WHO GUIDELINE ON THE IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEMS FOR NATIONAL REGULATORY AUTHORITIES

(July 2019)

DRAFT FOR COMMENTS

Medicines Quality Assurance working documents will be sent out electronically only. They will also be placed on the Medicines website for comment under “Current projects”. 
http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en

If you have not already received our draft working documents, please send your email address (jonessi@who.int) and we will add you to our electronic mailing list.

Note from WHO Secretariat: this working document was prepared by the Regulatory Systems Strengthening (RSS) Group with the support of the Medicines Quality Assurance (MQA) Group.
WHO GUIDELINE ON THE IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEMS FOR NATIONAL REGULATORY AUTHORITIES

1 BACKGROUND

Implementation of the Thirteenth World Health Organization (WHO) General Programme of Work (2019-2023), as adopted by the Seventy-First World Health Assembly (2018) and the WHO Leadership Priorities, has attracted much international public health attention to the theme of Universal Health Coverage and to increased access to safe and effective medical products.

Several World Health Assembly (WHA) resolutions, including WHA67.20 (2014), mandate WHO to provide support to its Member States (MS) in strengthening national regulatory systems for medical products. It recognizes that “effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes; that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products” [1]. Accordingly, to facilitate access to these products, WHO’s vision is for all MS to have a regulatory system that ensures medical products and other health technologies in the market meet internationally recognized standards of quality, safety and efficacy.

National Regulatory Authorities (NRAs) are responsible for ensuring safety, quality and efficacy of medical products within the respective MS, demonstrating that the services they provide consistently meet legal and regulatory requirements, delivering effective and efficient services, evaluating performance and making improvements. A quality management system (QMS) can ensure that the products or services an NRA provides consistently meet statutory and regulatory standards and meet customers’ expectations. A QMS provides opportunities to enhance customer satisfaction, address context-associated risks and opportunities for continuing improvement, demonstrate conformity to specific QMS requirements, and assure the quality, safety and efficacy of medical products.
In 2015, WHO developed and launched the WHO Global Benchmarking Tool (GBT). This tool assists regulators worldwide in evaluating the developmental status of their regulatory system and its related functions. The GBT includes one indicator that assesses the NRA’s level of development with respect to QMS.\(^1\) Benchmarking results of low and middle-income countries indicate that most NRAs need to establish and implement a QMS or, if already established, enhance and maintain the QMS.

QMS implementation is challenging for NRAs due to the diversity of NRA legal mandates and organizational structures, to the different levels of NRA development and to the number of regulatory functions that need to be addressed. WHO has developed this guideline to respond to requests by MS to have an international guideline on implementation of QMS by NRAs.

### 2 OBJECTIVE

The aim of this guideline is to assist NRAs to develop, implement and improve QMSs based on principles from International Standardisation Organization (ISO) document ISO 9001 Standard requirements [2]. It provides recommendations on what NRAs should implement and maintain under the QMS to effectively and efficiently support the execution of NRA functions as mandated by national laws and regulations. The guideline is expected to promote consistency in regulatory practices within and across NRAs to facilitate harmonisation, mutual reliance and recognition mechanisms among MS.

Therefore, the guideline has the following objectives:

a) Describe principles for implementing a QMS to support planning, execution, monitoring and evaluation of performance of all applicable functions and activities for NRAs.

b) Provide requirements for the QMS to support and facilitate systematic linkages and integration of different processes and systems of the regulatory functions and activities within NRAs.

c) Provide requirements that NRAs should consider for evaluating the performance of the QMS and measures that the NRA should implement for continually improving the QMS.

---

\(^1\) References to the GBT VI.
3 SCOPE OF THE GUIDELINE

This is an overarching guideline that should be applied across all regulatory functions and activities, including registration and marketing authorization, vigilance, market surveillance and control, licensing establishments, regulatory inspections, laboratory access and testing, clinical trials oversight, national lot release and others as applicable to the implementing NRA. The guideline should be implemented to cover all types and categories of medical products and technologies under the responsibility of an implementing NRA.

