Manual version 3.0 and Guidelines

Padi

CBR

Program for the Accreditation of Diagnostic Imaging Clinics

www.padi.org.br

SUMMARY

1. INTRODUCTION

For more than 20 years, the *Colégio Brasileiro de Radiologia e Diagnóstico por Imagem* (CBR, Brazilian College of Radiology and Diagnostic Imaging) has concerned itself with the accreditation of diagnostic imaging clinics. Since 1991, the CBR has been developing and updating qualification programs for the fields of mammography, ultrasonography, computed tomography (CT), and magnetic resonance imaging (MRI). The experience gained, the results obtained, and the recognition received by those programs led to the development of the *Programa de Acreditação em Diagnóstico por Imagem* (PADI,) Program for the Accreditation of Diagnostic Imaging Clinics).

In recent years, the Brazilian *Agência Nacional de Saúde Suplementar* (ANS, National Health Insurance Agency), a branch of the Brazilian National Ministry of Health, has developed norms and standards, such as the Program for the Dissemination of the Qualifications of Health Insurance Providers, established by normative resolution (NR) no. 267 (passed on August 24, 2011), and the *Programa de Monitoramento da Qualidade dos Prestadores de Serviços na Saúde Suplementar* (QUALISS, Program for Monitoring the Quality of Health Insurance Providers), established by NR no. 275 (passed on November 1, 2011), to promote quality among the providers, with a focus on the beneficiaries. The CBR accreditation program is designed to achieve those objectives. In addition, the variations among facilities in terms of their type and size, together with constant innovation and the development of new equipment, require continuous updating of the standards in order to serve patients better and ensure that the results are more accurate.

The PADI aims to encourage facilities to pursue excellence, focusing on the quality of tests and reports, as well as on patient safety. Quality improvement can be achieved through educational grants and through objective, impartial assessments by teams of trained auditors with cumulative experience in management, as well as in the areas of radiology and diagnostic imaging.

The PADI covers the evaluation of all of the steps involved in performing a diagnostic imaging test, from the test itself to the scheduling of the receipt of the report, as well as focusing on patient safety. This norm is aimed at offering ongoing training to the staff of diagnostic imaging facilities in Brazil. Therefore, the PADI was developed, with the support of partners such as the *Sociedade Brasileira de Radiologia Intervencionista e Cirurgia Endovascular* (Sobrice, Brazilian Society of Interventional Radiology and Endovascular Surgery) and the *Sociedade Brasileira Biologia Medicina Nuclear* (SBMN, Brazilian Society of Biology and Nuclear Medicine), the objective being to offer accreditation for facilities that provide diagnostic imaging and interventional radiology services.

The PADI principles and criteria were developed on the basis of best practices and minimum legal requirements. The process included the participation of and revision by radiologists representing the various methods, together with contributions of professionals working at various facilities and on the technical committees of the CBR.

This PADI manual is founded on five principles, the purpose of each of which is described, as are the criteria and checklists, where applicable. The principles can not be considered in isolation. Therefore, for the purpose of accreditation, all of the principles and criteria will be assessed, taking into account the close interaction between the processes and the patient-provider relationship.

To be exempt from any criterion considered non-applicable, the Registration Form submitted by the facility should provide the proper justification, which will be evaluated during the audit. The PADI considers a criterion to be non-applicable if it is not within of the scope of the diagnostic imaging facility to be audited.

2. OBJECTIVE

This manual aims to define the minimum criteria for accreditation of the QMS of facilities offering services related to bone densitometry, mammography, nuclear medicine, general radiology, interventional radiology, MRI, CT, and ultrasound, as well as checklists for candidate facilities, PADI auditors, and even for internal quality assurance.

3. APPLICATION

This manual applies to facilities offering services related to bone densitometry, mammography, nuclear medicine, general radiology, interventional radiology, MRI, CT, and ultrasound. The criteria can be applied to facilities of any size, regardless of the number of employees, types of tests offered, and number of tests performed. The manual applies to public, private, and philanthropic facilities that meet the eligibility requirements described in the PADI regulations.

4. GLOSSARY OF TERMS

*loss of a limb or a loss of function

Abrasso: *Associação Brasileira de Avaliação Óssea e Osteometabolismo* (Brazilian Association for the Evaluation of Bone and Bone Metabolism)

Accident: Unintended or unexpected event or occurrence that can result in injury or death; unplanned, unexpected, unwelcome event, often with adverse consequences (see also Incident)

ACLS: advanced cardiovascular life support

Adverse event: event that results in unintended harm to the patient by an act of commission or omission that is unexpected given the course of the disease or condition of the patient, including unpleasant incidents, inappropriate therapeutic approaches, iatrogenic injuries, and other adverse events directly associated with the care or services provided under the auspices of a health care facility

Anvisa: *Agência Nacional de Vigilância Sanitária* ([Brazilian] National Health Oversight Agency)

ARLS: advanced radiology life support

BLS: Basic Life Support

CBR: *Colégio Brasileiro de Radiologia e Diagnóstico por Imagem* (Brazilian College of Radiology and Diagnostic Imaging)

CFM: *Conselho Federal de Medicina* (Federal Medical Council)

Checklist: a list of recommendations provided to aid in the interpretation of the criteria, not intended to specify requirements that must be met, including examples of evidence that could meet the criteria

CNEN: *Comissão Nacional de Energia Nuclear* (National Nuclear Energy Commission)

Corrective maintenance: maintenance performed on equipment to solve a current problem related to image quality, quality control (QC), or unexpected downtime

Corrective measure: measure taken to eliminate the cause and avoid the repetition of a situation of Noncompliance or other undesirable situation Immediate measure: containment measure to correct, but not necessarily avoid the repetition of, a situation of Noncompliance

Criteria: Definitions of what should be implemented at diagnostic imaging facilities, for quality improvement and for PADI accreditation

Critical activity: activity that endangers the safety of patients, employees, visitors, or the community or activity that endangers the sustainability of the diagnostic imaging facility

Critical analysis: analysis carried out to determine the relevance, appropriateness, and effectiveness of a particular process in order to meet the stated objectives

Critical findings: Clinically important imaging findings that constitute threats to life and require urgent intervention, including diagnostic conditions that can significantly impact the life of the patient and laterality errors

Critical records: All records that are related, directly or indirectly, to patient safety: identification of patients at all stages of the process; duly signed questionnaires; traceability of the administration of medications and contrast media; traceability, by lot, of the medications and contrast media administered; deep sedation authorization form signed by the anesthesiologist, including authorization for patient discharge; discharge record for patients who underwent invasive procedures signed by the physician; report (physical or electronic) signed by the authorized professional and any changes made to that report; record of incidents; documentation by physicians and staff, including reports of critical findings; records related to calibration and QC, as well as preventive and corrective maintenance

Critical supplier (of a product or service): any supplier that impedes the functioning of the facility or provides a product or service that directly affects the execution of diagnostic imaging services

CT: computed tomography

Deep sedation/analgesia: a depressed level of consciousness, obtained through the use of medication(s), in which the patient is hardly aroused by verbal commands but responds to painful stimuli, spontaneous ventilation can be impaired and insufficient, intervention can be necessary in

order to maintain airway patency, and cardiovascular function is usually preserved, although responses to deep sedation vary from patient to patient

Disinfection: removal of the vegetative growth of infectious agents from inert surfaces

Efficacy: the extent to which planned activities are realized and planned results are achieved

Efficiency: relationship between the outcome achieved and the resources allocated

Ethics procedures: procedures aimed at ensuring that management and staff are not subject to commercial, political, or financial influences, generating conflicts of interest that could adversely affect the quality, reliability, or impartiality of their work

Febrasgo: *Federação Brasileira das Associações de Ginecologia e Obstetrícia* (Brazilian Federation of Gynecology and Obstetrics Associations)

HCFWMP: health care facility waste management plan

Incident: generally unexpected, undesirable event or occurrence; event or circumstance that might or might not lead to an unwanted or unnecessary situation; damage to or complaint by a person (see also Accident)

Individual dose limits: effective or equivalent dose values

Just culture: an atmosphere of trust in which professionals are encouraged to provide essential information related to safety and there is a clear dividing line between acceptable and unacceptable behavior within an organization that manages quality in an orderly manner, in the pursuit of continuous improvement

LMP: (date of the) last menstrual period

MEC: *Ministério da Educação e Cultura* (Ministry of Education and Culture)

Mild sedation: state, obtained through the use of medication(s), in which the patient is comfortable but responds to verbal commands, cognitive function and coordination can be impaired, and cardiovascular/respiratory function are preserved

Moderate sedation/analgesia ("conscious sedation"): a depressed level of consciousness, obtained through the use of medication(s), in which the patient responds to verbal stimuli alone or verbal stimuli accompanied by tactile stimulation, no intervention is necessary to maintain airway patency, spontaneous ventilation is sufficient, and cardiovascular function is usually adequate

MRI: magnetic resonance imaging

Near miss: situation or event that could have resulted in an accident, injury, or illness but did not, because the action was not completed, by chance, or because there was a timely intervention to prevent the occurrence

Noncompliance: not meeting a requirement

PACS: picture archiving and communication system

Policies: intentions and overall direction of an organization relating to a given topic, formally expressed by senior management

Potential noncompliance: undesirable or unexpected situation or event that has not yet occurred but could occur if preventive measures are not implemented

PPE: personal protective equipment

Preventive maintenance: maintenance carried out periodically on equipment to prevent unexpected downtime or problems in image quality

Preventive measure: measure taken to eliminate the cause of a potential situation of Noncompliance or other potentially undesirable situation—either through a change in the system/process or through an attempt to reduce the probability of an event and return to an acceptable level of risk, including any measure taken to reduce the frequency and severity of risk (related to a Near miss)

Principles: values defined to express what a diagnostic imaging facility should practice as the basis of the QMS

QC: quality control

QMS: quality management system (a set of policies and interrelated goals) (not a quality sector) that should permeate the entire organization, at all levels and processes, including all stakeholders and facilities directly or indirectly involved in the performance and delivery of services

RBC: *Rede Brasileira de Calibração* (Brazilian Calibration Network)

RDC: *Resolução de Diretoria Colegiada* ([Anvisa] Collegiate Board Resolution)

Record: document that presents the results obtained or furnishes proof of the activities performed

RIS: radiology information system

Risk: situation in which there is potential for harm but no incident has occurred; typically related to the likelihood of damage and the consequences of such damage

Root cause analysis: structured process to identify the causal or underlying factors that can contribute to the occurrence of adverse events or other critical incidents

Root cause: the main factor contributing to the occurrence of adverse events or other critical incidents

SBM: *Sociedade Brasileira de Mastologia* (Brazilian Breast Disease Society)

SBNR: *Sociedade Brasileira de Neurorradiologia Diagnóstica e Terapêutica* (Brazilian Society of Diagnostic and Therapeutic Neuroradiology)

Sedation: the use of medication(s) to make patients comfortable during the performance of medical procedures; can be classified as mild, moderate, or deep

Serious adverse event or sentinel event: unexpected occurrence involving severe physical injury*, psychological damage, death, or the risk of such

Sterilization: physical or chemical process that destroys all types of microorganisms, including those that are sporulated

SUS: *Sistema Único de Saúde* ([Brazilian] Unified Health Care System)

US: ultrasound

5. GOVERNANCE AND FINANCIAL MANAGEMENT PRACTICE

Principle: The facility is responsible for defining the policies, strategies, objectives, and goals, including a performance evaluation system, focusing on patient safety and the financial sustainability of the organization. The strategic, administrative, and financial management can meet the strategic, operational, and financial goals effectively.

