

1. The radiology center has an approved medical equipment management plan that addresses all elements from a) through l) in the intent.
2. Staff is fully aware and trained on the center's medical equipment management plan and how to use equipment with critical alarms.
3. Records are maintained for all elements from i) through viii) in the intent.
4. Only trained and competent staff handle critical alarms and specialized equipment(s).
5. The plan is evaluated and updated annually with aggregation and analysis of necessary data.

Related standards:

ICD.09 Emergency equipment and supplies, MRS.02 Technical medical imaging procedures, IPC.05 Environmental and equipment cleaning activities, EFS.08 Calibration of equipment, EFS.09 Quality assurance and control program.

EFS.08 Radiology center ensures performing an effective calibration process for all radiology equipment.

Effectiveness

Keywords:

Calibration of equipment.

Intent:

All equipment in the radiology center should be calibrated to ensure its quality and proper functionality. The calibration tests and periodicity are determined by the equipment manufacturer and the regulatory body, and these calibrations are documented. The calibration certificates shall be authorized by a well-known, accredited calibration provider.

The radiology center leaders are responsible for ensuring the performance of the

equipment calibration plan, to determine situations when calibration has required that include at least the following:

- a) Initial acceptance test
- b) After any maintenance procedure that could affect the received dose and acquisition accuracy
- c) Calibration intervals that approved by the regulatory body
- d) Calibration of dosimetry tools

The radiology staff members shall ensure that all sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;

Calibrations of radiation therapy units are subject to independent verification prior to clinical use;

Calibration of all dosimetry tools is done in a standard dosimetry laboratory.

Survey process guide:

- GAHAR surveyor may review the calibration plan.
- GAHAR surveyor may interview staff to check their awareness of the equipment calibration plan.

Evidence of compliance:

1. The radiology center has a current, approved equipment calibration plan.
2. Action taken is documented in case of deviation from acceptable criteria that is determined by the equipment manufacturer and the regulatory body.
3. The staff is fully aware of the center's equipment calibration plan.

Related standards:

EFS.07 Medical equipment management plan, EFS.09 Quality assurance and control program, QPI.03 Risk management plan/program.

EFS.09 Radiology center establishes an effective quality assurance and control program for all radiology equipment.

Effectiveness

Keywords:

Quality assurance and control program.

Intent:

Management of the routine quality control (QC) of radiology equipment is a major responsibility of medical imaging professionals.

Quality control measures are performed to monitor and ensure the reliability of study results produced by the medical imaging service.

Quality controls can identify performance problems not identified by quality control systems and helps the radiology center to determine the accuracy of images.

Management of routine quality control includes developing the QC protocols, implementing the program, oversight the program, and being responsible for determining the need for corrective action.

Quality control data is reviewed at regular intervals and recorded.

Outliers or trends in examination performance, that may indicate problems in the examination system, are analyzed, followed up and preventive actions are taken and recorded before major problems arise.

The quality assurance and control program may be regularly reviewed and assessed for its appropriateness to the organization's scope and policy of the provided radiology services

The radiology center shall develop and implement a quality assurance and control program that includes:

- a) Measuring and recording the physical parameters of medical radiological equipment:
 - i. At the time of acceptance and commissioning of the equipment prior to its clinical use on patients;
 - ii. Periodically thereafter according to the manufactures recommendations and national regulations;
 - iii. After any major maintenance procedure that could affect the protection and safety of patients;
 - iv. After any installation of new software or modification of existing software that could affect the protection and safety of patients.
- b) Implementation of corrective actions if measured values of the physical parameters are outside established tolerance limits.
- c) Verification of the physical parameters as (kVp and mA) and clinical factors used in radiological procedures.
- d) The quality control measurements shall be verified by the authorized organization and has to be certified.

Survey process guide:

- GAHAR surveyor may review the quality control program procedures and records.
- GAHAR surveyor may interview radiology staff members to check their awareness of quality control performance.

Evidence of Compliance:

1. The radiology center has an approved program describing the quality control and assurance addressing all elements in the intent from a) through d).

2. The radiology staff members involved in quality control are competent in quality control performance.
3. Quality control program relevant procedures and results are recorded.
4. A responsible authorized staff member(s) oversees the quality control process
5. Corrective actions are taken when the results are unmet.

Related standards:

MRS.02 Technical medical imaging procedures, EFS.07 Medical equipment management plan, EFS.08 Calibration of equipment, EFS.01 Radiology center environment and facility safety structure, QPI.03 Risk management plan/program.

Infection Prevention and Control

Chapter intent:

Infection Prevention and Control (IPC) is a scientific approach and practical solution designed to prevent harm caused by infection to patients and/or health workers. It is grounded in infectious diseases, epidemiology, social science, and health system strengthening. IPC occupies a unique position in the field of patient safety and quality in Universal Health Coverage since it is relevant to health workers and patients at every single healthcare encounter.

The IPC program aims at identifying and reducing or eliminating the risks of acquisition and transmission of infections among patients, healthcare providers, workers, volunteers, visitors, and the community. Usually, the IPC program is risk-based; this means that a risk assessment is required to promptly identify and proactively address possible infection risks among individuals and in the environment. Then, solutions shall be tailored accordingly by developing appropriate policies and procedures, in conjunction with proper staff education.

Therefore, IPC activities shall differ from one organization to another, depending on the radiology center's clinical activities, the scope of services, and served patient population. It is the responsibility of the IPC team members to oversee the IPC program, and they should all have detailed job descriptions. The staff member(s) shall be qualified enough to meet the radiology center's needs. These needs are driven by the radiology center size, complexity of activities, and level of risks, as well as the program's scope. The required qualifications could be in the form of education, training, experience, and certification.

The IPC program and its activities are based on current scientific knowledge, the national guidelines, and accepted international practice guidelines (CDC, APIC, IFIC), besides applicable laws and regulations. The program shall need to be planned, disseminated, taught, and monitored.

Chapter purpose:

1. To ensure the effective structure of infection prevention and control.
2. To address the standard precautions policies and procedures, implementation, and monitoring.
3. To highlight the environmental cleaning and disinfection activities.
4. To describe safe injection practices.
5. To explain the transmission-based precautions and patient placement.
6. To explain the infection prevention and control program in all supportive services (kitchen, laundry, and waste management).

7. To illustrate the preventive measures during construction and renovation.
8. To link infection control activities to the organizational quality program and determine needs for IPC improvement projects.

Implementation guiding documents:

(All mentioned references need to be read in the context of their conditions, amendments, substitutes, updates, and annexes)

- 1) National guidelines for infection control
- 2) MOHP Ministerial decree for developing infection prevention and control departments
- 3) MOHP Ministerial decree 187/2004 for infection control personnel
- 4) Presidential decree 14/2014 for performance evaluation
- 5) MOHP Ministerial decree 753 / 2015 for medical waste management
- 6) MOHP Ministerial decree 153 / 2004 for prevention of viral hepatitis
- 7) MOHP Ministerial decree 523 / 2015 for reuse of single used devices and instruments
- 8) The Egyptian code for healthcare facilities design
- 9) Egyptian law of the Environment.
- 10) Law 59/1960 – Radiation Protection against Ionizing Radiation
- 11) Law 7/2010 - Regulating nuclear and radiological activities

Efficient structure of the infection prevention and control program

IPC.01 Dedicated and qualified healthcare professional(s) oversee the infection prevention and control activities according to applicable laws and regulations, national and international guidelines.

Effectiveness

Keywords:

Infection prevention and control assigned team.

Intent:

The presence of a qualified and dedicated IPC professional(s) in the radiology center ensures increased effectiveness of the IPC program in all its phases including development, implementation, and monitoring.

The radiology center shall assign a qualified team to be responsible for all activities related to the IPC program, supervise, put an action plan to implement this program, and educate all staff members on their roles.

The team members' qualifications and numbers shall meet the radiology center's needs. These needs are driven by the radiology center size, complexity of activities, and level of risks, as well as the program's scope.

the presence of a multidisciplinary IPC committee is crucial to provide a continuous link between the upper managerial level, the IPC team, and all other radiology center staff. Committee needs are driven by the radiology center size, complexity of activities, and level of risks, as well as the program's scope.

When there is a structured infection control committee; all relevant disciplines should be represented in the committee and the committee should have the right to summon whoever it deems appropriate.

The IPC committee is responsible for at least the following:

- a) Setting criteria to define radiology center-associated infections.
- b) Surveillance methods and processes.
- c) Strategies to prevent infection and control risks.
- d) Reporting infection prevention and control activities.

Survey process guide:

- GAHAR surveyor may interview the IPC team and inquire about their qualifications and check their awareness of their job description.
- GAHAR surveyor may review the committee Terms of References and may review a sample of monthly minutes of the meeting.
- GAHAR surveyor may review evidence of recommendations follow up and implementation.

Evidence of compliance:

1. The radiology center has an assigned dedicated IPC team/ committee.
2. The IPC team leader and each member has a defined job description.
3. The IPC team members are qualified by certification and education that match their job description requirements.
4. There is a clear process of communication with the top management and all other relevant departments\disciplines.

Related standards

WFM.02 Job description, OGM.02 Qualified director, IPC.02 infection prevention and control program.

IPC.02 A comprehensive infection prevention and control program is developed, implemented, and monitored.

Safety

Keywords:

Infection prevention and control program.

Intent:

Constructing a comprehensive IPC program is of utmost importance to effectively reduce infection risks. The IPC program is an integrated part of quality improvement and patient safety programs, using measures that are epidemiologically important to the radiology center. Measurement information is essential to improve infection prevention and control activities and reduce healthcare-associated infection rates.

An effective IPC program shall be comprehensive and shall include all aspects of patient care, staff health, and the entire services provided by the radiology center.

The program development requires a multidisciplinary approach that is carried on by qualified staff members and is reinforced by sound up-to-date knowledge and resources to fulfill its mission and objectives.

The program shall also assure the education and training of all working staff members and provide necessary patients, visitors, and families' education. Surveillance of all activities that shall be performed by the radiology center based on the IPC program is also a necessity.

The IPC program shall be based on the annual radiology center risk assessment plan, national and international guidelines (CDC, APIC, IFIC, etc.), accepted practices, and applicable laws and regulations. The radiology center shall identify the procedures associated with increased infection risk by defining policies, procedures followed by staff education, and evidence-based activities, to reduce these identified risks.

Each radiology center shall design its own key performance indicators to monitor, assess, and improve the IPC program. Examples of KPI include the percentage of hand hygiene compliance.

Survey process guide:

- GAHAR surveyor may review the infection control program to evaluate the presence of a risk assessment, a Risk assessment based-IPC program that covers all radiology center areas and includes all relevant individuals, a training plan, or an annual evaluation report and update of the IPC program.
- GAHAR surveyor may review the documentation of monitoring of data, performance measures, data analysis reports, recommendations for improvement and observe the implementation

Evidence of compliance:

1. The radiology center has an IPC program that includes the scope, objectives, expectations, infection risk assessment, and surveillance methods.
2. The IPC program includes all areas of the radiology center and covers patients staff and the visitors according to the scope of radiology center.
3. The IPC program includes a training plan for all healthcare providers.
4. The radiology center tracks, collects, analyzes, and reports data on its infection control program.
5. The radiology center act on improvement opportunities identified in its infection control program.

Related standards:

IPC.01 Infection prevention and control assigned team, IPC.03 Hand hygiene, IPC.05 Environmental and equipment cleaning activities, EFS.03 Hazardous materials and waste disposal, WFM.06 Continuous education and training program, QPI.03 Risk management plan/program, MRS.08 Personal protective equipment (PPE), EFS.04 safety and Security plan.

Safe and effective infection prevention practices

IPC.03 NSR.06 Evidence-based hand hygiene guidelines are adopted and implemented throughout the radiology center to prevent healthcare-associated infections.

Safety

Keywords:

Hand hygiene.

Intent:

Hand hygiene is the cornerstone for reducing infection transmission in all healthcare settings including radiology centers. It is considered the most effective and efficient strategy for infection prevention and control. Hand hygiene facilities should be present

in appropriate numbers.

Hand hygiene supplies (hand soap, hand antiseptics, and single-use towels) must be present in the appropriate places. Hands are washed before and after patient contact, after removing the gloves, and when contaminated with body or bloody fluids. Alcohol-based hand rubs are now the preferred products for routine hand hygiene in healthcare facilities, unless hands are visibly soiled, to overcome the shortage in sinks. A povidone-iodine scrubs or equivalent is used when making contact with persons known to have or suspected of having an infection, handling contaminated articles or equipment or when preparing to perform invasive procedures.

The radiology center shall develop and implement a policy of hand hygiene that addresses at least the following;

- a) Availability of hand hygiene education posters and records.
- b) Hand hygiene techniques that are applied in the center and according to the degree of contamination.
- c) Explaining the WHO five moments of hand hygiene and staff training.
- d) Methods of integrating the hand hygiene measures in the staff appraisal and evaluation process.

Survey process guide:

- GAHAR surveyor may review the hand hygiene policy and hand hygiene guidelines.
- GAHAR surveyors may review hand hygiene education posters and records.
- GAHAR surveyor may interview radiology center staff, to check their awareness of hand hygiene technique and WHO five moments of hand hygiene.
- GAHAR surveyor may observe hand-washing facilities in all areas and check the availability of supplies (soap, tissue paper, alcohol hand rub, etc.).
- GAHAR surveyor may observe compliance of staff with hand hygiene technique and WHO five moments of hand hygiene.

Evidence of compliance:

1. The radiology center has an approved hand hygiene policy based on evidence-based guidelines that address the elements from a) through d).
2. Healthcare professionals are trained on how to apply hand hygiene policy.
3. Hand hygiene posters are displayed in required areas, as per center policy.
4. Hand hygiene facilities are available in numbers and places, as per center policy.
5. The radiology center measures and monitors staff compliance with the hand hygiene policy.
6. Results of staff compliance are linked and documented in the staff appraisal\ evaluation process, and corrective actions are taken based upon.

Related standards

ICD.03 Clinical practice guidelines, OGM.05 Supply chain management, IPC.02 infection prevention and control program, IPC.01 Infection prevention and control assigned team, QPI.02 Performance measures, WFM.06 Continuous education, and training program.

IPC.04 The Standard precautions measures and appropriate infection prevention practices apply in any setting where healthcare is provided.

Safety

Keywords:

Standard precautions measures.

Intent:

According to CDC, standard precautions are aimed to intercept contamination and restrict the spread of disease within the facility. the radiology center shall implement at least the minimum infection prevention practices throughout the provision of patient care, regardless of the suspected or confirmed infection status of the patient, in any setting where health care is provided. In addition to hand hygiene, standard precautions include:

- a) Use of personal protective equipment (PPE) (e.g., gloves, masks, eyewear).
- b) Use of soap, washing detergents, antiseptics, and disinfectants.
- c) Respiratory hygiene/cough etiquette.
- d) Sharps safety (engineering and work practice controls).
- e) Safe injection practices (i.e., the aseptic technique for parenteral medications).
- f) Sterile instruments and devices.
- g) Clean and disinfected environmental surfaces.
- h) Handling of textile and contaminated fabrics.

Proper selection of standard precautions depends on risk assessments that are performed at the points of care, and according to the patient's suspected infection so staff education and training are therefore of utmost importance.

Although contaminated textiles and fabrics in healthcare facilities are a source of substantial numbers of pathogenic microorganisms, reports of health-care-associated diseases linked to contaminated fabrics are so few in number that the overall risk of disease transmission during the laundry process likely is negligible. Therefore, the use of current control measures shall be continued to minimize the contribution of contaminated laundry to the incidence of healthcare-associated infections. The radiology center shall develop a clear process for handling contaminated textiles and fabrics that include at least the following:

- I) Processes of collection, storage, and transporting to the laundry for contaminated textile.
- II) Processes of receiving, storage, and distribution of clean textile.

Survey process guide:

- GAHAR surveyor may observe the implementation of standard precautions measures.
- GAHAR surveyor may observe the availability and accessibility of PPE.
- GAHAR surveyor may interview staff members to inquire about the constant availability, accessibility, and proper use of PPE.
- GAHAR surveyor may review PPE standardized products specifications.

Evidence of compliance:

1. The radiology center uses standard precautions measures that include items from a) through h) in the intent depending on a risk assessment that is performed at the points of care.
2. The radiology center has PPE that is easily accessible and available.
3. Selection and use of PPE are based on the risk assessments that are performed at the points of care and according to the patient's suspected infection.
4. Responsible staff is aware of standard precautions measures, PPE proper use, and disposal.

Related standards

IPC.02 infection prevention and control program, IPC.01 Infection prevention and control assigned team, IPC.05 Environmental and equipment cleaning activities, MRS..08 Personal protective equipment (PPE), EFS.04 safety and Security plan, QPI.02 Performance measures, MRS.06 Radiation Safety Program.

IPC.05 Environmental and equipment cleaning activities are aligned with current evidence-based guidelines.

Safety

Keywords:

Environmental and equipment cleaning activities.

Intent:

Cleaning products are substances used to remove organic material such as dirt, and body fluids. it includes liquid soap, enzymatic cleaners, and detergents. Disinfectants are only for disinfecting after cleaning and are not substitutes for cleaning unless they are a combined detergent-disinfectant product. The healthcare environment is considered a reservoir for pathogens and may be a significant source of healthcare-associated infections so, cleaning and disinfection of environmental and equipment surfaces is an important tool to prevent the development of these infections.

