متطلبات تسجيل
مراكز الأشعة

Version 1.2

الهيئة العامة للاعتماد والرقابة الصحية

نظام تسجيل المنشآت الصحية:

استناداً إلى قانون رقم (2) لسنة 2018 بشأن نظام التأمين الصحي الشامل والصادر في يناير 2018 ولائحته التنفيذية الصادرة بقرار رئيس مجلس الوزراء في مايو 2018 وقرار رئيس مجلس الوزراء رقم 2040 لسنة 2018 بتشكيل مجلس إدارة الهيئة العامة للاعتماد والرقابة الصحية.

وفي إطار الخطوات الحثيثة والمتلاحقة التي تخطوها الدولة نحو تنظيم القطاع الصحي بما يضمن سلامته واستقراره وتحسين جودته وتوكيد الثقة في جودة مخرجات الخدمات الصحية بجمهورية مصر العربية على كافة المستويات المحلية والإقليمية والدولية.

فقد قرر مجلس إدارة الهيئة العامة للاعتماد والرقابة ما يلي:

أولاً: وضع قواعد وشروط تسجيل المنشآت الصحية تمهيداً لاعتمادها من قبل الهيئة، والتي تشمل على سبيل الحصر والتحديد ما يلي:

أ- تحقق الاشتراطات الأساسية للمنشآت الصحية.

ب- تحقق المتطلبات الوطنية للسلامة بالمنشآت الصحية بما يضمن سلامة المرضى والمرافقين والزوار والعاملين بتلك المنشآت.

ج- وجود دليل تشغيل فعلي للمنشأة الصحية والالتزام به بما يحقق أداءً احترافياً مستقراً للمنشأة في كافة أقسامها وعلى كافة مستويات تقديم الخدمة بها في جميع الأوقات ومع جميع الحالات.

د- تحقق متطلبات القيادة في المنشآت الصحية بما يضمن الوصول إلى أعلى درجات الوعي والقدرة والالتزام من القيادات في المنشآت الصحية على اختلاف مستوياتهم القيادية.

هـ- تحقق المتطلبات الأساسية للموارد البشرية في المنشآت الصحية بما يضع الأسس السليمة لاختيار العاملين وتوزيعهم وتقييم أدائهم وتحسينه بشكل مستمر وتنمية قدراتهم والاحتفاظ بهم على اعتبار أن الموارد البشرية هي من الأصول المهمة للمنشأة والتي يجب الحفاظ عليها وتنميتها بشكل مستمر.

ثانياً: مع مراعاة التدرج الجغرافي في التطبيق، تحتفظ الهيئة العامة للاعتماد والرقابة الصحية في البت في تسجيل واعتماد المنشآت الصحية في كافة أنحاء الجمهورية وفي كافة القطاعات وفقاً للقانون (2) لسنة 2018.

ثالثاً: إلزام كافة المستشفيات ومراكز ووحدات الرعاية الصحية بالمحافظات بالتقدم للتسجيل في موعد أقصاه ستة أشهر من تاريخ دخول المحافظة نطاق التطبيق للقانون وفقاً لأحكام القانون (2) لسنة 2018م.

رابعاً: تلتزم المنشآت المسجلة بالهيئة بالتقدم للحصول على اعتماد الهيئة خلال موعد أقصاه سنة من تاريخ التسجيل وإلا اعتبر التسجيل لاغيا ويجب إعادته مرة أخرى.

خامساً: تلتزم الهيئة العامة للاعتماد والرقابة بتعريف وتعليم وتدريب الأطراف المعنية بإجراءات تسجيل المنشآت الصحية وفق خطة محددة ومفهوم لا يتعارض مطلقا مع أي من القواعد الحاكمة لمبدأي الشفافية وتجنب تضارب المصالح.

سادساً: تلتزم الهيئة بإتاحة ما يلي:

أ. الوثائق المرفقة (في البند سابعاً) والتي توضح تفاصيل متطلبات تسجيل المنشآت الصحية لديها.

ب. أدلة مفصلة للاسترشاد بها في تحقيق تلك المتطلبات، مع الوضع في الاعتبار عدم التقيد الحرفي بها والعمل على موائمتها بما يتناسب وطبيعة كل منشأة على حدة.

سابعاً: الوثائق المرفقة:

أ- الاشتراطات الأساسية للمنشآت الصحية كما وردت بالقانون (51) لسنة 1981 المعدل بالقانون (153) لسنة 2004 أو ما يساويها في المنشآت التي لا ينطبق عليها القانون.

ب- المتطلبات الوطنية للسلامة بالمنشآت الصحية.

ج- دليل تشغيل المنشأة الصحية.

د- دليل متطلبات القيادة في المنشأة الصحية.

هـ- دليل المتطلبات الأساسية للموارد البشرية في المنشأة الصحية.

متطلبات ترخيص مراكز الأشعة

أولاً: متطلبات عامة:

1- أن تكون حجرات المنشأة الطبية جيدة التهوية والإضاءة.

2- أن تكون المنشأة مزودة بوسائل تغذيتها بالمياه النقية بصفة مستمرة.

3- أن تكون المنشأة مزودة بوسائل الصرف الصحي المناسبة.

4- أن تزود المنشأة بالوسائل والأدوات الصحية اللازمة للتخلص من القمامة والفضلات.

5- أن تزود المنشأة بالأجهزة اللازمة لإطفاء الحرائق.

