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## Chapter 1
### Access, Assessment and Patient Care (AAPC)

### Summary of Standards

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## Standards and Objective Elements

### Standard

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<tr>
<th>AAPC.1.</th>
<th>The organization defines and displays the medical imaging services that it provides.</th>
</tr>
</thead>
</table>

### Objective Elements

a. The Scope of Medical Imaging Services being provided are clearly defined and prominently displayed.

b. Patients are accepted only if the organization can provide the required Medical Imaging Service.

c. The staff are oriented to these services.

### Standard

<table>
<thead>
<tr>
<th>AAPC.2.</th>
<th>The organisation has a well-defined registration and admission process.</th>
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</table>

### Objective Elements

a. Documented policies and procedures are in place for registering the patient and a unique identification number is generated for each patient at the end of registration.

b. All attempts are made to ensure that the unique identification number is maintained for each patient on all subsequent visit.

c. There is a system in place to capture all information about the procedure requested, the relevant clinical and lab details and information about prior imaging and this information is readily available to all the staff involved in patient care for verification prior to performing the procedure.
d. The organization has a process in place to ensure that the imaging is appropriate for the patient and the clinical indication.

e. There is a system in place for appropriate schedule in and prioritization according to patient’s condition and urgency of diagnosis.

Standard

| AAPC.3. | The organization protects patient and family rights and informs them about their responsibilities during care. |

Objective Elements

a. Patients and families are informed of their rights and responsibilities in a format and language that they can understand.

b. The information about specific procedure is available to patients and accompanying persons in relevant format and language including the local language.

c. The expected cost is informed prior to imaging.

d. Imaging services provided are uniform for a given health problem in all settings.

e. The privacy and dignity of the patient is preserved without any discrimination.

f. Confidentiality of patient information will be maintained.

g. Patient and family have a right to seek an additional opinion.

h. The staff are aware and oriented to these.
Standard

AAPC.4. The organization has a documented procedure for obtaining informed consent from the patients to enable informed decision making about their care.

Objective Elements
a. Documented policy incorporates the list of situations where informed consent is required and the process for taking informed consent.

b. Informed consent includes information regarding the procedure, its risks, benefits, alternatives in a language that they can understand.

c. The procedure describes who can give consent when patient is incapable of independent decision making.

d. Informed consent is taken by the person performing the procedure or by a staff member of his team.

Standard

AAPC.5. Emergency Imaging services are guided by documented policies, procedures and the applicable laws and regulations.

Objective Elements
a. The organization had a process of identification of emergencies.

b. Documented policies and procedures guide the triaging of patients for prioritization of Imaging.

c. Documented protocols guide the handling of emergency patients in the premise and during imaging.
d. Documented protocols guide the handling and management of medico-legal cases.

e. There is an identified area in the organization to receive and manage emergency patients.

f. Staff are appropriately trained to manage these.

**Standard**

| AAPC.6. | Patient transportation and ambulance services are guided by documented policies, procedures, applicable laws and regulations. |

**Objective Elements**

a. Documented policies and procedures exist to ensure safe and timely transportation of patient within, to and from the Imaging services.

b. There is adequate access and space for the ambulance(s) and/or Patient transport vehicle(s).

c. The ambulance and/or Patient transport vehicle(s) adheres to statutory requirements and are manned by trained personnel as per the existing laws and regulations. The manpower is adequate to provide the defined scope of services.

d. The ambulance(s) and/or Patient transport vehicle(s) is appropriately equipped.

**Standard**

| AAPC.7. | Documented policies and procedures guide the care of patients requiring emergency intervention in case of any life threatening event or cardio-pulmonary resuscitation. |
Objective Elements

a. Documented policies and procedures guide the uniform use of resuscitation throughout the organisation.

b. Staff providing direct patient care are trained and periodically updated in emergency life support and cardio-pulmonary resuscitation.

c. An appropriately equipped crash cart or a resuscitation tray is maintained.

d. The events during any emergency life support and cardiopulmonary resuscitation are analysed.

e. There is a system in place for the transfer of patients to an appropriate acute care facility when required.