Contact with contaminated surfaces in the radiology center can easily lead to cross-contamination of microorganisms between the environment and healthcare

professionals

To provide quality of care, the radiology center shall develop a clear method and schedule for environmental cleaning and disinfection including walls, floors, ceilings, and furniture, this must be performed according to the classification of areas.

The environmental and equipment cleaning schedule must address the cleaning activities for each area as follows:

- a) Activities to be done every day.
- b) Activities to be done every shift, with more frequent cleaning of high-touch surfaces.
- c) Deep cleaning activities.

Survey process guide:

- GAHAR surveyor may review the list of all environmental services that require cleaning, cleaning schedules, and the presence of spill kits.
- GAHAR surveyor may interview healthcare professionals and environmental cleaning staff members to check the availability, accessibility, and use of disinfectant, and spill kits properly.

Evidence of compliance:

1. Cleaning activities with determined times are listed for each area and include all elements mentioned in the intent from a) through c).
2. Responsible staff is trained on the process of environmental cleaning activities that include; availability, accessibility, use of disinfectant, and spill kits. (especially if radioactive contaminated).
3. Disinfectants selection and cleaning methods used are matching with the requirements of each cleaning area and/or equipment and are supervised by a qualified, trained staff member.

Related standards

EFS.03 Hazardous materials and waste disposal, EFS.07 Medical equipment management plan, IPC.04 Standard precautions measures, IPC.07 Equipment disinfection, sterilization, IPC.06 communicable diseases preventive measures.

Communicable diseases preventive measures and transmission-based precautions

IPC.06 Patients with clinically suspected and/or confirmed communicable diseases follow preventive measures according to the probable mode(s) of transmission.

Safety

Keywords:

Communicable diseases preventive measures.

Intent:

As radiology rooms are used for both inpatient and outpatient, the rate of contamination of surfaces, devices, and equipment is increased. Hence, standard precautions, and transmission-based precautions are used for patients known or suspected to be infected or colonized with a certain infectious agent. Isolation precautions create barriers between people and microorganisms that help in preventing the spread of germs in the radiology center. Prolonged waiting time and exposure of patients and their accompanying family members, especially in a suboptimal ventilated environment, raises the inevitable potential for infection transmission, particularly in the presence of outbreaks of highly infectious diseases such as COVID.

If the patient is determined to be at an increased risk for transmission of microorganisms, the radiology center shall follow at least the following;

- a) Develop an appropriate, efficient protocol for receiving patients from abroad or from other hospitals or facilities.
- b) Create "clean" and "Contaminated" areas, with dedicated transport routes for each of them, "contaminated" area refers to areas traversed by suspected or confirmed cases of infection.
- c) Perform the radiological procedures for confirmed/suspected cases in batches, spaced out.
- d) Instruct patients who present with clinical respiratory syndromes to practice respiratory hygiene and cough etiquette and give a surgical mask to wear until an examination room can be provided.
- e) Ensure that contacting staff always wear appropriate PPEs and respiratory protection (such as N95 respirator).
- f) Provide firm training and supervision in knowledge and skills of IPC.

The safe handling of the contaminated surfaces, articles, tools, or equipment in radiology settings should be done according to evidence-based guidelines and the national laws and regulations.

Survey process guide:

- GAHAR surveyor may review the process of the communicable diseases' preventive measures.

- GAHAR surveyor may interview staff members to check their awareness of the process.

Evidence of compliance:

1. The radiology center has a clearly defined process of communicable diseases' preventive measures and include items from a) to f) in the intent.
2. Patients with suspected or confirmed clinical communicable diseases are identified and placed in the assigned area.
3. Health care providers caring for patients with a suspected or confirmed communicable disease are aware of the process and adherent to suitable PPE.

Related standards:

IPC.02 infection prevention and control program, ICD.05 High-risk patients and procedures/ services, EFS.01 Radiology center environment and facility safety structure, QPI.03 Risk management plan/program, IPC.05 Environmental and equipment cleaning activities, IPC.07 Equipment disinfection, sterilization

IPC.07 Patient care equipment is disinfected/sterilized based on evidence-based guidelines and manufacturer recommendations.

Safety

Keywords:

Equipment disinfection, sterilization.

Intent:

Processing of patient care equipment is a very critical process inside any radiology center. In clinical procedures that involve contact with medical/surgical equipment, it is crucial that healthcare professionals follow standard practices and guidelines to clean and disinfect or sterilize. The cleaning process is a mandatory step in the processing of patient care equipment. Cleaning, disinfection, and sterilization may take place in a centralized processing area. The radiology center shall develop and implement a policy and procedures to guide the process of sterilization/disinfection. The policy shall address at least the following:

- a) There is a physical separation between the contaminated and clean areas.
- b) Receiving and cleaning of used items.
- c) Preparation and processing.
 - i. Processing method to be chosen according to Spaulding classification:
Disinfection of medical equipment and devices involves low, intermediate, and high-level techniques. High-level disinfection is used (if sterilization is not possible) for only semi-critical items that come in contact with mucous membranes or non-intact skin. Chemical disinfectants approved for high-level

- disinfection include glutaraldehyde, orthophthaldehyde, and hydrogen peroxide.
- ii. Sterilization shall be used for all critical and heat-stable semi-critical items.
 - iii. Low-level disinfection (for only non-critical items) shall be used for items such as stethoscopes and other equipment touching intact skin. In contrast to critical and some semi-critical items, most non-critical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area.
- d) Labeling of sterile packs.
 - e) Storage of clean and sterile supplies: properly stored in designated storage areas that are clean, dry, and protected from dust, moisture, and temperature extremes. Ideally, sterile supplies are stored separately from clean supplies, and sterile storage areas shall have limited access.
 - f) Logbooks are used to record the sterilization process.
 - g) Inventory levels.
 - h) Expiration dates for sterilized items.

Survey process guide:

- GAHAR surveyor may review the policy for the disinfection \sterilization process.
- GAHAR surveyor may interview the responsible staff to check their awareness of the policy.
- GAHAR surveyor may observe clean and sterile supplies store to check for proper storage.

Evidence of compliance:

1. The radiology center has an approved policy to guide the process of disinfection and sterilization that addresses all elements in the intent from a) through h).
2. Healthcare professionals are aware of how to apply the policy.
3. The sterilization or disinfection process is performed according to the national laws and regulations, Spaulding classification, and manufacturer' surerer's requirements\recommendations.
4. Clean and sterile supplies are properly stored in designated storage areas that are clean, dry, and protected from dust, moisture, and temperature extremes.

Related standards:

EFS.03 Hazardous materials and waste disposal, IPC.02 infection prevention and control program, EFS.05 Utilities management plan, EFS.06 Emergency preparedness plan, QPI.02 Performance measures, IPC.08 Disinfection/sterilization quality control program, IPC.09 Safe injection practices, IPC.10 Aseptic technique

IPC.08 A disinfection/sterilization quality control program is developed and implemented.

Effectiveness

Keywords:

Disinfection/sterilization quality control program.

Intent:

Disinfection/sterilization is a critical process. Therefore, monitoring of the disinfection/sterilization process is crucial for ensuring a reliable and efficient disinfection/sterilization process. Quality control program measures are performed to monitor and ensure the reliability of the disinfection/sterilization processes. Quality control tests for monitoring sterilization and high-level disinfectants shall be done regularly. The radiology center shall fulfill logbooks for documentation of the sterilization monitoring process. The radiology center shall develop a program for quality control, which includes at least the following:

- a) Quality control elements, method, and frequency include:
 - i. Physical parameters (temperature, time, and pressure), which are monitored every cycle.
 - ii. Chemical parameters (internal chemical indicator inside the sterilization pack-external chemical indicator on the outside of the sterilization pack), which are monitored every pack.
 - iii. Biological indicator, which is done at least weekly.
 - iv. The test for adequate steam penetration and rapid air removal shall be done every day before starting to use the autoclave using Class 2 internal chemical indicators and process challenge devices, which is either a porous challenge device or a hollow challenge device.
 - v. Porous challenge Pack: Bowie-Dick Sheets (class 2 indicator) inside a porous challenge pack (every load). Hollow load challenge (Helix test): a class 2 chemical indicator (strip) inside a helix (every load).
 - vi. Chemical test strips or liquid chemical monitors shall be used for determining whether an effective concentration of high-level disinfectants is present despite repeated use and dilution. The frequency of testing shall be based on how frequently these solutions are used.
- b) Quality control performance expectations and acceptable results shall be defined and readily available to staff so that they will recognize unacceptable results to respond appropriately.
- c) The quality control program is approved by the designee prior to implementation.
- d) Responsible authorized staff member reviews Quality Control results at a regular interval.

- e) Remedial actions taken for deficiencies identified through quality control measures and corrective actions taken accordingly.

Survey process guide:

- GAHAR surveyor may review quality control of the disinfection/sterilization program.
- GAHAR surveyor may interview staff involved in the sterilization/disinfection process to check their awareness of quality control performance.
- GAHAR surveyor may observe quality control procedures in disinfection/sterilization areas
- GAHAR surveyor may review logbooks for chemical indicators and biological indicators documentation

Evidence of compliance:

1. The radiology center has a quality control program of disinfection/sterilization process addressing all elements in the intent from a) through e) in the intent.
2. The quality of packaging material, as chemical and biological indicators, are determined based on standardized product specifications.
3. Healthcare providers involved in sterilization/disinfection are trained in quality control performance.
4. Quality control measures and monitoring indicators are recorded.
5. Corrective action is taken whenever results are not satisfactory.

Related standards:

IPC.01 Infection prevention and control assigned team, IPC.02 infection prevention and control program, IPC.07 Equipment disinfection, sterilization, EFS.09 radiology equipment quality control and assurance, WFM.08 Clinical Privileges, QPI.02 Performance measures.

Safe injection practices

IPC.09 The radiology center ensures safe injection practices.

Safety

Keywords:

Safe injection practices.

Intent:

In the radiology center, patients are in need of injections whether for diagnostic or therapeutic purposes, unfortunately, it carries an associated risk of infection for the patients.

Moreover, needle stick injuries among healthcare professionals is a common accident so, safe injection practices are crucial to ensure both patient and healthcare professionals'

safety.

Healthcare professionals must always use a sterile, single-use disposable syringe, and needle for each injection given, and ensure that all injection equipment and medication vials remain free from contamination.

Survey process guide:

- GAHAR surveyor may observe the availability of Intravenous bottles and their proper use and the proper use of single-dose vials and multi-dose vials.
- GAHAR surveyor may interview staff to check their awareness of safe injection practices

Evidence of compliance:

1. Intravenous bottles/bags, single-use fluids infusion /administration sets (e.g., tubing and connections) are disposed of directly, in-between patients.
2. The use of single-dose vials or multi-dose vials is done in accordance with the manufacturers' recommendations to ensure that vials are remaining free from contamination.
3. The radiology center ensures that all staff are trained and aware of safe injection practices.

Related standards:

IPC.02 infection prevention and control program, EFS.04 safety and Security plan, EFS.03 Hazardous materials, and waste disposal, IPC.04 Standard precautions measures, QPI.03 Risk management plan/program.

IPC.10 Current evidence-based aseptic techniques are followed during all medical procedures.

Safety

Keywords:

Aseptic techniques.

Intent:

Aseptic technique refers to practices designed to render and maintain objects and areas maximally free from microorganisms.

The term 'aseptic technique' encompasses several key elements: clean environment, conscientious practicing of hand hygiene, use of appropriate personal protective equipment, and use of standardized routine cleaning, disinfection, and sterilization practices.

All healthcare professionals shall be cognizant of their movement, barrier use, and practices to prevent inadvertent breaks in aseptic techniques, alerting others when the

field or objects are potentially contaminated. Choice of the level of antisepsis shall be risk assessment based.

Asepsis is defined as the process of keeping away disease-producing microorganisms. The radiology center shall develop a policy for aseptic techniques that define and outline the procedures including at least the following:

- a) Surgical asepsis is the use of a sterile technique to prevent the transfer of any organisms from one person to another or from one body site to another. The goal of the sterile technique is to maintain the microbe count at an irreducible minimum.
- b) Surgical aseptic technique outside of the operating room refers to a practice in a setting outside the operating room that may not have the capacity to follow the same strict level of surgical asepsis applied in the operating room. However, the goal to avoid infection remains in all clinical settings.
- c) Medical asepsis or clean technique refers to practice interventions that reduce the number of microorganisms to prevent and reduce transmission risk from one person (or place) to another.

Survey process guide:

- GAHAR surveyor may review the policy for aseptic techniques.
- GAHAR surveyor may interview healthcare professionals to check their awareness of the policy and to assess that the implementation is done as relevant to their jobs.

Evidence of compliance:

1. The radiology center has an approved policy for aseptic techniques that defines items from a) to c) in the intent.
2. Healthcare professionals are trained on how to implement the aseptic techniques, as relevant to their jobs.
3. Choice of the level of antisepsis is based on the IPC Risk assessment and analysis.

Related standard

IPC.02 infection prevention and control program, IPC.04 Standard precautions measures, QPI.03 Risk management plan/program, WFM.06 Continuous education and training program.

Effective epidemiological surveillance and monitoring

IPC.11 Healthcare-associated infections surveillance processes and outbreak investigations are implemented.

Effectiveness

Keywords:

Infection surveillance process.

Intent:

Surveillance is an essential component of any effective IPC program that contributes to improving the healthcare quality system and helps in detecting emerging and reemerging of healthcare-associated infections. The effective surveillance program shall be based on comprehensive epidemiological and statistical principles.

Surveillance plays a critical role in identifying outbreaks, emerging infectious diseases, and multidrug-resistant organisms to institute appropriate IPC measures.

Outbreaks of infectious diseases can occur in healthcare settings and pose a threat to patient safety. The outbreak investigations aim to identify the most probable contributing factors to stop the outbreaks and prevent their recurrence. Outbreaks can be suspected in cases of increased rate of healthcare-associated infections or when new or unusual pathogens are recovered from samples. Effective management of outbreaks shall require cooperation between the infection prevention and control team and other clinical specialties. Outbreak management shall include immediate control measures, general control measures, and recovery measures. The radiology center shall develop and implement a policy and procedure to guide the surveillance process and types.

Survey process guide:

- GAHAR surveyor may review the policy of surveillance process and types.
- GAHAR surveyor may interview staff to check their awareness of the surveillance process.
- GAHAR surveyor may review surveillance documents, quarterly surveillance reports that are reviewed by the IPC committee, and recommendations for improvement.
- GAHAR surveyor may review the reporting system for notifiable communicable diseases and outbreaks investigation analysis reports.

Evidence of compliance:

1. The radiology center has an approved policy that addresses the infection surveillance process.
2. Responsible staff is trained on how to apply the policy.
3. Outbreak management includes immediate control measures, general control measures, and recovery measures.

4. Data collected from the surveillance program is analyzed, investigated, and acted upon.

Related standards:

IPC.02 infection prevention and control program, IPC.01 Infection prevention and control assigned team, IPC.04 standard precautions, IPC.06 communicable diseases preventive measures, QPI.02 Performance measures.

Organization Governance and Management

Chapter intent:

This chapter is concerned with structures for governance and accountability that may differ according to the organization and its size, mandate, and whether it is publicly or privately owned. Possible structures include an individual or group owner, government committee or ministry, or Board of Directors. Having a defined governance structure provides clarity for everyone in the organization, including managers, clinical leadership, and staff regarding who is accountable for making final decisions and oversight of the organization's overall direction. While governance provides oversight and support, it is the commitment and planning efforts of the organization leadership as well as the departments and services leaders that ensures the smooth and efficient management of the organization.

Effective planning is initiated by identifying the stakeholders' needs and designing the service accordingly, Egypt's 2030 vision that has been recently developed provides a direction and common goal to all healthcare organizations to ensure effective safe and patient centered care is provided equally for all Egyptians and is to be considered the cornerstone for organization planning. The organization's plan should be continuously aligned with the governmental initiated campaigns addressing therapeutic, prophylactic, social and nutritional aspects of healthcare. The chapter guides the organization to assign duties to the different levels of management and to ensure effective communication to achieve planned goals and objectives.

Recently the landscape of healthcare is shifting closer to a fully quality-driven future and pay for performance model, the chapter has focused on the financial side of healthcare; a focus that affects both patients and providers. With value-based care and higher levels of efficiency on the rise, the keys to medical practice success are evolving rapidly. The chapter handles various organization wide topics as contracted services, ethical management and staff engagement, which may reflect the efficient and effective collaborative management efforts.

GAHAR surveyors through leadership/ staff interviews, observations and process evaluation shall assess the efficiency and effectiveness of the governance and leadership structure. The ability of leaders to motivate and drive the staff is instrumental for the success of an organization and can be assessed throughout the survey.

Chapter purpose:

The chapter focuses on checking the radiology center structure to determine the following:

1. Effectiveness of governing body.
2. Effectiveness of direction.
3. Effectiveness of leadership.
4. Effectiveness of financial stewardship.
5. Efficient contract management.
6. Ethical management.
7. Effective staff engagement, health, and safety.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes.)

- 1) Egyptian Constitution.
- 2) Egypt 2030 vision, Ministry of Planning.
- 3) Law 51/1981 organization healthcare facilities.
- 4) MOHP Ministerial 186/2001 Patient right to know the expected cost of care.
- 5) Law 181/2018 on Egyptian Consumer Protection.
- 6) Egyptian standards for accounting, 609/2016.
- 7) Women council publications on gender equality.
- 8) Professional code of ethics—prime minister decree 238, the year 2003.
- 9) Law 206/2017 on advertisement for healthcare services.
- 10) Staff Health and Safety regulations.
- 11) Law 59 /1960 – Radiation Protection against Ionizing Radiation.
- 12) Law 7 /2010 - Regulating nuclear and radiological activities.
- 13) MOHP Ministerial decree number 513 / 2016 for the licensing and control of magnetic resonance imaging devices.

