متطلبات تسجيل
معامل التحاليل الطبية

الهيئة العامة للاعتماد والرقابة الصحية
GAHAR

متطلـــبات تسجيل
معامـل التحاليـل الطبيـة

Version 2 - 2020

Table of Contents

مقدمة

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 وتأكيد 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.

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

رابعاً: 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.

خامسا: الوثائق المرفقة:

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

ب- المتطلبات الوطنية للسلامة بالمنشآت الصحية.

ج- دليل تشغيل المنشأة الصحية والذي يوضح تفصيلا نظام الجودة الشامل داخل المنشأة.

د- دليل متطلبات القيادة في المنشأة الصحية.

ه- دليل المتطلبات الأساسية للموارد البشرية في المنشأة الصحية.

سادسا: تلتزم الهيئة بإتاحة ما يلي:

أ. الوثائق المرفقة (في البند خامسا) 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.

سابعا: يكون تسجيل المعمل وفقا لمجال الخدمات المقدمة بأنواع وأسماء والأرقام المسلسلة للأجهزة وأنواع التحاليل ولا يجوز وضع علامة التعاقد مع التأمين الصحي الشامل الا على التحاليل التي يتم اجراؤها بنفس الأجهزة، وفيما يختص بالتحاليل التي يتم عملها في معمل آخر خارجي لا يجوز ذلك الا إذا كان هذا المعمل مسجلا لدى الهيئة العامة للاعتماد والرقابة الصحية مع مراعاة ملحوظة (1)، مع الاحتفاظ بالحقوق المنصوص عليها بقانون (2) لسنة 2018 للهيئة في ها الشأن.

❖ ملحوظة (1): في حالة أن المعمل الخارجي غير مسجل بالهيئة يجب اخذ موافقة مسبقة من الهيئة على هذا التعامل بناء على السياسات والإجراءات المتبعة في هذا الشأن بالهيئة.

ثامنا: اكتشاف أي تلاعب أو تزوير أثناء عمليات التقييم أو بعدها يعرض المنشأة لإلغاء التسجيل.

الفصل الأول

متطلبات ترخيص معامل التحاليل الطبية

(وفقا للإدارة المركزية للمعامل بوزارة الصحة)

الوثائـق:

1. أصل ترخيص مزاولة المهنة لأحد أفرع التحاليل الطبية الذي يفيد القيد في أحد سجلات وزارة الصحة الأربعة (كيميائي طبي – بكتريولوجى – باثولوجى – باثولوجى إكلينيكي) أو مستخرج رسمي منها، وذلك لصاحب المعمل وكذلك للمدير المسئول.
2. رسوم هندسية للمعمل معتمدة جميعها من مهندس نقابي ويبين على الرسم ما يلي:
   - مسقط أفقي بمقياس رسم لا يقل عن 100/1 (وهو عبارة عن قطاع يبين المساحات الأفقية والوحدات).
   - مسقط رأسي بنفس مقياس الرسم (وهو عبارة عن قطاع طولي يبين الارتفاعات).
   - موارد المياه وطرق الصرف الصحي (بعلامات مميزة على المسقط الأفقي)
   - الرسم الإرشادي (وهو رسم كروكي يبين موقع المعمل).
3. إقرار من المدير المسئول يقر فيه سيادته بأنه مسئول عن إدارة المعمل طبقا لتعليمات الوزارة.
4. الشهادة الصحية الدالة على خلو العاملين بالمعمل من الأمراض المعدية والجلدية وتستخرج من مكتب الصحة الواقع في دائرتها المعمل للعاملين الذين لا يعملون بالحكومة أو القطاع العام (في حالة عدم وجود عمال أو عاملين يستوجب الإقرار بذلك لإلغاء شرط تقديم شهادة صحية).
5. إقرار من صاحب المعمل، وكذلك من المدير الفني المسئول، يقر فيه سيادته بأنه لم يسبق صدور حكم ضده ترتب عليه غلق عيادته أو معمله السابق.
6. صورة فوتوغرافية من عقد الملكية الموثق أو عقد الإيجار المثبت تاريخه للمعمل أو أي سند ملكية آخر مع الأصل للاطلاع عليه وإعادته.
7. صورة بطاقة الرقم القومي لكل من صاحب المعمل ومديره المسئول وكذلك صورة البطاقة لمدير المنشأة الطبية الملحق بها المعمل في حالة كونه كذلك.
8. صورة من ترخيص المنشأة الطبية في حالة المعمل الملحق بمنشأة طبية كخدمة مكملة.
9. صورة من تسجيل المنشأة الطبية بنقابة الأطباء.
10. صورة من عقد المحرقة المتعاقد معها وصورة تفيد سداد رسم التخلص من النفايات الخطرة للثلاث أشهر السابقة للزيارة التقييمية وصورة ترخيص تداول النفايات الخطرة طبقاً لقانون البيئة رقم 4 لسنة 2004م.

11. بيان بتجهيزات المعمل يتضمن أسماء الأجهزة والأرقام المسلسلة لكل جهاز وأسماء العاملين به وتراخيص مزاولة المهنة الخاصة بهم.