Standard

| AAPC.8 | Documented policies and procedures guide the care of patients undergoing anaesthesia and moderate sedation. |

Objective Elements

a. Informed consent for administration of anaesthesia and moderate sedation is obtained.

b. Competent and trained persons perform anaesthesia and sedation.

c. The patient is appropriately monitored on predefined parameters during and after the procedure till the discharge.

d. The type of anaesthesia and anaesthetic medications used are documented in the patient record.

e. Adverse Sedation/anaesthesia events are recorded and monitored.
# Chapter 2
## Imaging, Procedures and Interpretations (IPI)

### Summary of Standards

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<th>IPI.1.</th>
<th>The organization defined the process for acquisition of optimal diagnostic quality images</th>
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<td>Documented policies and procedures guide the care of patients undergoing Diagnostic and Therapeutic Interventional procedures.</td>
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<td>IPI.5.</td>
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<td>IPI.6.</td>
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<td>IPI.7.</td>
<td>There is an established risk control and safety program in the Imaging services.</td>
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Standards and Objective Elements

Standard

| IPI.1. | The organization defined the process for acquisition of optimal diagnostic quality images. |

Objective Elements

a. Appropriately qualified and trained personnel perform the imaging studies.

b. The protocols for image acquisition for all examination are developed based on current best practices, documented and are available at the place of work.

c. The protocols are appropriate for the specific age, sex; clinical indications, anatomical part and modality.

d. The protocol implementation is monitored, and protocol deviations are documented and analysed to ensure appropriateness.

e. The protocols include appropriate post processing, and quantification as appropriate for the clinical indication.

f. The protocols for image acquisition for all examination are reviewed at a defined periodicity for improvement and adaptation of the current best practices.

g. Documented procedures exist to prevent events like a wrong site, wrong patient and wrong procedure.

h. Patients are appropriately monitored during and after the procedure.

i. The quality of diagnostic images and completeness of the procedures is monitored through a documented process.

j. Staff are appropriately trained to manage these.
Standard

| IPI.2. | Documented policies and procedures guide the care of patients undergoing Diagnostic and Therapeutic Interventional procedures. |

Objective Elements

a. Adequately qualified and trained staff members perform and assist the procedures.

b. The protocols for all diagnostic and therapeutic interventional procedures are developed and documented.

c. Interventional procedure patients have a pre procedural assessment and a provisional diagnosis documented prior to procedure.

d. An informed consent is obtained by a member of the Team performing the procedure prior to the procedure and same is documented.

e. Documented policies and procedures exist to prevent adverse events like wrong site, wrong patient and wrong procedure/ Indications.

f. Radiation safety procedures are followed.

g. Infection control practices are followed.

h. Appropriate facilities and equipment/ appliances/ instrumentation are available in the procedure area.

i. Appropriate sedation/anaesthesia, clinical and emergency support is available before, during and after the procedure.

j. A procedure note is documented prior to transfer out of patient from the facility.

k. The outcomes of diagnostic and therapeutic interventional procedures are monitored.
Standard

| IPI.3. | Organization defines the content of the imaging reports and discharge documents. |

 Objective Elements  

a. Appropriately qualified and trained personnel interpret the imaging studies on display systems appropriate for the studies and modalities.

b. Imaging report or a discharge document is provided to the patients for each procedure.

c. Results are reported in a standardized manner and the best practices.

d. The document contains the patient’s name, unique identification number, and date of the procedure.

e. The document contain Diagnosis or Differential diagnosis, the procedure performed, medication and sedation administered, details of any adverse event and any other treatment given.

f. The report ensures that the current Clinical Indication for the Imaging study is addressed.

g. The document contains advice for any other further investigation, follow-up imaging advice, medication and other instructions as appropriate in an understandable manner.

h. There is a defined Standard Operating Procedure to address recall / amendment of reports when required.
Standard

IPI.4. The Organization defines the process of communication of the imaging results and discharge documents.