Effective governing body

OGM.01 The radiology center has a defined governing body structure with clear responsibilities and accountabilities.

Effectiveness

Keywords:

Governing body structure and clear responsibilities.

Intent:

The governing body is responsible for defining the radiology center's direction and ensuring the alignment of its activity with its purpose. It is also responsible for monitoring its performance and future development. radiology center governing body can be a group of individuals (such as the board of directors), one or more individual owners and in a centralized system several subsidiary centers are governed by one governing body, in order to ensure the proper governance and efficient management of any resources thus its structure has to be well defined. Therefore, defining the governing structure of the radiology center that shows lines of authority and accountability and ensures that it operates effectively and efficiently.

The mission statement is a description of any radiology center's core purpose.

Defining the main purpose of the radiology center in the form of a mission is one of the fundamental roles of the governing body, as the radiology center's mission must be aligned with the national healthcare mission and communicated to all relevant stakeholders, including staff, patients, and visitors.

The radiology center shall develop a policy that describes the structure responsibilities and accountabilities of the governing body. The governing body's responsibilities include at least the following:

- a) Developing and disseminating the vision, mission and values statements.
- b) Developing and achieving the strategic plan.
- c) Developing the operational plan and budget.
- d) Promoting and supporting the quality management, patient safety and risk management programs and performance improvement plan.
- e) Allocating resources and effective financial planning.
- f) Promoting and monitoring safety culture activities and reports.
- g) Responsiveness to internal and regulatory inspection reports.
- h) Clear delegation of responsibilities to the director of the center.

The governing entity shall be represented or displayed in an organizational chart or other similar documents with a clear determination of the flow of orders through the approved line of authority.

In case there is governing board the center shall have a clear two-way communication

process between governance and management, usually between the head of the governing body and the radiology center director with a clear delegation of responsibilities.

Radiology centers shall define the types of communication channels between the governing body, leaders and the radiology center staff. Communication channels may be in the form of social media, monthly meetings or annual conferences, or other channels.

Survey process guide:

- GAHAR surveyor may review the policy that describes the structure, responsibilities and accountabilities of the governing body.
- GAHAR surveyor may observe governing body structure and flow of orders through the approved line of authority.
- GAHAR surveyor may interview staff to check their awareness of the policy.

Evidence of compliance:

1. The radiology center has an approved policy that defines the structure, responsibilities and accountabilities of the governing body that include items from a) to h) in the intent.
2. The radiology center has a vision and mission statement approved by the governing body and is visible in public areas to staff, patients and visitors.
3. There is a defined process of communication between the governing body and the radiology center's leaders and staff.
4. Staff is aware of the methods for the flow of orders through the approved line of authority.

Related standards:

OGM.03 Radiology center leaders, QPI.02 Performance measures, OGM.04 Strategic and operational plans, WFM.05 Orientation program, IMT.06 Medical record review process, QPI.01 Quality management program, OGM.09 Positive Workplace Culture, OGM.02 Qualified director.

Effective organization direction and leadership

OGM.02 The radiology center appoints a qualified director responsible to manage the center.

Effectiveness

Keywords:

Qualified director.

Intent:

Any radiology center needs a director who is responsible and accountable for implementing the approved radiology center policies. Such a position requires a qualified director guided by relevant laws and regulations. The radiology center director's responsibilities include at least the following:

- a) Performing the delegated tasks from the governing body.
- b) Providing oversight of day-to-day operations.
- c) Ensuring clear and accurate posting of the center's services and hours of operation to the community.
- d) Ensuring that policies and procedures are developed and implemented.
- e) Providing oversight of human, non-human, financial and physical resources as well as monitoring, organizing and controlling monetary resources to ensure the quality and safety of care.
- f) Ensuring appropriate response to reports from any inspecting or regulatory agencies, including accreditation.
- g) Ensuring that there is a functional, radiology center-wide program for performance improvement, patient safety, and risk management with appropriate resources.
- h) Creating a safe and just culture for reporting errors, near misses, and complaints, and using the information to improve the safety of processes and systems.
- i) Ensuring submission of regular reports to the governing body on how the legal requirements are being met on an ongoing basis. response to reports from inspecting or regulatory agencies and any other faced problems and obstacles.
- j) Developing a framework to support coordination within and/or between departments or units, as well as a clear process of coordination with relevant external services.
- k) Regular reporting to the governing body including performance improvement, risk management.

Survey process guide:

- GAHAR surveyor may interview a radiology center's director to check his awareness of the job description, role, and responsibilities.

- GAHAR surveyor may review his personnel file to check compliance with all required documents of training, job description, role, and responsibilities.

Evidence of compliance:

1. There is a qualified director managing the radiology center.
2. There is a job description for the center director covering the items mentioned in the intent from a) through k).
3. The center director is aware and knowledgeable of his responsibilities.

Related standards:

OGM.04 Strategic and operational plans, OGM.01 Governing body Structure and clear responsibilities, WFM.02 Job description, OGM.09 Positive Workplace Culture.

OGM.03 Responsibilities and accountabilities of the radiology center leaders are identified.

Effectiveness

Keywords:

Radiology center leaders.

Intent:

Usually, governing body identify a clear responsibility and accountability for their executives to see that their decisions are carried out and that the day-to-day operations of the radiology center are performed successfully. The radiology center shall establish administrative authorities and responsibilities for radiology center leaders. The radiology center leadership is responsible for:

- a) Sustaining a firm radiology center structure:
 - I. Provide an efficient and centralized process for recruiting and hiring staff members for available positions. The process shall address at least the following:
 - i. Collaboration with service/unit leaders to identify the need for a job.
 - ii. Communicating available vacancies to potential candidates.
 - iii. Announcing criteria of selection.
 - iv. Application process.
 - v. Recruitment procedures.
 - II. Collaboratively developing a plan for staffing the radiology center that identifies the numbers, types, and desired qualifications of staff.
 - III. Providing appropriate facilities and time for staff education and training should be tailored to serve both the radiology center and staff needs through an iterative process of need assessment, planning, implementation, and evaluation.
 - IV. Ensuring all required policies, procedures, and plans have been developed and implemented.

b) Running smooth directed operations:

- I. Creating a safe and just culture for reporting errors, near misses, and complaints, and using the information to improve the safety of processes and systems; a safety culture within the radiology center is essential where staff feels confident when reporting on a safety incident that they will be treated fairly, in a confidential manner, and that the information they provide will be used to improve the care process and environment.
- II. Designing and implementing processes that support continuity, coordination of care, and risk reduction.
- III. Ensuring that services are developed and delivered safely according to applicable laws and regulations and approved strategic plan with input from the users/ staff.

c) Continuous monitoring and evaluation:

- I. Ensuring that all quality control monitoring is implemented, monitored, and action is taken when necessary.
- II. Ensuring that the radiology center meets the conditions of facility inspection reports or citations.
- III. Annually assessing the operational plans of the services provided to determine the required facility and equipment needs for the next operational cycle.
- IV. Annually reporting to the radiology center governance or authority on system or process failures and near misses, and actions are taken to improve safety, both proactively and in response to actual occurrences.

d) Continuous Improvement.

Data from all over the radiology center shall be collected, reviewed, analyzed, and reported to the upper management in order to determine the opportunities for improvement through effective data-driven decision-making.

Survey process guide:

- GAHAR surveyor may interview radiology center leaders to check their awareness of their roles and responsibilities.
- GAHAR surveyor may review radiology center leaders' job descriptions.

Evidence of compliance:

1. The radiology center leaders are identified based on the service provided, and their accountabilities are described in written documents and include at least items from a) through d) in the intent.
2. The radiology center leaders are educated in the concepts of quality improvement and patient safety plans.

3. The radiology center leaders are fully aware of their written responsibilities.
4. There is evidence of leaders' participation in safety rounds to encourage reporting errors and near misses, enhancing the concept of a Just -culture.

Related standards:

WFM.02 Job description, OGM.09 Positive Workplace Culture, QPI.01 Quality management program, QPI.04 Incident reporting system, WFM.06 Continuous education and training program

OGM.04 Strategic and operational plans are developed under the oversight and guidance of the governing body.

Effectiveness

Keywords:

Strategic and operational plans.

Intent:

Strategic planning is a process of establishing a long-term plan to achieve an organization has specified vision and mission through the attainment of high-level strategic goals. A strategic plan looks out over an extended time horizon from three to five years or more. A strategic plan is developed to help the organization in achieving its long-term vision. Conversely, operational plans which involve the process of deciding what needs to be done to achieve the tactical objectives of the radiology center.

An operational plan is created to support strategic planning efforts. The strategic plan comes first, quickly followed by a robust and measurable operating plan. Operating plans help in running the day-to-day activities in the radiology center as efficiently as possible.

The radiology center shall develop a strategic plan containing defined achievable goals/ desired outcomes with predefined timelines.

Operational plans are the means through which an organization fulfills its mission. They are detailed and contain specific information regarding targets, related activities, and needed resources within a timed framework.

The operational plans shall include at least the following:

- a) Clear goals and objectives.
- b) Specific activities and tasks for implementation.
- c) Timetable for implementation.
- d) Assigned responsibilities.
- e) Sources of the required budget.
- f) Means of achievement measuring.

Leaders regularly assess the annual operational plans of the services provided to

determine the required facility and required needs for the next operational cycle. Any planning cycle ends with an analysis or an assessment phase through which planners understand what went well and what went wrong with the plan. This analysis or better-called lessons learned should feed into the new cycle of planning to improve the performance.

Survey process guide:

- GAHAR surveyor may review the strategic plan and may interview relevant staff to access the involvement and monitoring of the strategic plan.
- GAHAR surveyor may review the radiology center's operational plans.
- GAHAR surveyor may observe evidence of monitoring plan progress, identification of opportunities for improvement and actions taken to improve performance.

Evidence of compliance:

1. The radiology center has a strategic plan with goals/desired outcomes and defined achievable timelines.
2. There are progress review reports to monitor the strategic and operational plans at least annually.
3. The radiology center has approved operational plans that include items from a) through f) in the intent.
4. The operational plans are developed with the participation of staff and communicated throughout the center.

Related standards:

OGM.01 Governing body Structure and clear responsibilities, QPI.02 Performance measures, OGM.02 Qualified director, OGM.03 radiology center leaders.

Efficient supply chain management

OGM.05 The radiology center has efficient supply chain management.

Efficiency

Keywords:

Supply Chain Management.

Intent:

The supply chain generally refers to the resources needed to deliver goods or services to a consumer.

Healthcare supply chain management shall involve obtaining resources, managing supplies, and delivering goods and services to providers and patients. To complete the process, physical goods and information about medical products and services usually go through a number of independent stakeholders, including manufacturers, insurance

companies, radiology center providers, group purchasing organizations, and several regulatory agencies.

For critical supplies, i.e. vital supplies to the support of operations, the radiology center shall identify the steps in the supply chains to decide where the significant risks reside. Resources include financial, human resources, technology, and information systems. the radiology center shall develop a policy and procedures for supply chain management which describe the process of resource procurement, prioritization and selection criteria.

The radiology center shall develop and implement a policy of the supply chain management that addresses at least the following:

- a) Supplier's identification and selection process.
- b) Methods for suppliers and/or distributors' monitoring and evaluation, to ensure that the purchased supplies are provided from reliable sources that refrain from dealing with counterfeit, smuggled, or damaged supplies.
- c) Setting pre-defined acceptance criteria for suppliers that may include evaluation based on the suppliers' response upon request, quality of received supplies, lot number, and expiry date.
- d) Supplies monitoring and evaluation, to ensure that no recalled medications, samples, devices, medical supplies, or equipment are provided.
- e) Monitoring transportation of supplies, to ensure that it occurs according to applicable laws and regulations, and manufacturer's recommendations.
- f) The radiology center shall highlight in the policy the procedures for managing stock\ inventory addressing at least the following:
 - i. Compliance with the applicable laws, regulations, and organization policies.
 - ii. Compliance of the stock management with the safe storage strategies that require at least the following records for stock items: date received, lot number, expiration date, date of disposition, if not used.
 - iii. Identify and track the use of critical resources and supplies.

Survey process guide:

- GAHAR surveyor may review supply chain management policy and records.
- GAHAR surveyor may interview responsible staff to check their awareness of the policy.
- GAHAR surveyor may observe the proper implementation of the safe storage strategies.

Evidence of compliance:

1. The radiology center has an approved policy of supply chain management that addresses all elements from a) through f).

2. Supplies are monitored and evaluated to ensure matching with the pre-defined acceptance criteria that are determined in the center's policy.
3. Critical supplies are identified and clear processes are followed in case of shortage.
4. Basic information is recorded for stock items as mentioned from i) through iii) of item f) in the intent.

Related standards:

MMS.01 Medication management, OGM.02 Qualified director, OGM.07 Monitoring contracted services, EFS.05 Utilities management plan, EFS.07 Medical equipment management plan, IPC.03 Hand hygiene.

Efficient financial stewardship

OGM.06 The radiology center manages the patient's billing system.

Efficiency

Keywords:

Billing system.

Intent:

The billing process is a crucial component of radiology center management. Due to the complexity of the billing processes, billing errors may result in costly financial losses, for example, billing errors due to lack of or the inappropriate invoices of medical materials used by the missing barcode due to missing or inappropriate result reports. The billing process includes that all of the services and items provided to the patient are recorded in the patient's account, then all information and charges are processed for billing. For third-party payer systems, the process for billing is based on the requirements of insurance companies/agencies which generally have reimbursement rules. The radiology center shall develop a policy and procedures for the billing process that addresses at least the following:

- a) Availability of an approved price list for services provided to patients and their sponsors.
- b) Patients and families are informed of an initial estimated cost of required services and any potential cost pertinent to the planned care.
- c) The process to ensure that patients and families obtain an accurate invoice for services rendered.
- d) Use of accurate and approved codes for diagnoses, interventions, and diagnostics, if applicable.
- e) Payment methods. e.g. itemized bill, package deal.

Survey process guide:

- GAHAR surveyor may review the approved policy and price list (s),
- GAHAR surveyor may interview responsible staff and some patients to check compliance with the approved policy.

Evidence of compliance:

1. The radiology center has an approved policy for the patient's billing process as mentioned in the intent from a) through e).
2. In the case of a third-party payer (or health insurance), the timeliness of approval processes is monitored.
3. Responsible staff is fully aware of the various health insurance processes and different payment methods.

Related standards:

PCC.02 Patient and family rights and responsibilities, OGM.02 Qualified director, OGM.03 radiology center leaders, IMT.02 Standardized codes, symbols and Abbreviations.

Proper contract management and monitoring process

OGM.07 The radiology center has a process for selection, evaluation, and continuously monitoring of contracted services.

Effectiveness

Keywords:

Monitoring contracted services.

Intent:

Radiology center leadership defines the nature and scope of services provided by contracted services, including clinical and non-clinical services. Radiology center leaders shall describe, in writing, the contractual agreements that outline the nature and type of the services to be provided through the contract.

The radiology center leader/head of units shall participate in the selection, evaluation, and continuously monitoring of contracted services to ensure service providers comply with required environmental safety, patient safety, quality requirements, policies and procedures, and all relevant accreditation standards requirements.

The radiology center has to ensure current competency, licensure, education, and continuous improvement of competency for contracted clinical staff.

The contracted services shall be monitored through key performance indicators and evaluated at least annually to determine if a contract should be renewed or terminated.

Survey process guide:

- GAHAR surveyor may review the process for selection, evaluation, and continuously monitoring of contracted services.
- GAHAR surveyor may interview the center's leaders and responsible staff to determine contractors' monitoring, evaluation, and renewal processes.

Evidence of compliance:

1. The radiology center has a documented process that describes the nature and scope of the services provided through a contractual agreement, including all outsourced clinical and non-clinical services.
2. The radiology center has a documented process for contract monitoring and evaluation.
3. The performance measures for monitoring contracted services are integrated into the center's performance improvement and patient safety plan.
4. Significant results of contract monitoring are reported to center leaders.
5. If contracts are terminated, the radiology center has a clear process to maintain the continuity of patient care.

Related standards:

OGM.05 Supply chain management, OGM.09 Positive Workplace Culture, OGM.03 radiology center leaders

Safe, ethical, and positive organizational culture

OGM.08 The radiology center ensures ethical management.

Effectiveness

Keywords:

Ethical Management.

Intent:

Radiology center's healthcare professionals may deal with a variety of ethical problems, for example, conflict of interest and inequity of patient care and clear disclosure of information. Solved ethical issues are used for education and staff professional development these ethical issues have to be solved within a determined time frame. The policy of the ethical management addresses at least the following:

- a) Developing and implementing the code of ethics.
- b) Developing and implementing center values.
- c) Handling errors that affect the patient and medico-legal case.
- d) Developing patient confidentiality rules.
- e) Identifying conflict of interest.
- f) Gender and religion equity.

Survey process guide:

- GAHAR surveyor may review radiology center policy for ethical management.
- GAHAR surveyor may interview staff to inquire about the code of ethics, and handling of medical errors.

Evidence of compliance:

1. The radiology center has an approved policy and procedures for ethical management that addresses at least a) through f) in the intent.
2. Ethical issues are discussed and managed according to the approved code of ethics within a determined time frame.
3. The staff is aware of the center's code of ethics.
4. Solved ethical issues are used for education and staff professional development.