6- شهادة من إدارة الدفاع المدني والحريق بتوفر الاشتراطات اللازمة لحماية المركز من أخطار الحريق.

7- أن تكون المنشأة مجهزة بوسائل الإسعاف الأولية.

8- شهادة تداول المواد والنفايات الخطرة.

9- ما يفيد الاشتراك أو التعاقد مع محرقة للنفايات.

10- التقدم بخطة محدد بها الأسلوب الذي سيتم اتباعه لمنع انتشار العدوى بالمنشأة.

11- التقدم بخطة محدد بها الأسلوب الذي سيتم اتباعه للتخلص الآمن من النفايات.

12- التقدم ببيان العاملين من أطباء وتمريض وممرضات وفنيين وخلافه.

13- صور تراخيص مزاولة المهنة للأطباء وهيئة التمريض والفنيين.

14- الالتزام بتنفيذ الاشتراطات الفنية والصحية المحددة بالقانون رقم ٥٩ لسنة ١٩٦٠ في شأن تنظيم العمل بالإشعاعات المؤينة والوقاية من أخطارها و القارارت الوازرية المكملة وتعديلاته

15- الالتزام بالقانون رقم 7 لسنة 2010 لتنظيم الأنشطة النووية و الإشعاعية و لائحته التنفيذية.

ثانياً: المتطلبات الواجب توافرها في مراكز الاشعة:

1. التراخيص المكانيه للمنشأة ومراكز الأشعة:-

- ترخيص مركز الاشعة لاجهزه الاشعه التشخيصية والمعجلات الخطية من المكتب التنفيذى للوقاية من الأشعة- وزارة الصحة.
- ترخيص وحده الطب النووى من هيئة الرقابة النووية والإشعاعية.

2. ضابط الاتصال (مسئول الوقاية الإشعاعية بالجهة).

- ترخيص مراكز الاشعه التشخيصية و المعجلات الخطية تحت إشراف طبيب الاشعة التشخيصية.
- ترخيص وحدات الطب النووى تحت اشراف خبير الوقايه الاشعاعية او مسئول الوقاية الاشعاعية.

3. المخططات الهندسية للمنشأة.

4. حسابات التدريع وتصنيف المناطق وأماكن استخدام أجهزة الأشعة .

5. وصف أنظمة الأمان الاشعاعي في المنشأة.

6. مواصفات أجهزة الأشعة التي سيتم استخدامها ومدى مطابقتها لأسس الوقاية الإشعاعية.

7. برنامج وقاية اشعاعية يتناسب مع طبيعة الممارسة.

8. أخصائي أشعة مُعتمد ومرخص.

9. فحص القبول لأجهزة الأشعة.

10. المسح الاشعاعي :-

- يتم عمل المسح الاشعاعي سنويا بشهاده معتمده لمراكز الاشعه من خلال المكتب التنفيذي للوقايه من الاشعه او اى جهه معترف بها لجميع الاقسام.
- أقسام الطب النووى: يتواجد جهاز مسح اشعاعي و يعاير سنويا في جهه معترف بها و يقوم مسئول الوقايه بعمل المسح الاشعاعي مره او اثنين كل اسبوع وكلما لزم الامر.

11. أن تكون الكوادر التي ستقوم بممارسة العمل الإشعاعي مرخصة.

12. وثائق اشتراك جميع العاملين على مصادر الأشعة في المنشأة بالرصد الإشعاعي الشخصي.

13. برنامج الإشراف الطبي للعاملين الإشعاعيين يتضمن اسم الطبيب المعتمد، والفحص الدوري للعاملين ونوع الفحص الطبي.

14. برنامج ضمان الجودة للممارسة وبرنامج ضبط الجودة لأجهزة الأشعة الذي سيتم إتباعه أثناء ممارسة العمل الإشعاعي.

15. الدليل الفني (الكتالوجات) الخاص بالأجهزة الإشعاعية.

16. قائمة بأجهزة ومعدات الوقاية الإشعاعية وفقاً لتعليمات أجهزة ومعدات الوقاية الإشعاعية الواجب توفيرها في المؤسسة.

17. برنامج للتصرف الآمن في النفايات المُشعة والتحكم بها، وأن يتم التخلص من تلك النفايات وفقاً للمتطلبات الرقابية.

18. توفير كل وثائق الأمان ذات الصلة باللغات الملائمة.

National Safety Requirements (NSR)
For Diagnostic/ Therapeutic Radiology

PREFACE:

The goal of developing NSR is enhancing individual's safety in health care facilities. The General Authority for Healthcare Accreditation & Regulation (GAHAR) selected those standards which may impact individual's safety, or in other words; the main killers, to establish these standards as basic requirements for facility looking for enrollment in the new healthcare system in Egypt.

ACKNOWLEDGEMENT:

The development of these NSR is based on the work of expert teams, who developed the current & previous versions of Egyptian Accreditation Standards for Hospitals. We would like to thank in particular the (Health Governance Unit/ Medical Research Institute/ Alexandria University) & World Health Organization (WHO) for sharing with us their previous efforts to improve patient safety.

EVALUATION OF NSR:

The General Authority for Healthcare Accreditation & Regulation (GAHAR) is individual's safety focused. These NSR intend to promote individual's safety in hospitals.

The NSR standards are modified from the Egyptian Hospitals Accreditation Standards (3rd Edition, 2017).

The NSR are Grouped into 4 groups (A, B, C, and D). A unit has to score 70% or more in each group separately and a total of 80% or more in all groups.

