

REPUBLIC OF KENYA



MINISTRY OF HEALTH

Quality of Care Certification Manual for the Kenyan Health Sector

MARCH 2020

the 1990s, the number of people in the UK who are employed in the public sector has increased from 10.5 million to 12.5 million (12% of the population). The public sector has also become a major employer of young people, with 1.5 million young people employed in the public sector in 2000 (15% of the young population).

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Kenyan Health Sector**

FOREWORD

The Government of Kenya in developing this manual has demonstrated its total commitment to ensuring that the rights of every person to the highest standard of health are upheld in keeping with the Constitution of Kenya 2010. In this regard, this Quality of Care Certification Manual and the Certification Framework for the Kenya Health Sector have been developed to guide the Sector in shaping the modalities for monitoring the quality of inputs, processes and outcomes of health services delivery in order to ensure that they are of high standard, safe, acceptable and provide positive experiences for both providers and users.

The Framework and Manual read together will set the stage for the establishment of a collective quality assurance platform for all service providers in the light of Universal Health Coverage thus creating a level playing ground to facilitate strategic purchasing of health services from different providers and to act as a comparative frame for users in decision making while accessing services. The Manual has leveraged on the synergies created by mandates and strengths of different players to define a division of labour that focuses on three key components namely; Licensure/Registration/Gazettement by the Regulatory authorities, Certification by Conformity Assessment Bodies, and Accreditation by the Kenya Accreditation Services; with strategic purchasing function expected to create incentives for quality standards compliance for Counties and service providers.

It is hoped that all the stakeholders and key players in the accreditation process will provide synergies in entrenching this Certification manual in an effort to heighten patient and health care worker safety therefore resulting in a high-quality service delivery in order to derive the desired health outcomes.



Hon. Mutahi Kagwe, EGH

Cabinet Secretary of Health

EXECUTIVE SUMMARY

The certification manual gives the background information and the introduction to guide the keys players and stakeholders in the certification and accreditation processes. The manual also gives you the purpose and the accreditation processes by highlighting the components of the certification framework. This manual clearly explains the procedures for the fulfillment of quality care certification from the time of pre-licensing, licensure, registration and gazettment.

In this certification manual several procedures are highlighted as follows: periodic inspection, scheduled inspections, reactive inspection, certification, and accreditation of conformity assessment bodies.

The role of the government and other key players in the certification and accreditation process are clearly highlighted and discussed in the certification manual.



Susan N. Mochache, CBS

Principal Secretary for Health

ACKNOWLEDGEMENTS

We wish to acknowledge and thank all those who facilitated and participated in the development of this Quality of Care Certification Framework. This included the multi-stakeholder Technical Working Group under the Leadership of the Directorate of Standards and Quality Assurance and Regulations, Universal Health Care advisory committee, Kenya Accreditation Service, National Hospital Insurance Fund, Faith Based Organizations – CHAK, KAMMP and KEC, Various Development Partners including IFC/World Bank, WHO, GIZ and JICA, Implementing partners- Amref Health Africa, PharmAccess Foundation, JHPIEGO and LVCT Health, Professional Associations including Kenya Medical Association, Hospitals – Kenyatta National Hospital, Aga Khan University Hospital, Mater Misericordiae Hospital and Jacaranda Health among others.

We wish to extend our heartfelt thanks to the smaller team that painstakingly refined the document through triangulation of views from various stakeholders. These included Dr Simon Kibias (MoH), Dr Maurice Wakwabubi (MoH), Dr Charles Kandie (MoH), Dr Aisha Mohamed (MoH), Dr Evelyne Wesangula and Dr Jared Nyakiba (MoH), Dr Frank Wafula (IFC/World Bank), Susan Munyiri (KENAS), Doris Mueni (KENAS), Dr Joyce Lavussa (WHO), Mary Nyachae (NHIF), Faith Muigai (PharmAccess), Dr Elizabeth Wala (Amref Health Africa), Walter Kibet (Amref Health Africa), Irene Omogi (GIZ), and Dr Daniel Kiura (Mater Hospital). Our appreciation also goes to World Bank that provided technical assistance through a consultant; Dr Salome Ngata and financial support to various activities.