12. في حالة التقدم للترخيص من غير الأطباء البشريين يلزم تعيين طبيب بشرى لأخذ العينات من المرضى، ويلزم لذلك- :

- صورة من ترخيص مزاولة المهنة الطب البشرى أو صوره من كارنيه النقابة.
- إقرار من صاحب المعمل (بتعيين الطبيب البشرى مسئول عن أخذ العينات من المرضى).
- إقرار من الطبيب البشرى بقبوله أن يكون مسئولاً عن أخذ العينات من المرضى.

الاشتراطات الصحية والفنية المطلوبة طبقاً لأحكام القانون:

أولاً: يجب أن تكون المباني من مادة مقبولة صحياً وهندسياً ويجب ألا يقل ارتفاع الحوائط عن 270سم على أن تكون الحوائط مدهونة بمادة ملساء (قيشانى – زيت – ورق).

ثانياً: يجب ألا تكون أرضية المعمل منخفضة عن مستوى الطريق العام (سطح الشارع).

ثالثاً: المعمل عبارة عن شقة مستقلة من بابها وتتكون من حجرة أو أكثر للمعمل، حجرة أو مكان محدد للتحضير واستلام العينات بالإضافة إلى حجرة أو مكان لاستراحة المرضى وحمام، ومن الممكن أن تكون هناك حجرة أخرى مكتب لطبيب المعمل إن أمكن ذلك، وفى حالة العيادات الطبية التخصصية والمستشفيات الخاصة الملحق بها معمل يتم التغاضي عن شرط الباب المستقل بشرط توافر كل التجهيزات المطلوب للمعمل بحيث تشكل في مجموعها وحدة واحدة تسمى "وحدة المعمل."

رابعاً: يجب وضع لافتة على المعمل مدون عليها بحروف ظاهرة باللغة العربية اسم المرخص له، اسم المدير المسئول، ونوع التخصص، ويحظر استخدام الأسماء الأجنبية مثل " المعمل الألماني أو الأمريكي أو الفرنسي أو الدولي أو ما شابه ذلك."

خامساً: يجب وضع سلك ضيق وثابت على النوافذ والفتحات منعا لدخول الحشرات، وجعل باب المعمل مغلق دائماً، ومدون عليه عبارة "المعمل – ممنوع الدخول لغير العاملين."

سادساً: يجب أن تكون الإضاءة والتهوية مناسبين بمعنى أن تكون مساحة الفتحات التي على ممر هوائي مفتوح مساوية 6/1 مساحة الأرضيات على الأقل ويجب أن تكون أرضيات المعمل من مادة صماء (سيراميك - بلاط – خشب باركيه – قنال تكس.. إلخ)، وأن تكون الأبواب والنوافذ نظيفة ومدهونة بطلاء زيتي.

سابعاً: يجب توافر مصدر مائي عمومي، وفى حالة عدم وجود مصدر مائي يجب توافر طلمبة رفع أو ضخ كابسة لتوريد المياه اللازمة بشرط أن تتوافر فيها وفى المياه الناتجة عنها الاشتراطات الصحية المطلوبة كما يجب أن يكون الصرف بطريقة صحية وموضحة على الرسم الهندسي المقدم للحصول على الترخيص.

ثامناً: يجب توافر حوض كامل الصرف داخل حجرة المعمل أو في حجرة التحضير واستلام العينات بشرط أن تكون قريبة من حجرة المعمل.

تاسعاً: يجب توافر الكيماويات والكواشف والأجهزة المعملية اللازمة للعمل بها وذلك حسب كل تخصص، وتنقسم الأجهزة المعملية الضرورية إلى:

أ- الأجهزة المعملية المتنقلة هي:

1. ميكروسكوب كامل العدسات ومزدوج العدسات العينية.
2. جهاز تعقيم "أوتوكلاف" ويكون هاما في تخصص التحاليل البكتريولوجية.
3. جهاز طرد مركزي (سنترفيوج) لا تقل سرعته عن 1000 لفة /دقيقة.
4. فرن هواء ساخن للتعقيم يمكن أن تصل درجة حرارته لأكثر من 120 درجة.
5. جهاز لتحضين الميكروبات "محضن."
6. ثلاجة مناسبة في الحجم لكمية العمل بالمعمل.
7. ميزان حساس.
8. جهاز تقطير للمياه، ويمكن الاستغناء عنه في حالة وجود مياه مقطرة تباع جاهزة.
9. أواني زجاجية مختلفة السعات والأشكال لوضع المستنبتات والأصباغ والسوائل اللازمة لعمل الأرضيات المعملية.
10. أواني خاصة لوضع المواد المطهرة التي يجب أن تكون معدة لتطهير الأماكن المعرضة للتلوث.
11. أواني خاصة للفضلات والنفايات الخطرة ذات أغطية محكمة يمكن فتحها أو غلقها بدون ملامستها باليد.

ملحوظات هامة:

في حالة معامل التحاليل الباثولوجية: يجب توافر جهاز لتقطيع عينات الأنسجة المختلفة إلى شرائح للفحص الميكروسكوبي "ميكروتوم" ويكون مستوفياً لجميع الأجزاء والمشغلات اللازمة لتشغيله.