5.1. Governance

Article	Criteria	Checklist
5.1.1.	The diagnostic imaging facility and its parent institution must be in good legal standing with public agencies and with the regional professional council. Prior to the audit, by the deadline specified in the current regulation, the institution must supply the PADI with copies of the following documents: location license; local Health Surveillance license; registration of the radiology and diagnostic imaging facility with the *Conselho Regional de Medicina* (CRM, Regional Council of Medicine); and registration with the National Registry of Health Care Facilities, listing the appropriate scope and function of the facility.	The corresponding documents are part of the eligibility criteria. Check that the institution has on hand the legal documents required by current law.

	Nuclear Medicine facilities must also produce the operating permit issued by the *Comissão Nacional de Energia Nuclear* (CNEN, National Nuclear Energy Commission) and the CNEN license establishing which radiopharmaceuticals the facility can acquire and in what quantities.	
5.1.2.	The diagnostic imaging facility must have a qualified attending technician, registered with the CRM, and a legally qualified alternate technician. The attending and alternate technicians must hold a specialist license issued by the CBR (for radiology and diagnostic imaging, including ultrasound) or by the Brazilian Society of Nuclear Medicine (for nuclear medicine techniques), as per CFM Resolution no. 2007/2013. In addition to the attending technician, radiology and nuclear medicine facilities must also have an attending radiation safety officer (RSO), certified by the CNEN, and an alternate RSO. The RSO should hold a specialist certificate in the physics of diagnostic radiology, issued by an entity of recognized competence in radiology or the same qualification credentials required for the technician in charge. Proof of these credentials should be sent to the PADI before the external audit within the time frame defined in the current regulations.	Check the current documents and specialist licenses of the attending and alternate technicians.
5.1.3.	The administration of the facility should define and communicate the organizational structure to all members of the organization.	Determine whether the organizational chart is up to date, has been distributed to all staff members, and reflects the true operational structure of the facility.
5.1.4.	The administration of the facility should define the vision, mission, and values of the organization, as well as the code of	Check whether the vision, mission, and values have been formally defined and communicated to stakeholders, such as

	ethics or conduct, reviewing them regularly—at least every three years, or when there is change in the organizational structure or administration. These guidelines should disseminated to all of the staff.	shareholders, employees, user groups, and other service providers, and have been systematically reviewed.
5.1.5.	The administration of the facility should define the strategic objectives, aligned with the vision, mission, and values of the organization, and conduct periodic evaluations of their performance, in order to determine whether the objectives have been achieved and the guidelines have been followed, which can inform the decision-making process.	Evaluate the defined strategic objectives and their accomplishment. Check evidence of periodic review to identify the need for adjustments or decisive action.
5.1.6.	The administration should analyze the strategic performance, operational efficiency, and financial sustainability of the facility on a timetable that meets its needs. The results of that analysis should be formalized in an action plan, registered and monitored periodically to confirm the implementation and determine the effectiveness of the measures taken. The analysis should address at least the following indicators and their respective goals: a) indicators of financial results b) patient complaint index c) patient satisfaction index d) rectification index for reports e) index of report delivery to the patient by the agreed-upon time f) contrast extravasation during intravenous infusion g) sharps injury index	Check the document that defines the indicators to be evaluated, their alignment with the strategic objectives and the periodicity of the critical analysis of their performance by the administration of the facility. Evaluate evidence: records, meeting minutes, graphical analyses (and the resulting action plan), records of measures of ongoing improvement (and verification of their effectiveness), long-term monitoring of indicators (with trend analysis), and monitoring of pending issues from previous meetings. The evaluation of the quality of tests conducted at the facility in a random sampling can be a proportion of the tests reviewed in relation to the volume of tests performed.

	h) index of situations of noncompliance, adverse events, and sentinel events, stratified by type as clinical, technical, or radiation safety situations i) results of internal and external audits j) evaluation of the quality of tests conducted at the facility in a random sampling of reports k) proportion of tests recalled, stratified by reason	
5.1.7.	The administration of the facility should provide the resources necessary to carry out its activities, in order to avoid compromising the quality, continuity of service, and patient safety, including the medical staff, technical staff, and the resources required to perform their duties in accordance with current legislation.	Evaluate the adequacy of the resources available and allocated by the facility, including those allocated to the quality management system (QMS). Determine whether the staffing, supplies, materials, medications, and equipment available are adequate to meet the demand.
5.1.8.	The administration of the facility should formally define institutional policies and monitor their implementation. At minimum, the administration should define and disclose the following: policy regarding quality assurance; patient safety policy; institutional policy of informed consent; institutional communication and information policy; human resources policy; privacy policy; supplier policy for the qualification of providers of products and services; financial policy; and trade policy.	Evidence includes the policies documented and duly approved by the administration or board of directors and the application of those policies to the processes of the facility.
5.1.9.	The administration of the facility should establish at least the mandatory minimum number of committees in accordance with current legislation, as well as other support committees, where relevant, as well as complying with the rules of each, maintaining a regular frequency of meetings and	Evidence can comprise the rules of each committee, as well as the minutes of the meetings in accordance with planned schedule to monitor the issues discussed, corrective measures or improvements and the effectiveness of the measures taken.

	keeping records of the meeting minutes in order to evaluate the topics discussed and the decision-making process for corrective measures or improvements, as well as to evaluate the effectiveness of the measures taken.	

5.2. Financial management practice

Article	Criteria	Checklist
5.2.1.	The administration of the facility, or designated responsible party, must monitor the planning and the financial indicators via a system designed to track the evolution of accounts payable and receivable.	Verify that the financial information furnishes the indicators that allow the administration to monitor the financial performance of the facility. and that financial planning is being used in order to prioritize the objectives and goals. The indicators should allow the administration to monitor the financial sustainability of the business.
5.2.2.	The facility should have a accounts payable and receivable process for the purpose of continuous collection of outstanding balances to ensure receipt of services and the payment of debts.	Check the management of accounts payable and receivable.
5.2.3.	The facility should have a process for disallowance resources with the objective of achieving a continuous reduction in disallowances by analyzing their causes and taking corrective measures.	Check for a monitoring process of disallowances with indicators and what measure and monitoring plans are made to reduce these.
	The administration of the facility, or the designated responsible party, must ensure that all services provided to the organization are regulated via contracts.	Check the contracts of service providers.

6. QUALITY MANAGEMENT

Principle: The facility manages and monitors the risks of its processes and seeks opportunities for improvement, ensuring quality and patient safety. The facility defines methods for the control of documents and quality records. The facility also evaluates and improves the effectiveness of the QMS through the use of the policy regarding quality, quality objectives, audit results, and data analysis, as well as corrective and preventive measures.

Note: Risks related to equipment, infrastructure and medications are described in specific articles.

6.1. Quality planning and documentation

Article	Criteria or requirements	Checklist
6.1.1.	The QMS must define and disseminate quality tools that support the various types of imaging and allow the use of a standardized methodology in the constant quest for improvement.	Evidence can include the following: a) quality improvement activities formally documented and managed b) action plans for corrective measures, preventive measures, adverse events, sentinel events, and improvements c) reports and instructions for the use of the tools in the daily routine of employees in the quest for improvement d) audit findings e) conduct related to patient complaints and the timeliness of their resolution
6.1.2.	The QMS must define a documented procedure regarding how to and who can prepare, approve, provide, implement, review, and manage quality documents and their different versions, ensuring that the information available is up to date and that the information from previous versions are traceable and accessible.	Evaluate the procedure that defines the flow of activities and responsibilities for the preparation and approval of quality documents, as well as how versions and updates are controlled.
6.1.3.	All critical facility activities should be described in a documented procedure, as well as being approved, implemented, and kept up to date.	Evaluate whether the critical activities are formally described, approved, updated, and implemented. Check that the release of the documents is controlled in a way that ensures that only

		the current version is available, thus preventing unauthorized access to obsolete documents. The preparation and approval of quality documents can be electronic or physical. Electronic systems must have controlled access, with individual passwords, as well as enabling data and information tracking.
6.1.4.	On every page, the quality documents must contain at least the following information: facility name, document title, version, page number, total pages, and the identification of the approving authority.	Verify that all documents contain at least the minimum information required.
6.1.5.	Documents of critical activities should be available to those involved in the described processes and the information contained therein must be updated.	Determine whether, during the execution of activities, all documents are available to all involved, in case they need to consult their own procedures, as well as whether the information in the documents is up to date and that only the latest versions are available.
6.1.6.	When the facility uses work instructions in the form of flow charts, abstracts, summaries, memos, or similar systems, the information must be extracted from an approved document and the facility must ensure that the connection between the two is traceable, with records that identify the document and the original version.	Verify compliance and traceability of work instructions with the original documents in the documentation system.
6.1.7.	The QMS should include a procedure to define the systematization of the management of records to ensure their identification, legibility, storage, access and retrieval, retention time, and disposition as defined in a documented procedure, as well as the protection of information.	Evaluate the records control procedure.
6.1.8.	Define how and for how long the records should be stored and protected, considering the following:	Identify a sample of patients seen at the facility and request the critical records involved in their care and in the provision of

	a) Current law requires that critical records be kept for a minimum of 20 years (30 years for those related to tests involving nuclear medicine). b) The facility can decide how long records that are exclusively related to management should be stored.	services. Check the legibility and accessibility of records, as well as the form in which they are filed. Records can be stored in physical or electronic forms.
6.1.9.	Changes made to critical records must allow tracking of the changes to critical information and identify the individual responsible for the changes.	If any surprising changes to a critical record appear during the audit, check how the changes can be tracked. For records in physical form, the use of "corrective" products (white-out, etc.) is not allowed.
6.1.10.	The QMS must establish that all processes with an effect on the administrative, technical, or support structure include a formalized contingency plan to ensure the continued provision of services and patient safety. The contingency plan should be tested in training sessions and deployment tests to ensure the continuity of service. Records should be kept.	Check that the contingency plan covers all processes, whether technical, support, or administrative. Also check the training records and the evaluation of the efficacy of the plan so as to ensure the continuity of service.