No standard should be scored Not Met (NM) for a facility to pass the NSR evaluation.

A. General Patient Safety Standards:

NSR.1:

Standard:

The patient's safety policy defines Egyptian & WHO Patient Safety recommendations & solutions, including at least the following:

NSR.1.1 Accurate standardized patient identification in all service areas.

NSR.1.2 Standardized process for dealing with verbal or telephone orders.

NSR.1.3 Hand hygiene throughout the organization.

NSR.1.4 Prevention of catheter & tubing miss-connections.

NSR.1.5 Prevention of patient's risk of falling.

NSR.1. 6 A standardized approach to hand over communications.

Rationale:

To address the most common & critical identified areas, thus preventing adverse events & to ensure full awareness of the Egyptian & WHO standards for patient safety.

Survey Process:

- Review the patient safety policy & procedures & check if it includes all the standard's items.
- Interview facility staff to ensure awareness of policy.

Documents	Interviews	Observations
Patient safety policy & procedures.	(5-10) staff to ensure awareness of policy.	

NSR.2:

Standard:

At least two (2) ways are used to identify a patient when giving medicines & other specimens for clinical testing, &/or providing any other treatments or procedures.

Rationale:

Providing care or performing interventions on the wrong patient are significant errors, which may have grave consequences. Using two identifiers for each patient is the key driver in minimizing such preventable errors, which is especially important with administration of high alert medications or conducting high risk or invasive procedures.

Survey Process:

- Review relevant policy & procedures & check whether it states those two identifiers (personal) & the occasions when they should be used.
- Review an appropriate number of medical records & check each sheet for the presence of the two identifiers mentioned in the policy & procedures document.
- Interview a number of healthcare staff (5-10) & ask them about the two identifiers & when should they be used according to what is mentioned in the standard.
- Observe patient identification wrist bands for the two identifiers.
- Observe patient identification before procedures or care.

Documents	Interviews	Observations
Patient Identification policy & procedures.	(5-10) interviews with any staff providing patient care.	Patients identification (10 observations at least).
Medical records.		Wrist Bands.

NSR.3:

Standard:

A well-defined & implemented process for taking verbal or telephone orders & for reporting of critical test results, that requires verification by write down & "read-back" of the complete order or test result by the person receiving the information.

Rationale:

Miscommunication is the commonest root cause for adverse events. Writing down & reading back the complete order or test result, by the person receiving the information, minimizes miscommunication & reduces errors from unambiguous speech, unfamiliar terminologies or unclear pronunciation. It also provides an opportunity for verification.

Survey Process:

- Review the policy of receiving verbal or telephone orders & of the critical test results reporting & check whether it clearly describes the process of documentation & "read-back" by the recipient & also the measures to be taken in case of critical test results.
- Review documentation in dedicated registers &/or medical records.
- Interview clinicians & technicians to assess knowledge & implementation.

Documents	Interviews	Observations
Verbal, telephone orders, critical test results (VTC) reporting policy & procedures.	- Clinicians. - Technicians.	
VTC Logbooks &/or Medical records.		

NSR.4:

Standard:

Generally accepted hand hygiene guidelines, laws, & regulations are currently publishes & implemented to prevent healthcare-associated infections.

Rationale:

Hand hygiene is the cornerstone for reducing infection transmission at all healthcare settings. It is considered the most effective & efficient strategy for facility wide infection prevention & control.

Survey Process:

- Review relevant policy & procedures of hand hygiene.
- Review hand hygiene guidelines.
- Interview facility staff, enquiring about hand hygiene technique & WHO five moments of hand hygiene.
- Observe hand washing facilities at each patient care area.
- Check availability of supplies (soap, tissue paper, alcohol hand rub, etc).
- Observe compliance of clinicians with hand hygiene technique & the 5 moments.

Documents	Interviews	Observations
Hand hygiene policy & procedures.	(5-10) facility staff.	Hand hygiene facilities (such as hand washing sinks, alcohol dispensers... etc).
Hand hygiene guidelines.		Hand hygiene supplies.
		Staff compliance (10 observations at least).

NSR.5:

Standard:

Systems are implemented to prevent catheter & tubing misconnections.

Rationale:

Patients, especially within critical & specialized care areas, are connected to many tubes & catheters, each with a special function (monitoring, access, drainage). During care, these tubes & catheters may be misconnected leading to the administration of wrong material via the wrong route resulting in grave consequences.

Survey Process:

- Review the policy & procedures for catheter & tubing misconnections & check for catheter differentiation, catheter maps... etc.
- Interview clinicians to ensure their understanding of misconnection prevention.
- Observe compliance of clinicians with misconnection prevention.

Documents	Interviews	Observations
Catheter & tubing misconnections policy & procedures.	Physicians & nurses.	Patients particularly at Critical Care Areas.
Catheter maps in Medical Records.		

NSR.6:

Standard:

Each patient's risk of falling, including the potential risk associated with the patient's medication regimen, is screened, assessed & reassessed whenever indicated. Action is taken to decrease or eliminate any identified risks of falling.

Rationale:

All patients are liable to fall; however, some are more prone to. Identifying the more prone is usually done through a risk assessment process in order to offer them tailored preventative measures against falling. Effective preventive measures to minimize falling are those that are tailored to each patient & directed towards the risks being identified from risk assessment.