The guideline can be used for other regulatory activities which are mandated by the national laws and regulations to ensure public health safety by assuring quality, safety and effectiveness of medical products. This extends to areas of medical products pricing, professional training and regulation and procurement of medical products, as well as to other areas within the legislative mandates and functions of the NRA.

This guideline provides recommendations for QMS implementation for all models of NRAs. NRAs can be legally, organisationally and operationally structured as follows:

a) **Discrete** – two or more institutions involved in partial or full enforcement of national laws and regulations for medical products in a country (e.g. one institution with legal mandates to enforce marketing authorizations (MAs) and another one within the same country for licensing establishments (LI) regulatory function).

b) **Decentralised** – one NRA with full legal mandates to enforce national laws and regulation of medical products within the country. Legally defined amount of enforcement, authority and operations are executed in localised zones or geopolitical zones of the country while the rest is enforced at country level. This model exists in MS having a federal governance system where laws and regulations are enforced at state/province and national levels.

c) **Centralised** – one NRA with full legal mandates to enforce national laws and regulation of medical products within the country. The enforcement, authority and operations are executed, managed and controlled centrally for all applicable regulatory functions and activities.
The provided recommendations are applicable to all sizes as the principles and intended results remain the same regardless of the complexity of NRA. Therefore, this guideline describes the requirements which should be implemented; the MS and respective NRAs reserve the right to decide on how to address these requirements within the existing contexts and provisions of the laws. This guideline can be utilized by institutions which are responsible for single or multiple specific regulatory functions related to medical products.

Use of this guideline is voluntary. NRAs are free to use this guideline or to choose other methods for implementing QMS. The implemented QMS should be demonstrated by documented evidence to have systematic processes which are controlled, maintained and evaluated for continuous improvement. NRAs are free to use any appropriate national or international standard or guideline as a basis for the implementation of the QMS.

Where different units within the NRA have already implemented QMS for specific regulatory functions (such as laboratory testing and/or regulatory inspection), this guideline could be used by the NRA to determine the functions and processes that have not been addressed by the already implemented management systems. This is to avoid duplications and overlaps of management systems and to ensure gradual integration of all existing management systems with the overall QMS of the NRA. The implementing NRA should determine the extent to which this guideline should be implemented without leaving out any of its processes and activities that are mandated by national laws and regulations.

Effective implementation of this guideline will not lead to any WHO certifications and WHO will not conduct any audits for verification of implementation of QMS for already certified NRAs. However, as part of the regulatory systems strengthening program, WHO will conduct the benchmarking of the MS regulatory functions including QMS related processes using the GBT to determine the strengths and gaps, if any, for capacity building and continuous improvements. This guideline should be implemented to cover regulatory functions which are part of the GBT and other functions and activities of the NRA that are addressed by national laws and regulations but which are not part of the GBT. References to GBT VI [6] provides a linkage of GBT indicators with the relevant chapters of this guideline.

The guideline should be implemented on the foundation of the principles and recommendations as provided in the current version of WHO guideline on Good Regulatory Practices (GRP) [3]. The implementation of the QMS should ensure that the GRPs are integrated to the extent possible without affecting the effectiveness and efficiency of the NRA to execute its functions.
4 GLOSSARY

The definitions given below apply to the terms used in this guideline which are not defined in existing WHO terms and definitions databases. They may have different meanings in other contexts.

**Competence**
Knowledge, skills and attitude required for successful work performance.

**Correction**
Any action that is taken to eliminate a nonconformity. However, corrections do not address causes.

**Corrective actions**
Steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence. The corrective action process tries to make sure that existing nonconformities and potentially undesirable situations do not happen again.

