



الهيئة العامة للاعتماد والرقابة الصحية
GAHAR

Version 1.2

متطلبات تسجيل المراكز الطبية
الخارجية والعيادات المجمعّة ومراكز
جراحات اليوم الواحد



متطلبات تسجيل المراكز الطبية الخارجية والعيادات المجهزة ومراكز جراحات اليوم الواحد

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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 الحديثة 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 لاغياً 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 مطلقاً 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.

اشتراطات ترخيص المراكز الطبية الخارجية والعيادات المجمعّة ومراكز جراحات اليوم الواحد

اشتراطات عامّة:

1. رسم هندسي مُعتمد من مهندس نقايي للمبنى بقياس رسم 1/150.
2. ما يفيد ملائمة المبنى لأداء الغرض المنشأ له فنياً وتقنياً وصحياً موضح به توزيع وتقسيمات وحدات المبنى الداخلية بالتفصيل، كل طابق على حده في حالة تعدد الطوابق.
3. أن تكون حجرات المنشأة الطبية جيدة التهوية والإضاءة.
4. أن تكون المنشأة مزودة بوسائل تغذيتها بالمياه النقية بصفة مستمرة.
5. أن تكون المنشأة مزودة بوسائل الصرف الصحي المناسبة.
6. أن تزود المنشأة بالوسائل والأدوات الصحية اللازمة للتخلص من القمامة والفضلات.
7. أن تزود المنشأة بالأجهزة اللازمة لإطفاء الحرائق.
8. شهادة من إدارة الدفاع المدني والحريق بتوفر الاشتراطات اللازمة لحماية المركز من إخطار الحريق.
9. أن تكون المنشأة مجهزة بوسائل الإسعاف الأولية.
10. شهادة تداول المواد والنفايات الخطرة.
11. ما يفيد الاشتراك أو التعاقد مع محرقة للنفايات الطبية.
12. التقدم بخطة محدد بها الأسلوب الذي سيتم اتباعه لمنع انتشار العدوى بالمنشأة.
13. التقدم بخطة محدد بها الأسلوب الذي سيتم اتباعه للتخلص الآمن من النفايات.
14. بيان واضح بالأجهزة الموجودة للتشغيل.
15. التقدم ببيان العاملين من أطباء وتمريض وممرضات وفنيين وخلافه.
16. صور تراخيص مزاوله المهنة للأطباء وهيئة التمريض والفنيين.
17. الالتزام بتنفيذ الاشتراطات الفنية والصحية المحددة بالقانون رقم ٥١ لسنة ١٩٨١ الخاص بالمنشآت الطبية ولائحته التنفيذية والقرارات الوزارية المكملّة وتعديلاته .

اشتراطات العيادات الخارجية:

1. أن يكون لها مدخل خاص.
2. أن تكون بها أماكن انتظار مناسبة ومزودة بأثاث جيد وملحق بها عدد كاف من دورات المياه.
3. أن يكون بها عدد كاف من غرف الكشف المزودة بوسائل التشخيص المناسبة.
4. يجب على المنشأة الطبية مراعاة أحكام قرار وزير الصحة رقم 291 لسنة 1980 والقرارات المعدلة له بشأن جمع وتخزين وتوزيع الدم في حالة وجود مركز بها لهذا الغرض.
5. تسري أحكام القانون رقم 367 لسنة 1954 في شأن مزاولة مهن الكيمياء الطبية والبكتريولوجيا والباثولوجيا وتنظيم معامل التشخيص الطبي ومعامل الأبحاث العلمية ومعامل المستحضرات الحيوية والقوانين المعدلة له واللوائح والقرارات المنفذة على معامل الفحوص البكتريولوجية والباثولوجية الموجودة بالمنشآت الطبية.