6.2. Risk management and patient safety

Article	Criteria or requirements	Checklist
6.2.1.	The QMS must define and disseminate a risk management methodology in order to document all significant risks to the facility, including strategic, financial, operational, and environmental risks. The methodology should also be aimed at minimizing or eliminating these risks.	Evaluate the methodology applied in each area or process audited. Seek evidence to show that the risk management of services and processes takes into account the views and needs of all stakeholders involved in the process or activity. Determine whether the risks and their management are documented, effectively managed, and include the following: a) identification of what can happen and

		how b) assessment of the degree of risk in terms of probability, consequences, and results c) assessment of how the risks can be avoided or reduced, transferred, shared/withheld, and planned for d) description of measures to be taken if the risk becomes a danger or the feared event occurs
6.2.2.	The QMS should foster the reporting of risk and of near-miss events based on transparency and just culture. Records of reporting, cause analysis, and risk treatment must be kept and managed.	Evaluate how risks are identified and recorded, as well as the treatment the staff gives to risks.
6.2.3.	The QMS must identify the individuals responsible for risk management, who should periodically assess the risks at the facility, assist in the investigation of adverse or sentinel events, train staff in the methodology and policy defined by the administration.	Check the risk management policy and the periodicity of meetings, as well as the minutes of meetings and reports related to the investigation of events.
6.2.4.	Periodically, those responsible for risk management must do the following: a) monitor risks and disseminate the results of risk management to the administration and its managers b) evaluate the effectiveness of the risk management plan to minimize the current risks and potential new risks c) review the plan with the responsible parties from each area, assessing compliance with policies, procedures, and guidelines d) assess the impact and results of efforts to improve processes and increase patient safety	It is recommended that those responsible for risk management be representatives of the various areas or processes and work independently, taking into account the confidentiality policy of the facility. Check the document that outlines the periodicity of these analyses. Review reports relating to risk management, the respective indicators or other relevant measures, performance against defined standards, and the critical analysis performed by the administration, together with how that analysis contributed to the taking of measures to improve the processes and increase

	e) communicate to stakeholders the steps taken toward improvement and the measures to deal with new risks arising from such management f) define who is responsible for communication with the patient in the event of adverse or sentinel events	patient safety. Determine whether the analysis of management has taken into consideration trends of occurrence of incidents, adverse events, and near-miss events, as well as the efficacy of education programs and communication strategies.
6.2.5.	The imaging facility must have a published protocol and a minimum staffing level, consisting of at least one radiologist, with certification in ARLS, ACLS, or BLS, or specialist physician able to treat complications such as adverse reactions to medications or contrast media, during all hours of operation. Supporting certificates of course attendance and records of the treatment of urgent and emergency cases, as well as of adverse reactions, should be maintained.	Check the protocol, records of the treatment of events, including reactions to contrast media, and that everyone knows which staff members should be called for emergencies. Verify that physicians working in the facility have at least the minimum certification in ARLS, ACLS, or BLS.
6.2.6.	Facilities that perform cardiac stress tests should have a cardiologist on staff. Facilities that administer therapeutic doses of radiopharmaceuticals with hospital admission must have nursing staff with specific training. Facilities that produce radiopharmaceuticals for their own use must have a trained pharmacist on staff. Training records must be kept up to date.	Check that, for cardiac stress tests, the cardiologist is present throughout the procedure. Check training records of the nursing staff at facilities where therapeutic doses of radiopharmaceuticals are administered. Check training records of nurses, pharmacists and the pharmacology technician in charge, all of whom must be duly registered with their regional professional council.
6.2.7.	For emergency care, facilities that conduct cardiac stress tests, tests performed under sedation, or tests requiring contrast injection must make available, on-site or in an easily accessible contiguous area, the following equipment, in good working	Check the availability of equipment, and verify that all equipment is in working order. Check equipment maintenance records, as well as the expiration dates of materials

	order: a) electrocardiograph b) wall oxygen or oxygen cylinder on a wheeled cart c) portable vacuum cleaner d) sphygmomanometer e) stethoscope f) cardiac monitoring equipment and defibrillator g) materials and medications for emergency treatment The function of all of these devices should be checked periodically, should be used only if the validity of the last decontamination has not expired, and should be decontaminated after each use. Monitoring records must be kept.	and medications.
6.2.8.	A continuing education program focusing on hand hygiene must be implemented in accordance with the protocols of the Brazilian National Ministry of Health, aimed at reducing the risk of health care-associated infection. The facility staff must act in accordance with the program.	Check training records and observe whether hand hygiene is practiced as directed by the Brazilian National Ministry of Health.
6.2.9.	The administration of the facility, or a formally designated responsible party, should establish a documented procedure to guide communication and disseminate records of potentially critical results to the physician or clinical staff. Records should be kept for contacts or contact attempts made by physicians.	Check the critical results reporting procedure, the criteria for and records of contacts or contact attempts made by the radiologist. Such records must contain the date/time, the name of the physician who made the contact or contact attempt, and the name of the individual contacted. Such records can also be included in the test report, depending on the policy defined by the diagnostic imaging facility. The criteria for potentially critical results should preferably be defined in

		collaboration with other physicians in the institution within which the diagnostic imaging facility is located. The criteria should also be based on the literature and the experience of the radiologists on staff at the facility.
6.2.10.	The diagnostic imaging facility must perform pharmacovigilance and technical surveillance, as well as investigating any adverse or sentinel event, especially those attributed to any of the following: a) treatment administered to a patient by mistake b) serious adverse events related to the use of medications, blood, equipment, or other health care products c) severe neurological or cardiovascular disorders	Check documents recording adverse or sentinel events attributed to the use of medications, contrast media, equipment, or other health care products.

6.3. Management of noncompliance, patient complaints, adverse events, and improvements

Article	Criteria or requirements	Checklist
6.3.1.	The facility must maintain channels of communication with patients and encourage the registration of positive feedback, suggestions, and complaints. The facility should encourage their staff and partners to register verbal complaints, respecting the just culture and confidentiality.	Check what channels of communication exist between patients and the facility, as well as determining whether those channels are properly disclosed.
6.3.2.	The facility must define a documented procedure for handling and registering negative patient feedback, from their receipt to their investigation and resolution, followed by a report to the patient regarding the action taken.	Evaluate the complaints received and how they are handled: whether complaints are answered in a timely manner and whether serious complaints are presented to supervisors or to the administration of the facility. Check evidence that unsatisfied patients

		received a report regarding the action taken in relation to their complaint.
6.3.3.	The facility must document the criteria for opening cases of noncompliance, whether real or and potential (near misses), and should keep records of noncompliance situations, including the immediate measure(s) taken, the results of the critical root cause analysis, the corrective measures taken to ensure that the situation does not recur, and verification of the efficacy of the measures and attributions. Records of noncompliance and potential noncompliance should be kept, as should the results of the root cause analysis; records of the corrective and preventive measures taken; and verification of the effectiveness of the measures taken.	Check documented procedures, as well as records of noncompliance situations and their management.

6.4. Audits of the QMS

Article	Criteria or requirements	Checklist
6.4.1.	The QMS must define a documented procedure that includes methodology for programming and planning of audits, their frequency, the training of auditors, and reporting guidelines.	Check the documented procedure.
6.4.2.	The QMS must include a program of periodic internal audits covering all processes. Each process should be audited at least once per year.	Determine whether the audit program covers all processes and has been completed within the period determined. It is recommended that outsourced critical services be included in the annual audit plan.
6.4.3.	The QMS should devise and disseminate an audit plan for each internal audit to be carried out, taking into consideration the status and	Determine whether the audit plan includes the audit criteria, scope, schedule, and set methodology.

	importance of the processes, as well as the results of previous audits and noncompliant processes. The audits must be performed by professional trained in an internal audit course based on the PADI norm, who can be a contract service provider. The selection of auditors and the audit process must ensure objectivity and impartiality, not requiring the auditors to audit their own process.	Evaluate the training of internal auditors. The staff of the diagnostic imaging facility must include a trained professional who can continue the necessary measures on the basis of the audit findings.
6.4.4.	The internal quality audit should result in a report containing information regarding any situation of noncompliance, observations and improvements to be made.	Review the audit report and the respective reports of noncompliance.

7. PROVISION OF SERVICES

Principle: The diagnostic imaging facility integrates the various processes and professionals involved to provide its services in a safe manner, not only for its patients, caregivers, and visitors but also for its staff and physicians. It ensures that all images are acquired according to defined protocols, based on the scientific literature. The image quality is in accordance with the current best practices and contributes to a consistent diagnosis and treatment. The reports are objective, and the diagnostic imaging facility seeks to maintain a certain standard, regardless of the imaging method employed or region of the body examined.

7.1. Management of the services provided

Article	Criteria or requirements	Checklist
7.1.1.	The facility should announce which diagnostic methods are available to patients.	Check whether the facility has made it known, by telephone, website, or other means, which types of diagnostic tests it provides.

7.1.2.	The facility should provide documents outlining its policies regarding the provision of its services, including the following: a) information and instructions to be provided to patients in relation to preparation for tests and procedures b) forms for obtaining written informed consent and documents providing information regarding post-procedure patient conduct, when applicable c) instructions and information for receptionists and clinical staff of the facility	Check the contents of the information document and instructions to patients and their forms.
7.1.3.	The facility must inform patients whether or not there is a need to schedule tests, approximately how long the patient will need to stay for the tests, and the predicted date of delivery of the test report(s).	Check for instructions on the need for scheduling or not of each type of test, and determine whether the facility provides information regarding the average time required to undergo each test, as well as on the predicted interval between the test and the availability of the report.
7.1.4.	The facility should ensure that, during the scheduling process, the patient is informed of restrictions or special instructions regarding age, gender, weight, and special needs.	Check that the instructions for tests provide information related to restrictions regarding age, gender, weight, and special needs, as well as any other restrictions related to the structure of the facility.
7.1.5.	The facility should ensure that the test requisition forms contain sufficient information to identify the patient, the referring physician, the test(s) to be performed, the respective area or organ to be examined, and the laterality, when applicable.	Make sure that the available requisition forms enable the identification of the patient, the referring physician, the test(s) ordered, and the respective area or organ being examined.

7.1.6.	The facility must provide to the patient or legal guardian information that is clearly stated, in plain language, regarding the preparation for the tests and what occurs before, during, and after each specific test, as well as regarding the administration of medications or radiopharmaceuticals and the specifics of the procedures.	There should be sufficient information to allow the patient or legal guardian to make informed decisions about the test or procedure, in order to reduce anxiety and inspire confidence.
7.1.7.	During the registration process, the facility should ask the patient to produce identification. For patients in emergency care or hospitalized patients, identifying data can be obtained from the medical charts or from family members.	Evaluate multiple cases of outpatient and inpatient care to determine how patient identity is confirmed and which documents are requested.
7.1.8.	The facility should ensure that patient registration forms contain at least the following information: a) patient identification number (preferably a unique number) generated by the facility and the identification number of each day of care b) full name, age, and gender c) full address and telephone number of the patient d) identity of the referring physician, with a contact telephone number or email, if available e) date and time of registration f) date and time of the test(s) g) test(s) ordered h) Additional information (medications used, menstrual cycle data, and clinical indication for the test) when appropriate or necessary	Evaluate multiple cases of outpatient and inpatient care to determine whether the registration form includes these items.

	i) expected date of delivery of the report j) emergency indication for the test, when applicable	
7.1.9.	The facility should have a registration process that allows the recording of the dates, times, locations, and responsible parties, by means that ensure verifiability of the following: a) test or procedure to be performed b) identification of the professional(s) who carried out the test or procedure	Check that the registration of each test or procedure generates traceable records of the test or procedure: date, time, location and responsible party.
7.1.10.	The facility should ensure that the patient has been properly prepared to undergo the required test(s) or procedure(s). If not, the facility must ensure that the patient or legal guardian, as well as the referring physician, is informed of the inadequacy of the preparation, preferably prior to the test or procedure. When performing a test without the appropriate preparation, the facility must note the lack of patient preparation in the report in order to allow the correct interpretation of the results.	Determine whether there is a way to check the preparations prior to the test and to add a note in the report when the test preparations are inadequate. Verify reports of test procedures performed in patients with restraint and the records of those responsible for their release. The policy regarding performing a test without the appropriate preparation is the responsibility of each facility.
7.1.11.	The facility must provide the patient with a proof of service that contains at least the following: a) full name of the patient b) patient registration number c) date of the test or procedure d) name of the test(s) performed	Inspect the items that make up the proof of service.