Objective Elements

a. There is a documented policy on routine, urgent and critical Imaging reports with a defined Turn Around time for each of them.

b. A list of conditions requiring critical and urgent communication is defined.

c. The reports are communicated to the patient and/or referrer within the appropriately defined timeframe based on the clinical indication and urgency.

d. Imaging tests and/or reporting outsourced to other organization(s) follow the same Turn Around time requirement.

e. There is a system in place to ensure that right report is communicated to the right patient at the right time.

Standard

IPI.5. The Tele radiology services address all issues pertaining to reporting and communication.

Objective Elements

a. The tele radiology services are provided under a documented agreement between the provider or consumer of the services.

b. All clinical, lab and prior imaging information is available to the tele radiology services provider.
c. Appropriately qualified and trained personnel interpret the imaging studies.

d. Appropriate equipment is used for acquisition, communication, display, and storage of images.

e. Results are reported in a standardized manner consistent with the organizational standards.

f. There is a defined Standard Operating Procedure to address recall / amendment of reports when required.

**Standard**

| IPI.6. | Documented procedures and policies guide all Research activities and Clinical Trials. |

**Objective Elements**

a. Documented policies and procedures for all activities in compliance with regulatory, national and international guidelines.

b. The organization has access to an appropriate ethics committee or Internal Review Board to oversee all research activities.

c. The committee has the powers to discontinue a research trial when risks outweigh the potential benefits.

d. Patient’s informed consent is obtained before entering them in research protocols in accordance with the prevalent Laws and Regulations.

e. Patients are informed of their right to withdraw from the research at any stage and also of the consequences (if any) of such withdrawal.
IPI.7. There is an established risk control and safety program in the Imaging services.

Objective Elements

a. The radiation-safety program is documented and developed by the radiation safety committee of the organisation and implements the principals of ALARA.

b. This program is implemented and overseen by an appropriately designated Radiation Safety Officer and is aligned with the organization’s safety program.

c. Radiation signage are prominently displayed in all appropriate locations.

d. Patients are appropriately screened for safety / risk prior to undergoing an imaging on a particular modality.

e. Staff personnel and patients are provided with appropriate radiation protection devices.

f. Personal radiation monitoring devices are provided to all the Radiation workers.

g. The safety program also addresses the risk associated with MRI.

h. The safety program also addresses Ultrasound Services.

i. The safety program also addresses the devices and environment utilizing Laser and RF devices.

j. Occupational health hazards are adequately addressed.
Chapter 3
Facility Management and Safety (FMS)

Summary of Standards

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<td>The organization has a system in place to provide a safe and secure environment.</td>
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<td>FMS.2.</td>
<td>The organization's environment and facilities operate in a planned manner to ensure safety of patients, their families, staff and visitors and promotes environment friendly measures.</td>
</tr>
<tr>
<td>FMS.3.</td>
<td>The organization has plans for fire and non-fire emergencies within the facilities.</td>
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Standards and Objective Elements

Standard

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<tr>
<th>Standard</th>
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<tbody>
<tr>
<td>FMS.1.</td>
<td>The organization has a system in place to provide a safe and secure environment.</td>
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</tbody>
</table>

Objective Elements

a. MIS coordinates development, implementation and monitoring of the safety plan and policies.

b. Patient-safety devices & infrastructure are installed across the organization and inspected periodically.
c. There is a documented procedure for equipment/material replacement and disposal.

d. Facility inspection rounds to ensure safety are conducted at least twice in a year in patient-care areas and at least once in a year in non-patient-care areas.

e. Inspection reports are documented and corrective and preventive measures are undertaken.

**Standard**

| FMS.2. | The organization's environment and facilities operate in a planned manner to ensure safety of patients, their families, staff and visitors and promotes environment friendly measures. |

**Objective Elements**

a. Facilities are appropriate to the scope of services of the organization.

b. Up-to-date drawings are maintained which detail the site layout, floor plans and fire-escape routes.

c. There is appropriate internal and external sign postings in the organization in a language understood by patient, families and community.

d. The provision of space shall be in accordance with the current good practices (Indian or International Standards) and directives from government agencies.

e. Potable water and electricity are available round the clock.

f. Alternate sources for electricity and water are provided as backup for any failure / shortage especially for the Equipment and the organization regularly tests these alternate sources.
g. There is a maintenance plan for electrical systems.

h. There are designated individuals (with appropriate equipment) responsible for the maintenance of all the facilities.

i. Maintenance staff is appropriately qualified, trained and contactable round the clock for emergency repairs.

j. There is a maintenance plan for facility and furniture.

k. Response times are monitored from reporting to inspection and implementation of corrective actions.

l. The organization takes initiatives towards an energy efficient and environmental friendly facility.