Survey Process:

- Review the policy & procedures for fall prevention & check for patient risk screening, assessment and reassessment whenever indicated; noticing that medication review is part of the assessment & also check for the presence of general measures generated to reduce risk of falling & for tailored care plans based on individual patient fall risk assessment.
- Check availability of fall risk assessment forms (including mediation care view).
- Review medical records for fall risk assessment (whenever indicated).
- Review fall prevention care plan forms & fall risk labels.
- Review patient & family education material.
- Review medical records for general measures & tailored care plans.
- Interview nurses & physicians to ensure their understanding & implementation of fall risk assessment.
- Interview clinicians to ensure their understanding & implementation of fall prevention care plans.
- Interview patients & families to ensure their awareness & involvement.
- Check organization wide general preventive measures (Call systems, lighting, corridor bars, bathroom bars, bedside rails, wheelchairs & trolleys with locks).

Documents	Interviews	Observations
Fall prevention policy & procedures.	Clinicians.	Organization wide general measures.
Fall assessment forms in Medical Record.		Specific measures for patients with high risk of falling.
Patient & family education forms.	Patients & families.	

NSR.7:

Standard:

A well identified & implemented standardized approach to hand over communications, including an opportunity to ask & respond to questions.

Rationale:

The primary objective of a 'handover' is the direct transmission of accurate patient care information among staff to ensure the continuity of care. Moreover, it ensures adequate chance for clarifications which subsequently decreases medical errors.

Survey Process:

- Review the policy & procedures for of handover of patients in-between different shifts (in same department) as well as in-between different department/ services & check for the presence of recommended framework (such as, SBAR, ISOBAR, I PASS the BATON.. etc), staff responsible, recommended environment, & documentation.
- Review medical record, Handover log book, Endorsement form, Electronic Handover tool, &/or other methods as evidence of implementation.
- Interview staff to ensure their knowledge of handover agreed framework.

Documents	Interviews	Observations
Handover policy & procedures.	Clinicians.	Handovers whenever possible.
Handover forms.		
Medical records.		

NSR.8:

Standard:

Well developed, documented, & implemented policy for preventive maintenance & testing of critical alarm systems. Alarms are tested & activated with appropriate settings & are sufficiently audible with respect to distances & competing noise within the unit.

Rationale:

Medical devices especially those related to vital functions are fitted with alarms that alert staff on conditions of device malfunction or patient's critical situation. Losing that function exposes patients to increased risk of morbidity & mortality. Alarms are intended to induce immediate appropriate action from staff to either check device malfunction or initiate action that will revert the situation. This can be ensured when all the staff becomes fully aware of alarm settings (values & volume) & their significance & are trained on the required actions to be taken when triggered.

Survey Process:

- Review policy & procedures developed for maintenance & testing of critical alarm systems, which should include staff responsible, control measures, assurance measures, & remedial action. Also check whether the procedures cover testing of alarms, appropriate settings procedures, priorities for competing alarms, staff authorization for disabling alarms or changing their settings, & monitoring of response to alarm activation.
- Review inventory of all devices with critical alarms including setting guidelines.
- Review maintenance document for evidence of responsible staff, responsible company, schedule, agreed settings, evidence of function, reporting of malfunction, & remedial action.
- Review the schedules of alarm tests & list of current active settings at difference care areas.
- Interview staff around devices with critical alarm & check their knowledge of critical alarm settings & response to their activation.
- Observe (listen) or activate critical alarms to check for suitability of alarm volume to working space.
- Interview maintenance staff & check for implementation.

Documents	Interviews	Observations
Critical alarms policy & procedures.	Maintenance staff.	Devices with critical alarm in areas such as Critical Care Areas.
Inventory of all devices with alarm.	Staff using or around devices with critical alarm.	
Alarm setting guidelines.		
Device /alarm maintenance registers.		

NSR.9:

Standard:

The facility has systems in place to ensure facility -wide recognition of & response to clinical deterioration.

Rationale:

Functional & long-term outcome of early detection & timely providing urgent care to deteriorating patients is more superior to resuscitation of patients with cardio-pulmonary arrest. Studies have shown that this strategy has positive impact on reducing in-facility mortality & improving patient safety.

Survey Process:

- Review the policies, procedures &/or process to develop, implement & maintain a facility-wide system established for recognition of & response to clinical deterioration.
- Review the process established to measure & document observations via general observation chart including; respiratory rate, oxygen saturation, blood pressure, heart rate, temperature, consciousness level, etc.
- Review the process established to build rapid response teams & to ensure regular rehearses.
- Check evidence & staff training concerning recognition & communication of clinical deterioration.
- Observe compliance with policies & procedures for recognition of & response to clinical deterioration.

Documents	Interviews	Observations
Policies & procedures for early recognition of & response to clinical deterioration include dye allergy.	Clinicians.	Compliance of rapid response team to clinically deteriorating patients
Staff training records.	.	
		Availability of crash card at least one will equip with defibrillator...
Medical Records for relevant forms		

B. Medication Management Safety Standards:

NSR.10:

Standard:

Policy & Procedures for medication management safety including at least the following:

NSR.10.1 Abbreviations not to be used throughout the organization.

NSR.10.2 Documentation & communication of patient's current medications & discharge medication.

NSR.10.3 Labeling of medications, medication containers & other solutions.

NSR.10.4 Prevent errors from high risk medications.

NSR.10.5 Prevent errors from look-alike, sound-alike medications.

Rationale:

Policies & procedures fostering a culture that supports standardization & documentation, which helps to create consistency in patient safety practices minimizing patient harm.