**Customer**
A person or organization that could or does receive a product or a service that is intended for or required by this person or organization. Customers of NRA include individuals or parties who receive or could receive and use products and services which are provided and offered by NRA. These parties include the general public, patients, manufacturers, distributors, health practitioners, researchers, Ministry of Health (MOH) and other individuals and intuitions that rely on the NRA products and services to make public health decisions.

**Customer satisfaction**
A customer’s perception of the degree to which the customer’s expectations have been fulfilled. This relates to the expectations that different parties have from the NRA. The expectations include assurance that safe, efficacious and high-quality medical products will be available under the NRA mandate to regulate and that the NRA will provide other products such as guidelines, public reports and related regulatory services that meet the expectations of different types of customers.

**Internal audit**
An examination and assessment of all or part of a quality system with the specific purpose of improving it. An internal audit is usually conducted by an independent (i.e., of the function to be audited) and qualified team of experts designated by the management for this purpose.
Process
A set of interrelated or interacting activities that use inputs to deliver an intended result.

Product
Output of an organization that can be produced without any transaction taking place between the organization and the customer. They are also called regulatory products in this guideline. Products of NRAs relate to the tangible items which the NRA produces for its customers. These items include regulatory guidelines, public health notices, guidance notes, alerts, databases, mobile phone applications, reports and other materials which are intended to provide regulatory information and communications to customers. Before their production, some of these products may require lengthy consultations for designing them.

Quality
The total set of characteristics of an entity that affect its ability to satisfy stated and implied needs and to ensure the consistent and reliable performance of services or products in conformity with specified requirements.

Quality Management System (QMS)
An appropriate infrastructure, encompassing the organizational structure, procedures, processes, resources and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.

Quality policy
A brief statement that describes the organization’s purpose, overall intentions and strategic direction, provides a framework for quality objectives and includes a commitment to meet applicable requirements.

Senior (Top) management
Person(s) who direct and control a company or site at the highest levels and who have the authority and responsibility to mobilize resources within the company or site. In NRAs, senior management or top management (TM) can be used interchangeably.

Services
Output of an organization with at least one activity necessarily performed between the organization and the customer. They are also called regulatory services in this guideline. This includes, for example, activities such as evaluation of applications for market authorisations, inspections of facilities and testing of health product samples.
5 QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR NRAS

NRAs should implement a QMS that is supported by the process approach concept, Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. NRAs should ensure that the implemented QMS meets its needs without making it unnecessarily complex to avoid it negatively affecting its effectiveness and efficiency. The QMS should be simple, fit-for-purpose and understandable.

An effective QMS should be implemented based on internal processes as identified and documented by the NRA from the input requirements, through the intermediate activities, and up to the output results shown in Figure 1.

![Figure 1: Process approach (ISO 9001:2015[2])](image)

The PDCA cycle requires NRAs to carry out planning, performing (implementing), checking (evaluating) and acting (to improve) processes in the QMS. The applied PDCA cycle covering the chapters in this guideline is provided in Figure 2. ISO 9001 standard [2] provides the following brief description of the PDCA process:

- **Plan**: establish the objectives of the system and its processes, obtain the resources needed to deliver results in accordance with customers’ requirements and the NRA’s policies, and identify and address risks and opportunities.
- **Do**: implement what was planned.
- **Check**: monitor and, where applicable, measure processes and the resulting products and services against policies, objectives, requirements and planned activities and report the results.
- **Act**: take actions to improve performance, as necessary.
The context of NRA and scope of its QMS are placed in the middle to provide the limitations to which the QMS should be implemented.

Leadership and management are centrally indicated as they are important requirements for effective QMS implementation. TM should commit and support all QMS processes from planning up to acting for continuous improvement.

Document and data management are centrally indicated because they should be part of every step of the PDCA cycle in the form of procedures, forms and records that facilitate the consistent implementation of QMS processes and record retention.