في حالة المعمل الكيميائي: يجب توافر جهاز طيفي مقارن للألوان على الأقل للاستعمال في التحاليل الكيميائية المختلفة بالطرق الطيفية الكيميائية "كلارومیتر – اسبكتروفوتوميتر."

- في حالة المعمل البكتريولوجى: يجب توفير جهاز التعقيم "الأوتوكلاف."
- يجب توافر جهاز إطفاء الحرائق "طفاية حريق مناسبة."

- يجب توفير كل ما تراه وزارة الصحة لازما لاستكمال المعمل من أدوات وأجهزة ومستحضرات كل حسب نوع المعمل ونطاق عمله.

ب- الأثـاث:

1. يجب توفير البنشات اللازمة لوضع الأجهزة المعملية عليها.
2. أرفف أو أدراج لحفظ الأواني الزجاجية.
3. دواليب لحفظ الكيماويات والأجهزة المعملية الزائدة، والمستنبتات والسموم.
4. يجب أن تظل جميع الدواليب والأرفف نظيفة ومرتبة ويلصـــق عليها البطاقات الدالة على نوعها ومحتوياتها .

قواعد اتخاذ القرار:

♣قواعد القرار الأول:

أ - اجتياز جميع المتطلبات الخمسة للتسجيل بنسبة تطابق 80 %فأكثر.

ب- اجتياز الأقسام الفرعية بالمتطلبات من الثاني الى الخامس من متطلبات التسجيل بنسبة تطابق 70 %فأكثر .

ج- عدم وجود معايير (غير مطابقة) بمتطلبات السلامة الوطنية .

♣القرار: تسجيل المنشأة لمدة عام بسجلات الهيئة العامة للاعتماد والرقابة الصحية.

♣قواعد القرار الثاني:

أ - نسبة التطابق بالمتطلبات الخمسة أقل من 80 % ولا تقل عن حد أدنى 70%.

ب- وجود حد أقصى معيارين غير مطابقين بأحد متطلبات السلامة الوطنية.

♣ القرار: تسجيل المنشأة تسجيل مشروط باجتياز الزيارات التقييمية الثانية بعد ستة أشهر بسجلات الهيئة العامة للاعتماد والرقابة الصحية.

♣ قواعد القرار الثالث:

أ - الحصول على نسبة تطابق أقل من 70 %بأحد المتطلبات.

ب- وجود خطر بّين على أرواح المتعاملين بالمنشأة يتفق عليه فريق المراجعين وتقره اللجنة العليا للاعتماد.

♣ القرار: رفض تسجيل المنشأة بسجلات الهيئة العامة للاعتماد والرقابة الصحية

طريقة احتساب المعايير:

❖ عند حساب درجة المعيار يكون بالطريقة الأتية:

يتم احتساب نتيجة المعايير المفردة كل على حده ويتم احتساب نتيجة المعايير التي تحتوي على معايير فرعية من مجموع متوسط كافة المعايير الفرعية الخاصة بها.

❖ أثناء حساب النتيجة الإجمالية يتم احتساب المعايير الرئيسية فقط.

لحساب كل معيار:

20 ٪ للوثائق والمستندات (السياسات والإجراءات والخطط).

20 ٪ لمقابلات القادة/ العاملين.

60 ٪ التطبيق العملي.

❖ الاستثناء فقط في المعايير التي تتطلب مستندات فقط:

50 ٪ للوثائق والمستندات (السياسات والإجراءات، الخطط، السجلات وملفات المرضي).

50 ٪ لمقابلة القادة/العاملين.

❖ معايير متطلبات السلامة الوطنية:

أقل من 50% = غير مطابق = 0

من 50% الى اقل من 80 %= مطابق جزئي =1

80% او أكثر = مطابق = 2

❖ ملحوظة: يقوم المراجعين بعملية المراجعة (للسجلات والأوراق والسياسات والملفات الطبية وكل ما تتطلبه عملية المراجعة) في زيارة التقييم الأولي عن مدة تصل الى (30) يوم سابقة للزيارة التقييمية وتمتد هذه المدة من تاريخ الزيارة الأولي الى أي زيارة لاحقة .

Chapter 2

National Safety Requirements (NSRs) for Clinical Laboratories

A. General Patient Safety Standards:

NSR.1

Standard:

The laboratory develops and implements a policy(ies) and procedure(s) for proper patient and specimen identification using at least two unique identifiers during the total testing process.

Rationale:

Wrong identification of the patient or the specimen is a significant error that may have grave consequences. Using at least two unique identifiers for each patient and specimen during the total testing process is the key driver in minimizing such preventable errors.

Survey Process:

- Review relevant policy(ies) and procedure(s) and check whether it states the unique identifiers for the patient and the specimen.
- Review an appropriate number of request forms and check each one for the presence of the identifiers mentioned in the policy(ies) and procedure(s).
- Observe patient identification in the pre-examination process.
- Observe identification of the specimen (label/barcode) for the identifiers during the total testing process.
- Interview a number of laboratory staff to ensure knowledge of patient and specimen identification.