Survey Process:

- Review the relevant medication management safety policy & check if it includes all the standard's items.
- Interview staff to check their full awareness of policies & procedures.

Documents	Interviews	Observations
Medication management safety policy & procedures.	Physicians, Nurses & Pharmacists.	

NSR.11:

Standard:

Abbreviations not to be used throughout the organization are:

- U/ IU.
- Q.D., QD, q.d., qd.
- Q.O.D., QOD, q.o.d., qod.
- MS, MSO4.
- MgSO4.
- Trailing zero (5.0).
- No leading zero (.5).
- Dose x frequency x duration.

Rationale:

Abbreviations avoidance prevents misunderstandings, miscommunications & administration of incorrect prescription. The abbreviations mentioned in this standard are commonly misinterpreted (such as IU could be understood IV).

Survey Process:

- Review appropriate number of medical records (not less than 10) & check for the used abbreviations with medication orders.
- Interview medical staff for awareness of the prohibited abbreviations.

Documents	Interviews	Observations
Medical records.	Medical staff for awareness.	

NSR.12:

Standard:

A process is established & implemented to obtain & document a complete list of the patient's current medications upon admission to the organization including patient involvement.

Rationale:

Medication reconciliation at every patient care transition effectively reduces medication errors such as; omissions, duplications, dosing errors, &/or drug interactions. This may result from unintended medication discrepancies.

Survey Process:

- Review appropriate number of medical records (at least 10) & check for the documentation of current medications upon admission.
- Interview with appropriate number of patients & asking them if they were asked by doctors about their current medication & if they were educated if any will interfere with the new prescribed medications.

Documents	Interviews	Observations
Medical records.	Physicians & Patients.	Patient's own medications to be compared with documented current medications.

NSR.13:

Standard:

All medications, medication containers (e.g., syringes, medicine cups, basins), &/or other solutions on & off the sterile field in peril-operative & other procedural settings are labeled.

Rationale:

Labeling of medication containers at the point of care assists health care providers to identify the correct medicine &/or fluid at all times & reduce the risk of medication error as well.

Survey Process:

Observe at the peril-operative & other procedural settings if medication containers are labeled.

Documents	Interviews	Observations
Policy of medication labeling in Peril-operative & other procedural settings.	Operating theater & anesthesia staff for awareness.	Peril-operative & other procedural settings observe the medication syringes or other containers labeling.

NSR.14:

Standard:

Look-alike & sound-alike medications are identified, stored & dispensed in a way which assures that risk is minimized.

Rationale:

Identification & differentiation is an error reduction strategy. Using look alike & sound alike (LASA) medications could lead to wrong dispensing & administration.

Survey Process:

- Review the updated list of look -alike & sound -alike medications.
- Interview pharmacists & nurses & check if they understand how to minimize the risk associated with using look- alike sound - alike medications.
- Observe at the pharmacy & the medication carts the labeling of LASA medications.
- Review the medical records to check if doctors write the purpose of drug usage, to avoid confusion due to LASA medication during dispensing by the pharmacist.

Documents	Interviews	Observations
List of look -alike & sound -alike medications policy & procedures.	Pharmacists or nurses.	LASA medication storage at pharmacy & medication carts.

C. Invasive Procedure Safety Standards:

NSR.15:

Standard:

Policy & Procedures for invasive procedures safety including at least the following:

NSR.15.1 Pre-procedural marking of site of procedures.

NSR.15.2 Process for Pre-procedural verification of all Documents& equipment needed for invasive procedures.

NSR.15.3 Accurate & documented patient identification done just before procedure (time out).

Rationale:

Performing the right procedures on the right patient & on the right side. Establishing related policies & procedures, otherwise known as the universal protocol, is the initial step for offering safe intervention.

Survey Process:

- Review the invasive procedures safety policy & procedures & check if it includes all the standard's items.
- Interview staff to check their awareness.

Documents	Interviews	Observations
Invasive procedures safety policy & procedures.	Radiologists & surgeons.	

NSR.16:

Standard:

The precise site where the invasive procedure will be performed is clearly marked by the physician with the involvement of the patient.

Rationale:

Visible & clear site marking is an error reduction strategy that should be performed by the authorized person performing the procedure while the patient is awake.

Survey Process:

- Review invasive site marking policy & procedure & check that it specifies situations for site marking (laterality, multiple structures or levels), states that organization wide site marking is done with a recognizable & consistent mark, which should resist disinfection procedures, should be visible after draping, should be made by the authorized person performing the procedure & should be done when the patient is awake & fully aware.
- Review the checklist & observe whether it is dedicated to this standard or it is a part of a wider checklist (surgical safety checklist, universal protocol checklist).
- Review relevant post- operative patients' medical records & check for documentation evidence.
- Interview surgeons/interventionists & check their understanding of this process.
- Interview relevant post-operative patients & check their involvement in site marking.
- Observe implementation of this process at the intervention room if possible.

Documents	Interviews	Observations
Invasive site marking policy & procedures.	Radiology & Surgical staff.	Pre-procedure verification (if possible).
Surgical safety checklist	Invasive procedures staff.	Site markers at patient care areas.

NSR.17:

Standard:

A process or checklist is developed & used to verify that all Documents& equipment needed for surgery or invasive procedures are on hand, correct & functioning properly before the start of the invasive procedure.

Rationale:

Ensuring availability of patient data & the necessary functioning equipment minimizes the risk of errors. Implementing regular checkup is a quality improvement process that should be guided by well-designed checklists performed by well-trained staff.