اشتراطات خاصة بمراكز جراحات اليوم الواحد:

1. تزود كل غرفة من غرف المرضى بالمنشأة بأثاث سهل التنظيف لا يعوق التهوية والإضاءة ولا تقل المساحة المخصصة لكل سرير عن 9 متر، على أن تنشأ دورة مياه وحمام لكل عشرة أسرة علي الأكثر في حالة عدم تزويد الغرفة بدورة مياه مستقلة.
2. يجب علي المنشأة تخصيص محطة تمريض مجهزة لكل أربعين سريرا علي أن تمتد هذه المحطة بأثاث خاصة بحفظ الملفات والسجلات وأخري لحفظ الأدوية والمهمات والآلات الطبية اللازمة للعمل التمريضي وكذلك بجهاز إستدعاء.
3. يشترط توافر الاشتراطات الآتية في حجرة العمليات بالمنشأة:
 - أ- ألا تقل مساحة الحجرة التي تجري بها العمليات الصغرى والمتوسطة عن 12م² على ألا يقل طول أحد الأضلاع عن 3 متر، أما الحجرة التي تجري بها عمليات كبيرة فلا تقل مساحتها عن 20م².
 - ب- أن تكون الأبواب والنوافذ جيدة الصنع ومحكمة وأن يكون زجاجها سليما دائما أو في حالة استعمال جهاز التكيف يفضل استعمال نظام التكيف المركزي المزود بالمرشحات.
 - ج- أن تكون الحجرة مزودة بضوء صناعي كاف فوق منصدة العمليات، وأن تكون هناك أجهزة إضاءة احتياطية للعمل في حالة انقطاع التيار الكهربائي.
 - د- تزود الحجرة بالحد الأدنى على الأقل من الآلات الجراحية وأجهزة التخدير والإفافة ووسائل الإسعاف التي تتناسب مع نوع العمليات التي تجرى بها.

- هـ- يلحق بالحجرة في حالة إجراء عمليات جراحية كبرى غرفة أو مكان للإفاقة يكون مجهزة بالتجهيزات المناسبة.
- و- في حالة عدم وجود قسم للتعقيم المركزي بالمنشأة الطبية التي بها جناح للعمليات يلحق بحجرة العمليات غرفة للتعقيم تكون مزودة على الأقل بأتوكلاف يعمل بالبخار وفرن تعقيم بالهواء الساخن وعدد مناسب من علب التعقيم.
- ز- يلحق بالحجرة مكان لتغيير الملابس وغسل الأيدي للجراحين وهيئة التمريض.
- ح- يجب أن تتوفر بكل منشأة طبية بها مائة سرير فأكثر صيدلية يطبق عليها الاشتراطات الواردة بالقانون رقم 127 لسنة 1955 بشأن مزاولة مهنة الصيدلة.
- ط- يجب على المنشأة الطبية مراعاة أحكام قرار وزير الصحة رقم 630 لسنة 1962 بإصدار اللائحة التنفيذية للقانون رقم 59 لسنة 196 في حالة وجود أجهزة للتشخيص أو العلاج بالإشعاعات المؤينة.

المطبخ:

- يجب أن يزود المطبخ بتغذية مياه نقية والوسائل المناسبة للصرف وللتخلص من الفضلات، وأن تكون التهوية والإضاءة جيدة وأن تزود الأبواب والشبابيك بسلك ناموسية.

National Safety Requirements (NSR)

For Ambulatory Services

EVALUATION OF NSR:

General Authority for Healthcare Accreditation & Regulation (GAHAR) is very much focused on individual's safety. These NSR are meant to promote individual's safety in facilities.

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.

DEFINITIONS:

Ambulatory services include but not limited to:

- Polyclinics.
- Cath. lab centers.
- Renal dialysis centers.

ACKNOWLEDGEMENT:

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

A. General Patient Safety Standards:

NSR.1:

Standard:

The patient's safety policy defines Egyptian and WHO Patient Safety recommendations and solutions that include 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 handling critical values/tests.

NSR.1.4 Hand hygiene throughout the organization.