Documents	Interviews	Observations

Patient and specimen identification policy(ies) and procedure(s)	Interviews laboratory staff to ensure knowledge of the patient and specimen identification policy(ies) and procedure(s)	Patients identification in the pre-examination process (10 observations)
		Specimens identification in the total testing process (10 specimens)

NSR.2

Standard:
A well-defined and implemented process for reporting, and documentation of enlisted critical test results with evidence of reporting.

Rationale:

Critical lab results reporting is a very important patient safety issue, in case of critical lab results (The patient and referring physician should be informed through a clear, unified, timely, and documented process).

Survey Process:

- Review relevant policy(ies) and procedure(s) for reporting the critical test results.
- Review records of the critical test results reporting.
- Review the list of defined critical values.
- Interview laboratory staff to assess knowledge and implementation of critical lab tests reporting.

Documents	Interviews	Observations
Critical test results reporting policies and procedures	Interview laboratory staff to assess knowledge and	

	implementation of critical lab tests reporting	
List of defined critical values		

NSR.3

Standard:
The laboratory has a documented and implemented policy(ies) and procedure(s) for the proper handover of patient data and specimens between laboratory staff/units.

Rationale:

The primary objective of handover is the correct transmission of accurate patient data and specimens among laboratory staff in the total testing process to ensure the correct result released to the patient.

Survey Process:

- Review policy and procedure for the handover of patient data and specimens between laboratory staff/units.
- Review a handover logbook, including a logbook of receiving samples from different units (manually or electronically).
- Interview laboratory staff to assess knowledge and implementation of handover.

Documents	Interviews	Observations
Handover communication policy and procedure	Interview laboratory staff to assess knowledge and implementation of the handover	Observation of handover policy implementation in different laboratory units
A handover logbook		

NSR.4

Standard:

The laboratory develops and implements policies and procedures of hand hygiene to prevent healthcare-associated infections.

NSR.4.1 Availability of hand hygiene facilities and supplies in different laboratory areas.

NSR.4.2 Availability of hand hygiene education materials in the relevant areas.

Rationale:

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

Survey Process:

- Review relevant policies and procedures of hand hygiene.
- Review available hand hygiene guidelines.
- Interview laboratory staff, enquiring about hand hygiene technique.
- Observe hand hygiene facilities in different laboratory areas.
- Check availability of supplies (soap, tissue paper, alcohol hand rub, etc.).
- Observe compliance of laboratory staff with hand hygiene technique.

Documents	**Interviews**	**Observations**
Hand hygiene policy and procedures	Interview from 3-5 laboratory staff members to assess knowledge about the hand hygiene policy and procedure	Hand hygiene facilities (such as hand washing sinks, alcohol dispensers. etc.)
Hand hygiene guidelines		Hand hygiene supplies

		Staff compliance (3-5 observations at least)

B. Environmental Safety Standards:

NSR.5

Standard:
The facility develops & implements fire and smoke safety plan that addresses prevention, early detection, response, and safe exit when required in case of fire or other emergencies and including:
NSR.5.1 Frequency of inspecting fire detection and suppression systems, including documentation of the inspections.
NSR.5.2 Maintenance and testing of fire detection and abatement systems in all areas.
NSR.5.3 Documentation of staff training on fire response and evacuation.
NSR.5.4 Regular fire drills are performed and documented at least quarterly
NSR.5.5 "No smoking "policy & procedures are developed and implemented

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

Survey Process:
- Review the fire safety plan, laboratory fire safety inspections, and fire system maintenance.
- The fire alarm should be effectively working.
- Firefighting and smoke containment should comply with civil defense requirements. A review plan of testing (drills) and staff training (all staff should be trained on fire safety).

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

NSR.6

Standard:
The facility develops and implements a plan for (Hazardous materials (Hazmat) and waste management) for the use, handling, storage, and disposal of hazardous materials and waste addressing at least the following:
NSR.6.1 Safety and security requirements for handling and storage.
NSR.6.2 Requirements for personal protective equipment.
NSR.6.3 Procedures and interventions to be implemented, following spills and accidental contact or exposures.
NSR6.4 Waste disposal in accordance with applicable laws and regulation.
NSR6.5 Labeling of hazardous materials and waste.

Rationale:

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

Survey Process:

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

Documents	Interviews	Observations
Hazardous material and waste disposal plan	Laboratory staff to ensure implementation of the policy	Storage and labeling of hazardous materials
Hazmat and waste inventories		• Waste collection bags • Storage place, regarding proper ventilation, cleaning, and appropriate labeling and signage
MSDS		Disposal of liquid hazardous waste
Relevant contracts		Disposal of microbiological waste
Hazardous material and waste risk assessment		Disposal of radioactive waste (when applicable)

NSR.7

Standard:
The facility develops and implements safety and security plan(s) addressing at least the following:

NSR.7.1 At least a semiannual risk assessment of the physical facility.

NSR.7.2 Implemented corrective actions are documented.