Risk-based thinking (included in planning stages) enables NRAs to identify factors that could cause QMS processes to deviate or that could prevent the planned results from being achieved, to put in place proactive measures and controls to minimize the impact of negative effects, and to leverage opportunities as they arise. Risk based thinking is applicable and should be implemented throughout the PDCA cycle.
NRAs should implement a QMS that identifies and integrates other management system standards that are applicable to the processes. The management systems which are for specific areas and processes should be documented. The NRA should ensure that the management systems do not create duplications, overlaps or inconsistencies within the overall QMS. While other WHO guidelines have been implemented for management systems of specific regulatory functions such as inspections and quality control testing, the overall QMS should be consistently implemented throughout the organisation across different regulatory functions and other supporting areas.

QMSs are influenced by the different policies, objectives, diverse work methods, resource availability and administrative practices specific to each NRA. NRAs are free to decide the mode and routes to use when implementing this guideline as long as the implemented QMS yields effective, consistent and reliable results in the regulation of medical products.

Effective implementation of this guideline by NRAs should be supported by the following principles as provided in ISO 9000 [4]:

**Customer focus.** The primary focus of a QMS is to meet customer requirements and to strive to exceed customer expectations. In this guideline, customer focus means meeting the needs and expectations of the public, patients, healthcare practictioners, manufacturers, researchers and procurers by providing regulatory products and services which assure access to high-quality, safe, effective and affordable medical products and health technologies.

**Leadership.** Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the NRA’s planned objectives.

**Engagement (involvement) of people.** Competent, motivated, empowered and engaged people at all levels throughout the organization are essential to enhance the organization’s capability to create and deliver value.

**Process approach.** Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system. This is critical as it avoids having systems which are based on individuals within NRA.

**Improvement.** Successful organizations have an ongoing focus on improvement. The NRA should ensure that it strives continually to improve its processes within the QMS.
Evidence-based decision-making. Decisions based on the analysis and evaluation of data and information are more likely to produce desired results. This requires NRAs to implement measures for monitoring, analysing and evaluating the collected data to assess if the processes are delivering the desired results.

Relationship management. For sustained success, organizations manage their relationships with relevant interested parties. Implementing an effective QMS requires the NRA to ensure that its relationships are managed strategically for continuous operations. The relationships include management of contractual agreements for activities subcontracted to individuals and institutions. The areas with subcontract agreements would either be technical or administrative and, if not managed properly, may have negative effects on the effective implementation of the QMS.

The QMS requirements which are described in the subsequent sub-chapters have descriptions of what NRAs should implement as part of their overall QMS. Table 1 provides a summary and focus for each sub-chapter.

Table 1. Summary of QMS requirements for each sub-chapter

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Summary of requirements for implementation in QMS</th>
</tr>
</thead>
</table>
| Introduction        | The requirements of this chapter focus on NRA describing and documenting the setup of its QMS. The setup includes:  
• Legislative mandates (functions) of the NRA,  
• QMS implementation history,  
• Standards and guidelines used in QMS implementation,  
• Integration (as applicable) with other management and software systems for personnel performance appraisals, finances and accounting, environment, occupational health and safety, workflow, customer relationship management, MOH policies and strategic action plans. |
| Scope of the QMS    | This chapter describes requirements for NRAs to document the processes that are covered by the implemented QMS. All processes and activities that are done by the NRA as mandated by national laws and regulations should be included in the QMS. |
| **Context for NRAs** | The focus is to provide guidance regarding what should be indicated when describing and documenting the setup of the NRA with its regulatory functions and activities within the MS. This extends to the model type (discrete, centralised or decentralised) and to the relationships with other institutions providing regulatory services for medical products and technologies. The context should also specify what to implement in the QMS to support the NRA in handling and managing internal and external issues within its regulatory mandates and functions as well as meeting the needs and expectations of interested parties (i.e. customers and stakeholders). |
| **Leadership, management and organisation** | This chapter describes requirements for what should be expected from TM for effective implementation of the QMS. It also includes the roles, responsibilities and authorities that should be part of the implemented QMS. |
| **Document and data management** | This chapter provides requirements that should be applicable to internally-generated documents and to those of external origins including data. The requirements include development, review, approval, distribution, version and access control, storage, retrieval and disposition of documents. |
| **Planning** | This chapter focuses on planning requirements for achieving set objectives, managing risks and opportunities across the NRA and planning of changes of QMS for continuous improvement. |
| **Support and resources** | This chapter includes requirements for input resources which are required for effective implementation of a QMS. |
| **Operation** | This chapter addresses the requirements for QMS implementation in core processes and activities which are within the mandates of NRA. It also provides guidance on documenting operational linkages of processes and systems for effective and efficient QMS implementation. |
| **Performance evaluation** | This chapter provides recommendations regarding what should be implemented by the NRA to facilitate accurate, objective and efficient performance monitoring, analysis and evaluation of operations indicators, QMS effectiveness, resources and customer satisfaction. |
| **Improvement** | Requirements for NRAs to implement in the QMS to support continuous improvements based on collected, analysed and evaluated data. |
5.1 Introduction