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

Rationale:

To address the most common and critical identified areas which can prevent adverse events and to ensure awareness of the Egyptian and WHO standards for patient safety.

Survey Process:

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

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

NSR.2:**Standard:**

At least two (2) ways are used to identify a patient when giving medicines, taking blood samples and 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.

Survey Process:

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

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

NSR.3:**Standard:**

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

Rationale:

Miscommunication is the commonest root cause for adverse events. Writing down and reading back the complete order or test result by the person receiving the information minimizes miscommunication and 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 and for the reporting of critical test results and check whether it clearly describes the process of documentation and "read-back" by the recipient and measures to be taken in case of critical test results.
- Review documentation in dedicated registers and / or medical records. Interview clinicians and technicians to assess knowledge and implementation.

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

NSR.4:**Standard:**

Current published and generally accepted hand hygiene guidelines, laws and regulations are implemented to prevent healthcare-associated infections.

Rationale:

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

Survey Process:

- Review relevant policy and procedures of hand hygiene.
- Review hand hygiene guidelines.
- Interview facility staff enquiring about hand hygiene technique and 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 and 5 moments.

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

NSR.5:**Standard:**

Each patient's risk of falling, including the potential risk associated with the patient's medication regimen is assessed and periodically reassessed. 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 and directed towards the identified risks from risk assessment.

Survey Process:

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

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

B. Medication Management Safety Standards:

NSR. 6:

Standard:

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

NSR.6.1 Abbreviations not to be used throughout the organization.

NSR.6.2 Documentation of patient's current medications.

NSR.6.3 Labelling of medications, medication containers and other solutions.

NSR.6.4 Prevent errors from high risk medications.

NSR.6.5 Prevent errors from look-alike, sound-alike medications.

Rationale:

Policies and procedures foster a right culture that supports standardization and documentation that helps create consistency in patient safety practices thus minimizing patient harm.

Survey Process:

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

Documents	Interviews	Observations
Medication management safety policy and procedures.	Physicians, Nurses and Pharmacists.	<ul style="list-style-type: none">- Patient care areas.- Labeling of.

NSR.7:**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 and 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) and 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.8:**Standard:**

A process is implemented to obtain and document a complete list of the patient's current medications upon assessment and with the involvement of the patient.

Rationale:

Medication history at assessment effectively reduces medication errors such as omissions, duplications, dosing errors, or drug interactions. This can result from unintended medication discrepancies.

Survey Process:

- Review appropriate number of medical records (at least 10) and check for the documentation of current medications upon assessment.
- Interview with appropriate number of patients and ask them if they are asked by doctors upon assessments about the current medication and educated if any of it will interfere with the new medications.

Documents	Interviews	Observations
Medical records.	Physicians & Patients.	

NSR.9:**Standard:**

All medications, medication containers (e.g., syringes, medicine cups, basins), or other solutions are labelled.

Rationale:

Labelling of medication containers at the point of care assist health care providers to identify the correct medicine and/or fluid at all times and reduce the risk of medication error.

Survey Process:

Observe at the patient care areas if medication containers labelled.

Documents	Interviews	Observations
Policy of medication labeling.	Physicians, nurses and pharmacists for awareness.	Patient care areas.

NSR.10:**Standard:**

Look-alike and sound-alike medications are identified, stored and dispensed to assure that risk is minimized.

Rationale:

Identification and differentiation is an error reduction strategy. Look alike and sound alike (LASA) medications could lead to dispensing and administration of wrong medications.

Survey Process:

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

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

C. Surgical Procedure Safety Standards:

NSR.11:

Standard:

Policy & Procedures for surgical procedures safety includes at least the following:

PS.11.1 Marking of site of surgery preoperative.

PS.11.2 Process for verification of all Documents and equipment needed for surgery preoperatively.

PS.11.3 Accurate documented patient identification preoperatively, and just before surgery (time out).