Survey Process:

- Review document & equipment verification policy & procedures & ensure that it supports a documented verification process for: patient Documents (consent, physical examination, medical assessment, nursing assessment, pre-anesthetic assessment), as well as patient laboratory & radiologic test results, procedure devices &/or blood products.
- Review the checklist & observe whether it is dedicated to this standard or it is a part of a wider checklist (surgical safety checklist, universal protocol checklist).
- Review medical records of post-operative patients & check for checklist utilization.
- Interview relevant staff checking their full understanding of this process.
- Observe implementation of this process at the intervention room if possible.

Documents	Interviews	Observations
Documents & equipment verification policy & procedures.	Radiologists & Surgical team staff.	Pre- invasive procedure verification including sign in process.
Documents & equipment verification checklist	Invasive procedures staff.	

NSR.18:

Standard:

There is a documented process of accurate patient identification just before starting invasive procedure (time out), to ensure the correct patient, procedure, & body part.

Rationale:

Double checking that is verified by others, declared & documented is a quality improvement process that minimizes errors.

Survey Process:

- Review pre-intervention policy & procedure for preventing wrong patient, wrong site/side, & wrong invasive procedure & ensure that it supports patient, procedure, as well as part of body verification just before start of the procedure, regardless whether the patient is anesthetized, sedated or awake (Time Out).
- Review the checklist & observe whether it is dedicated to this standard or it is a part of a wider checklist (such as surgical safety checklist, universal protocol checklist).
- Ensure that the policy states clearly the responsibilities of each of the operative/intervention team members in implementing this standard.
- Review medical records of post-operative patients & check for checklist utilization.
- Interview relevant staff to check their understanding of this process
- Observe implementation of this process at the intervention room if possible.

Documents	Interviews	Observations
Pre- intervention patient identification policy & procedure,	Radiologists & Surgical team staff,	Time out process,
Time out/surgical safety checklist in Medical Record,	Invasive procedures staff,	

D. Environmental Safety Standards:

NSR.19:

Standard:

There is a well-structured & implemented fire & smoke safety plan that addresses prevention, early detection, response, & safe exit when required by fire or other emergencies & including at least the following:

NSR.19.1: Frequency of inspecting fire detection & suppression systems, including documentation of the inspections.

NSR.19.2: Maintenance & testing of fire protection & abatement systems in all areas.

NSR.19.3: Documentation requirements for staff training on fire response & evacuation.

NSR.19.4: Assessment of fire risks when construction is present in or adjacent to the facility.

Rationale:

The facility must be vigilant about fire safety as fire is an ever present risk in a facility.

Survey Process:

Review the fire safety plan, facility fire safety inspections, & fire system maintenance. Fire alarm should be effectively working. Fire fighting & smoke containment should comply with civil defense requirements. Review plan of testing (drills) & staff training (all staff should be trained on fire safety).

Documents	Interviews	Observations
Fire Safety Plan.	Facility staff.	Functioning fire alarm, firefighting equipment, smoke containment facilities, emergency exit signs, emergency exit doors, & assembly points.
Documents showing staff participation in evacuation drills & Fire safety training.		Staff response in case of fire & evacuation.
Fire Safety Inspection Reports & risk assessment.		Safe storage, smoking outside safe areas, using kettles, unsafe electric cords, & other high risk devices.
Fire & alarm system maintenance records & contracts.	Maintenance Staff.	

NSR.20:

There is a well-structured& implemented plan for hazardous materials (Hazmat) & waste management for the use, handling, storage, & disposal of hazardous materials & waste addressing at least the following:

NSR20.1 Safety & security requirements for handling & storage.

NSR20.2 Requirements for personal protective equipment.

NSR20.3 Procedures & interventions to implement following spills & accidental contact or exposures.

NSR20.4 Disposal in accordance with applicable laws & regulation.

NSR20.5 Labeling of hazardous materials & waste.

NSR20.6 Monitoring data on incidents to allow corrective action.

Rationale:

The facility should have a hazmat& waste management program that addresses different requirements. The facility environment, staff, patients, relatives & vendors should be safe from hazardous material exposure & waste all over the time.

Survey Process:

- Review the hazardous material & waste management program to make sure that it covers all safety requirements of hazardous materials, safe storage, handling, spills, required protective equipment & waste disposal in accordance to local laws & regulations.
- Review the hazardous material & waste disposal plan, hazardous material & waste inventories, as well as Material Safety Data Sheet (MSDS), & inspect hazardous material labeling & storage in addition to waste collection, segregation storage & final disposal.

Documents	Interviews	Observations
Hazardous material & waste disposal plan.	All facility staff.	Storage & labeling of hazardous materials.
Hazmat & waste inventories.		Waste collection bags Storage place as regard: proper ventilation, cleaning &appropriate labeling &signage.
MSDS.		Centers that use PET CT and/or nuclear medicine (NM) shall have suitable hot lab for preparation of the radioactive isotopes & waste storage & disposal area is leaded according to local laws and regulations.
Relevant contracts.		
Hazardous material & waste risk assessment.		

NSR.21:

Standard:

There is a well-structured & implemented safety & security plan/s.

Rationale:

The facility should have safety & security plan/s that cover all requirements. The facility should ensure a safe & secure physical environment all the time.