NSR.7.3 High-risk areas are identified, labeled, and secured.

NSR.7.4 All staff are carrying identification badges.

Rationale:
The facility shall have a safety and security plan that cover all requirements. The facility shall ensure a safe and secure physical environment all the time.

Survey Process:

- Review safety program and security plan, and make sure of including suitable risk assessment surveillance, security high-risk areas, and security requirements, as well as access control areas.
- Review inspection rounds plan, checklist, different observations, and check for proper corrective actions when applicable.
- Inspect workers in different areas like work areas and waste to make sure of using suitable personnel protective equipment (PPE).
- Check for a security plan, camera monitors, staff ID and access-controlled areas.
- Appropriate working safety devices and equipment are present wherever needed.
- Evidence of implementation of the immunization program as required.
- Presence of separate areas for the staff lounge room.

Documents	Interviews	Observations
Safety program and security plan	Safety officer/responsible	• Inspection rounds are conducted in laboratory areas periodically (not less than twice yearly) • A suitable inspection tool is used with clear corrective actions for inspection observations • Furnishing and equipment are safe and maintained • Access control to technical laboratory areas

Documents	Interviews	Observations
Inspection checklist		• Appropriate PPE for staff • Appropriate warning signage • There are measures to protect patients, visitors, and staff against harm, including assault, violence, and aggression
		• Eyewash stations, safety showers, are tested and checked periodically for proper function • Suitable biosafety cabinet for microbiology lab
		Separate area for the staff lounge
	Laboratory staff to ensure awareness of immunization program	

NSR.8

Standard:
The facility develops and implements a plan for selecting, inspecting, maintaining, testing, and safe usage of medical equipment addressing at least the following:
NSR.8.1 Inventory of all medical equipment
NSR.8.2 Schedule for inspection, preventive maintenance& calibration according to manufacturer's recommendations.
NSR.8.3 Testing of all new equipment before use and repeat testing when required with documentation of the results.
NSR.8.4 Qualified individuals who can provide these services.
NSR.8.5 Data monitoring for the frequency of repair or equipment failure.

Rationale:
The laboratory shall have a documented program for medical equipment that covers all required standards. The laboratory should ensure that all diagnostic medical equipment is maintained and calibrated properly to minimize diagnostic errors.

Survey Process:

- Review the medical equipment maintenance program
- Availability of all required documents
- Inventory of medical equipment
- Schedule of preventive maintenance and calibration.
- Documents of staff training.
- Interview with Biomedical engineer/responsible and authorized laboratory staff.

Documents	Interviews	Observations
• Medical equipment program • Schedule of preventive maintenance and calibration • Inventory of medical equipment	Biomedical engineer/responsible	Preventive maintenance and calibration cards on the medical equipment
Staff training and competencies	Authorized laboratory staff	Work instructions are available for all equipment

NSR.9

Standard:
The facility develops and implements a plan for regular inspection, maintenance, testing, and repair of essential utilities addressing at least the following:
NSR.9.1 Electricity, including back up system.
NSR.9.2 Heating, ventilation, and air conditioning, including; appropriate temperature, humidity, and odors' elimination.
NSR.9.3 Communications systems.
NSR.9.4 Regular inspections, testing, and maintenance according to the manufacturer's recommendations.
NSR.9.5 Correction of identified risks and deficiencies.

Rationale:
The laboratory should have a documented program for utility management that covers all required standards. The laboratory should keep a safe and effective key utility system.

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, as well as testing results of generators, tanks, and/or another key system to make sure of facility coverage.

Documents	Interviews	Observations
• Utility management plan • Utility inventory • Preventive maintenance schedule • Contract	• Utility responsible person • Maintenance responsible person	• Preventive maintenance Documents are present on the machines or easily accessible to the end-user • Safe and labeled electric boards and connections • Safe and labeled fuel sources • Temperature monitoring of all fridges is in place
Utility inspection and testing documents		• Suitable temperature and humidity monitoring of the lab • Appropriate sewage system

NSR.10

Standard:
The facility develops and implements an active first aid system whenever indicated addressing at least the following:
NSR.10.1 All needed equipment including (crash cart, automated external defibrillator, sphygmomanometer, stethoscope, bag valve mask in different sizes).
NSR.10.2 Staff are trained in basic life support.

Rationale:
As laboratory one of Healthcare organizations, it has an obligation to provide a high-quality resuscitation service and to ensure that staff are trained and updated regularly and with appropriate frequency to a level of proficiency appropriate to each individual's expected role. The laboratory shall have a documented plan for the first aid system, including policies and procedures for cardiopulmonary resuscitation, required equipment, and related code/codes.

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, as well as testing results of generators, tanks, and/or another key system to make sure of facility coverage.

Documents	Interviews	Observations
• Cardiopulmonary resuscitation (CPR) policy	• Staff awareness of CPR policy	
• Basic life support certificates of staff • CPR logbook • Code blue drill		

Chapter 3
Clinical laboratory operating manual

The operating manual is divided into three categories:

A. Items related to licensures or National Safety Requirements (NSRs) will have both interviews and evidence for implementation.