Rationale:

Performing the right surgery on the right patient and on the right side is the mainstay objective of surgical safety. Establishing related policies and procedures is the initial step for offering safe surgery.

Survey Process:

Review the operative procedures safety policy and procedures and check if it includes all the standard's items. Interview staff to check awareness.

Documents	Interviews	Observations
Operative procedures safety policy and procedures.	Related staff	

NSR.12:

Standard:

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

Rationale:

Vvisible and clear site marking is an error reduction strategy that should be performed by the operating surgeon.

Survey Process:

- Review surgery site marking policy and procedure and check that it specifies situations for site marking states that site marking is done with a recognizable and consistent mark organization wide, should be made by the authorized person performing the procedure and should be done when the patient is awake and aware.
- Review the checklist and observe it is dedicated to this standard. Review relevant post- operative patients' medical records and check for documentation evidence.
- Interview surgeons and check their understanding of this process. Interview relevant post-operative patients and check their involvement in site marking.
- Observe implementation of this process at the intervention room if possible.

Documents	Interviews	Observations
Surgery site marking policy and procedures.	Related staff.	Pre-procedure verification (if possible).
Checklist.		Site markers at patient care areas.

NSR.13:**Standard:**

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

Rationale:

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

Survey Process:

- Review document and equipment verification policy and procedures and ensure that it supports a documented verification process for: patient Documents (consent, physical examination, and medical assessment), patient laboratory and radiologic test results, procedure devices.
- Review the checklist and observe whether it is dedicated to this standard
- Review medical records of post-operative patients and check for checklist utilization. Interview relevant staff checking their understanding of this process.
- Observe implementation of this process at the intervention room if possible.

Documents	Interviews	Observations
Documents and equipment verification policy and procedures.	Related staff.	Pre-surgery procedure verification process.
Documents and equipment verification checklist.		

NSR.14:**Standard:**

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

Rationale:

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

Survey Process:

- Review preoperative policy and procedure for preventing wrong patient, wrong side, and wrong surgery procedure and ensure that it supports patient, procedure, part of body verification just before start of the procedure (Time Out).
- Review the checklist.
- Review medical records of post-operative patients and check for checklist utilization. Interview relevant staff to check on their understanding of this process.
- Observe implementation of this process at the related areas.

Documents	Interviews	Observations
Preoperative / pre-intervention patient identification policy and procedure.	Related staff.	Time out process.
Time out checklist in Medical Record.		

D. Environmental Safety Standards:

NSR.15:**Standard:**

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

NSR15.1 Frequency of inspecting fire detection and suppression systems, including documentation of the inspections.

NSR15.2 Maintenance and testing of fire protection and abatement systems in all areas.

NSR15.3 Documentation requirements for staff training in fire response and evacuation.

NSR15.4 The assessment of fire risks when construction is present in or adjacent to the Facility.

Rationale:

Facility must have an ongoing assessment of compliance with the fire safety requirements and National Civil Defence regulations to effectively identify and minimize risks.

Survey Process:

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

Documents	Interviews	Observations
Fire Safety Plan.	All facility staff.	Functioning fire alarm, firefighting equipment, smoke containment facilities, emergency exit signs, emergency exit doors, and assembly points.
<ul style="list-style-type: none">- Staff participation in fire and evacuation drills.- Firefighting training.		Staff response in case of fire and evacuation.
Fire Safety Inspection Reports and risk assessment.		<ul style="list-style-type: none">- Safe storage.- Smoking is kept in a safe area.- Using kettles and other high risk devices.- Unsafe electric cords.
Fire and alarm system maintenance records.	Maintenance Staff.	

NSR.16:**Standard:**

Fire drills are conducted at least quarterly in different clinical areas and different shifts, including at least one unannounced annually.

Rationale:

The facility staff should be well trained on fire fighting and safe evacuation through practical simulations and regular drills.