Related standards:

PCC.01 radiology center advertisement, PCC.02 Patient and family rights and responsibilities, OGM.07 Monitoring contracted services, APC.05 Professional standards during surveys, OGM.09 Positive Workplace Culture.

OGM.09 The radiology center ensures positive workplace culture.

Safety

Keywords:

Positive Workplace Culture.

Intent:

Studies highlighted the importance of attention to healthcare professionals' needs for a safe and comfortable work environment especially for females in the childbearing period. The radiology center has an approved policy and procedures for a positive workplace culture that addresses at least the following:

- a) Workplace cleanliness, safety, and security measures.
- b) Management of workplace violence, discrimination, and harassment.
- c) Communication channels between staff and radiology center leaders.
- d) Staff feedback measurement.
- e) Planning for staff development.
- f) Management of staff medico-legal issues.
- g) Planning to maintain a staff healthy lifestyle and well-being.

Survey process guide:

- GAHAR surveyor may review the approved policy for positive workplace culture
- GAHAR surveyor may observe workplaces and may interview staff to inquire about workplace incidents.

Evidence of compliance:

1. The radiology center has an approved policy for positive workplace culture, that addresses at least items a) through g) in the intent.
2. The workplace is clean, safe, and security measures are implemented.
3. Measures to prevent workplace violence, discrimination, and harassment are implemented.
4. Staff feedback and satisfaction are measured and periodically analyzed and acted upon.

Related standards:

OGM.01 Governing body Structure and clear responsibilities, OGM.02 Qualified director, OGM.03 radiology center leaders, OGM.07 Monitoring contracted services, OGM.08 Ethical management, WFM.01 Staffing plan, QPI.02 Performance measures.

Effective staff engagement, safety, and health

OGM.10 The radiology center has an effective staff health program in accordance with the applicable laws and regulations.

Safety

Keywords:

Staff health Program.

Intent:

The radiology center shall implement a staff health program to ensure the safety of the staff according to workplace exposures. A cornerstone of the staff occupational health program is the hazard/risk assessment, which identifies the hazards and risks related to each occupation. This is done in order to take the necessary steps to control these hazards to minimize possible harm arising and, if not possible, to lessen its negative sequel.

This is achieved through the radiology center's wide risk assessment program that identifies high risks areas and processes. The program scope covers all staff, the program addresses at least the following:

- a) Pre-employment medical evaluation of new staff.
- b) Pre-employment medical examinations and investigations of new staff are required for all employees' categories to evaluate their appropriateness for safe performance, and staff that is exposed to certain hazards, such as radiation should have periodic specific medical examinations (such as eye and skin medical assessment).
- c) Periodic medical evaluation of staff members.
- d) Screening for exposure to infectious diseases, if any.

- e) Exposure control and management to work-related hazards.
 - i. Ergonomic hazards that arise from the lifting and transfer of patients or equipment, strain, repetitive movements, and poor posture.
 - ii. Physical hazards such as lighting, noise, ventilation, electrical, and others.
 - iii. Biological hazards from blood-borne and airborne pathogens and others.
- f) Staff education on the risks within the radiology center environment as well as on their specific job-related hazards.
- g) Staff preventive immunizations. All staff members are subject to the Immunization program and to work restrictions according to evidence-based guidelines, laws, and regulations, all test results are recorded in the staff health record.
- h) Recording and management of staff incidents (e.g., injuries or illnesses, taking corrective actions, and setting measures in place to prevent recurrences).
- i) Periodic specific medical evaluation (tests and examinations) is required for staff members (as indicated) to evaluate their appropriateness for safe performance. A situational examination may be required in case of exposure to specific substances. Results of the medical evaluation are recorded in staff health records, and action is taken when there are positive results, including employee awareness of these results and provision of counseling and interventions as might be needed.
- j) Infection control staff shall be involved in the development and implementation of the staff health program as the transmission of infection is a common and serious risk for both staff and patients in healthcare facilities.
- k) All staff occupational health program-related results (medical evaluation, work injuries) shall be recorded and kept according to laws and regulations.

Survey process guide:

- GAHAR surveyor may interview staff members who are involved in developing and executing staff health program to check program structure, risks, education and orientation records.
- GAHAR surveyor may review a sample of staff health records to ensure standard compliance.

Evidence of compliance:

1. There is an approved radiology center's staff health program that covers items from a) through k) in the intent.
2. There is an occupational health risk assessment that defines occupational risks within the radiology center.
3. Staff members are educated about the risks within the radiology center environment, their specific job-related hazards, and periodic medical examination.

4. All staff members are subjected to the immunization program and to work restrictions according to the approved radiology center's staff health program.
5. All test results, immunizations, post-exposure prophylaxis, and interventions are recorded in the staff's health record.

Related standards:

MRS.06 Radiation Safety Program, EFS.04 safety and Security plan, OGM.09 Positive Workplace Culture, QPI.03 Risk management plan/program.

OGM .11 Radiology center services are planned in line with international, national, regional, or local community initiatives.

Patient-centered

Keywords:

Community Initiatives.

Intent:

A community is a group of individuals, families, groups, facilities or organizations that interact with one another cooperate in common activities, and solve mutual concerns, usually within the geographic area served by the center. The radiology center develops and implements a plan for community assessment and involvement initiatives for example; the implementation of international women's health, and the national initiatives of Universal Health Insurance, 100 Million Healthy Lives or others.

Survey process guide:

- GAHAR surveyor may review the community involvement plan to check that it is aligned with other initiatives and with laws and regulations.
- GAHAR surveyor may inquire about the community involvement plan.
- GAHAR surveyor may interview staff to check their awareness of community initiatives.

Evidence of compliance:

1. All radiology care center plans reflect alignment with international, regional, and/or national community initiatives.
2. All staff is aware of the community involvement plan and initiatives.
3. The community involvement plan is updated periodically to meet the needs of the community.

Related standards:

OGM.01 Governing body Structure and clear responsibilities, OGM.02 Qualified director, OGM.03 radiology center leaders

Work Force Management

Chapter Intent:

The health care organization needs an appropriate variety of skilled, qualified people to fulfill its mission and to meet patient needs. The organization's workforce refers to the staff within the organization. Planning the appropriate number and skill mix of the workforce is essential. Developing clear job descriptions, strong orientation and training programs help staff in delivering proper healthcare. A good organization should always have a clear structure of its medical staff, including departments, divisions, and medical committees.

This chapter defines the medical staff leaders' roles and responsibilities in credentialing, privileging, bylaws development, committees and departments' management (head), as well as performance improvement.

The medical staff includes licensed physicians and licensed dentists, it's particularly important to carefully review the credentials of all medical staff and other health care providers, The organization should provide medical staff with opportunities to learn and to advance personally and professionally.

Independent healthcare practitioners are other licensed healthcare providers as (pharmacists, nurses, nutritionists...) that are permitted by law and regulation to provide patient care services independently in the organization, those special groups of healthcare providers shall be identified by the organization and their clinical competencies shall be clarified and reviewed.

Globally, the shortage of healthcare providers is seen in multiple places in the world. In some countries, licenses are renewable which means that physicians, nurses, and other providers need to go through a renewal process periodically and prove their competence and continuous development. National bodies that govern medical and nursing education are established in different countries. National performance evaluation and ranking of healthcare providers is on the rise with many healthcare systems moving towards the pay-per-performance concept.

MOH licensing body requires specific lists of documents for almost all healthcare providers, the licensing registers including physicians, radiologists, radiology technicians, nurse supervisors, nurses, nurse technicians, Anesthesia technicians, Biostatisticians, and medical equipment technicians.

GAHAR surveyors shall review the implementation of laws and regulations, medical bylaws, nursing bylaws, Policies, procedures and plans reflecting processes of human resources department through interviews with leadership and staff and reviewing different healthcare professional's staff files.

Chapter purpose:

1. The main objective is to ensure that the radiology centers maintain an effective Workforce Management program; the chapter addresses the following objectives:
2. Effective workforce planning.
3. Effective orientation, continuous medical education, and training program.
4. An efficient mix of staff.
5. Periodic evaluation of staff performance.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes).

- 1) Egyptian code of medical ethics 238/2003.
- 2) Egyptian code of nursing ethics (Nursing Syndicate Publications).
- 3) Code of ethics and behavior for civil service staff, 2019, if applicable.
- 4) Pharmacist code of ethics.
- 5) Law 415/1954 Practicing the profession of human medicine.
- 6) Law 127/1955 on practicing the profession of pharmacy.
- 7) MOHP ministerial decree 70/1996 work of foreign experts.
- 8) MOHP ministerial decree 90/1999 for the use of foreign experts.
- 9) MOHP Ministerial decree 236/2004 on anesthesia service requirements.
- 10) MOHP Ministerial Decree 153/2004 on minimum requirements for anesthesia services.
- 11) Law 213/2017 of trade unions and protection.
- 12) MOHP Ministerial decree 25/2002 for medical responsibility and suspension of medical practice.
- 13) MOHP Ministerial decree 293/2000 on the promotion of doctors.
- 14) MOHP Ministerial decree 62/2004 on the promotion of healthcare professionals.
- 15) MOHP Ministerial decree 244/2001 on competencies of surgeons.
- 16) Law 59 /1960 – Radiation Protection against Ionizing Radiation.
- 17) Law 7 /2010 - Regulating nuclear and radiological activities.

Efficient workforce planning

WFM.01 The radiology center develops a staffing plan to ensure that provided services meet the needs of safe patient care.

Efficiency

Keywords:

Staffing plan.

Intent:

The staffing plan sets the number of staff and defines the desired skill mix, education, knowledge, and other requirements of staff members. Staff planning is the process of making sure that a radiology center has the right people to carry out the work needed for business success through matching up detailed staff data including skills, potential aspirations, and location with business plans. The shortage of competent healthcare professionals in multiple areas is an alarming sign. The radiology center shall comply with laws, regulations, and recommendations of professional practices that define desired education levels, skills, or other requirements of individual staff members or that define staffing numbers or a mix of staff for the radiology center. The plan is reviewed on a regular basis and updated as necessary. The leaders of each clinical or managerial area define the individual requirements of each staff position. The radiology center should maintain a safe level of staff members' numbers and skill levels. Leaders consider the following factors to project staffing needs:

- a) The radiology center's mission, strategic and operational plans.
- b) Complexity and severity mix of patients served by the radiology center.
- c) Scope of services provided by the radiology center.
- d) Technology and equipment used in patient care.

Survey process guide:

- The GAHAR surveyor may review the staff documents,
- The GAHAR surveyor may observe workforce allocation and skills.
- The GAHAR surveyor may review staff files to check compliance of the staffing plan with laws, regulations, and professional practices recommendations.

Evidence of compliance:

1. The staffing plan matches the radiology center's mission, strategic, and operational plans.
2. The staffing plan complies with laws, regulations, and recommendations of professional practices.
3. The staffing plan identifies the estimated needed staff numbers and skills with staff assignments to meet the radiology center's needs.

4. The staffing plan is reviewed and updated at least annually.

Related standards:

OGM.01 Governing body Structure and clear responsibilities, OGM.02 Qualified director

WFM.02 The Radiology center develops job descriptions that address each position requirements and responsibilities.

Effectiveness

Keywords:

Job description.

Intent:

The job description is a general written statement of a specific job, based on the findings of a job analysis. It generally includes duties, purpose, responsibilities, scope, and working conditions a job.

In the radiology center, a job description is required to make sure that staff responsibilities are current and aligned with the radiology center policy.

The radiology center shall ensure that the job description is based on the education, training, and experience level of each staff. The job description is a process to identify and authorize the individual to practice independently in the radiology center. In addition, the job description is a process to evaluate the extent to which the staff fulfills their job responsibilities.

Job descriptions are required for all types of staff, clinical, non-clinical, full-time, and part-time, temporary staff, and those who are under training or supervision.

Each radiology center leader or head of a department is responsible to develop a staff job description that fulfills all the necessary requirements approved by the radiology center. It includes at least; the job title, main duties and responsibilities, reporting relationships, qualifications, education, experience, training, and technical skills necessary for entry into this job, and special demands that may be needed.

Survey process guide:

- GAHAR surveyor may review a sample of staff files to check staff job description availability.
- GAHAR surveyor may interview staff to check their awareness of their job description and compliance with its items.

Evidence of compliance:

1. There is a current job description for every position and recorded in the staff's file.
2. Job descriptions include all-necessary requirements as described in the intent.
3. All staff is aware of their job description specifications and requirements.

Related standards:

WFM.03 Staff files, WFM.06 Continuous education, and training program, IMT.03 Confidentiality, security and integrity of data and information, WFM.07 Staff performance and competency, WFM.08 Clinical Privileges.

WFM.03 The radiology center has a staff file for each workforce member.

Effectiveness

Keywords:

Staff files.

Intent:

It is important for the radiology center to maintain a staff file for each staff member. An accurate staff file provides a recording of staff knowledge, skill, competency, and training required for carrying out job responsibilities. In addition, the record shows evidence of staff performance and whether they are meeting job expectations.

Each staff member in the radiology center, including those who are permitted by law and the radiology center to work independently, also shall have a record(s) with information about his/ her qualifications; required health information such as evidence of immunizations, evidence of participation in orientation as well as on-going in-service and continuing education, results of evaluations, including staff member performance of job responsibilities and competencies, and work history. The records shall be standardized and kept current according to the center policy. Staff files may contain sensitive information and thus should be kept confidential.

The radiology center should develop and implement a policy and procedures that guide the management of staff files. The policy shall address at least the following:

- a) Staff file initiation.
- b) Standardized contents such as;
 - i. Verified certification, license, education, training, and work history,
 - ii. Current job description,
 - iii. Recorded general orientation to the radiology center, the assigned department, and the specific job orientation,
 - iv. Evidence of initial (pre-employment) evaluation, to ensure that the staff member able to perform the assigned job,
 - v. Ongoing In-service education received,
 - vi. Copies of the first three months' evaluations and copies of annual evaluations
 - vii. Any required health information.
- c) Update of file contents.
- d) Storage.
- e) Retention time.
- f) Disposal.

Survey process guide:

- GAHAR surveyor may review a sample of staff files to assess compliance to standard requirements.
- GAHAR surveyor may observe the area where staff files are kept to assess storage conditions, retention, confidentiality and disposal mechanism.
- GAHAR surveyor may interview staff involved in the initiation, use and storage of staff files to assess the process.

Evidence of compliance:

1. The radiology center has an approved policy that addresses at least elements from a) through f) in the intent.
2. Staff members who are involved in the initiation, storage and use of staff files, are aware of the management of staff files policy.
3. Staff files include all the required records as described in item b) from the intent and according to the center's policy.
4. Staff files are stored, maintained and disposed of as per the management of staff files policy.

Related standards:

WFM.08 Clinical Privileges, WFM.06 Continuous education and training program, WFM.02 Job description, WFM.07 Staff performance and competency, OGM.10 Staff health program, IMT.01 Documentation management system.

Effective orientation, training and education programs

WFM.04 The radiology center implements an effective process to verify the credentials of all staff members.

Effectiveness

Keywords:

Verifying credentials.

Intent:

Credentials are documents that are issued by a recognized entity to indicate completion of requirements or the meeting of eligibility requirements, such as a diploma from a medical school, specialty training (residency) completion letter or certificate, completion of the requirements of the related syndicates, authorities and/or others, a license to practice.

These documents, some of which are required by law and regulation, and need to be verified from the original source that issued the document. The radiology center shall develop a process of verifying credentials for all staff members (including independent

practitioners) and match the requirements of the position with the qualifications of the prospective staff member must be done.

Survey process guide:

- GAHAR surveyor may review the documents of the credential verification process.
- GAHAR surveyor may review a sample of staff member (including independent practitioners) files to check the availability of required credentials for each position.
- GAHAR surveyor may interview staff members who are involved in the credentialing process to check their awareness of the process.

Evidence of compliance:

1. There is a process for verifying the credentials of all staff in the radiology center.
2. Required credentials for each position are identified and available in each staff file (including independent practitioners' files).
3. Actions are taken and documented when credentials cannot be verified.

Related standards:

WFM.02 Job description, WFM.03 Staff files.

WFM.05 Appointed, contracted, and outsourced staff undergoes a formal orientation program.

Effectiveness

Keywords:

Orientation program.

Intent:

The decision to appoint an individual to a radiology center sets several processes in motion. To perform well, a new staff member, no matter what his or her employment experience, needs to understand the entire radiology center structure and how his/her specific clinical or nonclinical responsibilities contribute to the radiology center's mission.

This is accomplished through a general orientation about the radiology center and its role and a specific orientation on the job responsibilities of their position.

Staff orientation, especially when first employed, on the radiology center policies, shall ensure alignment between the radiology center mission and staff activities. It also helps to create a healthy radiology center culture where all staff works with a shared mental model and towards agreed-upon objectives.

Staff orientation also facilitates the integration of new staff with the existing staff to rapidly form effective teams that offer safe and quality care. The radiology center shall build a comprehensive orientation program that is provided to all staff members

regardless of their terms of employment. Staff orientation shall occur on three levels: General orientation, service/unit orientation, and job-specific orientation.

The general orientation program shall address at least:

- a) Review of the radiology center's mission, vision, and values.
- b) Radiology center's structure.
- c) Radiology center's policies for the environment of care, infection control, performance improvement, patient safety, and risk management.

Service/Unit orientation program shall address at least:

- d) Review of relevant policies and procedures.
- e) Operational processes.
- f) Work relations.

Job Specific orientation:

- g) High-risk processes.
- h) Technology and equipment use.
- i) Staff safety and health.