Dr. Patrick O. Amoth

Ag. Director General for Health

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LIST OF ACRONYMS

CABs	Conformity Assessment Bodies
CHAK	Christian Health Association of Kenya
CPD	Continuous Professional Development
DHSQAR	Directorate of Standards and Quality Assurance and Regulations
ISO	International Organization for Standardization
ISO/IEC	International Organization for Standardization/ International Electro-technical Commission
JHIC	Joint Health Inspection Checklists
KAMMP	Kenya Association of Muslim Medical Professionals
KEC	Kenya Episcopal Conference
KENAS	Kenya Accreditation Service
KEPH	Kenya Essential Package of Health
KHF	Kenya Health Federation
KHP	Kenya Health Policy
KHPOA	Kenya Health Professions Oversight Authority
KHSSP	Kenya Health Sector Strategic Plan
KMLTTB	Kenya Medical Laboratory Technician and Technologists Board
KMPDB	Kenya Medical Practitioners & Dentists Board
KQMH	Kenya Quality Model of Health
MoH	Ministry of Health
NHIF	National Hospital Insurance Fund
UHC	Universal Health Care

DEFINITION OF TERMS

Licensure¹	Process by which a governmental authority grants time-limited permission to an individual practitioner or health care organization to operate or to engage in an occupation or profession related to health care delivery. The organization or individual meets minimum standards to protect public health and safety. Licensure to individuals is usually granted after some form of examination or proof of education and may be renewed periodically through the payment of a fee and/or proof of continuing education or professional competence. Organizational licensure is granted following an on-site inspection to determine if minimum health and safety standards have been met.
Registration	<p>For individuals: The recognition of successful completion of mandated requirements for the practice of a particular profession. Once a health professional has been registered, they can then be licensed to practice as either full time or part-time private practice.</p> <p>For institutions: The health facility has met all the infrastructural, technical and medical approvals with duly licensed and or retained practitioners deemed necessary by the Regulatory Authority to provide the relevant health service(s).</p>
Gazettement	Formal notification by the national government of the existence of a health facility and published by the Kenya Government Press
Certification²	Formal notification by the national government of the existence of a health facility and published by the Kenya Government Press
Accreditation³	Third-party attestation that fulfilment of specified requirements have been demonstrated related to products, processes, systems or persons. Therefore Certification is defined as the compliance with a standard or specification for a system or product.
Inspection	Third-party attestation that a conformity assessment body has demonstrated competence to carry out specific conformity assessment tasks. Accreditation is the recognition of specific competence of an organization normally based on a highly specific scope that evaluates people, skills, and knowledge.

¹Licensure, Accreditation, and Certification: Approaches to Health Services Quality: Rooney A, Ostenberg P, (1999)

²ISO/IEC 17000:2004. Conformity assessment - Vocabulary and general principles

³ISO/IEC 17000:2004. Conformity assessment - Vocabulary and general principles

Regulatory Body	A regulatory body is a public authority or government agency responsible for exercising autonomous authority over some area of human activity in a regulatory or supervisory capacity. An independent regulatory agency is a regulatory agency that is independent from other branches or arms of the government. Regulatory bodies usually enforce safety and standards and are responsible for protecting consumers
Conformity Assessment Activity	Activity conducted by a conformity assessment body to assess compliance. These may include but are not limited to testing, calibration, inspection, certification, proficiency testing, validation and verification
Conformity Assessment Body	An accredited body that performs conformity assessment activities and seeks to demonstrate that specified requirements relating to a product, process, system, person or body are fulfilled
Certification Body	An accredited body that offers a third-party attestation of compliance with standards related to products, processes, systems, or persons
Accreditation Body	<p>An organization that issues credentials to third parties to attest competence to conduct specific conformity assessment tasks. Some accreditation bodies have specific capabilities, such as accreditation of the competence of laboratories, or for accreditation of certification bodies. Accreditation bodies are often appointed by national governments and hold an important position in the conformity assessment hierarchy. They provide confidence in the impartiality and competence of conformity assessment bodies. The criteria for accreditation bodies are specified in ISO/IEC 17011:2004.</p> <p>As accreditation bodies are at the top of the confidence pyramid, there is no higher-level body to assess their conformity with the requirements. Instead, accreditation bodies from different countries have formed multi-lateral agreements through which they carry out peer assessments on each other</p>