**Standards**

<table>
<thead>
<tr>
<th>FMS.3.</th>
<th>The organization has plans for fire and non-fire emergencies within the facilities.</th>
</tr>
</thead>
</table>

**Objective Elements**

a. The organisation has plans and provisions for early detection, abatement and containment of fire and non-fire emergencies.

b. The organization has a documented safe-exit plan in case of fire and non-fire emergencies.

c. Staff is trained for their role in case of such emergencies.

d. Mock drills are held at least twice in a year.

e. There is a maintenance plan for fire-related equipment & infrastructure.
# Chapter 4

## Equipment, Material and Medications (EMM)

### Summary of Standards

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<td>EMM.4.</td>
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<tr>
<td>EMM.5.</td>
<td>Documented policies and procedures guide the use of Medical supplies and consumables, Stents, coils and other implantable and ablative medical devices.</td>
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<td>EMM.6.</td>
<td>The organization has a documented policies and procedures govern Therapeutic usage of radiopharmaceuticals</td>
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</table>
Standards and Objective Elements

Standard

| EMM.1. | Documented policies and procedures guide the management of all Equipment |

Objective Elements

a. The organization plans for equipment in accordance with its services and strategic plan.

b. Equipment are inventoried and proper equipment history and logs are maintained.

c. The installation of the equipment is safe and commensurate with the applicable laws.

d. The operation of the equipment is safe and compliant with the applicable laws.

e. Appropriate Calibration and Quality Assurance of the equipment is performed at a defined periodicity.

f. There is a documented operational and maintenance (preventive and breakdown) plan for All Equipment.

g. Equipment cleaning and disinfection adheres to the transmission based precautions at all times.

h. The organization identifies and plans for obsolescence, condemning and decommissioning of the equipment.

i. Qualified and trained personnel inspect, test and maintain equipment and utility systems.
**EMM.2.** Documented policies and procedures guide the procurement, storage and usage of medication.

**Objective Elements**

a. There is a documented policy and procedure for procurement and stocking of contrast media, Radiopharmaceuticals and other medications commensurate with the scope of services.

b. Documented policies and procedures exist for storage of medication in a clean, safe and secure environment.

c. Sound inventory control practices guide storage of the medications.

d. There is a documented policy for usage of multidose packaging, and their discard.

**Standard**

**EMM.3.** Documented policies and procedures guide the safe and rational use of contrast media and medications.

**Objective Elements**

a. There is a documented Contrast Media Policy which is commensurate with current best practices and the staff is aware of this.

b. Contrast media and other Medications are handled and administered by those who are permitted and trained to do so.

c. There is a documented procedure for managing drug reactions, and other adverse drug events.

d. There is a system in place to identify patients at a high risk for adverse events following contrast injections.
e. Documented procedures guide monitoring of patients during and after administration of contrast media and other medication.

Standard

| EMM.4. | The organization has a documented policies and procedures govern Diagnostic usage of radiopharmaceuticals. |

Objective Elements

a. The policies and procedures include the safe storage, preparation, handling, distribution, administration and disposal of radiopharmaceuticals.

b. These policies and procedures are in consonance with laws and regulations.

c. This includes management of spills and personnel contamination.

d. The patients at higher risk of adverse reactions to specific drugs, isotopes and radiopharmaceuticals are identified, assessed and managed.

e. Staff, patients and visitors are educated on safety precautions and management of adverse events.

Standard

| EMM.5. | Documented policies and procedures guide the use of Medical supplies and consumables, Stents, coils and other implantable and ablative medical devices. |

Objective Elements

a. The usage is rational, safe and commensurate with the current best practices.
b. Documented policies and procedures govern procurement, storage and usage, incorporating manufacturer’s guidelines.

c. It includes the policy and procedures for reuse and re-sterilization of single use devices.

d. Patient and family are educated about the implanted prosthesis and medical device including their maintenance and precautions.

e. Sound inventory control practices guide storage and usage of medical supplies and consumables.