Survey Process:

- Review safety & security plan/s, & make sure of including suitable risk assessment surveillance, security high-risk areas & security requirements, as well as access control areas. Review surveillance rounds plan, checklist, different observations & check for proper corrective actions when applicable &Personnel protective equipment (PPE).
- Check for security plan, cameras monitors, staff ID & access controlled areas.

Documents	Interviews	Observations
Safety & security plan	Safety officer /responsible.	- Interior space meets the needs for staff, patients, visitors & vendors safety. - Furnishing & equipment are safe & maintained. - Proper security and access control of identified high risk areas (ionizing radiation rooms, MRI and others) - Proper warning signage and lamps are in place.
Surveillance checklist.		- Appropriate PPE for staff - There are measures to protect patients, visitors, &staff against harm, including assault, violence & aggression.

NSR.22:

Standard:

The facility has well-structured & implemented radiation safety program.

Rationale:

The facility should have documented radiation safety program according to local laws & regulations. The facility environment, staff, patients, relatives & vendors should be safe from radiation hazards.

Survey Process:

- Review the radiation safety program & make sure of presence of level of exposure according to local laws & regulations, shielding methods & safety requirements for staff & patients.
- Review environmental radiation measures, thermo luminescent dosimeter (TLD) &/or badge films of the staff results, CBC results, & lead aprons inspection & check for staff awareness. Review MRI safety program if applicable.

Documents	Interviews	Observations
- Radiation safety program /MRI safety program. - License.	Radiology staff.	Radiology equipment maintained & calibrated.
- TLD/badge films monitoring results. - Environmental monitoring results.		Staff have self-monitoring tool like; badge film, dosimeter or Thermo-luminescent dosimeter (TLD).

Documents	Interviews	Observations
Regular CBC of exposed staff		- For facilities that have "nuclear medicine or PET CT). - Appropriate & safe waste disposal for radioactive materials when applicable. - Isolated sewage disposal. - Safe hot lab for radioisotope processing. - Isolated waiting area for injected patients.
Log book of lead aprons or other shielding tools inspection.		MRI safety program in place and implemented include screening for metals, metallic implants and devices & use of MRI compatible devices. How to manage claustrophobia and medical emergencies.

NSR.23:

Standard

There is a quality control program covering inspection, testing, maintenance and calibration of medical devices.

Rationale:

The facility should have a quality control program to make sure of accurate results, safe and accurate equipment & to keep patients and staff safe from radiation exposure.

Survey process:

Review the quality control program & ensure availability of all required documents, inventory of medical equipment, planned preventive maintenance (PPM) and calibration schedules & Documents of staff training, quality control procedures.

Documents	Interviews	Observations
- Quality control program - Inventory of medical equipment. - PPM & calibration schedule.	Radiology manager /in charge.	-Preventive maintenance & calibration cards on the medical equipment.
Staff training (radiation safety and MRI safety).	Nurses & ask about how to use critical devices as defibrillator.	- Work instructions are available for critical equipment. - Quality control procedures (image uniformity, slice thickness, resolution). - How to minimize radiation dose as possible.

Operating Manual Outlines

A. General Components:

1. overview:

a. A brief general description of the facility.
b. Scope of services.
c. Organizational charts.
d. NO Smoking policy.
e. Parking policy (Accessibility of emergency vehicle to the facility).
f. Internal and external communication processes.
g. Contract oversight / monitoring process.

2. Management of information system:

a. Data management plan.
b. List of approved &prohibited abbreviations.
c. Data retention process.
d. Data backup process.
e. Release of CD Exams to Patient and/or another Party.

3. Medical Record:

a. Initiation (unified medical record number).
b. Contents and organization.
c. Medical record release.
d. Tracking.
e. Retention/storing.
f. Standardized coding system.
g. Medical record destruction.
h. Standardized forms.
i. Monitoring of medical record completion.

4. **Provision of Services:**
    a. Consistent process of registration.
    b. Patient identification policy.
    c. Uniform care process.
    d. Communication with patient having special communication needs.
    e. Care of psychiatric patients.
    f. Effective process to provide cardiopulmonary resuscitation whenever needed.

5. **Quality management & Patient safety:**
    a. Quality improvement, Patient safety & risk management plans.
    b. OVR management system.
    c. Sentinel events management system.
    d. Initiation of a new process or changing of existing one.
    e. Process to prevent wrong patient, wrong site, wrong /procedure.
    f. Patient fall:
        i. Identification of patient at risk.
        ii. Assessment.
        iii. Intervention.

6. **Infection prevention and Control:**
    a. Infection prevention and control structure:
    b. Infection prevention and control plan.
    c. Handling sharps.
    d. Standard and transmission based precautions.
    e. Housekeeping P&P:
        i. A list of all environmental surfaces to be cleaned.
        ii. Schedule of cleaning.
        iii. Procedures to be used.
        iv. Agents to be used.
    f. Handling blood /body fluids spills.
    g. Safe disposal of medical waste.
    h. Handling construction projects.

i. Personnel protective equipment use.
j. Proper hand hygiene practices.
k. Employees' immunization & post exposure management.
l. Safe injection practices.

7. **Effective patient & family education process:**

8. **Patient & family rights:**
   a. Patient & family rights and responsibility statement.
   b. Patient privacy throughout the care process.
   c. Protection of Patient belongings.
   d. Patient protection against abuse, unauthorized access.
   e. Informed consent policy.
   f. Patient complaints policy.