Survey Process:

Review the Documents of fire drills with dates, timings and staff who participated and involved areas in the facility. Review corrective action plan based on the drill evaluation. Interviewing staff to check the awareness of fire safety plan and basic procedures in such cases like RACE (Rescue, Alarm, Confine, Eextinguish /Evacuate) &PASS (Pull, Aim, Squeeze &Sweep).

Documents	Interviews	Observations
Drill evaluation and corrective actions.	All facility staff.	Fire alarm system, firefighting methods, smoke containment facilities.
Documents showing staff participation in fire drills.		Staff response in case of fire (such as using fire extinguisher).
Discussion of the drill results in the safety committee meeting.	Firefighting plan responsible staff.	

NSR.17:**Standard:**

There is a well-structured and implemented hazardous materials and waste management plan for the use, handling, storage, and disposal of hazardous materials and waste that addresses at least the following:

NSR17.1 Safety and security requirements for handling and storage.

NSR17.2 Requirements for personal protective equipment.

NSR17.3 Procedures and interventions to take following spills and accidental contact or Exposures.

NSR17.4 Disposal in accordance with applicable laws and regulation.

NSR17.5 Labeling of hazardous materials and waste.

NSR17.6 Monitoring data on incidents to allow corrective action.

Rationale:

The facility environment, staff, patients, relatives and vendors should be safe from hazardous material exposure and waste all over the time and the facility has a hazardous and waste management plan.

Survey process:

Review hazardous material and waste disposal plan, hazardous material and waste inventories, MSDS, and inspect hazardous material labeling, storage and waste collection, segregation storage and final disposal.

Documents	Interviews	Observations
Hazardous material (hazmat) and waste disposal plan.	All facility staff.	Storage and labelling of hazardous materials.
Hazmat and waste inventories.		<ul style="list-style-type: none"> - Waste collection bags, storage place as regard: - Proper ventilation, cleaning and appropriate labelling and signage.
MSDS (material safety data sheet).		
<ul style="list-style-type: none"> - Relevant contracts. - Hazardous material, waste risk assessment. 		

NSR.18:

Standard:

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

Rationale:

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

Survey process:

- Review the safety and security plan, and make sure of presence of high risk areas, suitable risk assessment surveillance, security high risk areas and security requirements, access control areas.
- Review surveillance rounds plan, checklist, different observations and check for proper corrective actions when applicable. Inspect workers in different areas like workshops and waste to make sure of using suitable personnel protective equipment (PPE). Check for security plan, cameras monitors, staff ID and access controlled areas.

Documents	Interviews	Observations
Safety & security plan.	Safety officer /responsible.	<ul style="list-style-type: none"> - Surveillance rounds are conducted in patient care areas no less than twice per year and in non-clinical areas no less than once annually. - Suitable tool is used with clear corrective action for survey observations. - Interior space meets the needs for staff, patient, visitors, vendor's safety. - Proper, comfortable and safe physical environment is there as regard light, ventilation, and odor. - Furnishing and equipment are safe and maintained.
Surveillance checklist.		<ul style="list-style-type: none"> - Appropriate PPE for staff. - Appropriate warning signage. - There are measures to protect against infant/child abduction and to protect patients, visitors, and staff from harm, including assault, violence and aggression.

NSR.19:

Standard:

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

Rational:

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

Survey Process:

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

Documents	Interviews	Observations
Radiation safety program / license.	Radiology staff.	Radiology department /equipment.
<ul style="list-style-type: none">- TLD/badge films monitoring results.- Environmental monitoring results.		Staff had self-monitoring tool like (badge film, dosimeter or TLD).
Regular CBC of exposed staff.		
Log book of lead aprons or other PPE inspection.		

NSR.20:**Standard:**

There is a well-structured and functioning Laboratory safety program.

Rational:

The facility should have a documented laboratory safety program that covers all safety requirements specific for the laboratory. The facility Environment, staff, patients, relatives and venders should be safe from laboratory hazards.