NRAs should have documented, available and accessible legislative laws and regulatory policies on medical products which describe the regulatory functions and activities that should be included in the QMS.

NRAs should list and maintain current versions and copies of national, regional and international management system standards and guidelines that are used for the QMS implementation.

NRAs should document the history and evolution of their QMS to demonstrate the controls and management of changes in the system to ensure that it is effective for the institution. The evolution and changes should be justified and related to any changes to the adopted national, regional and/or international management system standards and guidelines (e.g. the case of the East African Community's Compendium of Quality Management System (QMS) Technical Documents for Harmonization of Medicine Regulation [5]).

NRAs should ensure that all existing and already implemented management systems are integrated in the QMS. The integration should ensure that there are systematic, adequate and appropriate linkages between the overall QMS and the management systems for specific technical or administrative functions. The QMS should be integrated into the business processes to ensure that it helps the NRAs achieve their legal mandates and functions.

The NRA should determine the functions and processes that are already covered by other management systems. This should be done to identify gaps and align specific management systems with the overall QMS of the NRA as much as possible to ensure consistency and facilitate effective performance monitoring and evaluation (M & E). The management systems for specific technical and administrative functions and processes are described in sub-chapters 6.5 to 6.10.
5.2 Scope of the QMS

This guideline aims to provide guidance on implementing a sustainable and effective QMS based on adapted ISO 9001 standard [2] requirements to address the needs of NRAs with respect to all regulatory functions, including administrative and supporting processes. The scope of the QMS should include functions, processes and the physical locations where they are undertaken.

NRAs should ensure that the implemented QMS provides a clear statement of scope that specifies the functions and processes that are covered as mandated by the national legal framework. The scope should include all applicable regulatory functions which are provided in the current version of the GBT [6]. In addition, the QMS should also cover all additional technical and administrative functions and processes that are part of the NRA’s routine operations.

Where there is more than one institution that is partially or fully involved in the regulatory activities of medical products of a country, the QMS for each institution should support consistency, effectiveness, efficiency and systematic collaborations to improve and strengthen coordination between institutions. The QMS should also include the technical and administrative functions and processes which are interrelated and interdependent for the effective undertaking of the affected regulatory function(s). The QMS should be clear on the scope for each involved institution to ensure that there are neither gaps nor overlaps of the processes and activities.

When a specific unit of an NRA has implemented a QMS (e.g. a quality control laboratory, inspectorate or province/zone/state), the scope should be clear on the inclusions and exclusions (with justifications as applicable) without weakening operational linkages and interdependencies for timely and effective regulatory decision-making. The scope statement of the implemented QMS should be documented and supported by relevant national legal framework and by current best practices of the affected functions and processes.
5.3 Organisational context of NRA

The NRA should demonstrate that it understands its organisational and operational context within the country’s regulatory framework as part of national health system. This understanding facilitates the identification and management of internal and external issues relevant to its ability to achieve the objectives as defined in the NRAs strategic plans.