9. **Moderate and deep sedation management system**

10. **Emergency transfer of patients.**

11. **Medication management:**
    a. Medication management plan including:
       i. Procurement.
       ii. Storage.
       iii. Prescribing.
       iv. Preparing.
       v. Administration.
       vi. Monitoring.

12. Facility Management and Safety

a. The facility management and safety program including the following written and approved plans:

i. Safety of the Building.

ii. Security.

iii. Hazardous materials and waste disposal.

iv. Internal emergency.

v. Fire Safety.

vi. Medical equipment.

vii. Utility System.

B. Specific Components:

1. Radiation safety plan.

2. Comprehensive training and competency assessment program .

3. Inventory management and tracking the use of critical materials, supplies, and reagents.

4. Quality control.

5. Radiology service:

a. Reporting critical results.

b. Interventional radiology process.

c. Contrast:

i. Comprehensive Contrast Policy.

ii. Guidelines for IV Access for Contrast.

iii. Intra osseous Iodinated Contrast Injection Guidelines.

iv. Administration of Contrast via Indwelling CVC in the Adult Patient.

v. Administration of Enteric and IV Contrast on Inpatient Unit.

vi. Education for Patients Receiving IV Contrast Policy.

vii. Education Sheet for Patients Receiving IV Contrast.

viii. MRI Criteria for EGFR Lab work.

ix. Contrast Protocol for CTA Brain and Cerebral Perfusion and CT Brain, CTA Brain and Cerebral Perfusion.

d. CT:

i. CT of Patients with Implantable and External Electronic Medical Devices.
ii. CT Protocol Development.
iii. CT Request for Protocol Change.
iv. CT IV Size Protocol for Pediatric Patients.
v. CT IV Size Protocol for Adult Patients.
vi. CT Breast Feeding Information Form.
vii. Body Imaging Percutaneous Procedures Anticoagulation Guidelines.

e. MRI:

i. Contrast Enhanced MRI Information Sheet.
ii. Emergency Situations in the MR Environment.
iii. MR Safety for MR and Non-MR Personnel.
iv. MRI Safety Policy.
v. Screening Patients for MRI Procedures.
vi. Breast Feeding Information Form.
vii. MRI Safety Practices.
viii. Standard of Care for Screening Outpatients Prior to MRI.
ix. MR Zoning Policy.
x. MRI Center Blueprint Zone.
xi. Procedure for Patients that are Breast Feeding After the administration of Gadolinium Intravenously.
xii. Reporting MR Safety Violations.

6. Radiotherapy:

a. Proper staffing.
b. Radiation therapy administration, side effects, and safety precautions.
c. Spill management.
d. Special radiation techniques (brachytherapy, stereotactic radiotherapy, unsealed sources, other techniques), including preparation and delivery guidelines.
e. Radioactive iodine Management.
f. Management of neutropenia and other related complications of radiation therapy.

Leader ship Related Requirements

1. **Leadership manual including:**

   a. Administrative:
      i. Mission, Vision and Values Statement.
      ii. Organizational Chart.
      iii. Leadership Structure.
      iv. Leadership Responsibilities.
      v. Standards of Patient Service.
      vi. Culture of Safety and Quality.
      vii. Leadership Support of Quality Initiative Monitoring and Improvement Activities.
      viii. Budget Process.
      ix. Orientation of Top Management and Senior Medical Staff.
      x. Confidentiality of Information – General Rules.
      xi. Information management plan.
      xii. Community Needs Assessment.
      xiii. Release of Patient Information to News Media.
      xiv. Dress code.
      xv. Disruptive and Inappropriate Behavior.
   b. Ethics:
      i. Research Conduction Guidelines.
      ii. Conduction of Clinical Research.
      iii. Sexual Harassment.
      iv. Conflict of Interest.

2. **Code of conduct.**
3. **Organizational ethics.**
4. **Governance Policy**

5. **Strategic and operational plans.**
6. **Contract monitoring policy.**
7. **Quality, Patient safety and risk management plan/s).**
8. **Key performance indicators.**
    a. Policy.
    b. Indicators.
9. **Training program of facility leaders including not limited to:**
    a. Quality concepts, skills and tools.
    b. Problem solving.
    c. Conflict resolution.
    d. Team management.
    e. Communication skills.
    f. Data management (as related).
    g. Change management.

Workforce Related Requirements

1. **Staffing plans:**
2. **Process of Recruitment.**
3. **Credentialing process.**
4. **Competency assessments:**
    a. Initial.
    b. Ongoing.
5. **Privileging process.**
6. **Radiation Safety Officer:**
    a. Recruiting.
    b. Credentialing.
    c. Clear role (Job Description).
    d. Appraisal.
    e. Training.
7. **Employee Manual including not limited to the following processes:**
    a. Assignment and Reassignment.
    b. Staff appraisal.
    c. Staff complaints.
    d. Staff satisfaction (staff retention).
    e. Code of conduct.
    f. Disciplinary actions.
    g. Termination.
8. **Staff health program with special consideration of:**
    a. Pregnant staff.
    b. Levels of radiation exposure.(proactive and reactive actions)

9. **Job descriptions:**
    a. Policy.
    b. Forms.
10. **New employee orientation program:**
    a. General orientation program.
    b. Specific orientation programs.
11. **Personnel file:**
    a. Initiation.
    b. Management.
    c. Contents.
    d. Update.
    e. Retention time.
    f. Disposal.
12. **Identification of staff training & educational needs.**
13. **Ongoing scheduled educational program.**
14. **Basic and advanced life support certification (as related).**