B. Items related to patient/staff safety will have both interviews and evidence for implementation.

C. The rest of the items will be conducted through interviews and document review only.

Laboratory operating manual content:

The operation manual is a document that explains the quality management system for the laboratory. It shall include policies, processes/and or procedures that cover the following requirements:

1. Laboratory Organization
2. Ethical Practice Policy

Facilities Management

3. Equipment Management
4. Purchasing and Inventory Management
5. Clinical Laboratory Total Testing Process
6. Nonconformity Event Management
7. Document and Record Management
8. Information Management
9. Infection Prevention and Control

1. Laboratory Organization:

This should cover the following:

1.1 Overview of the organization.

1.2 Mission statement.

1.3 Vision statement.

1.4 Organizational structure:
The structure of the organization should be clearly defined, and this should be reflected by a functional organizational chart with a clear assignment of responsibility.

1.5 Scope of services, detailed by lab tests, and relevant equipment with equipment name and serial number.

1.6 List of provided tests with their turnaround time.

2. Ethical Practice Policy:

The laboratory has a policy and/or procedure, or policies and/or procedures for ethical practice. The well-being of patients and their rights must be the primary consideration of clinical laboratories. Ethical practice should consider at least the following:

- The patient must be given the opportunity to provide and to be provided with information for the pre-examination and post-examination phases of the Request-Test-Report Cycle: for example, the provision of information to the patient regarding the test process, associated costs, or when to expect results.
- Clinical laboratory services must have an open disclosure policy and procedure that allow for discussion with a patient (and/or their support person(s)) about a patient safety incident that did result or may have resulted in harm to that patient.
- Patients, including their specimens and body parts, must be treated with respect.
- There must be a policy regarding informed consent, when applicable. It is inferred that informed consent has been obtained from the patient when the patient allows the collection or procedure to be carried out. However, for some tests specified in technical documents, written informed consent may be needed.
- The privacy and confidentiality of patients' personal information, as well as their results, must always be maintained.
- Policies and procedures that define ethical standards of the clinical laboratory service must be in place.

3. Purchasing and Inventory Management

The operation manual includes a policy and/or procedure, or policies and/or procedures for successful purchasing and inventory management. The following elements should be considered:

- Vendor or manufacturer qualifications.
- Purchase agreements.
- Receiving, inspecting, testing, storing, and handling of materials: all purchased material should be inspected and appropriately tested to ensure that specifications are met, and policies should be established for storing and handling materials as they are delivered to the laboratory.
- Assessing and maintaining inventory.
- Controlling expiration periods.

4. Clinical Laboratory Total Testing Process:

The applying laboratory has a policy and/or procedure, or policies and/or procedures that define the requirements of the whole testing processes, including pre-examination, examination, and post-examination activities. The following should be taken into consideration.

Pre-examination processes that include:

a. All the information needed for patients and users of the laboratory services. The information includes as appropriate: the location of the laboratory; types of clinical services; opening hours of the laboratory; appropriate, information concerning specimens required, primary specimens' volumes, special sample precautions, turnaround time, instructions for completion of the request form; instruction for preparation of the patient; instructions for transportation of samples; and the laboratory's criteria for accepting and rejecting specimens.

b. Test requisition: the laboratory must ensure all needed information in the laboratory request for proper handling and reporting of test results.

c. Specimen collection and preservation: as they will vary depending on the test and the type of specimen to be collected, the laboratory must carefully define a specimen collection process for all tests performed (evidence for implementation is required).

d. Specimen labeling: each sample should be clearly labeled with a unique double identification that is traceable to the request form (evidence for implementation is required).

e. Specimen transportation (evidence for implementation is required).

f. Specimen reception with acceptance and rejection criteria (evidence for implementation is required).

g. Pre-examination specimen handling, preparation, and storage (evidence for implementation is required).

Examination processes that include:

a. Verification of examination procedures.
b. Identification of biological reference intervals.
c. Documentation of examination procedures (standard operation procedures).
d. Quality control procedure (evidence for implementation is required).
e. External quality assessment procedures.

Post-examination processes that include:

a. Final report data fulfillment.
b. Review of results.
c. Storage, retention, and disposal of specimens.
d. Reporting of results, according to the lab-specific accepted timeframe for reporting (evidence for implementation is required).

5. Nonconformity Event Management

The applying laboratory has a policy and/or procedure, or policies and/or procedures for nonconforming event management, taking into consideration the following:

- Designation of the individuals responsible and actions necessary for handling nonconformities.
- Ensuring that each nonconforming event is documented, recorded, and reviewed at identified intervals, a root cause analysis performed, and that corrective action is taken and documented.
- Defining when testing procedures and data reporting will be withheld due to nonconformities and when, and under what conditions, an examination can resume.
- Defining the steps taken when examination data resulting from a nonconforming event has already been released.
- All nonconforming events (from occurrence reports, claims, audit reports, patient/customer complaints, failed proficiency testing, etc.) are recorded, tracked, trends identified, and root cause analysis performed, and the appropriate corrective actions are taken.