**Standard**

| EMM.6. | The organization has a documented policies and procedures govern Therapeutic usage of radiopharmaceuticals. |

**Objective Elements**

a. The policies and procedures include the safe storage, preparation, handling, distribution, administration and disposal of radiopharmaceutical.

b. These policies and procedures are in consonance with laws and regulations.

c. Radiopharmaceuticals will be handled and administered by appropriately qualified and authorized & trained individuals.

d. Protocols for dosage, administration and monitoring of patients undergoing therapy are developed, documented and implemented.

e. Patient and patient care providers are appropriately informed & trained.
f. This includes management of spills as well as body fluids and biological waste and personnel contamination.

g. The patients at higher risk of adverse reactions to specific drugs, isotopes and radiopharmaceuticals are identified, assessed and managed.

h. The facility is in compliance with the National regulations regarding the facility layout and construction.

i. The protocols followed in the isolation units are defined.

j. All patients are provided a comprehensive discharge document.

k. Procedure for handling of a cadaver with radioactive pharmaceutical is defined.
Chapter 5
Human Resource Management (HRM)

Summary of Standards

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<th>Standard</th>
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<td>HRM.2</td>
<td>The organization has a documented training program for the staff</td>
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<tr>
<td>HRM.3</td>
<td>The organization has a documented human resource management process.</td>
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<tr>
<td>HRM.4</td>
<td>There is documented personal information for each staff member.</td>
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Standards and Objective Elements

Standard

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<th>Standard</th>
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<tbody>
<tr>
<td>HRM.1</td>
<td>The organization has a documented system of human resource planning.</td>
</tr>
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</table>

Objective Elements

a. The organization maintains an adequate number and mix of staff to meet the need of the organization.

b. There is a documented procedure for recruitment, selection.

c. Job specification and job description are defined and documented or each category of staff.
d. The credentials, skills and training of the staff is verified.

e. The organization verifies the antecedents of the potential employee with regards to criminal/negligent background.

f. There is a defined process of authorization and privileging for all healthcare providers for the services assigned to them.

g. There are clearly defined roles and supervisory requirements for the students, trainees and volunteers.

**Standard**

| HRM.2. | The organization has a documented training program for the staff |

**Objective Elements**

a. Every staff member is made aware through induction training of organization’s wide policies and procedures.

b. A documented training and development policy exists for the staff.

c. Retraining occurs at a defined periodicity; and also when job responsibility changes and/or new equipment is introduced.

d. Staff are trained on the risks as applicable to the organization's environment at a defined periodicity.

e. Staff are also trained on occupational safety aspects.

**Standard**

| HRM.3. | The organization has a documented human resource management process. |
Objective Elements
a. A documented performance appraisal and competency evaluation system exist in the organization at a defined periodicity.

b. The organization has documented disciplinary and grievance handling policies and procedures based on the principles of natural justice and the staff is aware of these.

c. There is a provision for appeals & redress procedure to addresses the grievance.

Standard

| HRM.4. | There is documented personal information for each staff member. |

Objective Elements
a. A personal file is maintained for each staff member.

b. The personal files contain information regarding the staff’s qualification, background and health status.

c. All records of in-service training and education are contained in the personal files.

d. This includes information on the credentialing and privileging of staff members for performing all imaging related procedures.

e. Personal files contain results of all evaluations.
Chapter 6
Management Of Quality And Safety (MQS)

Summary of Standards

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<th>Standard</th>
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<td>MQS.4</td>
<td>Organization Identifies And Monitors Managerial Services.</td>
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<td>MQS.5</td>
<td>The management ensures patient &amp; staff safety in the organisation.</td>
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Standards and Objective Elements

Standard

| MQS.1 | Roles of management are defined. |

Objective Elements

a. Management defines the organisation’s Vision, Mission and Values.

b. Management chooses leaders and establishes hierarchy in the organization.
c. Management is aware of current applicable laws and ensures that the organization adheres to them.

d. Management ensures acquisition of all relevant licenses and their updation.

e. Management ensures ethical management of all patient services that the organization provides.

f. The Management ensures that all policies and protocols are developed and documented to guide the functioning of the Organization.