	e) expected date of delivery of the report(s)	
7.1.12.	The facility should ensure that patients are treated with respect in all contacts with the facility, actively promoting privacy, dignity, patient safety, and deference to patient preferences. Special attention should be paid to differences in culture, religion, age, and other factors, with reference to current legislation.	Verify that the process encourages the staff to be welcoming to, with discretion and respect for, patients and their representatives, ensuring the privacy, dignity, and safety of the patients, with respect for their preferences.
7.1.13.	For certain tests (those involving the administration of contrast media, medications, or radioisotopes; biopsies; procedures requiring anesthesia; invasive procedures; and other procedures that carry some risk) as well as for teaching or research purposes, the facility should ensure that patients (or their legal guardians in case of minors or patients with special needs) give written informed consent. The completed informed consent forms should be kept on file.	Check the informed consent records, how are applied to patients or legal guardians, and how they are stored.
7.1.14.	All female patients of reproductive age should be screened, with a questionnaire or in an interview, regarding their pregnancy status before undergoing any imaging study involving the use of radiation or a magnetic field. A pre-test mammography questionnaire should contain information on the purpose of the test (screening or diagnosis), as well as collecting data on the family or personal history or breast cancer and hormonal status (LMP or	Check questionnaires for the entry "pregnancy/LMP", as well as for a history of disease and medication use, when applicable.

	menopause). A pre-test bone densitometry questionnaire should contain information on the purpose of the test (screening or subsequent control), as well as collecting data on the use of medications that might be associated with reduced bone mass (such as glucocorticoids), diseases that might be associated with low bone mass or bone loss, and pharmacological treatment for osteoporosis. Records should be kept.	
7.1.15.	The facility should ensure formal referral and counter-referral for receiving outpatients or inpatients from other facilities, for the purpose of performing test(s) or referring patients for further care. The same procedure applies to patients, caregivers, visitors, or professionals that experience a change in health status while on the premises of the facility.	Check contracts and procedures that define the process and identify the party responsible for the contact with and approval to receive patients from other facilities to undergo tests, as well for referring patients to other facilities after those tests.
7.1.16.	In the event of a biopsy or the collection of a biological sample for testing, the facility must ensure the proper use of containers and preservatives, and indelible marking of the samples at the time of collection, with at least the following data: a) full name of the patient b) case number c) sample collection date d) name of the diagnostic imaging facility Samples should be sent to the laboratory in a timely and appropriate manner, to ensure their stability.	Check the flow of samples, identification, transport, and control records.

	Routing control records must be kept.	

7.2. Analytical quality management (execution of the tests)

A – General requirements

Article	Criteria or requirements	Checklist
7.2.1.	Before the tests, the facility must ensure the correct identification of each patient, the collection of the completed informed consent form, and the taking of a new history for the identification of any relevant condition that might contraindicate the test, including claustrophobia, the metal artifacts, and implants, all of which could constitute contraindications to MRI. In case of the need for invasive procedures that require the administration of medications, contrast media, or radiopharmaceuticals, the facility must evaluate the patient history of allergy, anticoagulant use, cardiac conditions requiring antibiotic prophylaxis, and renal failure.	Check the process of identification and traceability of the patient, as well as that of the collection of information relevant to patient safety and execution of the test. Check the history questionnaires as they are filled out, as well as the history taken face-to-face with the patient. Verify that the questionnaire includes specific questions about the use of metals in patients scheduled to undergo MRI.
7.2.2.	The facility must ensure the correct identification of each patient, in each test or procedure, as well as that the patient identification is interfaced with the system of care, either manually or electronically, and that laterality is noted, when applicable.	Check the process of identification and traceability of the patient at all stages of care.
7.2.3.	The facility should have protocols for diagnostic image acquisition and for therapeutic services, when applicable, for each modality. In the case of CT and MRI, such protocols should follow the CBR minimum guidelines. In the case of densitometry, the protocol should follow the guidelines established by the *Associação Brasileira de Avaliação*	Check the institutional protocols for each diagnostic modality.

	Óssea e Osteometabolismo (Abrasso, Brazilian Association for the Evaluation of Bone and Bone Metabolism).	
7.2.4.	Materials, medications, psychotropic substances (for sedation), and contrast media should be properly stored, in a controlled environment when recommended by the manufacturer, and identified. Their use must be controlled. The following information must be traceable: prescription records; name of the prescribing physician; the CRM registration number and signature of the professional in charge; the name of the staff member who administered the substance; and the corresponding lot number. Expiration dates must be respected.	Check the expiration dates of materials, medications, and contrast media available for use, as well as the conditions in which they are stored, together with the records related to their prescription and administration.
7.2.5.	There must be a clear description of the indications and contraindications for the use of contrast. In the case of contraindications, explanations must be given to the patient and family, if present, and there must be a record of that. The final report must also include any information regarding contraindications.	Check the protocols with the indications for the use of contrast in each type of test. Check the contraindication records. It is recommended that a comment on this aspect be included in the report.
7.2.6.	For collective-use contrast media there must be proof of safety and that there is no contamination, in accordance with the manufacturer's criteria.	Check injection pumps and tubing connectors, which must have safety certificates and be free of contamination.
7.2.7.	The facility shall submit to the PADI, prior to each audit, images and reports, electronically (conforming to the Digital Imaging and Communications in Medicine standard) or by mail (on compact disc), in accordance with the Submission of Images and Reports appendix to this manual. The names of patients should be anonymized.	Check the results of the analysis made by the CBR Technical Committees.

	The PADI predetermines the deadline for delivering the audit findings. The images will be submitted to the CBR Technical Committees, which will analyze them on the basis of the current appendices and guidelines.	
7.2.8.	All images must include the following items for proper identification: a) full name of the patient b) case registration number or patient identification number c) name of the institution d) gender of the patient e) age and date of birth f) date of the test g) laterality, if applicable h) abbreviation of the incidence (for breast examinations) i) kVp and mAs (in tomography documentation)	Check how images are identified and include at least the items described in this requirement (7.2.8.) For tomography, it is recommended that the documentation contains dose report (readable), provided that the device provide this data.

B – Tests and procedures performed under sedation

Article	Criteria or requirements	Checklist
7.2.9.	The physical environment must be suitable for tests performed under anesthesia, with an induction room and a recovery room (or one room used for both purposes).	Check induction/recovery room(s).
7.2.10.	The induction room should have a gas output to feed the ventilator, a source of supplemental oxygen, and a vacuum suction port or a vacuum cleaner on a wheeled cart.	Check induction/recovery room(s).

7.2.11.	For procedures performed under deep sedation, it is expected that an anesthesiologist will be present throughout the procedure and discharge should be given formally by the anesthesiologist. Records of the anesthesia procedure(s) should be kept. For procedures performed under moderate or mild sedation, the radiologist must assess the need for the presence of the anesthesiologist on the basis of the level of risk to the safety of the patient.	Check the care received by patients under anesthesia and the respective records.
7.2.12.	In the case of MRI, the room must contain a mechanical ventilation cart compatible with the magnetic field, in case deep sedation is required.	Check the mechanical ventilation cart and its compatibility with the MRI equipment.
7.2.13.	For procedures requiring any kind of sedation, there should be a vital signs monitor in the room. For MRI scans, the vital signs monitor must be compatible with the magnetic field environment.	Check whether the appropriate equipment is in place and is compatible with the MRI equipment, when applicable.

C – Bone densitometry

Facilities accredited by the PADI in the area of bone densitometry should be evaluated by qualified professionals on the basis of the calibration controls, the quality of the devices, and the quality of the reports.

Facilities that have received quality certification from the Abrasso Program for Quality in Densitometry (ProQuaD) will be exempt from the PADI phase that involves analyzing densitometry images and reports.

Article	Criteria or requirements	Checklist
7.2.14.	The QC program for densitometry equipment must comply with the manufacturer's recommendations for	Check the QC records.

	system maintenance. If not listed in the manufacturer's protocol, the following procedures are recommended, in accordance with the 2007 Official Position of the International Society for Clinical Densitometry (ISCD) or other directive that the CBR or Abrasso publishes: a) Scans of phantoms should be performed at least once a week. b) The results of scans of phantoms and calibration should be plotted graphically and analyzed. c) The average bone density of the phantom should be determined only after the completion of any technical maintenance performed on the densitometer. d) Corrective measures should involve the use of cut-off points to serve to "trigger" the specialized technical maintenance. e) Records of corrective measures and maintenance records should be kept up to date.	
7.2.15.	Evaluations of the precision of densitometry equipment should comply with the regulations of the 2007 ISCD Official Position or other directive that the CBR or Abrasso publishes: a) For each densitometer, the precision error and least significant change (LCS) should be calculated. b) The precision error provided by the manufacturer should not be used. c) If a densitometer has more than one technician, an average precision error, combining data from all technicians, should be	Check analyses of the precision of the densitometer, their frequency, and records.

	used in order to establish the precision error and LCS for said apparatus, assuming that the precision error for each technician is within the acceptable range of performance. d) Each technician must carry out the *in vivo* assessment of precision using a group of patients that is representative of the current patient population of the facility. e) Each technician must perform a full evaluation of precision after learning basic acquisition skills (such as in training sessions offered by the manufacturer) and after performing scans of approximately 100 patients. f) A new precision assessment should be performed every two years and whenever a new densitometry system is installed, software is updated, or generation/detection components are replaced. g) A new precision assessment should be done whenever the skill level of the technician changes.	
7.2.16.	For each densitometry system, cross-calibration (acquisition of 10 phantom measurements) should be performed every time any of the following occur: a) a hardware change b) replacement of the densitometer with another of the same make and model	Check the records of the cross-calibrations.
7.2.17.	When there is complete substitution of	Check the records of the cross-calibrations.

	the densitometry system for another from the same manufacturer that uses a different technology or for another from a different manufacturer, the cross-calibration should be performed in accordance with the Abrasso guidelines.	

D – Mammography

Facilities accredited by the PADI in the area of mammography should be evaluated on the basis of the qualifications of their medical staff and their safety policy, as well as the quality of their images and reports.

Facilities that have obtained the CBR Seal of Quality in Mammography will be exempt from the PADI phase that involves analyzing mammography images and reports, as described in the PADI Regulations.

Article	Criteria or requirements	Checklist
7.2.18.	Facilities that perform mammography must meet the quality requirements set forth in Ordinances MS/SVS no. 453 (issued jointly by the Brazilian National Ministry of Health and Department of Health Surveillance, 06/01/1998) and MS/GM no. 2898 (issued by the Brazilian National Ministry of Health, Cabinet of the Minister, 11/28/2013) or in any other legislation that might supersede those.	Check the equipment QC records.
7.2.19.	During a mammogram, the breast must be compressed in order to reduce the effects of overlapping of the breast tissues. The compression force should be approximately 11– 18 kgf, need to be documented in QC. Should not be left any image artifact during compression of the breast, for example, bending the skin tissue.	Check this item for mammograms performed at the facility.
7.2.20.	In the test routine, the automatic control device should be used in order to establish the level of exposure of the	Check this item in mammograms performed at the facility.

	breast to X-rays, so that the images show a grayscale range that allows good differentiation of mammary tissues.	
7.2.21.	To verify the quality of mammography equipment, QC testing provided for by applicable legislation should be performed, at least at the following intervals: A. Daily: test of film characteristics, with a sensitometric strip B. Monthly: simulation imaging study in accordance with the American College of Radiology guidelines C. Semiannually: a) accuracy test of the collimation system b) chassis integrity and touch screen/film testing c) check of the condition of their X-ray illuminator d) alculation of the mammogram rejection index D. Annually: a) accuracy test of the tube voltage indicator b) reproducibility test of the tube voltage c) accuracy test of the exposure time d) reproducibility test of the exposure time e) reproducibility test of the exposure f) test of the half-value layer g) linearity test of the air kerma (in mAs) h) reproducibility test of the	Check the list of QC tests provided for in current legislation, as well as the records of the results. Verify that the test results are within the tolerance limits.

	automatic exposure system i) determination of the focal point size j) integrity testing of accessories and personal protective equipment (PPE) k) test of the light-tightness of the darkroom l) test of the compressive force m) test of the compression plate alignment E. Biennially: entrance surface dose (skin dose) Records should be kept.	
7.2.22.	in the case of mammography equipment that uses technologies for which QC tests have not been established by law, facilities should make an exception to the norm and should carry out the tests recommended by the manufacturers of such equipment.	Check the QC testing protocols provided by the manufacturers, as well as the records of the results and the measures taken.