- The results of an occurrence assessment are communicated to management and become part of the periodic management review to ensure continuous improvement of the quality system.

6. Document and Record Management:

The applying laboratory has a policy and/or procedure, or policies and/or procedures that address both the use and maintenance of documents and records, taking into consideration the following:

- The laboratory ensures that documents and records are managed, starting from creation and receipt to archival and disposal, according to national laws, local regulations and international standards.
- The quality manager/supervisor reviews and approves all requests for amendments of the existing documents and the development of new procedures, processes, and policies.
- All documents, including the operating manual, shall be reviewed periodically by designated and authorized staff.
- All documents are uniquely identified (date of issue, revision version, the total number of pages, and authorizing signatories are included in the document).
- Documents are signed as a paper copy or authorized electronically.
- The laboratory respects the national regulations or legislation concerning the retention time of all records.
- A copy of an obsolete document is kept to provide a means for review if the situation arises.

7. Information Management:

The applying laboratory has a policy and/or procedure, or policies and/or procedures for information management, taking into consideration the following:

- The laboratory information system (LIS) (whether computerized or paper-based) provides for the collection, processing, recording, storage, and retrieval of data, and has documented procedures in place to ensure the confidentiality of patient information and the security of the data during each step of the process.
- The personnel (temporary, permanent, etc.), whatever the duration of their contract, will sign a confidentiality agreement.
- The laboratory has a secure process for archiving and/or data disposal.

8. Infection Prevention and Control:

- Infection prevention and control structure.
- Infection prevention and control plan.
- Handling sharps (evidence for implementation is required).
- Standard and transmission-based precautions.
- Reprocessing of single-use items (evidence for implementation is required).
- Housekeeping P&P: (evidence for implementation is required)
    i. A list of all environmental services to be cleaned.
    ii. Schedule of cleaning.
    iii. Procedures to be used.
    iv. Agents to be used.
- Handling blood/body fluids spills (evidence for implementation is required).
- Safe disposal of medical waste (evidence for implementation is required).
- Handling pathology specimens (evidence for implementation is required).
- Handling construction projects.
- Personnel protective equipment use.
- Proper hand hygiene practices.
- Reporting of communicable diseases to relevant authorities.
- Employees' immunization & post-exposure management.
- Safe injection practices (evidence for implementation is required).

Chapter 4

Leadership Related Requirements

The survey process of the leadership-related requirements will be conducted through interviews with the organization leaders regarding their related documents and how they developed them, indicating their plans for implementation.

Selected items will have both interviews and evidence for implementation.

1. Leadership structure
    - Leadership responsibilities
    - Leadership support of quality initiative monitoring and improvement activities
    - Budget process
    - Confidentiality of information (general rules, release of patient information to news media)
    - Community needs assessment
    - Dress code
2. Strategic and operational plans
3. Contract monitoring policy
4. Quality, patient safety, and risk management plan(s) (evidence for implementation is required)
5. Key performance indicators
    a. Policy
    b. Evaluation of indicators
6. The training program of facility leaders, including, but not limited to:
    a. Quality concepts, skills, and tools
    b. Team management
    c. Communication skills
    d. Data management (as related)

Chapter 5

Workforce Related Requirements

The survey process of the operating workforce-related requirements will be conducted by interviews with the organization leaders regarding their related documents and how they developed them, indicating their plans for implementation.

1. Registered healthcare professionals at GAHAR (Evidence for implementation required)
2. Staffing plan (Evidence for implementation required).
3. Recruitment Process
4. Employee orientation program:
    - General orientation program.
    - Lab policies and procedures.
    - Job specifications.
    - Training and continuing education program.
    - Performance appraisal:
        - Including competency assessment (initial – ongoing)
        - Staff health program (including pre-employment and regular checkup). (Evidence for implementation required)
5. Personnel file includes at least the following:
    - Initiation
    - Update
    - Retention time
    - Training and education records
    - Competency assessments records
6. Basic life support certification (as related) from the following: Egyptian Society of Cardiology, American Heart Association, European Resuscitation Council, or other similar organizations.

Glossary

Term	Definition
Biohazard	An infectious agent, or part thereof, that presents a real or potential risk to the well-being of humans, animals, or plants. It can present a hazard directly through infection or indirectly through the disruption of the environment.
Biosafety	The active, assertive, evidence-based process that laboratorians use to prevent microbial contamination, infection, or toxic reaction as they actively manipulate live microorganisms or their products, thus protecting themselves, other laboratory staff, the public, and the environment.
Clinical Laboratory/ Laboratory	Premises where medical laboratory services are performed. A Medical Laboratory Service may be: • Stand-alone or be part of a medical laboratory network • Part of a hospital (governmental or private) • Part of primary care unit
Clinical Laboratory Service	Any service whereby laboratory testing provides information for: • diagnosis, exclusion, and monitoring of disease processes and their treatment • health screening epidemiological purposes.
Continuing education	An educational program that brings employees up-to-date in a particular area of knowledge or skills.
Cross-training	Training for staff to acquire skills outside their own discipline. This allows for flexibility in shifting or reassigning personnel whenever needed; this may occur in crisis situations or with absences of staff due to illness or vacation.
Documents	Written information about policies, processes, and procedures: • communicate information to all persons who need it, including laboratory staff, users, and laboratory management personnel;