Survey process:

Review laboratory safety program which should include at least: list of chemicals and hazardous materials, dealing with spills, safety requirements, suitable PPE, maintenance and calibration of medical equipment, and staff orientation, and proper waste disposal. Review laboratory safety reports to the facility safety responsible.

Documents	Interviews	Observations
Lab safety program.	Lab staff.	Lab ventilation, safety of medical equipment.
MSDS include hazardous material inventory.		Storage of hazardous material, staff using suitable PPE and waste disposal, spill kits.

NSR21.**Standard:**

There is a well-structured and implemented plan for selecting, inspecting, maintaining, testing, and safe usage of medical equipment that addresses at least the following:

NSR21.1 Inventory of all medical equipment.

NSR21.2 Schedule for inspection and preventive maintenance according to manufacturer's recommendations and frequency of repair and breakdown.

NSR21.3 Testing of all new equipment before use and repeat testing, as part of the preventive maintenance.

NSR21.4 Testing of alarm systems.

NSR21.5 Qualified individuals who can provide these services.

NSR21.6 Data monitoring for frequency of repair or equipment failure.

NSR21.7 Ensure only trained and competent people handle specialized.

Rationale:

The facility should have a documented program for medical equipment that covers all required standers.

The facility should ensure that all diagnostic medical equipment are maintained and calibrated to minimize diagnostic errors.

Survey process:

- Review the medical equipment maintenance program, and ensure availability of all required documents.
- Review staff training documents, inspect preventive maintenance cards and calibration on different equipment, and check for work instructions on some critical equipment.

Documents	Interviews	Observations
<ul style="list-style-type: none">- Medical equipment maintenance program.- Inventory of medical equipment updated and accurate.- Staff orientation /training of medical equipment.	Biomedical maintenance responsible.	<ul style="list-style-type: none">- Preventive maintenance and calibration documents.- Medical equipment.

NSR22.**Standard:**

There is a well-structured and implemented plan for regular inspection, maintenance, testing and repair of essential utilities addresses at least the following:

NSR23.1 Electricity, including stand-by generators.

NSR23.2 Water.

NSR23.3 Heating, ventilation, air conditioning, appropriate temperature, humidity and eliminates odors.

NSR23.4 Medical gases.

NSR23.5 Communications systems.

NSR23.6 Waste disposal.

NSR23.7 Regular inspections.

NSR23.8 Regular testing.

NSR23.9 Regularly scheduled maintenance.

NSR23.10 Correction of identified risks and deficiencies.

Rationale:

The facility should have a documented program for utility management that covers all required standers.

The facility should keep safe and effective key utility system 23 hour 7 days per week.

Survey Process:

Review utility management plan and confirm availability of all required systems, regular inspection, maintenance and backup utilities. Review inspection Documents and preventive maintenance schedule, contracts and equipment, testing results of generators, tanks or other key system to make sure from facility coverage 23/7.

Documents	Interviews	Observations
<ul style="list-style-type: none"> - Utility management plan. - Utility inventory. - Preventive maintenance schedule. - Contracts. 	<p>Utility manger and workers.</p>	<ul style="list-style-type: none"> - Preventive Maintenance Documents are present on the machines or easily accessible to the end user. - Safe and labelled electric boards and connections - Fuel tanks are safe and suitable. - Water tanks are suitable to the facility needs with disinfection and cleaning evidence. - Temperature monitoring of all fridges is in place.
<ul style="list-style-type: none"> - Utility inspection and testing documents. 		<ul style="list-style-type: none"> - Medical gases. - Appropriate sewage disposal. - Suitable temperature and humidity monitoring of concerned areas.

Operating Manual Outlines

1. **Facility 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.

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 Care and Services:

- a. Consistent process of registration.
- b. Assessment and Reassessment processes.
- c. Patient identification policy.
- d. Uniform care process.
- e. Communication with patient having special communication needs.
- f. Care of psychiatric patients.
- g. Effective system to provide cardiopulmonary resuscitation across all facility areas.
- h. Pain management.
- i. Plan of care development.