The NRA should document the context in which it exists and in which it has been given the legal mandate to perform regulatory functions that are within the scope of the QMS. The context should indicate the limitations of the NRA and the relationships with other institutions which are part of its routine operations.

The documented context of the NRA should clearly indicate the technical and administrative areas which are not exclusively under the control and management of the NRA. This could include areas such as personnel recruitment, management of finances, procurement, and management of equipment and infrastructure.

Determination and documentation of internal and external issues should be integrated in the business processes of the NRA based on the needs and expectations of customers and stakeholders. The determination of internal and external issues should also be linked to the development of a strategic plan to ensure that the implemented QMS helps the NRA achieve the objectives.

Internal and external issues can change (e.g. changes to medical product acts or regulations, government restrictions on international travels or procurements, changes in national labour laws, or changes to professional practice regulations), and therefore they should be monitored and reviewed. The NRA should conduct and document reviews of its organisational context at planned intervals and whenever there are changes to the legal framework or when there are organisational or structural changes.

NRAs should understand the context as well as the internal and external issues that provide the foundation and inputs for determining a strategic plan, scope of QMS, quality policy, quality objectives and related risks and opportunities.
NRAs may use national legal provisions to identify different types of interested parties (customers and stakeholders) to the regulatory products and services that are provided. Where customers and stakeholders are defined in the national laws and regulations, this would be sufficient as long as it addresses all outputs and services provided by NRA. This identification helps NRAs to separate other stakeholders from customers who should also be the focus of the QMS. NRAs should focus on all interested parties that can affect its ability to achieve the quality objectives. In addition, these interested parties should be categorised along with those respective needs and expectations from the NRA that the implemented QMS is designed to support.

NRAs should have a robust and defined system in place to monitor, review and document the relevant requirements of interested parties at planned intervals.

NRAs should ensure that inputs and resources which are required to perform the processes and functions covered in the scope of the QMS along with expected outputs are determined, documented and provided. NRAs should document the sequences and interactions of the regulatory processes together with related measures and criteria for their control (e.g. key performance indicators (KPIs)). The level and type of controls which are applied to the regulatory processes should be determined and documented with a risk-based approach and should utilise the available opportunities. The QMS should provide procedures for evaluating the QMS processes and allow for the implementation of corrective actions under a controlled and managed change process. This should facilitate continuous improvements of the processes and the entire QMS.

The QMS should be integrated in the business processes to ensure that the personnel who are assigned with responsibilities and authorities in performing regulatory and administrative activities have the required competencies.
5.4 Leadership, management and organization

NRA TM should demonstrate leadership and commitment towards the effective implementation and sustainability of the QMS within the national legal framework through continual identification of the needs and expectations of its customers. The following are responsibilities of TM with respect to QMS:

a) Providing needed resources for the implementation of an effective QMS which is consistently implemented across the NRA units, functions and processes;
b) Integrating QMS requirements into the business processes and aligning the quality policy and quality objectives with strategic plans of NRAs;
c) Implementing a QMS which incorporates risk-based thinking and which is based on processes and functions rather than being built around individual personnel or specific activities;
d) Communicating the importance of QMS and conforming to the requirement to maintain consistency in NRA functions and to improve effectiveness and efficiency of QMS;
e) Engaging, supervising and supporting all NRA personnel to contribute to the implementation and effectiveness of the QMS and to ensure that the NRA achieves the intended expectations;
f) Reviewing the performance of the QMS and promoting improvements.

TM should ensure that the risks and opportunities that can affect the ability of the NRA to provide products and services of the quality expected by customers are determined and documented. TM should also ensure that NRA implements measures to enhance customer satisfaction. To increase customer satisfaction, innovation and best practices may be introduced into the NRA’s processes with the appropriate determination of related risks and practicality.