E – Nuclear medicine

Facilities accredited by the PADI in the area of nuclear medicine should be evaluated on the basis of the qualifications of their medical staff and their safety policy, as well as the quality of their images and reports.

Article	Criteria	Checklist
7.2.23.	Radiopharmaceuticals prepared for parenteral use must be used within 48 (forty-eight) hours, counted from the beginning of the preparation process to the end of the administration, or as directed by the manufacturer. There should be written instructions on	Check instructions on how to ensure the identification, integrity, quality, and effectiveness of the radiopharmaceutical, as well as its storage, and evaluate the traceability of the validity of the prepared radiopharmaceutical.

	how to ensure the identification, integrity, quality, and effectiveness of the radiopharmaceutical. Radiopharmaceuticals should be stored separately in an exclusive location. Products for preparation and the prepared products should both be inspected in terms of their physical integrity and color, as well as for the presence of foreign bodies, which would invalidate its use, even within the period of validity. Radiopharmaceuticals prepared for parenteral use in a period exceeding 48 (forty-eight) hours, from the beginning of the preparation process to the end of the administration, must meet the requirements of Anvisa RDC no. 67/07 or other that may supersede it.	
7.2.24.	The technical responsibility for the preparation and administration of radiopharmaceuticals should be that of professionals with advanced training in health care, registered with the relevant professional council, and possessing the necessary professional skills as defined by current law.	Check the qualifications and training of the professional responsible for the preparation and administration of radiopharmaceuticals.
7.2.25.	To ensure traceability, at least the following data should be recorded: a) serial number of each of the products used in the preparation of radiopharmaceuticals b) manufacturer name(s) c) lot number(s) d) patient name e) activity of the radiopharmaceutical f) date and party responsible for the	Check the traceability of the data described in this article.

	preparation g) date and party responsible for the preparation and administration Records should be kept.	
7.2.26.	The bottles prepared for optimization of doses and their respective shields must have labels showing at least the following information: a) name of the radiopharmaceutical b) date and time of preparation c) level of radioactivity d) volume e) professional responsible for the preparation f) expiration date	Check the identification labels on the prepared bottles and determine whether they contain the data described in this article.
7.2.27.	Radiopharmaceuticals should be transported in shielded containers, as established in the radiation safety plan.	Check how the radiopharmaceuticals are transported.
7.2.28.	The labeling of leukocytes for reinjection must be done in a class II, type A biosafety cabinet and must meet the radiation safety requirements described in the radiation safety plan.	
7.2.29.	Before a radiopharmaceutical is administered, the following must be checked: the identification of the patient; the radiopharmaceutical to be administered; and its level of radioactivity.	
7.2.30.	The facility must evaluate the quality of the generator eluate and of the radiopharmaceuticals in accordance with manufacturers' recommendations, scientific evidence, or current law.	
7.2.31.	The facility should calibrate the dose to be administered to the patient and should test the dose calibrator as	Check QC records of the dose calibrator testing.

	follows (or according to current law): A. Daily tests: a) repeatability, measures to be reproducible to ±5% (five percent) b) zero adjustment c) background radiation, measures to be reproducible to within 20% (twenty percent) d) high voltage, measures to be reproducible to within 1% (one percent) B. Semiannual tests: a) accuracy, measures to be reproducible to within 10% (ten percent) b) reproducibility, measures to be reproducible to within 5% (five percent) c) Linearity and the measures to be reproducible within ± 10% (ten percent) C. Annual tests: a) test of the dose calibrator measurement geometry Records must be kept.	
7.2.32.	The facility should test the quality of the scintillation camera as follows (or according to current law): A. Daily tests: a) visual inspection of the physical integrity of the system b) intrinsic or extrinsic uniformity, or both, of the differential and integral fields (if the equipment has that function) for low counts c) background radiation in the	Check the QC records for tests of the scintillation camera.

	examination room d) centralization and width of the energy window for each radionuclide B. Monthly tests: a) the intrinsic integral and differential uniformity (if the equipment has that function) for high counts b) Resolution and spatial linearity c) center of rotation of the single-photon emission CT (SPECT) camera C. Semiannual tests: a) energy resolution b) spatial resolution for multiple energy sources, when applicable c) spatial co-registration of images to multiple energy sources, when applicable d) sensitivity e) maximum count rate f) check for defects in the angle of the holes of all collimators g) speed of the examination table in a total body scan h) integral and differential uniformity (if the equipment has that function) of the system for all collimators in use i) overall performance of the SPECT camera Records must be kept.	
7.2.33.	The facility must carry out QC of positron emission tomography, as	Check the QC registers for positron emission tomography.

	follows (or according to current law): A. Daily tests: a) visual inspection of the physical integrity of the system b) check of the sensitivity per line of response and adjustment of the standardization of the detectors, also known as a blank scan B. Monthly tests: a) system calibration check C. Quarterly tests: a) sensitivity and calibration of the system D. Semiannual tests: a) energy resolution b) spatial resolution in the transverse and axial directions c) change in detection sensitivity with volume E. Annual tests: a) uniformity b) width of the temporal coincidence window c) slice thickness d) count rate (also known as noise equivalent count rate) e) overall performance with a specific simulator f) mechanical parts of the equipment Records should be kept.	
7.2.34.	When using the images produced by positron emission tomography combined with CT scans, for radiotherapy planning, the facility should follow the criteria for simulators	Check the records for the simulator tests.

	established in Anvisa RDC no. 20/06 or other legislation that might supersede it.	

F – Radiology

Facilities accredited by the PADI in the area of radiology should be evaluated on the basis of the qualifications of their medical staff and their safety policy, as well as the quality of their images and reports.

Article	Criteria	Checklist
7.2.35.	The QC of radiographic tests must follow the guidelines of Federal Ordinance no. 453/98 and the 2005 Anvisa manual entitled Diagnostic Radiology: Equipment Performance and Security, or any applicable law or guideline that might supersede them. Records should be kept.	Check the equipment QC records.

G – Magnetic resonance

Facilities accredited by the PADI in the area of magnetic resonance should be evaluated on the basis of the qualifications of their medical staff and their safety policy, as well as the quality of their images and reports.

Facilities that have obtained the CBR Seal of Quality in Magnetic Resonance will be exempt from the PADI phase that involves analyzing magnetic resonance images and reports, as described in the PADI Regulations.

Article	Criteria	Checklist
7.2.36.	Helium levels should be monitored at least once a day.	Check records of helium level monitoring.
7.2.37.	During preventive maintenance, QC of the MRI apparatus should be performed, in accordance with the manufacturer's suggestions.	Check the records of preventive maintenance.

7.2.38.	There must be a written safety policy related to the magnetic field, containing absolute and relative contraindications.	Check the safety protocol and contraindications of the facility.
7.2.39.	All patients should be provided with hearing protection during MRI scans.	Check the use of hearing protection.

H – CT

Facilities accredited by the PADI in the area of CT should be evaluated on the basis of the qualifications of their medical staff and their safety policy, as well as the quality of their images and reports.

Facilities that have obtained the CBR Seal of Quality in Computed Tomography will be exempt from the PADI phase that involves analyzing CT images and reports, as described in the PADI Regulations.

Article	Criteria	Checklist
7.2.40.	There should be an annual QC analysis of CT devices, using phantoms, conducted by a physicist (accuracy of the parameters used in the acquisition and of the dosimetry reported by the device, as well as the alignment of lasers, etc.) Less complex analyses should be made on a quarterly basis or during preventive maintenance by the manufacturer. A physician, a physicist, or biomedical/designer can be responsible for this quarterly control. The frequency and test results must be recorded. Records of the analysis of unsatisfactory results should be kept, as should records of the necessary corrective or preventive measures, and the efficacy of the measures taken should be determined.	Check the QC records.

I – Ultrasound

Facilities accredited by the PADI in the area of ultrasound should be evaluated on the basis of the qualifications of their medical staff and their safety policy, as well as the quality of their images and reports.

Facilities that have obtained the CBR Seal of Quality in Ultrasound will be exempt from the PADI phase that involves analyzing ultrasound images and reports, as described in the PADI Regulations.

Article	Criteria	Checklist
7.2.41.	The QC of the ultrasound equipment should be performed at least every six months, when phantoms are available, as should the necessary calibrations.	Check the QC records.
7.2.42.	At least one piece of MRI equipment available at the facility must have three transducers (linear, convex, and endocavitary), with the capacity to perform color and spectral Doppler ultrasound.	Check the availability of equipment.
7.2.43.	There should be a written policy for the cleaning of the transducer between tests. For intracavitary tests, there should be a written policy for the use of protective barriers.	Check the procedures. Check how the transducers are cleaned. Check the use of protective barriers for intracavitary tests. It is recommended that gloves be used, and that a new pair of gloves be used each test. Gloves should be put on in front of the patient, for safety.

7.3. Management of the post-test analysis and reporting process

A – General requirements

Article	Criteria or requirements	Checklist
7.3.1	The ultrasound report must contain at least the following information: a) name and surname of the patient	Verify that the reports include this information.

Updated	b) date of birth c) registration number d) name and registration number of the institution e) Name and CRM registration number of the referring physician f) Date of the test g) Name and CRM registration number of the technician responsible for ultrasound imaging services h) Type of test and laterality, when applicable i) Name and CRM registration number of the physician who made the report	It is recommended when available, the report stated that the test of the subject (medical request).
7.3.2.	A summary of the techniques used for the test should be included in the report, highlighting whether or not contrast was used. While there technical problems, problems in patient preparation, or patient refusal, such problems should be reported.	Verify that the reports include this information. It is recommended that this information be provided in the report for tests performed under sedation.
7.3.3.	The body of the report (analysis), must include the following: a) the normal findings described in the body of the report b) the deviations from normality in the body of the report, especially those that can influence the therapeutic success or the diagnosis hypothesis provided in the test request	Verify that the reports include this information. It is recommended that all reports have a conclusion (final opinion), where only the main findings should be reported. Can be used prominent mechanisms such as italic, underline, bold, color, combined or not. In the report, recommendations can be made regarding the methods that could complement the diagnostic investigation, whether part of a clinical/biochemical evaluation or of another modality, radiological or not. The decision as to whether or not to make such recommendations rests with the diagnostic imaging facility.