4.1. For ambulatory surgical and outpatient procedural centers:

- a. VTE screening & prophylaxis processes.
- b. Discharge planning.
- c. Blood and blood products handling and administration.
- d. Mortality and morbidity review.
- e. Most responsible physician policy.
- f. Integrated, continued & coordinated care including not limited to:
 - i. Standardized handover.
 - ii. Consultancy.
 - iii. Transfer within the facility.
 - iv. Efficient discharge process.
 - v. Transfer (and transport) to other organization.

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. Patient fall:
 - i. Identification of patient at risk.
 - ii. Assessment.
 - iii. Intervention.
- f. Verbal and telephone communication.

5.1. For ambulatory surgical and outpatient procedural centers:

- a. Process to prevent wrong patient, wrong site, wrong surgery /procedure, including not limited to:
 - i. Site marking.
 - ii. Verification.
 - iii. Surgical check list.
 - iv. Time out.

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. Staff safety within CSSD.
- f. Housekeeping P&P:
 - i. A list of all environmental services to be cleaned.
 - ii. Schedule of cleaning.
 - iii. Procedures to be used.
 - iv. Agents to be used.
- g. Handling blood /body fluids spills.
- h. Safe disposal of medical waste.
- i. Laundry:
 - i. Linen management starting from collecting linen from patients' rooms until completion of the cleaning process.
 - ii. Handling, transfer and storage of clean linen.
- j. Handling construction projects.

- k. Personnel protective equipment use.
- l. Proper hand hygiene practices.
- m. Reporting of communicable diseases to relevant authorities.
- n. Employees' immunization & post exposure management.
- o. Safe injection practices.

6.1. For ambulatory surgical and outpatient procedural centers:

- a. Disinfectants usage outside the CSSD (bronchoscope /endoscopy).
- b. Reprocessing of single use items.
- c. Surgical site infection care bundle.
- d. Kitchen staff hygiene and health policies.

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. Dealing with patient who refuses treatment.
- g. Patient complaints policy.

9. Social care:

- a. Psychosocial screening.
- b. Psychosocial comprehensive assessment.
- c. Psychosocial plan of care (when required).

10. Radiology service:

- a. Radiation safety plan.
- b. Reporting critical results.
- c. Interventional radiology.
- d. Proper staffing.

11. Medication management:

- a. Medication management plan including:
 - i. Procurement.
 - ii. Storage of regular, refrigerated, frozen, Biologicals & vaccines in stores, pharmacies and patient care areas.
 - iii. Prescribing.
 - iv. Preparing.
 - v. Dispensing.
 - vi. Administration.
 - vii. Monitoring.
- b. Handling high alert medications.
- c. Handling look-alike & sound-alike (LASA) medications.
- d. Handling out of stock, shortage and disaster needs of medications.
- e. Storage & safe management of hazardous medications and pharmaceutical chemicals.
- f. Accessibility, availability, monitoring & security of emergency medications.
- g. Handling narcotics, psychotropic and controlled medications.
- h. Prescribing antibiotics.
- i. Labeling of medications.
- j. Infection prevention and control in pharmacy.
- k. Handling recalled and damaged medications.
- l. Pharmaceutical outpatient education and counseling.
- m. Handling adverse drug reactions.
- n. Handling medication errors.

12. Dental services:

- a. Comprehensive assessment.
- b. Informed consent.
- c. General, moderate & deep sedation.
- d. Infection control in dental services.

13. Laboratory services:

- a. Clear scope of services.
- b. Staffing plan and qualifications.
- c. Comprehensive training and competency assessment program.
- d. Laboratory safety program.
- e. Safety and infection control training program.
- f. Requests for laboratory tests.
- g. Contract oversight.
- h. Inventory management and tracking the use of critical materials, supplies, and reagents.
- i. Specimen collection, handling and management.
- j. Correct specimen labeling.
- k. Establishing, verifying and reevaluation of reference ranges.
- l. Reagents and solutions management system.
- m. Quality control of test methods.
- n. Results reporting including.
 - i. Contents of its reports.
 - ii. Critical results reporting.
 - iii. Amending reported laboratory results.
- o. Laboratory records retention.
- p. Sample retention.
- q. Reference laboratory services.
- r. Point of care testing.
- s. Proficiency Testing (PT).