1. INTRODUCTION

This Quality of Care Certification Manual serves to guide the different key players and stakeholders on the accreditation/certification process in the Kenyan Health Sector. The manual is developed in line with the Quality of Care Certification Framework of the Kenya Health Sector and various guiding documents that spell out the constitutional mandates and responsibilities of different actors in the Quality of Care Certification process.

The Manual also spells out the procedures to be followed to ensure that the health facilities are certified in accordance with the set guidelines and standards to ensure the provision of health services in the most effective way and in a manner that cultivates positive experiences for patients/ clients and ensures safety.

2. BACKGROUND

The Ministry of Health endeavours to establish a Quality of Care Certification Framework for the health sector through a recognized legal body to provide certification to health provider institutions in compliance with set standards of health care. This is in line with the Constitution of Kenya 2010 which enshrines the right of every person to the highest standard of health, and Kenya Health Policy (2014–2030) that envisions quality and responsive healthcare in line with the needs of the population.

This is also underscored by the Universal Health Coverage (UHC) principles with a vision of equitable access to quality essential health services for all individuals and communities. The implementation of the Kenya Health Sector Strategic Plan (KHSSP) 2018-2023 intentions accelerating the operationalization of UHC to institute a Social Health Protection mechanism while creating incentives for quality of care improvement with an aim to derive the desired health outcomes.

3. PURPOSE

The purpose of this manual is to:

- a. Outline the procedures to be followed for
 - i. Health Facility licensure/registration/gazettement
 - ii. Health Facility Certification process on compliance to the set service delivery standards
 - iii. Conformity Assessment Body (CAB) accreditation on demonstrating competence to conduct conformity assessment of the health facilities with respect to the set standards
- b. Provide clarity of roles and responsibilities to avoid overlaps among the different key players in the Quality of Care Certification framework.

4. COMPONENTS OF THE QUALITY OF CARE CERTIFICATION FRAMEWORK

The Quality of Care Certification Framework has three main components namely; Registration/Licensure/Gazettement, Certification and Accreditation.

- **Registration/Licensure/Gazettement:** Mandatory for all Health Facilities and ensures compliance with the minimum standards using the Joint Health Inspection Checklist (JHIC)
- **Certification:** Voluntary for Health Facilities and is conferred upon evaluation by an authorized CAB to establish compliance with designated standards (KQMH) and demonstration of continuous quality improvement. Certification is based on star rating and linked to incentives (*NHIF rebates/compensation from other insurers*).
- **Accreditation:** Voluntary for CABs and is conferred by Kenya Accreditation Service (KENAS) upon demonstration of compliance with minimum requirements (*ISO/IEC 17021-1 + KQMH*)

5. PROCEDURES FOR FULFILLMENT OF QUALITY OF CARE CERTIFICATION FRAMEWORK COMPONENTS

5.1. Registration/Licensure/Gazettement

According to Act Cap 242 non-public (*private, faith-based, NGO etc.*) health facilities should be registered and respective cadres licensed to operate the health facilities. Similarly, all public health facilities should be gazetted upon recommendation by the respective oversight organs (*County government, National government, Armed forces, Prisons, and Training institutions etc.*).

For a health facility to be registered/ licensed/ gazetted, it shall demonstrate fulfilment of entry-level requirements and attainment of minimum patient safety standards. These requirements are defined in the JHIC which draws on standards defined by the respective Acts of Parliament for the nine independent health regulatory agencies⁴ in the country. Thus, to determine compliance with minimum standards in JHIC, the health facilities shall undergo inspection during these instances;

- Pre-registration/ licensing/ gazettement
- Periodically scheduled inspections to ensure continued compliance with minimum standards
- Reactive inspection following incidences of disgruntlement from the public.