Term	Definition
	need to be updated and maintained; must be changed when a policy, process, or procedure changes; establish formats for recording and reporting information by the use of standardized forms.
Equipment	Means instruments, reference materials, consumables, disposables, reagents, cabinets (incubators, refrigerators), analytical systems, and electronic information systems.
Examination /Analytical phase	Activities and steps related to performing laboratory examinations. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing
External Quality Assessment	A system for objectively checking the laboratory's performance using an external agency or facility.
Hand over communication	Hand over in the laboratory is referred to the practice of exchanging a patient information/ specimen with other laboratory professionals during the total laboratory process
Laboratory Director /Supervisor	Person(s) with responsibility for, and authority over, a laboratory.
Laboratory staff	Healthcare professionals, technicians and assistant staffing working in the clinical laboratory
Mission	a short statement of why an organization exists, what its overall goal is, identifying the goal of its operations: what kind of product or service it provides, its primary customers or market, and its geographical region of operation. It may include a short statement of such fundamental matters as the organization's values or philosophies, a business's main competitive advantages, or a desired future state—the "vision."

Term	Definition
Occurrence management	A central part of continual improvement; the process by which errors are identified and handled.
Organization	Group of people and facilities with an arrangement of responsibilities, authorities, and relationships.
Organizational chart	Defines the working structure for the organization; organizes jobs along the lines of authority; defines reporting structure and span of control; defines authority to make decisions and accountability for results; works together with job descriptions to define the working structure of the organization.
Organizational structure	The pattern of responsibilities, authorities, and relationships that control how people perform their functions and govern how they interact with one another.
Policy	It is a documented statement of overall intentions and direction defined by those in the organization and endorsed by management. Policies give broad and general direction to the quality system. : • tell "what to do," in a broad and general way; • include a statement of the organizational mission, goals, and purpose; • serve as the framework for the quality system and should always be specified in the quality/operation manual.
Post-examination (also post-analytical phase)	Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples after the examinations. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.
Pre-examination (also pre-	Steps, in chronological order from the clinician's request, including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the examination phase

Term	Definition
analytical phase)	begins. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.
Process	Processes are the steps involved in carrying out quality policies. ISO 9000 [4.3.1] defines a process as a “set of interrelated or interacting activities that transform inputs into outputs.” A process is as "how it happens." Processes can generally be represented in a flow chart, with a series of steps to indicate how events should occur over a period of time.
Procedure	Procedures are the specific activities of a process (ISO 9000 [3.4]). A procedure tells “how to do it” and shows the step-by-step instructions that laboratory staff should meticulously follow for each activity.
Quality Assessment	Means a measurement and monitoring function of quality assurance for determining how well health care is delivered in comparison with applicable standards or acceptable bounds of care.
Quality Assurance	Means a part of quality management focused on providing confidence that quality requirements will be fulfilled.
Quality System	Means those management activities involved in the direction and control of the organization regarding quality.
Records	Once the forms are used to record information, they become records. Characteristics of records are that they: • need to be easily retrieved or accessed; • contain information that is permanent and does not require updating.
Retraining	Training required when competency assessment reveals the need for improving an employee’s knowledge and skills.

Term	Definition
Training	A process to provide and develop knowledge, skills, and behaviors to meet requirements. Training is linked to the job description and competency assessment and addresses identified gaps in specific tasks to be performed by the employee. Competency should be reassessed after any job specific training.
Turnaround time	Length of time that a sample's final result may be issued to the ordering physician.
Vision	An overarching statement of the way an organization wants to be; an an ideal state of being at a future point.
Waste	Any activity that consumes resources and produces no added value to the product or service a customer receives
Work environment	All the factors that influence work; including social, cultural, psychological, physical, and environmental conditions. The term work environment includes lighting, temperature, and noise factors, as well as the whole range of ergonomic influences. It also includes things like supervisory practices, as well as reward and recognition programs. All of these things influence how work is performed.

References:

- ISO 15189:2012. Medical laboratories—particular requirements for quality and competence. Geneva, International Organization for Standardization.
- ISO/IEC 17025:2017. General requirements for the competence of testing and calibration laboratories. Geneva, International Organization for Standardization.
- Joint Commission International, Accreditation Standards for Clinical Laboratories, 2nd Edition, 2010.
- CLSI/NCCLS. Application of a quality management system model for laboratory services; approved guideline—3rd ed. GP26-A3. Wayne, PA, NCCLS, 2004.
- CLSI/NCCLS. A quality management system model for health care; approved guideline—2nd ed. HS1-A2. Wayne, PA, NCCLS, 2004.
- National Safety Requirements
- WHO, 2011: Laboratory Quality Management System.

Document Review:

Date	Type of review A= Annual B=On demand	Signature

Document History:

Version	Revision Date	Document Status

Copies Distribution List:

Name of Location	No. of copy	Name of Location	No. of copy	Name of Location	No. of copy