Standard

<table>
<thead>
<tr>
<th>MQS.2.</th>
<th>The Organisation Has A Structured Quality Improvement Program</th>
</tr>
</thead>
</table>

Objective Elements

a. A continual quality improvement program is developed, documented and implemented throughout the organization.

b. The program is periodically reviewed and updated at least once in a year.

c. The organization conducts regular audits for efficiency of services.

d. The organization conducts regular audits for protocol adherence and deviations

e. The organization conducts regular audits for completeness and accuracy of reports.

f. The organization identifies and monitors priority clinical, managerial, infrastructural parameters in the organization.
Standard

MQS.3. Organisation Identifies And Monitors Quality Of Imaging

Objective Elements
a. The organization monitors appropriateness of imaging.

b. The organization monitors image quality and completeness of imaging for a given indication.

c. The organization monitors redo of Imaging procedures and recalls of Reports.

d. The program addresses periodic internal/ external peer review.

e. The program addresses surveillance of imaging results with clinical correlation and follow up where ever possible.

f. The program includes a system to obtain feedback from referring colleagues.

g. There is a system of periodic review to ensure that feedback is utilized to improve services.

Standard

MQS.4. Organization Identifies And Monitors Managerial Services.

Objective Elements
a. The organization monitors utilization of space equipment, service and manpower.

b. The organization monitors TAT of reports generation.

c. The organization monitors patient waiting times.

d. The program includes a system to obtain feedback from patients and visitors on all aspects of services.
e. There is a system of periodic review to ensure that feedback is utilized to improve services.

**Standard**

| MQS.5. | The Management Ensures Patient & Staff Safety In The Organisation. |

**Objective Elements**

a. A comprehensive safety program is developed, documented and implemented throughout the organization.

b. The patient safety program includes pro-active risk assessment.

c. The program is periodically reviewed and updated at least once in a year.

d. The organization conducts regular audits for patient safety program.

e. The program addresses radiation safety of patients and attendants.

f. The program addresses risk of contrast, sedation and anaesthesia.

g. The program addresses physical safety and security of premises.

h. The program addresses the availability of patient safety devices across the organization.

i. The program addresses safety from violence, aggression and abuse.
j. The program includes reporting, analysis of adverse events ranging from 'no harm' to 'sentinel' events.

k. The program addresses Sexual harassment & POSH.
Chapter 7
Information Management System (IMS)

Summary of Standards

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<td>IMS.1.</td>
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</table>

Standards and Objective Elements

Standard

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<thead>
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<th>Description</th>
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Objective Elements

a. The Information and Information-Technology needs of the organization are identified.

b. Documented policies and procedures guide the use of Tele radiology facility as required, in a safe and secure manner.
c. The organization contributes to external databases in accordance with the law and regulations. (AERB, PC-PNDT, NABH and others).

d. The organization has an effective process for document control.

e. Documented procedures exist for storing and retrieving data.

Standards

| IMS.2. | The organization has an imaging record for every patient and it aids continuity of care. |

Objective Elements

a. Every imaging record has a unique identifier which is maintained for each patient on all subsequent visits.

b. Organization policy identifies those authorized to make entries in imaging record.

c. The mandatory contents of imaging record are identified and documented.

d. Information on the Invasive procedures performed are incorporated and the medical record contains a copy of the discharge summary duly verified by appropriate and qualified personnel.

Standards

| IMS.3. | Documented policies and procedures are in place for maintaining confidentiality, integrity and security of records, data and information. |

Objective Elements
a. Documented policies and procedures exist for maintaining confidentiality, security and integrity of records, data and information.

b. The policies and procedure(s) incorporate safeguarding of data/record against loss, destruction and tampering.

c. A documented procedure exists on how to respond to patients/physicians and other public agencies requests for access to information in the medical record in accordance with the local and national law.