⁴Kenya Medical Practitioners and Dentists Board (KMPBD), Nursing Council of Kenya (NCK), Pharmacy and Poisons Board (PPB), Clinical Officers Council (COC), Kenya Medical Lab Technicians and Technologists Board (KMLTTB), Kenya Nutritionists and Dieticians Institute (KNDI), Radiation Protection Board (RPB), Public Health Officers and Technicians Council (PHOTC) and Physiotherapy Council (PC)

5.1.1 Procedure for Pre-Licensing/Registration/Gazettement Inspection

All health facilities will undergo inspection prior to Registration/ Licensing/ Gazettement. The following steps shall be followed:

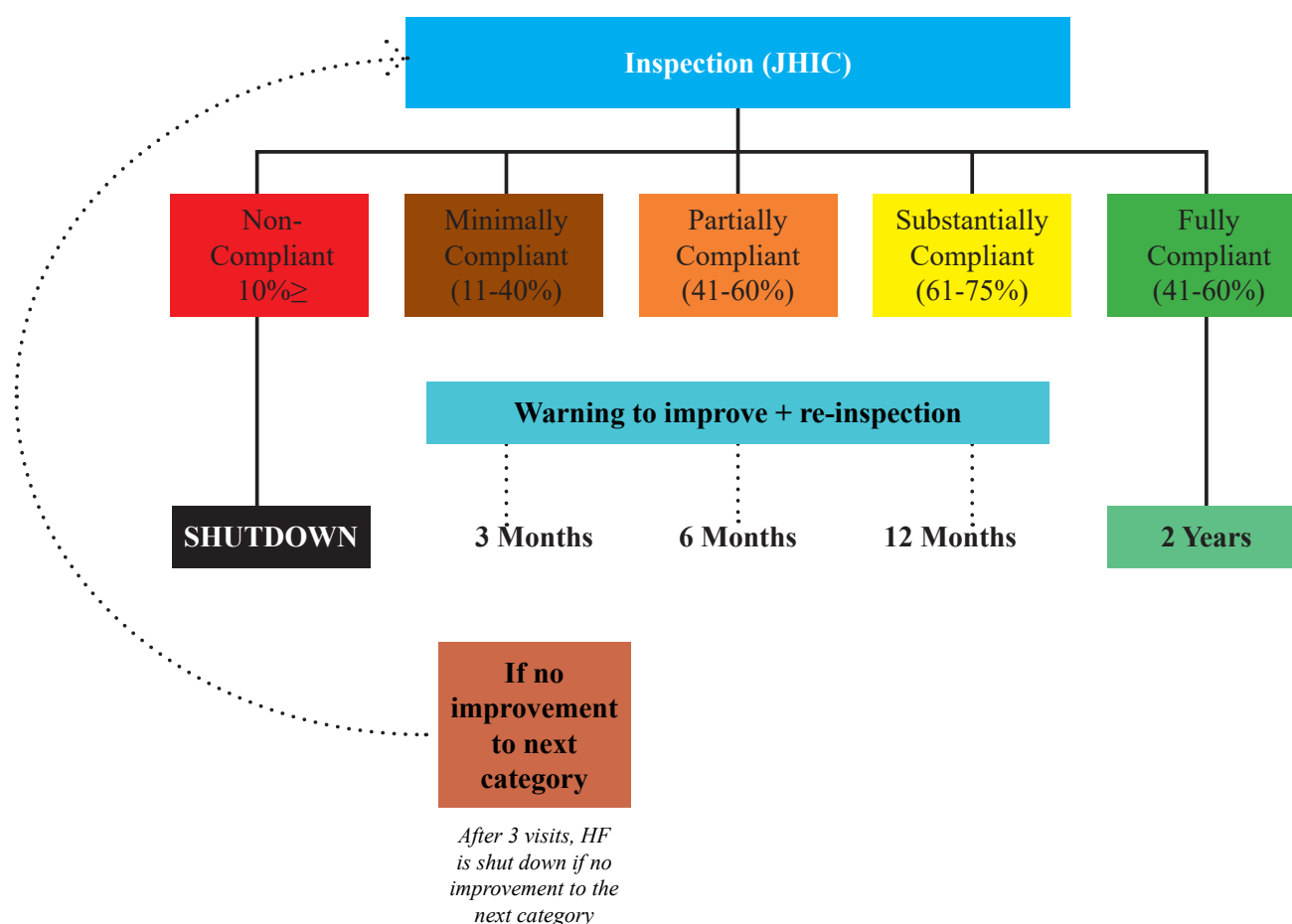
- The proprietor(s) establishes the new health facilities in line with the recommended infrastructural and environmental standards
- The proprietor(s) makes an application to the County based Joint Health Inspectors (or to the respective regulatory body for the national level)
- The Joint Health Inspection Team (JHIT) inspects the health facility using the JHIC and gives recommendations for any improvements prior to the commencement of the registration/ licensing/ gazettement procedures.
- The biodata for the health facilities including geocodes are collected in readiness for entry into the Master Facility List upon licensing/registration/ gazettement.
- The JHIT recommends the health facility to the County Health Management Team (CHMT) for endorsement for licensing/registration/gazettement.
- The CHMT endorses the health facility for licensing/registration/gazettement to the relevant regulatory body/gazettement organ.
- The health facility is issued with license/registration/gazette notice.