The radiology center shall develop a staff manual that describes the processes of staff appointment and reappointment, staff appraisal, staff complaints management, staff satisfaction measurement, code of ethics, disciplinary actions, and termination.

Survey process guide:

- GAHAR surveyor may interview some staff members and inquire about the process of orientation.
- GAHAR surveyor may review a sample of staff files to check evidence of attendance of general, service/unit, and job-specific orientation.

Evidence of compliance:

1. The general orientation program is performed and it includes at least the elements from a) through c) in the intent.
2. A service/unit orientation program is performed and it includes at least the elements from d) through f) in the intent.
3. The job-specific orientation program is performed and it includes at least the elements from g) through i) in the intent.
4. Any staff member attends the orientation program regardless of the employment terms.
5. There is an evidence that each staff member has completed the Orientation program and is recorded in his file.

Related standards:

WFM.03 Staff files, WFM.06 Continuous education, and training program, OGM.01 Governing body Structure and clear responsibilities.

WFM.06 The radiology center has a continuous education and training program.

Effectiveness

Keywords:

Continuous education and training program.

Intent:

For any radiology center to fulfill its mission, it has to ensure that its human resources have the capacity to deliver its services over time. Continuous education and training programs help guarantee that, especially if designed to satisfy staff needs necessary to deliver the radiology center's mission. The program should be designed in a flexible manner that satisfies all staff categories based on a process of need assessment, tailored training plan, delivery, and reflection. The program is designed based on services provided, new information, and evaluation of the staff needs. Evidence-based medical and nursing practices and guidelines and other resources are accessible to all staff. The radiology center ensures that education and training are provided and recorded according to the staff member's relevant job responsibilities needs which may include the following:

- a) Patient assessment.
- b) The infection control program, and main activities such as needle stick injuries, and exposures.
- c) Environment safety plans.
- d) Occupational health hazards and safety procedures, including the use of personal protective equipment.
- e) Information management, including patient's medical record requirements as appropriate to responsibilities or job description.
- f) Clinical guidelines used in the radiology center.
- g) Basic cardiopulmonary resuscitation training for all staff that provides direct patient care in every shift and is updated at least every two years.
- h) Quality concept, performance improvement, patient safety, and risk management.
- i) Patient rights, patient satisfaction, and the complaint/ suggestion process.
- j) Provision of integrated care, shared decision making, informed consent, interpersonal communication between patients and other staff cultural beliefs, needs and activities of different groups served.
- k) Medical equipment and utility systems operations and maintenance.

Survey process guide:

- GAHAR surveyor may interview some staff members and inquire about the process of continuous education and training.
- GAHAR surveyor may check a sample of staff files to check evidence of attendance of education and training program.

Evidence of compliance:

1. There is a documented program of continuing education and training that includes all staff categories.
2. Resources needed to deliver the program are identified in the education and training program.
3. The program is based on the needs assessment of all staff.
4. Results of a performance review are integrated into the program design.

Related standards:

PCC.04 informed consent, PCC.02 Patient and family rights and responsibilities, ICD.01 screening and assessment, ICD.05 High-risk patients and procedures/ services, MRS.02 Technical medical imaging procedures, MRS.08 Personal protective equipment, EFS.03 Hazardous materials and waste disposal, EFS.05 Utilities management plan, EFS.06 Emergency preparedness plan, IPC.02 infection prevention and control program.

Equitable staff performance evaluation

WFM.07 Staff performance and competency are regularly evaluated.

Equity

Keywords:

Staff performance and competency.

Intent:

Staff performance evaluation is an ongoing process that is also called performance appraisal or performance review, which is a formal assessment for managers to evaluate an employee's work performance, identify strengths and weaknesses, offer feedback and set goals for future performance. Performance evaluation effectively contributes to individual, team and radiology center improvement when based on a defined and transparent process with clearly declared criteria relevant to the job functions.

Performance evaluation also promotes communication between employees and leaders, enabling them to make informed decisions about staff planning, selection, incentives, training and education, and career planning. Performance appraisal offers the chance to give feedback to staff about what they do well or poorly in a confidential respectful manner, thus promoting a learning culture within the radiology center.

The radiology center shall use a performance evaluation tool to ensure staff has the required criteria for doing jobs and achieving objectives. Recorded process of employees' performance evaluation including performance review methods, tools, evaluation dimensions, criteria, time interval, appeal process, and responsible person for each staff category. Performance evaluation of medical staff members addresses certain

criteria that include those related to patient's medical record recording and medication use such as:

- a) Patient's medical record review for completeness and timeliness.
- b) Utilization practice and medication use.
- c) Compliance with an approved clinical guideline.
- d) Complications, outcomes of care, mortality, and morbidity.
- e) Professional development.

Competency is the process to determine the ability of staff to fulfill the primary responsibilities of the position for which a person was hired. Observing and measuring competency for every position in the center is one of the most important duties of the department leaders and to ensure that each staff member shall understand the expectations, responsibilities, activities, and competencies required for his or her position.

Competency shall be done after the probationary period (initial competency assessment), then on an ongoing basis at least annually for at least the following (the nursing staff, staff who provide medical imaging services, procedural sedation services, and staff who are handling critical medical equipment).

Survey process guide:

- GAHAR surveyor may interview service/unit or radiology center leaders and inquire about used tools for staff performance and competency evaluation.
- GAHAR surveyor may review a sample of staff files to assess the completion of performance and competency evaluations.

Evidence of compliance:

1. Performance evaluation is performed at least annually for each staff member and linked to the education and training provided.
2. Performance evaluation criteria for medical staff members include at least all elements from a) through e) in the intent.
3. Performance and competency evaluation is performed based on the current job description.
4. There is evidence of employee feedback on performance and competency evaluation.
5. Clear procedures for the effective management of underperformance are implemented.
6. Performance evaluation is recorded in staff files.

Related standards:

WFM.01 Staffing plan, WFM.02 Job description, ICD.03 Clinical practice guidelines, WFM.08 Clinical Privileges, WFM.03 Staff files.

WFM.08 Medical staff members have current and specific delineated clinical privileges.

Safety

Keywords:

Clinical Privileges.

Intent:

The radiology centers shall define and require clinical privileges to apply for all medical staff members based on the evaluation of the individual's credentials and performance. The determination of a medical staff member's current clinical competence and making a decision about what clinical services the medical staff member will be permitted to perform often called privileging is the most critical determination that the radiology center will make to protect the safety of patients and to advance the quality of its clinical services.

Decisions regarding a practitioner's clinical competence, and thus what clinical privileges he/she is to be granted, are based primarily on information and documentation received from outside the radiology center. Independent practitioners who provide patient care services on the premises of the radiology center but are not employees or permanent staff are privileged and evaluated.

Specialty training programs may identify and list the general competencies of that specialty in areas of diagnosis and treatment with the radiology center assigning privileges to diagnose and treat patients in those specialty competency areas.

The radiology center shall develop a policy of clinical privileges delineation. The policy shall focus and highlight at least the following points:

- a) Medical staff members and independent practitioners with clinical privileges are subject to bylaws.
- b) Privileges indicate if the medical staff can examine, consult, and treat patients.
- c) Privileges define the scope of patient care services and the types of procedures they may provide in the radiology center.
- d) Privileges are determined based on documented evidence of competency (experience- qualifications – certifications-skills) that are reviewed and renewed at least every three years.
- e) Privileges are available in areas where medical staff provides services pertinent to granted privileges.
- f) Medical staff members with privileges do not practice outside the scope of their privileges.
- g) Situations when the physicians need to work outside their approved clinical privileges.

Survey process guide:

- GAHAR surveyor may review the policy of clinical privileges delineation.
- GAHAR surveyor may interview medical staff members and inquire about delineated privileges.
- GAHAR surveyor may review a sample of staff files to assess compliance with standard requirements.

Evidence of compliance:

1. The radiology center has an approved policy that addresses at least all elements from a) through g) in the intent.
2. Medical staff members are aware of the process of clinical privileges delineation and when they need to work outside their approved clinical privileges.
3. Clinical privileges are delineated to medical staff members based on defined criteria.
4. Physicians' files contain personalized recorded clinical privileges, including renewal when applicable.
5. Physicians comply with their clinical privileges.

Related standards:

WFM.03 Staff files, WFM.07 Staff performance and competency, WFM.03 Job description

Information Management and Technology

Chapter intent:

Information management is the process by which relevant information is provided to decision-makers in a timely manner. Effective information management system is a vital component of the healthcare service. Information management and technology in healthcare organizations includes clinical, managerial information, and information required by external authorities and agencies. There are major risks associated with information management and technology in healthcare. One of these risks is the potential breach of patient confidentiality.

Patient confidentiality means that personal and medical information given to a health care provider shall not be disclosed to others unless the patient has given specific permission for such release. Maintaining patient confidentiality is an ethical and legal concern especially with emerging technology of implementation of electronic information systems.

Artificial intelligence is on the surge where symptom checkers and clinical decision support systems are becoming widely used. More medical facilities are moving to be paperless and special certifications are dedicated to encourage that movement.

Practically, Healthcare organizations need to provide resources for implementation of information management system that ensures patient safety, continuity of care, security and confidentiality of information.

Radiology service is one of the medical services that started to use information systems many years ago and now the information systems became an essential part of the radiology services. Information technology in radiology services include:

- a. Radiology Information System (RIS).
- b. Picture Archiving and Communication System (PACS).

The use of these systems in radiology service allows easy and fast transmission of radiology images and reports which enabled the use of Tele-Radiology technology. Egypt has adopted a national project for automation of radiology services in MOHP hospitals since 2010, through which many hospitals are now using RIS and PACS systems in radiology departments.

During GAHAR Survey, surveyors shall be able to measure how organizations implement information management systems and technologies through reviewing documents pertinent to this chapter and doing patient tracers and interviews with staff. The leadership interview session may touch on this topic as well.

Chapter purpose:

1. To address Effective Information Management Processes.
2. To maintain Information Confidentiality and Security.
3. To ensure the availability of patient's medical record.
4. To describe effective information Technology in Healthcare.

Standards included in this chapter applies to paper and electronic data and information.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes).

- 1) Egyptian code of medical ethics 238/2003.
- 2) Egyptian code of nursing ethics (Nursing Syndicate Publications).
- 3) MOHP - General Directorate of Technical Inspection. The administrative tool.
- 4) Ministry of finance decree 270/2009: Governmental Archives list.
- 5) Ministry of finance decree 18/2019: Non-Monetary Payment.
- 6) MOHP Ministerial decree 254/2001 Discharge summary requirements.
- 7) Ministry of communication and information technology decree 109/2005: Electronic signature.
- 8) Law 35/1960 National census and statistics.
- 9) Law 2915/1964 Establishment of CAPMAS.
- 10) Jeddah Declaration on Patient Safety 2019.
- 11) Health Insurance Portability and Accountability Act HIPAA Regulations 1996.
- 12) The Institute for Safe Medication Practices (ISMP): List of Error-Prone Abbreviations, Symbols, and Dose Designations.
- 13) Egyptian consent laws .
- 14) Law 59 /1960 – Radiation Protection against Ionizing Radiation.
- 15) Law 7 /2010 - Regulating nuclear and radiological activities.

Effective document management and recording

IMT.01 Documentation management system is developed for all the radiology center documents.

Effectiveness

Keywords:

Documentation management system.

Intent:

Documentation management system is important for the standardization of the document formatting as well as developing a controlled process for the creation, distribution, amendment and disposal of documents. Documents may be of internal origin as policies, instructions for use, flowcharts, procedures, specifications, forms, and documents of external origin such as regulations, standards and textbooks from which the interventional procedures are taken. Unified document formatting will allow easier tracking and searching for any information. Periodic review of all documents ensures that obsolete document is not used. The radiology center shall develop an approved process of the documentation management system to cover the main organizational key functions such as emergency service, assessment, referral, discharge, procurement and other operational and clinical key functions.

The radiology center shall develop and implement a policy and procedures for documentation management system that addresses at least the following:

- a) Standardized formatting.
- b) Tracking system for tracking any changes.
- c) The document control system (document to be identified by title, issue date, edition and/or current revision date, the number of pages, who is authorized to issue and/or review the document and identification of changes of version).
- d) Controlling of the obsolete documents (it shall be dated and marked as obsolete).
- e) Distribution of policies to the relevant staff.
- f) Policies' time period revisions and updates.

Survey process guide:

- GAHAR surveyor may review policy of documentation management system followed by check for the standardized format, tracking system, identified approver, issuing and revision date for all policies of the radiology center.
- GAHAR surveyor may interview staff to check their awareness of the process of developing, approving, tracking, and revising of policies.
- GAHAR surveyor may interview staff to check their awareness of the proper access to relevant policies, tracking changes in the policies and process for management of retirement of documents.

Evidence of compliance:

1. The radiology center has an approved policy that clearly describes the process of the documentation management including elements in the intent from a) through f).
2. Relevant staff is fully aware and trained on the documentation management system.
3. There are standardized formats for all similar documents throughout the radiology healthcare center.
4. The obsolete documents are dated and marked as obsolete.
5. Required policies and documents are distributed to the relevant staff.

Related standards:

EFS.02 Fire and smoke safety plan, IMT.02 Standardized codes, symbols and Abbreviations, WFM.03 Staff files, ICD.05 High-risk patients and procedures/ services, IMT.03 Confidentiality, security and integrity of data and information, , IMT.05 Medical record management.

IMT.02 The radiology center defines standardized diagnosis codes, procedure codes, definitions, symbols, and abbreviations.

Safety

Keywords:

Standardized codes, symbols, and Abbreviations.

Intent:

The main goal of using codes, symbols, and abbreviations is downsizing the writing. Uniform and consistent use of approved symbols and abbreviations across the radiology center shall be ensured by using a standardized diagnosis and abbreviation list. International classification of the disease (ICD) intends to define the diseases, disorders, injuries, and other related health conditions, listed in a comprehensive, hierarchical fashion that allows for sharing and comparing health information between different healthcare providing settings. The radiology center shall adopt well-recognized, evidence-based diagnoses, investigations, and procedures codes to ensure that codes are matched to those provided by national health authorities and/or 3rd party payers. Patients and families may not be familiar with or understand the abbreviations and may not be comfortable asking for clarification. In addition, if a summary of the patient's care and treatment contains abbreviations and is sent with a patient being transferred to another health care organization, there is a risk to patient safety if the receiving organization uses some of the same abbreviations but with different meanings, or simply does not know the meanings of the abbreviations in the summary.

The radiology center shall develop and implement a policy that defines the processes implemented to prevent and reduce the adverse effect of using unstandardized abbreviations, symbols and codes. The policy shall address at least the following:

- a) Not-to- use symbols/abbreviations list. For example; adopt a “do-not-use abbreviation list” for medication from reliable references, e.g., The Institute for Safe Medication Practices (ISMP) list and includes at least the following:
 - U/IU
 - Q.D.,
 - QD,
 - q. o. d
 - q o d
 - MS
 - MSO4
 - MgSO4
 - Trailing Zero
 - No leading Zero
- b) Situations where Symbols and abbreviations (even the approved list) are not allowed; such as informed consent and patient rights documents, discharge/home instructions, and discharge summaries and any record that patients and families receive from the radiology center about the patient’s care.
- c) Standardized approved diagnosis, investigation and procedure codes.

Survey process guide:

- GAHAR surveyor may review radiology center policy for abbreviations symbols and codes.
- GAHAR surveyor may review a sample of medical records (to check for the used abbreviations).
- GAHAR surveyor may interview medical staff for awareness of the prohibited abbreviation.

Evidence of compliance:

1. The radiology center has an approved policy for abbreviations symbols and codes that includes all the elements in the intent from a) through c).
2. Staff who record in the patient’s medical record are educated and trained on the process of the standardization and uniform use of the center’s codes, symbols, and abbreviations.
3. There is a uniform use of standardized diagnosis and procedure codes,symbols, and abbreviations across the center.

4. Approved codes are matched to those provided by health authorities and/or 3rd party payers.
5. The prohibited abbreviations are not used in patients' medical records.
6. Symbols and abbreviations (even the approved list) are not used in informed consent and any record that patients and families receive from the radiology center about the patient's care.

Related standards:

MMS.04 Medication ordering_ preparation, and administration, IMT.01 Documentation management system, IMT.05 Medical record management.

Ensuring confidentiality, integrity, and security of information

IMT.03 The radiology center ensures data and information confidentiality, security, and integrity.

Patient-centeredness

Keywords:

Confidentiality, security, and integrity of data and information.

Intent:

Patient confidentiality means that personal and medical information given to a health care provider shall not be disclosed to others unless the patient has given specific permission for such release. Information shall be protected from being accessed by unauthorized individuals. The job description is the base when the radiology center defines who may have access to medical records and information. All staff should commit to information confidentiality and security; by signing an agreement that they understand the details of the confidentiality policy and procedures and know their roles well.

Maintaining data integrity is an important aspect of information management. The information contained in a database must be accurate in order to ensure that the interpretation of results from data analysis is meaningful. In addition, data integrity is maintained during planned and unplanned downtime of data systems. This is accomplished through the implementation of downtime recovery tactics and ongoing data backup processes.

The information confidentiality, security and integrity policy address at least the following:

- a) Determination of who can access what type of data and information list of authorized individuals.
- b) The circumstances under which access is granted.
- c) Confidentiality agreements with all those who have access to patient data.

- d) Procedures to follow if confidentiality or security of information has been breached.
- e) Reporting process to the inspecting and regulatory agencies of any required confidential specific information according to the national laws and regulations.