7.3.4.	Whenever possible, a comparative evaluation with available prior tests should be performed. If that is not possible, it is recommended that the reason be mentioned.	Verify that the reports include this information. It should be stressed that reports in Response Evaluation Criteria in Solid Tumors (RECIST) format are valid only for solid tumors.
7.3.5.	In cases requiring the issue of an interim report, in which the report will be confirmed by a second professional (for facilities where there are double readings by experts), the fact that it is an interim report and will be reviewed by another expert should be stated and highlighted. Disagreements by the second signatory that result in a change in practice should immediately be reported to the physician responsible for the patient and should be noted in the report. Records of such communication and of the rectification of the report must be kept on file.	Check the records of communication with the physician in charge and of the rectification of the report.
7.3.6.	When a report must be altered after having been made available (in physical or electronic form) to the patient and the physician, the facility must specify the findings that have been modified. The original report should be filed in a secure and traceable way, preventing its subsequent printing. Records of changes and notifications must be kept. Records of noncompliance should also be kept for each rectification.	Check the change logs and notifications of rectified reports and the respective records of noncompliance. Check the security and traceability of the original and rectified reports.
7.3.7.	For all cases in which there are critical findings, whether related to severity or unexpected findings, in accordance with the CBR guidelines, the facility should have a systematic process for contact	In the event of critical findings, check the records of communication with the referring physician.

	with the referring physician. Records of such contact should be tracked. We recommend their inclusion in the report.	
7.3.8.	Reports of invasive procedures must contain at least the following information: a) identification of the facility, age of the patient, and date of the test b) brief clinical history (reason for the test) c) Description of the procedure and the possible complications d) Name and signature of the interpreting physician	Check radiographic reports. It is also recommended that a supplementary report be issued after the pathology report has been received, in order to check the concordance between the two.
7.3.9.	The QMS should include a systematic, documented procedure to assess the quality of the reports issued by the facility, as well as corrective and preventive measures to improve that quality. Records of the evaluations should be maintained.	Check the records of the QC evaluation of reports.

B – Bone densitometry

Article	Criteria or requirements	Checklist
7.3.10.	The reports of bone densitometry tests must follow the guidelines established in the 2007 Official Position of the Brazilian Society of Bone Densitometry (now Abrasso) or any new Abrasso or CBR guidelines that might supersede them.	Determine whether these reports are in keeping with the guidelines cited.

C – Mammography

Article	Criteria or requirements	Checklist
7.3.11.	Mammograms should be read in of the following ways: a) on a light box (for tests that do not use digital technology) b) on high-resolution monitors (minimum 3 megapixels) for tests using digital technology	Check the mode of presentation of images for the reading of the test.
7.3.12.	The mammogram report should use the Breast Imaging Reporting and Data System® (BI-RADS®) and should contain the following information: a) identification of the facility, age of the patient, and date of the test b) the system used (conventional radiography, digital computed radiography, or direct digital radiography) c) number of films or images d) brief clinical history (if a screening or diagnostic test) e) description of the test, comparison with previous results, classification, and recommended courses of action f) Name and signature of the interpreting physician	Check radiographic reports. Exception to the norm for the facilities they provide SUS using the compulsory system of report directed by the Brazilian National Ministry of Health—*Sistema de Informação do Câncer* (SISCAN, Cancer Database) or other that may supersede it.
7.3.13.	The report of the preoperative markup procedure must contain the following information: a) identification of the facility, age of the patient, and date of the test b) brief clinical history (reason for the test)	Check radiographic reports.

	c) description of the procedure, including information on the location and size of the lesion, distance between the lesion and the skin/nipple, and possible complications d) name and signature of interpreting physician	

8. DIAGNOSTIC SUPPORT FACILITIES

Principle: Diagnostic imaging facilities work with qualified professionals who have been trained in their functions and ensures that the infrastructure and training are sufficient to preserve the safety of the staff, patients, caregivers, and visitors.

Such facilities define, qualify, and monitor third-party providers on the basis of the principles of empowerment and quality, while ensuring ongoing maintenance of testing procedures, with an up-to-date technology park, and that the QC and maintenance protocols are followed.

Diagnostic imaging facilities also ensures the security and traceability of information (on physical or electronic media) in a consistent manner.

Such facilities ensure proper hygiene in and cleanliness of the environment, as well as the provision of medical/hospital supplies in working condition and the maintenance of clothing (uniforms) in hygienic and good general conditions.

8.1. Management of human resources and occupational safety

Article	Criteria	Checklist
8.1.1.	The staff of the facility (physicians, technicians, and administrative staff) should be adequate to fill the facility schedule and meet the demand for diagnostic imaging services, as well as being scaled to the complexity and profile of the facility.	Evaluate the human resource planning considering the number of employees and independent professionals needed and the different specialties and functions relevant to the services to be provided.
8.1.2.	The human resources policy should define the minimum necessary procedures to ensure training and compliance with current legislation related to the staff: a) For all positions (including administrative positions), the responsibilities, powers, and	Check job descriptions and functions and their qualification record, experience, capacity building and training of enrollment on the professional regional council, regardless of employment (including management positions, employees, independent professionals, volunteers, etc.)

	functions must be clearly defined and documented in a job description or similar document, regardless of the type of position (affiliated or unaffiliated). b) The skills set/credentials defined must be detailed in a document listing the minimum qualifications, experience, skills training, and regional professional council registration, when applicable, required for the position c) All employees, regardless of status (affiliated or unaffiliated) must have a work contract with the facility Records of employee qualifications, experience, training, and professional regional council registration should be kept on file, as should formal work contracts.	The job description can be used to assist in the selection of new staff members and can facilitate performance evaluations. The description should mention to which position in the organization chart it refers.
8.1.3.	For the positions of technical director, medical supervisor, medical coordinator, head of medicine, and head of diagnostic imaging services, a medical specialist degree is mandatory. Professionals must hold the title of specialist or be certified in the area of interest by the CBR or by the Brazilian Society of Nuclear Medicine (for nuclear medicine physicians). Records should be kept.	Check with the respective CRM to confirm the registration of the title of specialist or certification in the area of interest.
8.1.4.	Biomedical technicians, radiology technicians, nuclear medicine physicians, and technology specialists must possess credentials issued by their respective regional professional councils. All such professionals should provide evidence of their capacity to perform	For staff working in each area, check the titles of specialist and registration with the respective regional professional councils. Check the records and certificates of training in the performance of specific tests.

	specific tests.	
8.1.5.	All physicians who work in the various sectors of diagnostic imaging at the facility and issue reports must have completed their residency in a radiology and diagnostic imaging program recognized by the *Ministério da Educação e Cultura* (MEC, Ministry of Education and Culture) or hold the title of Specialist in Radiology and Diagnostic Imaging. Exceptions: a) Specialists in Neurology or Neurosurgery who perform diagnostic imaging tests must be certified jointly by the CBR and the *Sociedade Brasileira de Neurorradiologia Diagnóstica e Terapêutica* (SBNR, Brazilian Society of Diagnostic and Therapeutic Neuroradiology). b) Cardiologists who perform exclusively cardiac MRI and coronary CT angiography tests must provide documented evidence of their capacity to exercise activities in the MRI and CT sectors, including the reports (type of training, length of training, and internship or residency). c) Physicians specializing in breast disease or gynecology must hold a Field of Work Certificate in Mammography, which is issued jointly by the CBR and the *Sociedade Brasileira de Mastologia* (SBM, Brazilian Breast Disease Society) and the *Federação Brasileira das Associações de Ginecologia e Obstetrícia* (Febrasgo, Brazilian Federation of Gynecology and Obstetrics Associations). Documented evidence must be presented. d) Physicians who perform ultrasound tests must produce documented evidence of their capacity to exercise	Verify the titles and certifications.

	such activities: a field of work certificate in ultrasound issued or recognized by the CBR; or proof of residency in a radiology and diagnostic imaging program recognized by the MEC. e) Professionals who work in the bone densitometry sector of the facility, if not radiologists, must have been issued a Field of Work Certificate in Densitometry issued by the CBR/Abrasso.	
8.1.6.	Foreign physicians need to have their diploma validated by the CFM and to provide evidence that they are able to carry out activities in their respective sectors of diagnostic imaging.	Check the validity of qualifications and evidence of training in radiology.
8.1.7.	The facility should offer a continuing education program for the technical, medical, and administrative staff, comprising the following: a) integration program b) training in biosafety, including the Radiation Safety Plan c) periodic training in the form of refresher courses d) supplemental training whenever a new protocol or new piece of equipment is incorporated e) encouragement for the technical, administrative, and medical staff to attend conferences, congresses, and off-site refresher courses Training records should be kept up to date.	Check the record and frequency of continuing education, as well as determining whether supplemental training is provided for each new protocol or new piece of equipment incorporated. Check certificates of participation in seminars, conferences, and refresher courses.
8.1.8.	The facility should have a confidentiality policy for all those who have access to facility and patient information, requiring that they obtain documented consent from all interested parties before	Check that all employees sign a confidentiality agreement and understand its importance.

	divulging any such information.	
8.1.9.	The administration of the facility should have a program to evaluate staff performance on their assigned tasks, with a defined periodicity, depending on the specific needs of the facility.	Check the scheduling and records of staff performance/competence evaluations.
8.1.10.	The facility must ensure the safekeeping of staff records for a period designated by law, regardless of their employment status, as well as ensuring that only authorized persons have access to such data.	Check for staff records, their content, and the criteria for gaining access to such documents.
8.1.11.	The facility must ensure the employee ombudsman who will turn the institution, whether they have resigned or have been dismissed, focusing on improving processes and internal communication.	Check for exit interview records or questionnaires and for records of measures taken (after the reported events) in order to improve the processes or human resources management.
8.1.12.	The facility must ensure compliance with all current legislation with regard to occupational safety, including analysis of occupational hazards, occupational health care, and control of radiation exposure. Normal occupational exposure of each individual must be controlled so as not to exceed the limits set forth in Resolution CNEN no. 12/88 or other legislation that might supersede it.	Verify compliance of the respective programs: the *Programa de Controle Médico e Saúde Ocupacional* (PCMSO, Medical Control and Occupational Health Program); the *Laudo Técnico de Condições Ambientais de Trabalho* (LTCAT, Environmental Working Conditions Technical Report); the *Programa de Prevenção de Riscos Ambientais* (PPRA, Environmental Risk Prevention Program); *Perfis Profissiográficos Previdenciários* (PPP, Graphic Professional Pension Profiles); *Programa de Proteção Radiológica* (PPR, Radiation Safety Program); vaccination control; dosimetry control; risk maps; occupational accident communications; records of accidents/incidents and the respective corrective measures; records of staff training in safety and use of appropriate PPE and collective protective equipment.
8.1.13.	During their workday and while in a controlled area, Every individual who works with diagnostic X-ray should use	Verify the proper use of the dosimeter and the monitoring of individual dosimetry.

	an indirect-reading individual dosimeter, positioned at the most exposed region of the torso and changed monthly. This should also apply to physicians who work at the facility. During the use of a lead apron, the personal dosimeter should be placed on the apron, and a correction factor of 1/10 should be applied in order to estimate the effective dose. While the user is absent, the individual dosimeters should be stored in a secure location, with mild temperatures, low humidity and away from sources of ionizing radiation, together with the standard dosimeter, under the supervision of the RSO.	
8.1.14.	For doses higher than that defined as safe by law, the possible causes should be investigated and corrective measures should be taken to prevent the recurrence of such unwanted exposure.	Check the results of dosimetry and the records of the investigation of cases of unwanted exposure.
8.1.15.	Records of administrative controls concerning radiation safety for occupationally exposed individuals must be kept for thirty (30) years, counted from the time the individual ceases to work with radionuclides, or for a minimum of five (5) years after the death of an exposed worker.	Check the availability of records.