5.1.2 Procedure for Periodic Scheduled Inspections

All health facilities will undergo periodic scheduled Joint Inspections using the JHIC. This will be carried out by the joint teams from the national and county-based teams. The following steps will be followed:

- The JHIT releases a yearly joint inspection schedule to all health facilities (*may not necessarily spell out the specific days of the inspection to allow for impromptu inspections*)
- The JHIT inspects the health facility using the JHIC and scores the health facility. An electronic tool is in place to facilitate this process
- Depending on the score the facility is categorized as;
 - » Non-compliant (0-10%)
 - » Minimally Compliant (11-40%)
 - » Partially Compliant (41-60%)
 - » Substantially Compliant (61-75%)
 - » Fully Compliant (>75%)
- A risk-based approach determines the follow-up actions with least scoring health facilities being re-inspected more regularly coupled with warning notices to ensure improvement before the next inspection. This is illustrated in **Figure 1** below.

Figure 1: Joint Health Inspection Findings and Risk Based Actions



5.1.3 Procedure for Reactive Inspections

Reactive inspections will be carried following suspicions of health facilities non-compliance to minimum standards or complaints/concerns from the public.

- The inspections will be immediate and unscheduled with no prior warning to the health facility
- The JHIT will incorporate teams from the relevant programme depending on the nature of the complaint-e.g. Reproductive Health, Child Health, Internal Medicine, Surgery, Anaesthesia etc.
- The JHIT/ programme teams will inspect the health facility using the JHIC and any additional specific programme requirements.
- The knowledge and the skills of the respective health facility staff will be assessed
- Commensurate remedial actions will be undertaken including on job training, mentorship etc.
- Relevant legal actions will be undertaken where a health facility is found in violation of the code of conduct and ethics

5.2. Certification

Though the certification process is voluntary, all health facilities are encouraged to undergo certification. Incentives and disincentives for participation in the certification process will be created and instituted.

5.2.1 Certification Process

For a health facility to be certified, it will need to be assessed by an accredited Conformity Assessment Body.