14. 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. External emergency.
 - v. Internal emergency.
 - vi. Fire Safety.
 - vii. Medical equipment.
 - viii. Utility System.

For ambulatory surgical and outpatient procedural centers:

15. Anesthesia:

- a. Anesthesia planning.
- b. Pre anesthesia assessment.
- c. Safe handling and storage of anesthetic medications/agents.
- d. Intraoperative monitoring of anesthetized patients.
- e. Documentation of anesthesia care.
- f. Post-operative transfer to recovery room.
- g. Patient care within the recovery room.
- h. Discharge from recovery room.

16. Moderate and deep sedation management system.

17. Operative care:

- a. Patient acceptance in OR.
- b. Assessment prior to surgery (including emergency operations).
- c. Handover process between unit/ward nurse and operating room nurse.
- d. Prevention of wrong patient, wrong surgery/procedure, or wrong site.
- e. Infection control measures in operating room and recovery room including isolation Precautions including Handling patients with infectious diseases (e.g. Tuberculosis, AIDS, and Hepatitis).

- f. Safe labeling, handling, storage and transportation of laboratory specimens in operating and recovery rooms.
- g. Safe handling, storage and transportation of commonly used chemicals in operating and recovery rooms.
- h. Safe handling, transportation and storage of blood in operating and recovery rooms.
- i. Prevention of inadvertent retention of instruments/sponges in surgical wounds.
- j. Operative report.
- k. Post-operative plan of care.
- l. Equipment checks and periodic maintenance.
- m. Environmental controls in operating room and recovery room.
- n. Fire safety plan in OR.

Leadership 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. Plan for the provision of Patient Care and Services.
- vii. Culture of Safety and Quality.
- viii. Leadership Support of Quality Initiative Monitoring and Improvement Activities.
- ix. Budget Process.
- x. Orientation of Top Management and Senior Medical Staff.
- xi. Information management plan.
- xii. Confidentiality of Information –General Rules.
- xiii. Community Needs Assessment.
- xiv. Release of Patient Information to News Media.

- xv. Dress code.
- xvi. Disruptive and Inappropriate Behavior.

b. Ethics:

- i. Sexual Harassment.
- ii. Conflict of Interest.

- 2- Code of conduct.**
- 3- Organizational ethics.**
- 4- Departmental leadership policy**
- 5- Requirements, responsibilities and appointment of leaders.**
- 6- Strategic and operational plans.**
- 7- Contract monitoring process.**
- 8- Quality, Patient safety and risk management plan/s).**
- 9- Key performance indicators.**
- 10- Policy**
 - a. Indicators.
- 11- Facility wide committees Structures and functions.**
- 12- Training program of hospital 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 (Departmental & Facility wide).**
- 2. Process of Recruitment.**
- 3. Credentialing process.**
- 4. Competency assessments.**
 - a. Initial and ongoing.
 - b. Specialized services competency assessments.
- 5. Privileging process.**
- 6. 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.
- 7. Medical Staff Bylaws.**
- 8. Nursing Staff Bylaws.**
- 9. Staff health program.**
- 10. Job descriptions.**
 - a. Policy.
 - b. Forms.
- 11. New employee orientation program:**
 - a. General orientation program.
 - b. Specific orientation programs.

12. Personnel file:

- a. Initiation.
- b. Management.
- c. Contents.
- d. Update.
- e. Retention time.
- f. Disposal.

13. Identification of staff training & educational needs.

14. Ongoing scheduled educational program.

15. Basic and advanced life support certification (as related).