8.2 Management of the procurement of equipment, products, and services

Article	Criteria	Checklist
8.2.1.	The administration of the facility, or a formally designated responsible party, should ensure the availability of the goods and services needed in order to maintain uninterrupted provision of	Check the process of procuring equipment, PPE, disposables, and other supplies, as well as inventory management.

	diagnostic imaging services at the facility, thus ensuring inventory control.	
8.2.2.	All products purchased must be regularized with Anvisa and the Brazilian National Ministry of Health, in accordance with current law.	Check the Anvisa records of the inputs purchased.
8.2.3.	The QMS must ensure that all supplies, materials, and medications are inspected on receipt and meet the specified purchase requirements.	Check the criteria and records related to the receipt and inspection of products.
8.2.4.	Inputs, materials, and products should be stored in a suitable place in order to ensure their stability and functionality.	Determine whether the form and place of storage are suited to ensuring the stability and function of the products for their intended use.
8.2.5.	The facility should have an inventory control system to ensure the traceability of data regarding the use, quality, and validity of the products purchased.	Check the inventory and receipts, as well as determining whether the manner of storage is in accordance with the manufacturer specifications and validity.
8.2.6.	The administration of the facility, or a formally appointed responsible party, should establish documented criteria for the qualification of suppliers of critical equipment, supplies, materials, medications, and services, as well as for the periodic evaluation of the quality of the product or service purchased. Qualification records should be kept, as should those of formal approval by management and periodic evaluations. The results of that evaluation should inform the decision-making process in critical analysis meetings of the administration.	Check the qualification criteria and evaluation of formally defined suppliers, together with records of supplier approval and of periodic evaluations including the analysis of performance.
8.2.7.	Medications and prepared (diluted) contrast media in the diagnostic imaging facility should have labels showing their name, concentration, lot number, date of preparation, identification of the person responsible for the preparation, expiration date, and storage conditions,	Check that the labels on medications and contrast media show these items. In case of "in house" preparation, check the protocols and the corresponding records.

	as well as information relating to the potential risks and safety precautions. When there is "in house" preparation of medications or gels, the facility should ensure that there are well-defined protocols, legal compliances, and records of the preparation.	
8.2.8.	Medications, contrast media and other materials should be used in accordance with the manufacturer's recommendations related to their use, preservation, storage conditions, and expiration dates. Revalidation is not permitted.	Check the availability of manufacturer instructions and the evidence that those instructions were followed, including respecting the expiration date.
8.2.9.	The QMS should establish criteria for the identification, segregation, disposal, and inactivation of materials, contrast media, inputs, and medications.	Check the criteria, together with the process of segregation and disposal of materials and medications.
8.2.10.	The administration of the facility, or a designated responsible party, should define responsibilities, processes and formalized criteria for the approval of new technical materials and medications. In addition to the financial analysis of the investment, those processes should include the analysis of the demand, the need for training of human resources, the impact on the quality of tests, and patient safety. Records of the analysis and approval must be maintained, including the purchase forms.	Highlight the analysis of records of new investments and the due approval by those responsible.

8.3. Equipment management

Article	Criteria	Checklist
8.3.1.	The administration of the facility, or a formally designated responsible party, must evaluate efficiently the need to	Evaluate the complexity of and demand met by the facility, as well as the equipment available. Check the alignment

	upgrade or purchase new equipment according to the demand for services, the strategic planning, and the budget of the facility.	among new purchases, equipment upgrades, demand, strategic planning, and budgeting.
8.3.2.	In planning the acquisition of new equipment, the administration of the facility should conduct a study of the demand, as well as of the technical, financial and strategic features that justify the investment.	Check the study developed.
8.3.3.	All equipment purchased must be formally approved by Anvisa.	Check the Anvisa equipment records.
8.3.4.	Equipment, coils, and software used exclusively for research are exempt from the rule stated above.	Check evidence that the equipment was used exclusively for research rather than routine use and that the facility has the Anvisa import declaration stating as much.
8.3.5.	After installation of new equipment or any changes to the premises of the facility or to equipment that emits ionizing radiation, there must be documentation of measurable parameters attesting to the efficiency and safety of the system according to the manufacturer, prior to its use in producing clinical images of patients. The equipment should be validated by a qualified professional prior to its release for the performance of the routine tests. The following records must be kept: a) radiometric survey issued by an expert in the physics of diagnostic radiology (or equivalent), proving compliance with the dose constraints established by law b) certificate of adequacy of the cap shield issued by the manufacturer c) records of acceptance of the technical testing equipment d) records of the applications (if	Check the records of the tests performed: safety testing, electrical testing, and quality testing. Those records should be signed by the responsible individual who is qualified and able to perform them. Determine whether the records contain the results obtained and the criteria for approval, as well as the formal approval of the director or the responsible technician.

	applicable for the method) e) reports of the validation of image quality and protocols, with formal approval by the technical director, the responsible nuclear radiologist, the responsible physician, or a medical specialist formally appointed by the technical director.	
8.3.6.	All equipment must be identified individually. Records must be kept, including the following: a) equipment identification b) manufacturer name and serial number of the unit c) name, contact data, and telephone number of the manufacturer and of the responsible technical support person d) date of receipt and location installed e) historical record of the equipment, including its condition (new, used, or refurbished) when received f) records of tests conducted at the facility h) maintenance and equipment cleaning records	Check records and the identification of the equipment.
8.3.7.	Those responsible for operating the equipment must be trained in its proper use. Records related to training and the evaluation of training effectiveness should be maintained.	Check the records of training and evaluation of the effectiveness of training for people who handle the equipment.
8.3.8.	The equipment must be used within the manufacturer's specifications, including room temperature and humidity, when applicable, which should be measured and recorded. For measurements outside the specifications, an analysis	Check records of the temperature and humidity in the room against that recommended by the manufacturer, as well as records of corrective or preventive measures.

	should be made and corrective or preventive measures should be taken and duly registered.	
8.3.9.	The QMS must define a documented procedure on the management of imaging facility equipment, from planning to procurement to decommissioning, including selection criteria, receipt, acceptance testing, installation, calibration and criteria for approval of the calibrations, controls, internal and external maintenance, respective frequencies/approval criteria and procedure for decommissioning, as formally defined by the manufacturer and respecting the intervals specified.	Evaluate the equipment management procedure and determine whether it includes the items described in this minimum requirement.
8.3.10.	Preventive maintenance should be performed in accordance with the manufacturer's recommendations, respecting the set minimum frequency. Records should be kept.	Check the records of preventive maintenance and determine whether the intervals recommended by the manufacturer (in the product manual or via a formal statement) are being respected.
8.3.11.	Use of injection pumps should follow the manufacturer's standards. Records should be kept.	Check the use and maintenance records.
8.3.12.	When preventive or corrective maintenance that might affect the quality of the images, sterility of medical supplies, and patient safety is performed, with or without calibration, new quality and safety testing should be performed. Records of tests and approval by the responsible party should be kept.	Review the records of the results of maintenance and any new quality and safety testing, when recommended.
8.3.13.	In cases of adverse events in patients who have interacted with the equipment at the facility, a formal notification should be send to Anvisa and technical surveillance measures should be monitored.	Determine whether there was monitoring of technical surveillance and whether there are reports of adverse events.

8.3.14.	Measuring equipment must be calibrated periodically, in accordance with the manufacturer's recommendation, the technical standard, or the law, where applicable. When there is no formal guidance, the calibration should be based on the use and risk of the measuring equipment. Instruments for measuring radiation levels in radiometric surveys and beam dosimetry should be calibrated every two years. Calibration records and calibration approval criteria should be retained. The traceability should be ensured in accordance with the standards established by the RBC or in accordance with international standards.	Check the periodicity defined in the equipment management plan for the measuring instruments, the criteria for approval of such, and the records of calibration performed at the frequency and with the traceability defined by the *Rede Brasileira de Calibração* (RBC, Brazilian Calibration Network).

8.4. Information technology

Article	Criteria	Checklist
8.4.1.	The QMS must ensure that all installations, upgrades (new versions), customizations, corrections, additions to the radiology information system/picture archiving and communication system (RIS/PACS) and data interface systems are validated, recorded, and formally adopted by the administration of the facility, or a formally designated responsible party, so as to ensure traceability, preferably before its implementation. Records should be kept. It is allowable to use non-computerized systems, provided that the quality of the process is ensured, that the traceability of information, remains rapid and secure	Check the records for the management of changes in information technology processes, including the planning, execution, testing, and approval. Determine whether the system includes versions for traceability.

	for a period established by law, and that the confidentiality of the data is maintained.	
8.4.2.	The administration of the facility, or a designated responsible party, must ensure that all information and patient data in the RIS meet the requirements for security, confidentiality, reliability, and preservation. Ensure that the information and data shared on the Internet are protected by a firewall or some up-to-date mechanism to ensure network security. Have mechanisms to identify and eliminate the risk of infection by computer viruses.	Confirm that the organization's information management plan meets the requirements for data security, confidentiality, reliability, and preservation (of RIS records), especially in the case of data related to the patient, as well as for data control and secure remote access to the system.
8.4.3.	The administration of the facility must ensure that the physical plant and environmental conditions are compatible with the proper functioning of the information technology equipment used (servers, computers, and other electronics). Servers, local or remote, should be adequately protected from power outages. There must be records showing that this protection system is monitored periodically.	Check environmental conditions, the uninterruptible power supply, and records of the effectiveness of the system in case of power outage. Confirm that CO_2 extinguishers are within easy reach. Investigate whether the imaging facility uses cloud-based systems and takes the appropriate security measures related to that.
8.4.4.	The administration of the facility, or an officially designated responsible party, must clearly define a policy of passworded access to the RIS, the PACS, and the reports database, allowing each employee to perform certain tasks and use RIS functions according to their qualifications and competence, with passwords that are unique to each individual and can be blocked when they are no longer authorized or are no longer in the employ of the facility.	Check the access permissions and blocking policies for the available systems and determine whether there are systems of protection against unauthorized access. Check the procedure for informing users that their access to the system has been discontinued and evaluate the password cancellation process.

	The system of remote access to the RIS via the Internet should employ security and confidentiality mechanisms.	
8.4.5.	The information system of the diagnostic imaging facility should ensure the integrity, reliability and security of data and information that is used for decision making, and that the data are stored in such a way that they are easily accessed by authorized users.	Verify that data integrity, precision, reliability, security, punctuality, and accessibility were considered in developing the information system.
8.4.6.	The administration of the facility, or a formally designated responsible party, should create a systematic process to ensure that professionals adhere to the policy regarding the confidentiality of information.	Determine how the confidentiality policy is implemented.
8.4.7.	All users should receive proper training in the use of the information system at strategic time points: a) on admission b) after critical system modifications, according to the scope of use per user or user group c) after the installation of new systems and modules Training records should be kept.	Check that the scope of training is aligned with the functions effectively used by the operator and verify the respective training records.
8.4.8.	Backup procedures and recovery of information system data must be provided and documented, with defined periodicity, to prove the traceability of information and system integrity after restoration programs backup files and data and prevent unexpected changes affecting the data stored, whether technical or administrative. Capacity and integrity should be evaluated through restore tests. The	Determine whether there is a documented procedure that defines the method and frequency for performing backup and recovery of data and programs in the event of breakdowns or disasters, including how the backup files and backup guard are treated. Backups should be stored at a location distant from the environment where the servers or within a fireproof safe.

	measures taken if there is evidence of a flaw in the restored information should also be evaluated. Records should be kept.	Backup and recovery records and must be made available.
8.4.9.	The QMS must include planning in reference to the following: a) RIS downtime for maintenance, which should be scheduled in order to minimize disruptions in the provision of services, assuming that the staff of the affected areas are notified b) a RIS crash contingency plan, which should identify the contingency team, the role of each of its members, and the mechanisms that trigger its implementation.	Check the procedure for and scheduling of maintenance shutdowns. Check the contingency plan, its scope and the hierarchy of personnel responsibilities.
8.4.10.	The RIS should allow the tracking of all information that affects patient care and the performance of tests, as well as the tracking of the reports, in terms of their content, their delivery to the patient, and the identification of the staff responsible. Traceability data must be kept for a period defined by current legislation.	Check the traceability of the system and determine whether it includes some sort of log or way of storing data related to accesses and changes. If any of the steps are untraceable by the RIS/PACS, this can be revealed manually.
8.4.11.	The administration of the facility, or a designated responsible party, must ensure the development and use of models of the basic findings of the report and the management of changes, approval, and traceability of these models after updates. Records of changes and of the approval of the updated reports should be kept.	Check versions, records of the approval, and the date of the review of the basic findings in the report.