- The certification of Health facilities will be based on KQMH standards (*however, other standards may be used but will require benchmarking with the KQMH standards*).
- For a health facility to seek certification, it needs to have been licensed/registered/gazetted.
- The health facility conducts own self-assessment- this may also be conducted by the County QI mentor who supports the health facility to identify gaps in quality and to address them.
- The Health Facility through the County or umbrella body (*CHAK, KEC, KHF etc*) communicates to the Certification Oversight Body and request for an external assessment.
- The Oversight Body delegates the health facility assessment to the CAB
- The CAB notifies the health facility of the day of the assessment and all the documentation expected to be availed for assessment.
- The CAB conducts an external assessment and scores the health facility and congratulates the health facility on the areas that it's doing well and identifies areas that require improvement.
- The Health Facility and the CAB agree on a QI plan with the health facility for the areas in need of improvement and a defined period for improvement.
- In the case of non-conformities, the CAB may allow time for a period not exceeding 30 days for the health facility to demonstrate compliance.
- The CAB communicates the KQMH scores to the Certification Oversight Body at the national level for entry into the national database.
- The Certification Oversight Body awards a star rating and a recognition certificate to the health facility with respect to its Kenya Essential Package of Health (KEPH) level.
- The star rating is as follows;
 - » **50% and above score on the KQMH - 1 star**
 - » **60% and above score on the KQMH - 2 stars**
 - » **70% and above score on the KQMH - 3 stars**
 - » **80% and above score on the KQMH - 4 stars**
 - » **90% and above score on the KQMH - 5 stars**

- Health facilities will be assessed yearly and star rating assigned for that specific period. The star rating will not be revised until 12 months have elapsed.
- The star rating will serve as a benchmark on which to determine the amount of incentives/ rebates the health facility will be compensated for its level.

5.2.2 Prerequisites for Certification

- Each health facility will establish a Quality Improvement Team (QIT) and for bigger health facilities Work Improvement Teams
- The QIT will:
 - » Ensure that QI is a permanent agenda in the Health Management Team (HMT) meetings
 - » Develop health facility QI plan and budget in line with the identified QI priorities of the Health Facility
 - » Oversee the implementation of QI plans/activities
 - » Evaluate the QI plans/activities
 - » Conduct health facilities self-assessments
- Departmental Work Improvement Teams will:
 - » Conducting departmental ‘mini’ self-assessment using the checklists and identify areas of improvement
 - » Introduce improvements and test changes in the departments
 - » Liaise with the Health Facility QI focal person and QI Team to report progress and request for resources and support.
 - » Organize departmental weekly QI meetings
- A health facility will identify champion(s) for Quality Improvement to act as the focal person for QI for the facility. The focal person will:
 - » Coordinate the QI activities in the health facility
 - » Facilitate networking with Departmental Work Improvement Teams in identifying quality gaps and solutions/testing changes at facility/departmental levels.
 - » Keep records of QI activities.

Composition of the QIT

- *Health Facility In charge*
 - *Departmental Heads*
 - *QI Focal person(s)*
- *Medical Records Officer*
 - *QI Champions.*