Medical records and information must be secured and protected at all times and in all places. Including protecting it from water, fire, or other damage, loss, destruction, tampering, and unauthorized access, protection measures include the suitable type of fire extinguishers in archiving, storage areas, and computer areas.

When there is electronic communication, such as e-mail, or any software application, used for maintaining patient information, the radiology center shall adopt guidelines to ensure the quality of patient care and to ensure that the security and confidentiality of information are maintained.

Survey process guide:

- GAHAR surveyor may review the policy, followed by checking the implementation through reviewing related documents such as the signed confidentiality agreement in each responsible staff member's personal file.
- GAHAR surveyor may observe the implementation of confidentiality measures including storage of patient's medical records in limited access places and staff has no access to the information not related to their job.
- GAHAR surveyor may interview staff to assess the process of information protection from loss, destruction, tampering, and unauthorized access or use,
- GAHAR surveyor may observe medical record protection measures that include the suitable type of fire extinguishers in archiving, storage areas, and computer areas.
- GAHAR surveyor may interview staff to assess their awareness of the information confidentiality, security, and integrity policy.

Evidence of compliance:

1. The radiology center has an approved policy that guides the confidentiality and security of medical records and information, that addresses at least items a) through e) in the intent.
2. Staff is aware of the confidentiality, security, and integrity of information policy.
3. Only authorized individuals have access to patient medical records.
4. Medical records and information are protected from loss, destruction, tampering, and unauthorized access or use.
5. Procedures are followed if confidentiality or security of information has been violated.
6. A signed confidentiality agreement is documented in each responsible staff member's personal file.

Related standards:

PCC.02 Patient and family rights and responsibilities, WFM.02 Job description, IMT.05 Medical record management, IMT.06 Medical record review process.

Effective, safe documents retention process

IMT.04 The radiology center has an effective process of managing the retention of records, data, and information according to applicable laws and regulations.

Effectiveness

Keywords:

Retention of records, data and information.

Intent:

While the medical records, data, and information have an important role in patient care, legal documentation, and continuity of care, the radiology center has to retain them for a sufficient period of time. The retention time is a requirement of law and regulation. The radiology center shall identify retention time for each type of document. Information confidentiality shall be maintained during the retention time.

The radiology center shall develop and implement a retention policy that addresses at least the following:

- a) The retention time for each type of document.
- b) Measures to maintain information confidentiality during the retention time.
- c) Retention conditions, archival rules, and permissible means of storage, access, and encryption.
- d) Data destruction methods that respect the security and confidentiality measures.

Survey process guide:

- GAHAR surveyor may review the retention policy.
- GAHAR surveyor may interview staff asking to demonstrate the process of records retention and destruction and/or removal of records, data, and information.
- GAHAR surveyor may observe record/logbook of documents destruction and/or removal.

Evidence of compliance:

1. The radiology center has an approved policy that includes all the items in the intent from a) through d).
2. Responsible staff is aware of the policy requirements.
3. The information confidentiality is maintained during the retention time in accordance with the center's policy.
4. Destruction and/ or removal of records, data, and information are done as per policy.

Related standards:

IMT.01 Documentation management system, IMT.03 Confidentiality, security and integrity of data and information, IMT.07 Health information technology, IMT.05 Medical record management.

Effective patient medical record management

IMT.05 Patient's medical record is managed effectively.

Effectiveness

Keywords:

Medical record management.

Intent:

The radiology center has a standardized process for proper medical record flow management that includes; Initiation of a patient's medical record, assigning the unique identifiers, tracking medical records movement and storing requirements.

The main goal of developing a uniform structure of the patient's medical record is to facilitate the accessibility of data and information to provide more effective and efficient patient care.

The radiology center shall assign a medical record's unique number to locate, retrieve a patient's medical record easily and document the care of the patient over time, and track medical records' movement and circulation through the center.

Patients' medical records are available to assist the healthcare professionals in having quick access to patients' information and to promote continuity of care and overall patient satisfaction.

The radiology center shall develop a policy for medical record management that addresses at least the following:

- a) Availability of medical records within a pre-determined timeframe.
- b) Medical record contents and order uniformity.
- c) Medical record appropriate use and storage methods.
- d) Patient's medical record release.
- e) Management of voluminous patient's medical record.

Survey process guide:

- GAHAR surveyor may review the medical record management policy followed by checking the implementation of the process.
- GAHAR surveyor may review some patient medical records to check that each patient's medical record has a unique identifier.
- GAHAR surveyor may observe patient's medical record availability when needed by healthcare professionals and contain up to dated information within an appropriate timeframe.

- GAHAR surveyor may interview staff to check their awareness of managing patient's medical record.

Evidence of compliance:

1. The radiology center has an approved policy that includes all the items in the intent from a) through e).
2. Responsible staff is aware of the policy requirements.
3. The patient's medical record contents, format, and location of entries are standardized.
4. The patient's medical record is available when needed by a healthcare professional within a timeframe matched to the centers' policy.
5. A patient medical record is initiated for every patient receiving care.

Related standards:

IMT.01 Documentation management system, IMT.02 Standardized codes, symbols, and Abbreviations, IMT.04 Retention of records, data, and information, QPI.02 Performance measures, IMT.03 Confidentiality, security, and integrity of data and information, IMT.05 Medical record management.

The effective medical record review process

IMT.06 Patient's medical record is reviewed effectively.

Effectiveness

Keywords:

Medical record review process.

Intent:

Each radiology center shall determine the content and format of the patient medical record and has a process to assess medical record content and the completeness of records. That process is a part of the center performance improvement activities and is carried out regularly. Patient medical record review is based on a sample review methodology. The review process is conducted by responsible staff who are authorized to make entries in the patient medical record. The review focuses on the timeliness, completeness, and legibility of the medical record.

Survey process guide:

- GAHAR surveyor may review a sample of patient medical records to ensure proper implementation of the medical record review process. The review focuses on the timeliness, completeness, and legibility of the medical record.
- GAHAR surveyor Interview staff to check awareness about the medical records review process.

Evidence of compliance:

1. The radiology center has a process of tracking and monitoring data collected and analyzed from the medical record review process.
2. An authorized responsible staff performs the medical record review focusing on timeliness, accuracy, completeness, and legibility of the medical record.
3. Significant medical review results are reported to the radiology center leader(s).
4. Corrective interventions are taken by the radiology center leader(s) when needed.

Related standards:

OGM.01 Governing body Structure and clear responsibilities, IMT.01 Documentation management system, IMT.05 Medical record management, QPI.06 Performance improvement plan, QPI.02 performance measures.

Effective information technology in healthcare

IMT.07 The use of Health information technology systems is safe and efficient.

Efficiency

Keywords:

Health information technology.

Intent:

Implementation of health information technology systems can facilitate workflow, and improve the quality of patient care, and patient safety.

Radiology service is one of the medical services that started to use information systems many years ago and now the information systems became an essential part of the radiology services. Information technology in radiology services includes:

- a) Radiology Information System (RIS).
- b) Picture Archiving and Communication System (PACS).

The use of these systems in radiology service allows easy and fast transmission of radiology images and reports which enabled the use of Tele-Radiology technology. The selection and implementation of health information technology systems require coordination between all involved stockholders to ensure proper integration with all interacting processes. Following implementation, evaluation of the usability and effectiveness of the system shall be done.

A downtime event is any event where a Health information technology system (computer system) is unavailable or fails to perform as designed. The downtime may be scheduled (planned) for purposes of maintenance or upgrading the system or unplanned due to unexpected failure. These events may significantly threaten the safety of the care delivery and interrupt of the operations in addition to the risk of data loss.

The radiology center shall develop and implement a policy to ensure continuity of

safe patient care processes during planned and unplanned downtime including the alternative paper forms and other resources required. The policy shall include the downtime recovery process to ensure data integrity. All staff shall receive training about the transition into a downtime environment in order to respond to immediate patient care needs.

Data backup is a copy of data that is stored in a separate location from the original, which may be used to restore the original after a data loss event. Having a backup is essential for data protection. Backups shall occur regularly in order to prevent data loss. The backup data may be inside or outside the radiology center. In both cases, the radiology center shall ensure the backup information is secure and accessible only by those authorized to use it to restore lost data.

Survey process guide:

- GAHAR surveyor may review the document of the program including the process of selection, implementation, evaluation of information technology and the planned and unplanned downtime response.
- GAHAR surveyor may review the policy for downtime including the recovery process.
- GAHAR surveyor may interview staff to assess awareness about the process of selection, implementation, and evaluation of information technology and also the response to planned and unplanned downtime.
- GAHAR surveyor may observe the implementation of the data backup program.

Evidence of compliance:

1. The radiology center health information technology systems are selected, and implemented in collaboration to the center's leaders and stakeholders.
2. The radiology center has an approved policy for downtime including the recovery process.
3. The staff is aware of the health information technology system.
4. Data backup process and frequency of backup are identified according to center policy.

Related standards

IMT.01 Documentation management system, IMT.03 Confidentiality, security and integrity of data and information.

Quality And Performance Improvement

Chapter Intent:

It is essential for radiology centers to have a framework to support continuous improvement and risk management activities. Performance improvement and risk management are parts of both the strategic and operational plans.

GAHAR standards don't mandate a specific improvement tool nor specific monitoring performance measures, yet, a minimum number of monitoring indicators are required. Among many improvement opportunities, GAHAR standards highlighted the importance of improving patient journey and supply chain. Implementation of the standards should be in accordance with applicable Egyptian laws and regulations.

During the GAHAR survey, surveyors are going to meet leadership and staff to discuss the QPI aspects, initiatives, and projects. Surveyors may perform tracers to check data selection, collection, analysis of data, and methods that are used to follow the improvement projects and the impact of projects on improving the quality dimensions.

Chapter purpose:

The main objective is to ensure the following:

1. Effective performance improvement program.
2. Effective performance measurement and data management.
3. Effective improvement of sustainability.

Implementation guiding documents:

(Any of the following mentioned references needs to be read in the context of its terms, conditions, substitutes, amendments, updates, and annexes)

- 1) MOH Quality and Safety Guide, 2019.
- 2) Performance Indicators Guide by HIO, 2013.
- 3) National EFQM based excellence award.
- 4) Law 35/1960 National census and statistics.
- 5) Law 2915/1964 Establishment of CAPMAS.

Availability of appropriate, effective quality management program

QPI.01 The radiology center has an organizational-wide quality management program.

Effectiveness

Keywords:

Quality management program.

Intent:

It is essential for organizations to have a framework for their quality management system to support continuous improvement. The quality management program shall be aligned with both strategic and departmental operational plans. To initiate and maintain effective quality management program leadership planning and commitment are essential. The center director with assigned personnel are included in the planning process whenever possible.

The radiology center's program for quality management shall be integrated, comprehensive and adequate to the size, complexity and the scope of services and addresses at least the following:

- a) The commitment to regulatory requirements and accreditation standards.
- b) The goals of the quality management program.
- c) The quality measures (technical and managerial).
- d) The quality management activities.
- e) The quality tools.
- f) Periodic review and update (at least annually).

Survey process guide:

- GAHAR surveyor may interview radiology center's director to identify leadership's approach for developing quality management program.
- GAHAR surveyor may review the quality management program, related documents, and tools.
- GAHAR surveyor may interview staff to check their awareness of the program.

Evidence of compliance:

1. The radiology center has a documented, updated and approved quality management program containing the items in intent from a) through f).
2. An individual with knowledge, skills and experience in quality management, related tools and activities is assigned to oversight the quality management program.
3. All staff are aware of the quality management program.

Related standards:

OGM.01 Governing body Structure and clear responsibilities, QPI.06 Performance improvement plan, QPI.02 Performance measures, OGM.02 Qualified director, QPI.04 incident reporting system, QPI.03 risk management plan/program.

QPI.02 Performance measures are identified, defined, and monitored for all significant processes.

Effectiveness

Keywords:

Performance measures.

Intent:

Performance measures are values, which demonstrate a radiology center's performance, strengths, and opportunities for improvement. Effective design and clarity of scope are fundamentals in establishing and maintaining value-added business indicators.

The radiology center shall select a mixture of performance measures that focuses on activities that might be risky in nature to patients or staff, occurring in high volume, associated with problems, or high cost. This includes at least the following:

- a) Patient's medical record completeness.
- b) National safety requirements.
- c) Patient outcome and adverse events.
- d) Patient complaints.
- e) Patient and family satisfaction rates.
- f) Staff satisfaction.
- g) Infection control program and surveillance.

An assigned staff member having appropriate knowledge and skills shall be responsible for data management related to performance improvement and improvement projects. The required knowledge is covering revision of data, aggregation, analysis, trending, properly displaying and transforming (language mistakes) into useful information.

Results of measures analysis shall be regularly reported to the governing body in order to reach conclusions and to make decisions.

The radiology center uses different charts to track the improvement progress and decides the next step in the improvement plan. Radiology center leaders are expected to understand data trends and charts to make a decision based on the provided information.

Survey process guide:

- GAHAR surveyor may review the selected measures, and assess the criteria of selection, prioritization, and data management skills that were used in the selected measures.

- GAHAR surveyor may observe the implementation of the measures.
- GAHAR surveyor may interview staff members and ask them about performance measurement.

Evidence of compliance:

1. The radiology center selects and implements appropriate performance measures according to its scope of services and includes at least measures from a) through g) in the intent.
2. There is a written process of data management that includes the aggregation and analysis of data.
3. Responsible staff members for data management are aware of their roles.
4. Performance measures are monitored regularly and reported to the governing body.
5. The radiology center makes its performance results/data publicly available at least annually.

Related standards:

PCC..06 Patient and family feedback, PCC.07 Complaints and suggestions, ACT.02 Patient identification, ICD.02 Fall screening and prevention, IPC.04 Standard precautions measures, IPC.02 infection prevention and control program, IPC.08 Disinfection/sterilization quality control program, OGM.03 radiology center leaders, OGM.04 strategic and Operational Plans, QPI.01 quality management program, QPI.06 performance improvement plan.

Efficient risk management program

QPI.03 A risk management plan/program is developed and implemented.

Safety

Keywords:

Risk management plan/program.

Intent:

Risk management is designed to identify potential events that may affect the radiology center and to protect and minimize risks to the radiology center's property, services, and employees. Effective risk management ensures the continuity of radiology center operations. An important step of risk management is risk analysis where you can assess the high-risk processes.

The radiology center needs to adopt a proactive approach to risk management that includes developing risk mitigation strategies Failure Mode Effect Analysis (FMEA) is one of the analysis tool that can be used in the radiology center as a proactive approach.

The radiology center should take reactive and proactive measures to address identified risks. Risk management plan/program shall contain essential components that include at least the following:

- a) Scope, objective, and criteria for assessing risks.
- b) Risk management assigned responsibilities and functions.
- c) Staff training on risk management concepts and tools.
- d) Risk policies and procedures that support the risk management framework.
- e) Risk identification and risk register.
- f) Risk prioritization and categorization (i.e. strategic, operational, reputational, financial, other).
- g) Risk reporting to governing body and communication with stakeholders within a defined timeframe.
- h) Risk Reduction measures and tools.

Survey process guide:

- GAHAR surveyor may review the risk management plan\program of the radiology center.
- GAHAR surveyor may review the risk reduction measures or tools for the high risks.

Evidence of compliance:

1. The radiology center has a risk management plan /program that includes all the elements from a) through h).
2. High-risk processes are redesigned based on the result of the analysis.
3. The radiology center develops and implements a proactive risk reduction tool for at least one high-risk process annually.
4. The risk management plan/program and the risk register are updated at least annually.

Related standards:

EFS.03 Hazardous materials and waste disposal, EFS.04 safety and Security plan, IPC.10 Aseptic techniques, IPC.06 communicable diseases preventive measures., OGM.10 Staff health program, QPI.04 Incident reporting system, QPI.05 Sentinel event, IPC.02 infection prevention and control program, MRS.08 personal protective equipment (PPE).

QPI.04 The radiology center develops and implements an incident reporting system.

Safety

Keywords:

Incident reporting system.

Intent:

Strong risk management is supported by efficient incident reporting systems that is defined as the system that can identify any event that could adversely affect patient or employee safety.

Incidents reporting has an important influence on improving patient safety. It can provide valuable insights on how and why patients can be harmed at the radiology center level and so measurements for improvement are taken. In most radiology centers injuries, medication errors, equipment failures, adverse reactions to drugs or treatments, or errors in patient care shall be included and reported.

The radiology center shall communicate with patient's/services users about adverse events they are affected by.

An incident reporting system helps to detect, assess, monitor, mitigate, and prevent risks.

The radiology center shall develop and implement a policy regarding incident reporting policy that helps to detect, monitor, assess, mitigate, and prevent risks. The incident reporting policy includes at least the following:

- a) Definition and classification of incidents with the list of reportable incidents, including near misses, adverse events, and sentinel events.
- b) Incident management process includes how, when, and by whom incidents are reported and investigated.
- c) Incidents requiring immediate notification to the management.
- d) Incident, analysis, and results reporting.
- e) Indication for performing intensive analysis and its process.
- f) Staff support program for staff involved in the adverse effect.

Survey process guide:

- GAHAR surveyor may review incident reporting policy, management system and review system activities.
- GAHAR surveyor may interview staff to check their awareness of the incident reporting policy and the proper implementation.
- GAHAR surveyor may review the evidence of corrective actions taken when gaps are detected

Evidence of compliance:

1. The radiology center has an approved incident reporting policy that includes mentioned elements a) through f).
2. All staff is aware of the incident-reporting policy, including contracted and outsourced staff.
3. Incidents are investigated and analyzed as per the center's policy.
4. Radiology center communicates with patient's/services users about adverse events they are affected by.
5. Corrective actions are taken in a timely manner and when gaps are detected.