8.5. Cleaning of items and surfaces

Article	Criteria	Checklist
8.5.1.	The facility should have a risk rating of its various environments and conduct cleaning procedures accordingly. The QMS must ensure that concurrent and terminal cleaning of the imaging facility environments occur according to the classification of areas by criticality.	Verify the classification of the areas and the type of cleaning procedure for each of them, as well as determining whether the recommended interval is being respected.
8.5.2.	The facility must provide a document detailing the procedures for cleaning surfaces, furniture, and other items, as well as who is responsible for implementing those procedures. Every member of the cleaning crew must be trained before the start of their activities, whether on staff or contract labor. Records should be kept.	Check cleaning and sanitizing procedures. Check the records of training received by the staff prior to the commencement of activities at the imaging facility.
8.5.3.	During the cleaning of areas, clear, easily understood signage should be used in order to prevent the occurrence of accidents or other adverse events.	Check that, during the cleaning activity, there is clear signage that is easy to understand, in order to prevent accidents.
8.5.4.	The administration of the facility must ensure that all products used for cleaning and disinfecting surfaces and materials are properly registered with or reported to Anvisa.	Check the cleaning products. Determine whether the products have been registered with Anvisa and are suitable for use in health care facilities.
8.5.5.	The QMS should establish a schedule for the control of pests and rodents, which should occur at least once every six months, and should furnish a list of the products used, which must be authorized by Anvisa. The effectiveness of those measures should be evaluated periodically.	Check the semiannual schedule for pest/rodent control and identify the products used.

8.5.6.	The QMS must define a health care facility waste management plan (HCFWMP), based on RDC no. 306/2004 or legislation that might supersede it.	Check the imaging facility HCFWMP and determine whether it takes into consideration the characteristics and risks of waste; activities to preserve health and the environment; and the principles of biosafety. Verify that the HCFWMP includes strategies for the prevention of accidents and complies with current legislation.

8.6 Disinfection and sterilization

Article	Criteria	Checklist
8.6.1.	The facility must have a classification of medical devices according to the criticality of their use. Cleaning and sterilization procedures should be conducted according to that criticality.	Check the classification of medical materials and the type of cleaning and sterilization procedure suitable for each.
8.6.2.	The facility should ensure that the space in which medical items are sterilized is in keeping with current legislation.	Check to ensure that the space for the sterilization of materials is in keeping with current legislation, with separate areas for dirty materials, clean materials, and storage.
8.6.3.	The facility should ensure that all stages of the processing medical supplies are carried out by qualified professionals trained in performing those activities.	Check the education and training records of professionals who work in the sterilization sector, according to their activities in this sector.
8.6.4.	If it is necessary to outsource cleaning services by sending items to other locations for cleaning, disinfection, or sterilization, the health products must undergo pre-cleaning at the facility of origin. If items are sent to satellite facilities, it is not always necessary for items to be pre-cleaned at the facility of origin. However, the secure transport of materials and carriers should be guaranteed.	Check the routing of the materials.
8.6.5.	The installation, operation, and performance of automated cleaning equipment should be qualified at least	Check qualification records and their periodicity.

	once per year, as should the equipment for the sterilization of medical supplies. Records should be kept.	
8.6.6.	Equipment that have an impact on the quality of the washing, disinfection, or sterilization processes must be periodically calibrated with traceable RBC standards. Readers of biological indicators, thermal seals, instruments for monitoring/evaluating steam sterilization and thermal disinfection equipment should be calibrated at least once per year, as should their requalification operations.	Check calibration records, frequency and traceability standards.
8.6.7.	The facility must provide written instructions for the sterilization procedures adopted, with details of all steps, in accordance with Anvisa RDC no. 15/12 or other legislation that might complement or supersede it. It is illegal to reprocess medical products that are classified as single-use, in accordance with Resolution no. 2605 (08/11/2006) or legislation that might supersede it.	Check sterilization procedures.
8.6.8.	A daily record, computerized or non-computerized, should be kept of the cleaning/disinfection or sterilization steps, and QC should be conducted. Records must be filed in order to ensure their traceability, in accordance with the law, or, failing that, for a minimum period of five years, for the purpose of sanitary inspections.	Check for records of materials processing and QC records. Determine their traceability.
8.6.9.	The facility should ensure that the sterilization process is monitored, at minimum, by conducting the following: a) test to evaluate the performance of the air removal system (Bowie	Check the records of chemical indicator use and its frequency, depending on the need.

	& Dick) by vacuum pump-assisted autoclave, for the first cycle of the day b) challenge test with a chemical integrator in each load pack c) monitoring of the sterilization process with physical indicators in each sterilization cycle d) daily monitoring, with a biological indicator, in a challenge package	
8.6.10.	The facility must ensure that the packaging used for the sterilization of medical articles has been approved by Anvisa for specific use in sterilization. The packaging of medical articles submitted to sterilization should have identifying labels and tags, which must remain attached and legible during sterilization, transport, storage, and distribution (up until the moment of use).	Ensure that the packaging is regulated and are designed specifically for use in sterilization. Check the labeling of sterilized items, which must contain the following information: product name, batch number, sterilization date, sterilization validity date, sterilization methods, and identification of the party responsible for their preparation.
8.6.11.	The facility must ensure that sterile materials are stored in a clean, dry environment to which access is restricted.	Check the suitability of the environment in which sterile materials are stored and the possible presence of past-dated material.

8.7. Processing of clothing

Article	Criteria	Checklist
8.7.1.	The administration of the imaging facility should ensure that the infrastructure of the location at which clothing are processed is in accordance with current legislation. If clothing processing services are outsourced, ensure that this is approved by the local health authorities.	Determine whether the local processing of clothing is in keeping with the current legislation. If the facility outsources its laundry services, check the record of the outsourcer and ensure that its operating license is valid, according to the local health surveillance agency.
8.7.2.	The QMS must ensure that the clothing processing staff are provided with the	Check the procedures manual of the clothing processing sector, which has

	procedures for all activities, which include at least the steps of collection, separation, and processing clothing, together with the cleaning and disinfection of cars and other vehicles used, as well as the cleaning/disinfecting of environments and surfaces.	descriptions of all activities.
8.7.3.	The QMS must ensure that when the clothing processing is outsourced, the imaging facility has a specific environment for the storage of dirty laundry awaiting collection and a separate environment for the receipt, checking, and storage of clean clothes.	For imaging facilities that outsource laundry services, check for the existence of separate rooms for the storage of dirty and clean clothes.

9. MANAGEMENT OF INFRASTRUCTURE, RADIATION, AND SAFETY

Principle: The diagnostic imaging facility ensures the minimum infrastructure related to the physical plant and equipment to allow the safe execution of activities for patients, caregivers, visitors, and staff.

Article	Criteria	Checklist
9.1.	The facility must provide and maintain infrastructure conditions that ensure the comfort, privacy, and safety of staff, patients, caregivers, and visitors.	Check that the environment and infrastructure provide comfort, privacy, and safety.
9.2.	The infrastructure must comply with the minimum recommendations found in RDC nos. 50/2002, 307/2002, 453/1998, and 38/2008, as well as the CNEN recommendations when applicable to the type of facility, or other laws that might supersede them.	Check that the environment and infrastructure are in keeping with the current legislation.
9.3.	The facility environments should be defined and classified as free areas or controlled areas, according to the characteristics of the activities carried out in each.	Check the access to controlled areas and determine whether there are signage risks that limit access.

	In the environments classified as controlled areas, specific measures of protection and safety should be taken in order to control, prevent, or reduce potential exposure to radiation and magnetic fields, with appropriate signage, in accordance with the current legislation.	
9.4.	Ionizing radiation warnings should be placed in appropriate locations within the affected environments. Electromagnetic risk warnings should be placed in appropriate locations within MRI zones.	Check warnings and the locations in which they were placed. Determine whether they ensure the safety of patients, caregivers, and visitors.
9.5.	Environments in which there can be ionizing radiation should have a leaded shield that ensures the protection of the environment external to the examination room. The MRI zone(s) should be shielded to ensure the protection of the external environment against the strong magnetic field (maximum of 5 Gauss).	Check lead protection reports. Check the spreadsheet calculation and shielding blueprint provided by the manufacturer.
9.6.	There must be access for patients and staff with limited mobility and access for patients in need of transportation by stretcher from other facilities, which should occur safely and in accordance with current legislation form.	Check that the access infrastructure ensures the safety of patients with limited mobility.
9.7.	The QMS should provide a biosafety manual and train the staff involved in all critical activities. Provide a radiation safety plan, which should also be disseminated and implemented.	Check the biosafety manual, the radiation safety plan, and the training records of the professionals involved in the respective risk activities.
9.8.	The facility should plan preventive and corrective building maintenance, ensuring safety and identifying areas	Check the preventive/corrective maintenance plan and determine whether there is evidence of compliance.

	with potential for improvement. Evidence of compliance with the plan should be kept on file.	
9.9.	When new construction, modifications, or renovations are necessary, the administration of the facility should plan the measures and have updated designs, regulated by the appropriate bodies, that focus on the radiological protection of equipment, facilities, and working procedures.	Check the construction/renovation plan and the documentation referenced.
9.10.	During renovations, the facility should provide clear, easy to understand signage for staff, patients, caregivers, and visitors, in order to avoid accidents or other adverse events.	Check that signage ensures the safety of staff, patients, caregivers, and visitors.
9.11.	The facility should establish and implement emergency exit routes, as well as installing clear, easily understood signage at the emergency exits. Records should be kept.	Check signage along the emergency exit route(s), as well as training and evidence of implementation.
9.12.	The facility should monitor the infrastructure, including elevators, water systems, electricity, protection against electric shock, air conditioning, fire fighting equipment, and emergency alert devices, according to the size and scale of its physical plant. Records should be kept.	Check the monitoring equipment described in this article and the related records.
9.13.	The facility should establish systems for the identification and control of the ingress and egress of people, materials, and equipment, advising staff and visitors regarding access to and movement within the premises.	Evaluate how the facility controls the ingress and egress of people, materials, and equipment, as well as how it ensures the safety of people and assets.
9.14.	The exposure of patients to radiation should be maintained at the minimum	Check that the exposure for image acquisition is the minimum possible and

	needed to obtain images compatible with the acceptable standards of image quality. When applicable, the use of PPE compatible with the type of radiological procedure is required by law, for staff, caregivers, and patients. Protective apparel should be tested periodically, and the results should be recorded, ensuring the efficacy of the radiation safety plan.	that protective apparel have been used. Check the QC records for the clothes available for use at the facility.
9.15.	The facility should deploy an HCFWMP that meets the requirements of RDC no. 306/2004 or other applicable law that might supersede it.	Check for the existence of an HCFWMP, determining whether it is effectively implemented and meets the minimum legal requirements.

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11. APPENDICES

- Guidelines for X-rays
- Guidelines for magnetic resonance imaging
- Guidelines for computed tomography
- Guidelines for submitting images and reports