Work Improvement Teams

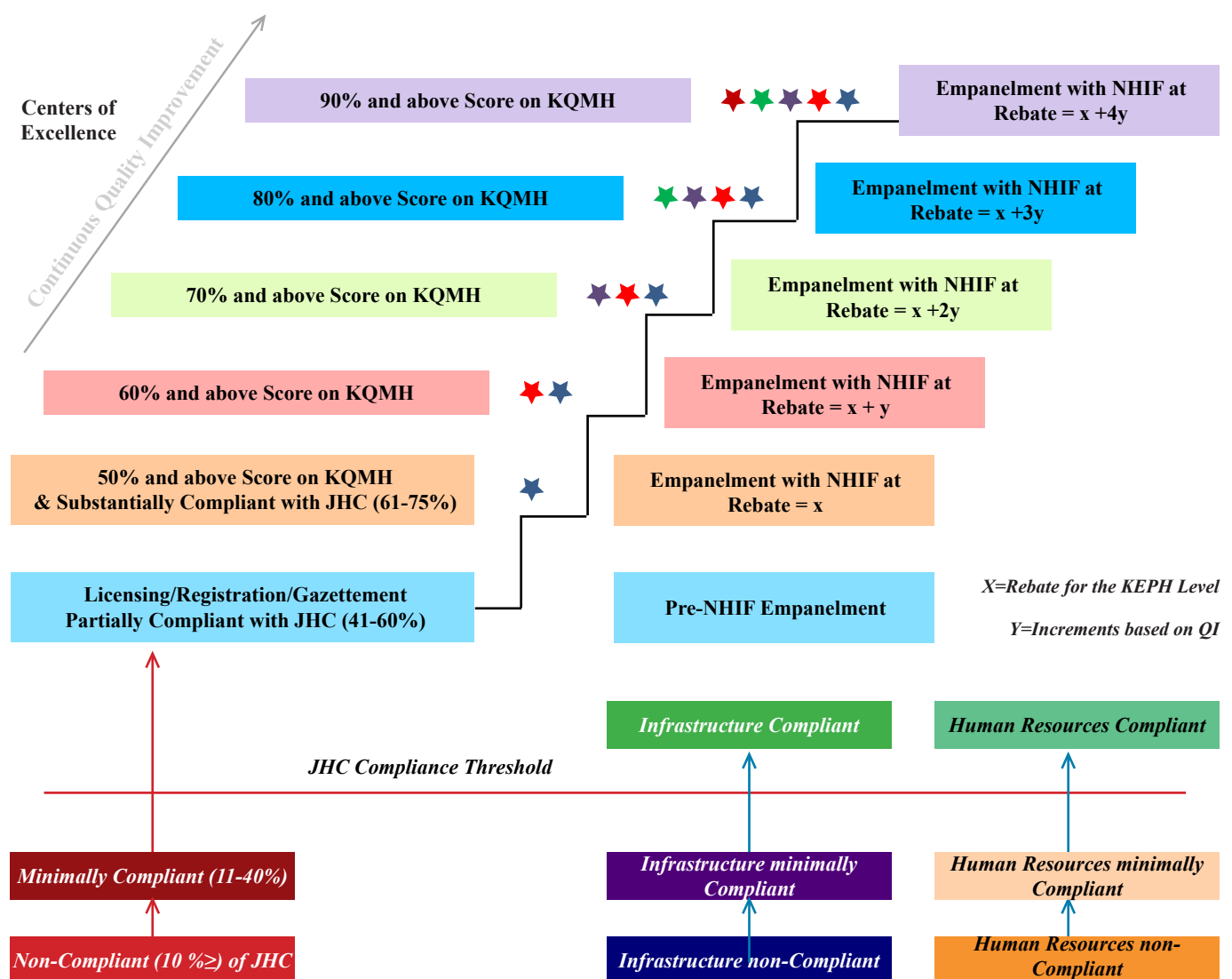
- *Departmental In charge*
 - *QI Champions*
 - *HRIO.*

5.2.3 Centers of Excellence

For a health facility to qualify as a Centre of Excellence (CoE), it will need to:

- » Deliver specialized programs in a particular medical discipline- Maternal and Neonatal Health, Orthopaedic Centre, Fistula Management Centres, Eyecare Centres etc.
- » Demonstrate a high level of competence and interdisciplinary collaboration
- » Have the prerequisite resources to deliver the service in a comprehensive manner.
- » Attain 80% and above on the KQMH score
- » Score highly on a set of identified outcome indicators for the medical discipline.

Figure 2: Certification Rating and Incentive Structure



5.3. Accreditation of Conformity Assessment Bodies

Any CAB that wishes to undertake assessment activities in the country will require to be accredited by KENAS. Accreditation is the attestation of competence to conduct specific conformity assessment tasks which in this case include assessment of health service provision in accordance with the set standards.

5.3.1 Accreditation Process

Below are the accreditation requirements for a CAB:

- The CAB making an application is a legal entity (*private company, NGO or a recognized government institution*)
- The CAB seeking accreditation will need to fulfil accreditation standards ISO/IEC 17021-1 + KQMH
- The CAB will demonstrate impartiality and good management systems of the health service delivery assessment
- Any identified areas of non-conformity by the CAB will be addressed in the specified period as defined by KENAS
- Any CAB that has been accredited by a foreign accreditation body will require to demonstrate fulfilment of requirements under ISO/IEC 17021-1 + KQMH before being allowed to conduct assessments using the KQMH
- The accreditation status will be maintained for 3 years or at a period as determined by the Accreditation Body from time to time subject to satisfactory periodic assessments.