Related standards:

QPI.01 Quality management program, MMS.05 Medication errors, near miss, problems, adverse drug reactions, QPI.03 Risk management plan/program, QPI.05 Sentinel event, OGM.03 radiology center leaders.

QPI.05 The radiology center defines, investigates, analyzes and reports sentinel events, and takes corrective actions to prevent harm and recurrence.

Safety

Keywords:

Sentinel events.

Intent:

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury. Serious injury specifically includes loss of limb or function a sentinel event signals an immediate investigation and response.

The radiology center shall develop a policy for sentinel event management that includes at least the following:

- a) Identify sentinel events, that include at least the following:
 - i. Unexpected mortality or major permanent loss of function not related to the natural course of the patient's illness or underlying condition.
 - ii. Wrong patient, wrong site, wrong procedure events.
 - iii. Patient suicide or attempted suicide leading to death or permanent loss of function.
 - iv. Rape, workplace violence such as assault (leading to death or permanent loss of function), or homicide (willful killing) of a patient, staff member, practitioner, medical student, trainee, visitor, or vendor
 - v. Wrong delivery of radiotherapy
- b) Internal reporting of sentinel events.
- c) External reporting of sentinel events.
- d) Root cause analysis' methodologies and tools.

Sentinel events identification and analysis help the radiology center to determine the actions needed to make improvements.

All sentinel events are communicated to GAHAR within seven days of the event or becoming aware of the event. A root cause analysis for all events that meet the definition shall be conducted analysis in order to have a clear understanding of contributing factors behind the system gaps. The analysis and action shall be completed within 45 days of the event or becoming aware of the event.

Survey process guide:

- GAHAR surveyor may review the radiology center's sentinel events management policy.
- GAHAR surveyor may review evidence of sentinel events analysis and reporting
- GAHAR surveyor may review evidence of corrective actions taken to prevent the recurrence of the event.

Evidence of compliance:

1. The radiology center has a sentinel events management policy covering the items mentioned in intent from a) through d).
2. The radiology center staff and leaders are aware of the sentinel events management policy.
3. All sentinel events are analyzed and communicated to the direct upper management by a root cause analysis in a time period specified by leadership as per the center's policy.
4. All sentinel events are communicated to GAHAR within seven days of the event or becoming aware of the event.
5. The root cause analysis identifies the main reason(s) behind the event and the leaders take corrective action plans to prevent recurrence in the future.

Related standards:

QPI.04 Incident reporting system, QPI.03 Risk management plan/program, QPI.01 Quality management program, MMS.05 Medication errors, near miss, problems, adverse drug reactions, OGM.09 Positive Workplace Culture, QPI.06 Performance improvement plan, APC.03 Accurate and complete information.

Sustaining improvement

QPI.06 There is a radiology center-wide performance improvement plan.

Effectiveness

Keywords:

Performance improvement plan.

Intent:

The radiology center uses the information from data analysis to identify potential improvements or reduce (or prevent) adverse events. Routine monitoring data, as well as data from intensive assessments, contribute to the understanding of where improvement will be planned and what priority is to be given to the improvement. In particular, improvements are planned for the priority areas identified through data collection. Documentation of improvement activities is an essential element of the process to ensure that improvement was done.

The plan shall address at least the following:

- a) The goal(s) (managerial and technical goals) that fulfill the center's mission.
- b) Organization structure and improvement reporting channels.
- c) Roles and responsibilities of leaders.
- d) Performance measures road map selection.
- e) Data collection, and data analysis tools.
- f) Defined criteria for prioritization and selection of performance improvement projects.
- g) Defined improvement activities.
- h) Quality Improvement model(s) used.
- i) Information flow and reporting frequency.
- j) Periodic evaluation of the plan, at least annually.

Participation of all staff in performance improvement activities is highly important for increasing service quality, boosting productivity, improving communication, reducing stress and building a stronger working community. The plan shall be communicated to the relevant stakeholders.

Survey process guide:

- GAHAR surveyor may perform a document review for the center plan.
- GAHAR surveyor may interview staff to check their involvement and awareness of the centers' improvement activities.

Evidence of compliance:

1. The radiology center has a current and approved performance improvement plan that defines at least items from a) through j) in the intent.

2. Quality improvement activities are monitored and results are reported to the governing body.
3. The plan is communicated to relevant stakeholders.
4. The plan is implemented, reviewed, evaluated and updated annually.

Related standards:

PCC.06 Patient and family feedback, PCC.07 Complaints and suggestions, OGM.02 Qualified director, QPI.01 Quality management program, QPI.02 Performance measures, OGM.01 Governing body Structure and clear responsibilities

Survey Activities and Readiness

Introduction:

- GAHAR survey process involves performing building tours, observations of patients' medical records, staff member files, credential files, and interviews with staff and patients.
- The survey is an information-gathering activity to determine the organization's compliance with the GAHAR standards.

Readiness Tips:

- To facilitate the completion of the survey within the allotted time, all information and documents should be readily available for the surveyors to review during the survey
- If certain staff members are missing, the team will continue to perform the survey; the appropriate missing staff members may join when they are available.
- Files may be in paper or electronic format; however, the information should, at all times, be safe and secure from unauthorized access, up-to-date, accessible, and readily retrievable by authorized staff members.

	Activity	Timeframe	Location in survey agenda
1	Arrival and Coordination	30-20 minutes	upon arrival
2	Opening meeting	15 minutes	as early as possible
3	Radiology center orientation	30-20 minutes	as early as possible
4	Survey Planning	45-30 minutes	as early as possible
5	Document Review Session	120-60 minutes	At the beginning of the survey
6	Patient / individual tracer	120-60 minutes	Individual Tracer activity occurs throughout the survey; the number of individuals who surveyors trace varies by organization

7	Break	30 minutes	At a time negotiated with the radiology center Team Meeting/Surveyor Planning
8	Staff members file review	40-30 minutes	After some individual tracer activity has occurred
9	Environment and facility safety plans review	30-15 minutes	After some individual tracer activity has occurred
10	Environment and facility safety tour	60-30 minutes	After document review
11	Leadership interview	60 minutes	During early or middle of survey
12	Financial stewardship review	45-30 minutes	In the middle of the survey
13	Patient centred care activities review	60 minutes	Towards the end of survey
14	Patient medical records review	40-30 minutes	In the middle of the survey
15	Medication management review	15 minutes	In the middle of the survey
16	Infection Prevention and Control Review	40-30 minutes	In the middle of survey
17	Quality Program Review	60-30 minutes	Towards the end of survey
18	Report Preparation	60-30 minutes	At the end of survey
19	Executive Report	15 minutes	At the end of survey
20	Exit meeting	30 minutes	Final activity of survey

Arrival and coordination

Why will it happen?

To start survey process on time, GAHAR surveyors shall use the time to review the focus of the survey in the light of submitted application.

What will happen?

GAHAR surveyors shall arrive to the radiology center and present themselves to the radiology center staff, survey coordinator shall be available to welcome GAHAR surveyors.

How to prepare?

Surveyors need a workspace they can use as their base during the survey. This area should have a desk or table, internet and phone coverage, and access to an electrical outlet, if possible. Provide the surveyors with the name and phone number of the survey coordinator

Who should collaborate?

Suggested participants include radiology center staff, director and leaders.

Opening meeting

Why will it happen?

This is an opportunity to share uniform understanding of the survey structure, answer questions about survey activities and create common expectations.

What will happen?

GAHAR surveyors shall introduce themselves and describe each component of the survey agenda.

Questions about the survey visit, schedule of activities, availability of documents or people and any other related topics should be raised at this time.

How to prepare?

Designate a room or space that will hold all participants and will allow for an interactive discussion.

Who should collaborate?

Suggested participants include centers' director and senior leadership.

Radiology center Orientation

Why will it happen?

GAHAR surveyors shall learn about the radiology center through a presentation or an interactive dialogue to help focus on subsequent survey activities.

What will happen?

A radiology center representative (usually radiology center director or their designee) shall present information about the radiology center.

How to prepare?

Prepare a brief summary (or a presentation) about the radiology center that includes at least information about:

- radiology center mission, vision, and strategic goals.
- radiology center structure and geographic locations.
- Information management, especially the format and maintenance of medical records.
- Contracted services.
- Compliance with National Safety Requirements.
- Summary of community involvement.
- The radiology center' patient population and the most commonly provided services.
- Compliance with GAHAR reports and recommendations during the pre-accreditation visit period.

Who should collaborate?

Suggested participants include the same participants as the opening conference.

Survey planning

Why will it happen?

To ensure efficiency of survey time.

What will happen?

Surveyors shall begin selecting patients for tracers based on the care and services the radiology center provides.

How to prepare?

Survey coordinator need to ensure that the Center's scope of services is available for surveyors

Who should collaborate?

GAHAR surveyors only.

Document review session

Why will it happen?

To help GAHAR surveyors understand radiology centre operations.

What will happen?

GAHAR surveyors shall review required policies (or other quality management system documents) and policy components based on GAHAR standards.

How to prepare?

Survey coordinator shall ensure that all valid current and approved quality management system documents are available for review either in paper or electronic format (approval

should be visible, clear and authentic)

Use of bookmarks or notes is advisable to help surveyors find the elements being looked for

1. Performance improvement data according to the applicable look back period.
2. High-risk process data Analysis from a high-risk process.
3. Annual risk assessment and Annual Review of the Program.
4. Infection Control surveillance data according to the applicable look back period.
5. All policies, procedures, and plans.

Who should collaborate?

Survey coordinator and policy stakeholders.

Patient\individual tracer

Why will it happen?

GAHAR surveyors shall follow course of care and services provided to the patient to assess relationships among the important functions and evaluate performance of processes relevant to the individual's care or services.

What will happen?

- The tracer process takes surveyors across a wide variety of services.
- The tracer methodology's use of face-to-face discussions with staff members and patients, combined with review of patient's medical records and the observations of surveyors.
- This shall help guide surveyors as they trace a patient's provided care or services.
- The individual tracer begins in the location where the patient is registered for service. The surveyor starts the tracer by reviewing a file of care with the staff person responsible for the individual's care or services. The surveyor then begins the tracer by following the course of care, or services provided to the patient from registration through post discharge, assessing the interrelationships between disciplines, departments, programs, services (where applicable), and the important functions in the care or services provided which may lead to identifying issues related to care processes.
- Most of GAHAR standards can be triggered during a patient\individual tracer activity which may also include interviewing staff, patients or family members.

How to prepare?

- Assure confidentiality and privacy of patients during tracers including no video or audio recording and no crowdedness
- All efforts will be done to avoid having multiple tracers or tours in the same place at the same time.

Who should collaborate?

Survey Coordinator and any staff member (when relevant).

Break

Why will it happen?

To allow time for surveyor and for radiology centre staff to have a break and use the information learned.

What will happen?

GAHAR surveyor shall meet in their base alone.

How to prepare?

Use separate place.

Who should collaborate?

GAHAR surveyors only.

Staff members file review

Why will it happen?

The surveyor shall verify process-related information that recorded in staff member's files. The surveyor shall identify specific staff whose files they would like to review.

What will happen?

GAHAR surveyor may ensure that a random sample of staff files is reviewed.

The minimum number of records selected for review is 5 staff member files

If findings are observed during the file review, the survey team may request additional file samples to substantiate the findings recorded from the initial sample.

Throughout the review process, if a big number of findings are observed, the survey team may document whether the findings constitute a level of non-compliance.

How to prepare?

The radiology center shall produce a complete list of all staff members including outsourced, contracted, full-timers, fixed-timers and part-timers.

Who should collaborate?

radiology centre directors and the most senior leaders.

Environment and facility safety plans review

Why will it happen?

GAHAR surveyor may assess the radiology center degree of compliance with relevant standards and identify vulnerabilities and strengths in the environment and facility safety plans.

What will happen?

The surveyor shall review the Environment of Care risk categories as indicated in the

radiology center risk assessment and safety data analysis and actions taken by the radiology center leaders.

How to prepare?

Make sure that those responsible for environment and facility safety plans are available for discussion.

Also, the following documents have to be available:

- radiology center licenses, or equivalent
- A map of the organization, if available
- Environment and facility safety Plans and annual evaluations
- Emergency\disaster preparedness Plan and documented annual review and update, including communications plans
- Annual staff training

Who should collaborate?

Environment and facility safety responsible staff members.

Environment and facility safety tour

Why will it happen?

- GAHAR surveyor observes and evaluate the radiology center actual performance in managing environment and facility risks.
- What will happen?
- GAHAR surveyor may begin where the risk is encountered, first occurs or take a top down-bottom-up approach.
- GAHAR surveyor may interview staff to describe or demonstrate their roles and responsibilities for minimizing the risk, what they are to do if a problem or incident occurs, and how to report the problem or incident
- GAHAR surveyor may assess any physical controls for minimizing the risk (i.e., equipment, alarms, building features), Assess the emergency plan for responding to utility system disruptions or failures(e.g., alternative source of utilities, notifying staff, how and utility systems fail preventive measures, and obtaining repair services), assess If equipment, alarms, or building features are present for controlling the particular risk, reviewing implementation of relevant inspection, testing, or maintenance procedures
- GAHAR surveyor may also assess hazardous materials management, waste management, safety or security measures.

How to prepare?

Ensure that keys, communication tools and contacts are available, so GAHAR surveyor able to access all radiology centre facilities smoothly.

Who should collaborate?

Environment and facility safety responsible staff members.

Leadership interview

Why will it happen?

The surveyor will learn about radiology center governance and management structure.

What will happen?

GAHAR surveyor addresses the following issues:

- Composition of the governing body
- The functioning, participation, and involvement of the governing body in the oversight and operation
- The governing body's perception and implementation of its role in the radiology center
- Governing body members understanding of performance improvement approaches and methods
- Leadership commitment to improvement of quality and safety, creating a culture of safety, Robust process improvement and Observations that may be indicative of systemlevel concerns

How to prepare?

GAHAR surveyor may need a quiet area for brief interactive discussion with radiology center leaders

The following documents may be reviewed during this session

- radiology center strategic plan
- radiology centres ethical framework
- Governing body minutes according to the applicable lookback period.
- Patient centeredness initiatives.

Who should collaborate?

Required participants include at least the following:

- radiology center director
- governing body representative.

Financial Stewardship Review

Why will it happen?

The surveyor will learn about radiology center financial stewardship structure and processes.

What will happen?

The GAHAR surveyor may address topics related to financial stewardship, such as observations noted during radiology center tours and tracers, the billing process,

contractor's performance, availability of staff, supplies, and equipment.

How to prepare?

The GAHAR surveyor may need a quiet area for a brief interactive discussion with financial stewardship representatives.

The following documents may be reviewed during this session.

- List of all contracted services.
- Agreement with outsourced providers of laundry, sterilization and housekeeping
- Contractor monitoring data.
- Feedback reports from payers.
- Cost reduction projects.

Who should collaborate?

Required participants include at least the following: radiologycenter director, procurement responsible staff member, clinical responsible staff member, and finance responsible staff member.

Patient centered care activities review

Why will it happen?

The surveyor will assess patient centeredness initiatives and related activities.

What will happen?

GAHAR surveyor addresses the following issues:

- The GAHAR surveyor may receive information about the patient-centered initiatives and culture support.
- GAHAR surveyor may review the related terms of references and meeting minutes with responsible staff members.
- GAHAR surveyor may ask questions to explore the mechanisms taken to plan, assist, and maintain patient-centered practices. GAHAR surveyor may interview staff to check their awareness about patient-centered initiatives.
- GAHAR surveyor may review patient assessment/reassessment forms.

How to prepare?

Assure confidentiality of documents during the review including no video or audio recording of any documents.

The following documents may be reviewed during this session:

- Patient family rights and responsibilities policy
- Patient family rights and responsibilities posters, brochures, flyers.
- Patient and family educational materials.
- Patient initial assessment and re assessment forms
- Patients suggestions, complaint and feedback.

Who should collaborate?

Required participants include at least the following: radiology center director, radiology center leaders and quality coordinator\director (if applicable).

Patient's medical record Review

Why will it happen?

The review of files, in itself, is not the primary focus of this session. However, the surveyor may verify process-related information through recording in patients' medical records. The surveyor may identify specific patients whose files they would like to review.

What will happen?

The GAHAR surveyor may ensure that a random sample of the patient's medical record is reviewed. A sample of both open and closed cases should be reviewed. Record review should include a random sample. The sample selected shall represent a cross-section of the cases performed at the radiology center. The minimum number of case file records required to be selected by the surveyor for review is no more than five records IN total. If findings are observed during the file review, the survey team may request additional file samples to substantiate the findings recorded from the initial sample. Throughout the review process, if a large number of findings are observed, the survey team may document whether the findings constitute a level of non-compliance. The total number of records within the six-month case period should be recorded in the review form.

How to prepare?

The radiology center is required to produce a log or other record of closed cases for the previous six-month period, and the surveyor may select a sample of medical records to review.

Who should collaborate?

Representatives from radiology center medical, nursing, and other healthcare teams in addition to information management representatives.

Medication Management Review

Why will it happen?

The GAHAR surveyor may learn about the planning, implementation, and evaluation of the medication management program, identify who is responsible for its day-to-day implementation, evaluate its outcome and understand the processes used by the radiology center to reduce medication errors.

What will happen?

The GAHAR surveyor may evaluate radiology center' medication management systems by performing system tracers. Discussions in this interactive session with staff include:

- The flow of the processes, including identification and management of risk points,

integration of key activities, and communication among staff/units involved in the process with a focus on the management of high-alert medications, look-alike, sound-alike, concentrated electrolytes, and medication errors.

- Strengths in the processes and possible actions to be taken in areas needing improvement, with a special focus on:

Process for reporting errors, system breakdowns, near misses or overrides, data collection, analysis, systems evaluation, and performance improvement initiatives.

How to prepare?

The GAHAR surveyor may need a quiet area for a brief interactive discussion with staff who oversee the medication management program. Then time may be spent where the medication is received, stored, dispensed, prepared, or administered.

The following documents may be reviewed during this session.

- Medication management policies.

Who should collaborate?

Suggested participants include clinical and support staff responsible for medication management processes.

Infection prevention and control program review

Why will it happen?

GAHAR surveyor will Learn about the planning, implementation, and evaluation of infection prevention and control program, identify who is responsible for its day-to-day implementation, evaluate its outcome and Understand the processes used by the radiology center to reduce infection

What will happen?

GAHAR surveyor will evaluate radiology centre IPC systems by performing system tracers.

Discussions in this interactive session with staff include:

- The flow of the processes, including identification and management of risk points, integration of key activities, and communication among staff/units involved in the process; How individuals with infections are identified, Staff orientation and training activities, Current and past surveillance activity
- Strengths in the processes and possible actions to be taken in areas needing improvement; Analysis of infection control data, Reporting of infection control data, Prevention, and control activities (for example, staff training, staff vaccinations and other health-related requirements, housekeeping procedures, organization-wide hand hygiene, and the storage, cleaning, disinfection, sterilization and/or disposal of supplies and equipment), staff exposure, Physical facility changes

that can impact infection control and Actions taken as a result of surveillance and outcomes of those actions.

How to prepare?

GAHAR surveyor may need a quiet area for brief interactive discussion with staff who oversee the infection prevention and control process. Then time is spent where the care is provided

The following documents may be reviewed during this session

- Infection prevention and control policies
- Infection control education and training records • Infection control measures data

Who should collaborate?

Suggested participants include the infection control coordinator; physician member of the infection control personnel, Safety management staff and staff involved in the direct provision of care or services.

Quality program\plan review

Why will it happen?

GAHAR surveyor will Learn about the planning, implementation, and evaluation of quality management program, identify who is responsible for its day-to-day implementation, evaluate its outcome and Understand the processes used by the radiology center to reduce risks

What will happen?

Discussions in this interactive session with staff include:

- The flow of the processes, including identification and management of risk points, integration of key activities, and communication among staff/units involved in the process;
- Strengths in the processes and possible actions to be taken in areas needing improvement; Use of data
- Issues requiring further exploration in other survey activities;
- A baseline assessment of standards compliance.

How to prepare?

GAHAR surveyor may need a quiet area for brief interactive discussion with staff who oversee the quality management program.

The following documents may be reviewed during this session:

- Quality management program
- Performance management measures
- Risk Management registers, records, and logs

Who should collaborate?

Suggested staff members include quality coordinator\director (if applicable), staff involved in data collection, aggregation, and interpretation.

Report preparation

Why will it happen?

To provide an opportunity of clarification and consolidation of any findings.

What will happen?

Surveyors use this session to compile, analyze, and organize the data collected during the survey into a report reflecting the radiology center compliance with the standards. Surveyors may also ask organization representatives for additional information during this session.

How to prepare?

GAHAR surveyors may need a room that includes a conference table, power outlets, telephone, and internet coverage.

Who should collaborate? GAHAR surveyors only.

Executive report

Why will it happen?

To give an opportunity to brief the most relevant outcomes of the survey and help prioritization of post-accreditation activities.

What will happen?

GAHAR surveyors will review the survey findings with the center director and the most senior leader and discuss any concerns about the report.

How to prepare?

GAHAR surveyor may need a quiet private area for brief interactive discussion with the center director and the most senior leaders.

Who should collaborate?

radiology centres available most senior leader and others at his/her discretion.

Exit conference

Why will it happen?

To thank the radiology centre team for participation and share the important findings in the accreditation journey.

What will happen?

Surveyors will verbally review the survey findings summary, if desired by the most senior leader, and review identified standards compliance issues.

How to prepare?

Radiology centre available most senior leader may invite staff to attend, an area that can accommodate attending staff is required.

Who should collaborate?

Suggested participants include the radiology center available most senior leader (or designee), senior leaders, and staff as identified by the most senior leader or design.

GLOSSARY

Adverse event an unanticipated, undesirable, or potentially dangerous occurrence in a health care radiology center.

Adverse drug event (ADE) This is an injury resulting from medication intervention related to a drug.

Airborne They are particles $\leq 5\mu$ in size that remain suspended in the air and travel great distances.

Antiseptics They are substances that reduce or stop the growth of potentially harmful microorganisms on the skin and mucous membranes. Or Antimicrobial substances that are applied to the skin to reduce the number of microbial

Appointment The process of reviewing an initial applicant's credentials to decide if the applicant is qualified to provide patient care services that the patient needs and the radiology center can support with qualified staff and technical capabilities.

Aseptic technique It is a method designed to reduce the risk of microbial contamination in a vulnerable body site. This may include procedures like undertaking a wound dressing or performing an invasive procedure such as inserting a urinary catheter or preparing an intravenous infusion.

Certification The procedure and action by which an authorized organization evaluates and certifies that a person, institution, or program meets requirements.

Cleaning It is the process of removing foreign material (e.g. soil, organic material, micro-organisms) from an object.

Clinical guidelines Statements that help radiology healthcare professionals and patients choose appropriate health care for specific clinical conditions. The radiology healthcare professionals is guided through all steps of consultation (questions to ask, physical signs to look for, assessment of the situation, and care to prescribe).

Communicable disease it is a disease that is capable of spreading from one person to another through a variety of ways, including contact with blood, body fluids and breathing, etc.

Competence or competency A determination of the staff's job knowledge, skills, and behaviours to meet defined expectations. Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific actions, behaviours, such as the ability to work in teams, are frequently considered as a part of competence.

Contamination The presence of unwanted material or organism, such as an infectious agent, bacteria, parasite, or another contaminant, that is introduced to an environment, surface, object, or substance, such as water, food, or sterile medical supplies.

Contaminated textiles and laundry OSHA define contaminated laundry as “laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contrast media A dye or other substance that helps show abnormal areas inside the body. It is given by injection into a vein, by enema, or by mouth. Contrast material may be used with x-rays, CT scans, MRI, or other imaging tests.

Credentials Evidence of competence, current and relevant licensure, education, training, and experience. Other defined criteria may be added by a healthcare organization.

Critical results and values A critical value/result is defined as any value/result or interpretation where a delay in reporting may result in a serious adverse outcome for the patient.

Disinfectants they are substances that are applied to the surface of non-living objects in order to destroy microorganisms but not necessarily bacterial spores.

Disinfection It is the process of reducing the number of pathogenic microorganisms, but not necessarily bacterial spores to a level which is no longer harmful to health. It may be high level, intermediate level or low level disinfection depending on the level of probable risk.

Dispensing preparing, packaging, and distributing to a patient a course of therapy on the basis of a prescription.

Electron therapy, or electron beam therapy is a form of radiotherapy which is used to treat superficial lesions. Electron beams are rapidly attenuated by soft tissue and thus can only treat to a depth of a few centimeters (typically 0-3 cm), compared to megavoltage x-rays which are much more penetrating. Suitable targets include.

Ergonomic hazards: are workplace situations that cause wear and tear on the body and can cause injury

gas mask: Gas masks are also known as “air-purifying respirators” because they filter or clean chemical gases and possibly particles out of the air as you breathe. This respirator includes a facepiece or mask, and a filter/cartridge (if the filter is in a metal shell it is called a “canister”).

Hand hygiene A general term that applies to hand washing, antiseptic hand wash, antiseptic hand rub, or surgical hand antisepsis.

Hazardous materials and waste plan The radiology center's written document that describes the process it would implement for managing the hazardous materials and waste from source to disposal. The plan describes activities selected and implemented by the radiology center to assess and control occupational and environmental hazards of materials and waste (anything that can cause harm, injury, ill-health, or damage) that require special handling. Hazardous materials include radioactive or chemical materials. Hazardous wastes include the biologic waste that can transmit disease (for example, blood).

Healthcare professional Any person working in a healthcare centre, whether he is a physician, nurse, technician, housekeeper, administrator etc.

HEPA filter High-efficiency particulate air filter, is defined as a filter with efficiency of 99.97% in removing particles 0.3 microns or more in size, which makes it suitable for prevention of airborne pathogens.

High alert medication: Medications that bear a heightened risk of causing significant patient harm when they are used in error.

Hygiene The practice that serves to keep people and environments clean and prevent infection.

Immunization is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine (active immunisation) or serum containing desired antibodies (passive immunisation). Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease Infection control practitioner.

Infection control program an organized system of services designed to meet the needs of the radiology centers in relation to the surveillance, prevention, and control of infection, which impacts patients, staff, physicians, and/or visitors.

Infection The transmission of a pathogenic microorganism.

Inventory A written list of all the objects, abilities, assets, or resources in a particular place.

Incident Report An event, or condition that could have resulted or did result in harm to a patient. Any deviation from normal process that may cause harm.

IPC committee The Infection Control Committee is generally comprised of members from a variety of disciplines within the healthcare facility; bringing together individuals with expertise in different areas of healthcare.

Job description Statements or directions specifying required decisions and actions. Penalties, legal or otherwise, are normally assessed when laws and regulations are not followed.

Laws and regulations Statements or directions specifying required decisions and actions. Penalties, legal or otherwise, are normally assessed when laws and regulations are not followed.

Leader A person who sets expectations plans and implements procedures to assess and improve the quality of the radiology centers' governance, management, clinical, and support functions and processes.

Legibility The possibility to read or decipher. The writing is clearly written so that no letter or number can be misinterpreted. It is legible when any individual can read the handwritten documentation or physician order.

Medical staff Licensed physician and licensed dentist.

Medication Any prescription medications including narcotics; herbal remedies; vitamins; nutraceuticals, over-the-counter medications; vaccines; biological, diagnostic and contrast agent used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood products; medication containing products, and intravenous solutions with electrolytes and/or medications. The definition of the medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases unless explicitly stated.

Near miss is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so also called a close call.

Nuclear medicine Nuclear medicine therapy uses radiopharmaceuticals targeting specific tumours, such as thyroid, lymphomas or bone metastases, delivering radiation to tumorous lesions as part of a therapeutic strategy to cure, mitigate or control the disease. It can be used either on selective targets or throughout the entire body.

Ordering is written directions provided by a prescribing practitioner for a specific medication to be administered to an individual. The prescribing practitioner may also give a medication order verbally to a licensed person such as a pharmacist or a nurse.

Optimization an act, process, or methodology of making something (such as a design, system, or decision) as fully perfect, functional, or effective as possible specifically : the mathematical procedures (such as finding the maximum of a function) involved in this.

Performance measures it is a quantifiable measure used to evaluate the success of radiology centre employee, etc.

Personal protective equipment it is equipment worn to minimize exposure to hazards that cause serious workplace injuries and/or illnesses.

Plan A detailed method, formulated beforehand that identifies needs, lists, and strategies to meet those needs, and sets goals and objectives. The format of the plan may include narratives, policies, and procedures, protocols, practice guidelines, clinical paths, care maps, or a combination of these.

Plan of care A plan that identifies the patient's care needs lists the strategy to meet those needs, records treatment goals and objectives, defined criteria for ending interventions, and records the patient's progress in meeting specified goals and objectives. It is based on data gathered during patient assessment.

Policy Is a guiding principle used to set direction in a radiology center.

Practice guidelines Tools that describe processes found by clinical trials or by consensus opinion of experts to be the most effective in evaluating and/or treating a patient who has a specific symptom, condition, or diagnosis, or describe a specific procedure. Synonyms include practice parameters, protocol, preferred practice pattern, and guideline. Also, see evidence- (scientific) - based guidelines and clinical practice guidelines.

Prescribing advising and authorizing the use of a medication or treatment for someone, especially in writing.

Privileging The process whereby specific scope and content of patient care services (clinical privileges) are authorized for all medical staff members by the organization, based on the evaluation of the physician's credentials and performance.

Procedure Is a series of steps to be followed as a uniform and repetitive approach to accomplish an end result, Procedures provide a platform for uniform implementation to decrease process variation, which increases procedure control? Decreasing process variation is how we eliminate waste and increase performance.

Process A series of actions (or activities) that transform the inputs (resources) into outputs (services). For example, a rural health education program shall require that staff develop an education strategy, develop educational materials, and deliver the education sessions.

Processing All operations performed to render a contaminated reusable or single-use (disposable) device ready again for patient use. The steps may include cleaning and disinfection/sterilization. The manufacturer of reusable devices and single-use devices that are marketed as non-sterile should provide validated reprocessing instructions in the labelling.

Procurement The process of acquiring supplies, including those obtained by purchase, donation, and manufacture. It involves efforts to quantify requirements, select appropriate procurement methods, and prequalify suppliers and products. It also involves managing tenders, establishing contract terms, assuring medications quality, obtaining the best prices, and ensuring adherence to contract terms.

Program A plan of action aimed at accomplishing a clear business objective, with details on what work is to be performed, by whom, when, and what means or resources shall be used.

Project Planned set of interrelated tasks to be executed over a fixed period and within certain cost and other limitations.

Protocol Detailed scientific care plan for using a new care.

Protons radiation therapy A type of radiation therapy that uses streams of protons (tiny particles with a positive charge) to kill tumor cells. This type of treatment can reduce the amount of radiation damage to healthy tissue near a tumor. It is used to treat cancers of the head and neck and organs such as the brain, eye, lung, spine, and prostate. Proton beam radiation is different from x-ray radiation.

Quality control is a part of quality management focused on fulfilling quality requirements

Quality assurance is related to how a process is performed or how a product is made.

Radiation safety program is designed to protect users, staff, patients, the general public and the environment from radiation exposure and to ensure the safe receipt, handling, use and storage of radioactive materials.

Radiographer, also known as radiologic technologists, diagnostic radiographers and medical radiation technologists are healthcare professionals who specialise in the imaging of human anatomy for the diagnosis and treatment of pathology.

Radiation safety officer The person responsible for implementing the radiation protection program is called the Radiation Safety Officer, or RSO. This individual may also be called the Radiation Protection Officer (RPO). The RSO needs independent authority to stop operations that he or she considers unsafe.

Radioisotope: Radioisotopes are the unstable form of an element that emit radiation to transform into a more stable form. Radiation is easily traceable and can cause changes in the substance it falls upon. These special attributes make radioisotopes useful in medicine, industry and other areas.

Radionuclide therapy: A type of radiation therapy in which a radionuclide (a radioactive chemical) is linked to a cell-targeting molecule, such as a monoclonal antibody, and

injected into the body. The cell-targeting molecule binds to a specific target found on some cancer cells. This may help kill the targeted cancer cells while limiting the harm to normal cells. Targeted radionuclide therapy is used to treat prostate cancer and some other types of cancer. Also called molecular radiation therapy.

Radiopharmaceutical refer to a group of pharmaceutical drugs that are radioactive and can be used as diagnostic and/or therapeutic agents for medical care.

Radiological hazards included congenital malformation in babies for exposed pregnant women and infertility in exposed men and women.

Respiratory hygiene This comprises infection prevention measures designed to limit the transmission of respiratory pathogens spread by droplet or airborne routes.

Referral The sending of a patient from one clinician to another clinician or specialist or from one setting or service to another or other resources.

Risk assessment The identification, evaluation, and estimation of the levels of risks involved in a situation, their comparison against benchmarks or standards, and determination of an acceptable level of risk.

Root causes analysis A process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a sentinel event. Scope (care or services): The range and type of services offered by the radiology center and any conditions or limits to the service coverage.

Staff Personal who provide patient care, care, and/ or services in the radiology center, for example (medical staff, nurses, and others).

Safe injection It is a practice intended to prevent needle stick injuries and other possible contamination during syringe introduction in a patient; ultimately preventing transmission of blood borne infectious diseases between one patient and another, or between a patient and a healthcare professional.

Sentinel event is an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof.

Sterilization The use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.

Stock A quantity of something accumulated, as for future use, regularly kept on hand, as for use or sale; staple; standard.

Storage Space or a place for storing, an amount stored, or the act of storing that it is kept in a special place until it is needed.

Surveillance The ongoing systematic collection and analysis of data and the provision of information, which leads to action, being taken to prevent and control disease, usually one of an infectious nature.

Survey meter are hand-held ionising radiation measurement instruments used to check such as personnel, equipment and the environment for radioactive contamination and ambient radiation.

Thermoluminescent dosimeter (TLD) is a passive radiation detection device that is used for personal dose monitoring or to measure patient dose.

Timeliness The time between the occurrence of an event and the availability of data about the event. Timeliness is related to the use of the data.

Utilization The use, patterns of use, or rates of use of a specified health care service. Overuse occurs when a health care service is provided when its potential for harm exceeds the possible benefits. Underuse is the failure to use a necessary health care service when it would have produced a favorable outcome for a patient. Misuse occurs when an appropriate service has been selected, but a preventable complication occurs. All three reflect a problem in the quality of health care. They can increase mortality risk and diminish the quality of life.

Variation The differences in results obtained in measuring the same event more than once. The sources of variation can be grouped into two major classes: common causes and special causes. Too much variation often leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services.

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