5.3.2 Procedure for Seeking Accreditation by the Conformity Assessment Bodies

- Conformity Assessment Body (CAB) submits inquiry through telephone, email or contact with KENAS staff
- A formal response by a KENAS officer on the terms and conditions applicable to the provision of accreditation
- CAB submits a formal application which is filled-in and signed
- Review of application and support documents done
- A formal response to the CAB regarding the outcome of the review of the application and documentation
- Selection of the Assessment Team
- On-site assessment
- Follow up assessments of the CAB to determine the effective implementation of the corrective action requests (CAR) raised
- An accreditation decision made based on the outcome and report of the assessment
- A formal communication to the CAB on the decision made
- Formal issuance of the accreditation certificate and schedule of accreditation to the CAB
- Periodical assessments of the accredited CAB as determined by the Accreditation Body.

6. ROLES AND RESPONSIBILITIES OF DIFFERENT KEY PLAYERS IN THE QUALITY OF CARE CERTIFICATION PROCESS

The following will be the roles and responsibilities of the key players in the Quality of Care Certification framework:

6.1. Oversight Authority for Certification Activities

- Acts as the ‘Certification Oversight for all Health Services Certification Activities
- Coordinates quality assessments in the country
- Delegates assessment to independent CABs
- Confers interim authorization to the proposed CABs to conduct assessments
- Acts as a repository for data and information
- Awards Star rating to the health facilities
- Benchmarks the performance of Health Facilities
- Shares information with strategic purchasers – NHIF, private insurers, funders etc.
- Disseminates information to the public
- Awards the best performers

6.2. Department of Health Standards, Quality Assurance and Regulations

Develops, reviews, gazettes and disseminates Health Standards for various purposes

- » KQMH standards for service delivery
- » Health Facilities Infrastructure
- » Human Resources standards
- » CABs accreditation standards in collaboration with KENAS etc.
- » Benchmarks other standards against the KQMH
- » Train County-based QI teams on KQMH standards
- » Provide mentorship to Counties on QI activities

6.3. Kenya Accreditation Service

- Accredits the Conformity Assessment Bodies based on the established scheme framework: ISO/IEC 17021-1 + KQMH for hospital certification
- Offers guidance on the accreditation process

6.4. Regulatory Boards and Councils

- Conducts baseline and follow up inspections
- Confers registration/licensure of health facilities and individuals
- Maintain a database of qualified cadres of staff
- Enforces Continuous Professional Development (CPD) of all cadres
- Coordinates reactive inspections and follow up actions

6.5. County Governments

- Facilitates QI activities of health facilities in the respective counties
- Facilitates periodic self-assessments of the health facilities in the respective counties
- Facilitates external assessments by CABs
- Follows up on the recommendation of the assessments by the CABs
- Mobilizes resources for all QI activities and external assessments

6.6. Conformity Assessment Bodies

- Conducts independent quality assessments of Health facilities
- Provide guidance to health facilities on the certification process
- Submits assessment findings to the Certification Oversight Body

6.7. National Hospital Insurance Fund

- Creates an incentive structure based on the quality assessment findings
- Communicates compensation structure to the stakeholders

6.8. Professional Bodies/Learning Institutions

- Ensure that the respective health professionals have requisite competencies in the core areas of their professional practice to facilitate the provision of quality health care to clients.
- Provision of training opportunities and CPD

6.9. Health Facilities Umbrella Bodies- KEC, CHAK and KHF

- Facilitates QI activities of health facilities under their jurisdiction
- Facilitates periodic self-assessments of the health facilities
- Facilitates external assessments by CABs
- Follows up on the recommendation of the assessments by the CABs
- Mobilizes resources for all QI activities and external assessments

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