TM of NRAs should establish, implement and maintain a documented quality policy which contains actionable and practical statements that:

a) take into consideration the organisational context and strategic directions and plans and provide a framework for setting quality objectives;
b) include a commitment to comply with applicable national legislation as well as regional and global regulatory requirements and best practices;
c) include a commitment to continual improvement of the QMS.
The TM should ensure that the quality policy also includes a commitment to adopt and implement GRPs as provided in the *WHO Good Regulatory Practices: Guideline for National Regulatory Authorities for Medical Products* [3].

TM should communicate the quality policy to all NRA personnel and ensure that the personnel have read, understood and applied it within their respective activities. Where applicable and appropriate, controlled copies of the quality policy should be published and provided to customers and stakeholders through established document control procedures as per QMS requirements.

To effectively implement the QMS, TM should assign and document roles, responsibilities and authorities, and should ensure that this information is communicated and understood within the NRA. Depending on the organisational context of NRA and on the scope and complexity of the QMS, TM should assign the following responsibilities and authorities to one or more job function:

a) ensuring that the QMS of the NRA conforms to the requirements of the adopted standards and guidelines;
b) ensuring that the integrated QMS and business processes are delivering their intended results as per action and strategic plans of the NRA;
c) monitoring and reporting on the performance of the QMS and proposing opportunities for improvements to TM;
d) ensuring the promotion of customer focus throughout the NRA while assuring quality, safety and efficacy/effectiveness of health products;
e) ensuring that the integrity of the QMS is maintained when changes (e.g. legislative, process, organisational or structural) to the QMS are planned and implemented.

TM should ensure that the job function(s) to be assigned the above responsibilities and authorities have the necessary competencies and have direct access and are accountable to TM.
5.5 Document and data management

NRAs should have guidelines, policies and procedures that are necessary for the effective implementation of the QMS within the legislative provisions.

QMS documents should include but are not limited to internally and externally generated hard copy and/or soft copy formats of regulations, drawings, policies, guidelines, strategic plans, action/work plans, manuals, procedures, registers, logbooks, databases, spreadsheets, templates and forms, codes of ethics and professional conduct, inventories, checklists and all other documents which are used in technical and administrative activities of NRAs.

QMS documents should include internally and externally generated evidential documents (e.g. records, files, and reports) in hard copy and/or soft copy formats which are retained by NRAs. NRAs should consider all published materials either on intranets or websites or in newsletters and other forms of publication to be part of QMS documents and covered by the requirements of this guideline.

Within the QMS, NRAs should implement policies and procedures for identifying, describing, formatting, reviewing, approving, controlling (e.g. distribution, access, retrieval and use), retaining and disposing of internally generated documents. QMS documents of external origin (e.g. regulations, standards, pharmacopeia and WHO guidelines) should be subjected to the same requirements as for those that are internally generated, to the extent possible and practical depending on the nature and intended use.

Where Information Technology (IT) is utilized to optimize business processes for technical and administrative functions, NRAs should ensure that the system templates, forms and software that are used are identified, reviewed, approved, controlled and maintained under the same QMS policies and procedures that apply for other documents.

NRAs should implement a data management, protection (i.e. confidentiality, loss and integrity) and retention policy/procedure to define clearly the types and categories of collected, analysed, evaluated and retained data. The policy/procedure should provide clear requirements for the format, medium and duration of retention for data and documents. In addition, there should be a policy/procedure for NRAs covering the maintenance and retention of all documents and data.
5.6 Planning

NRAs should plan and document how it will meet the needs and expectations of its customers and stakeholders as stipulated in the national legal mandates and regulations. The plan should include all technical and administrative functions, processes and activities of the NRA and their respective objectives.

When planning for the QMS, the NRA should consider the issues (internal and external) and requirements of the stakeholders and determine the risks and opportunities that need to be addressed in the context of the organization. The NRA should plan actions to address these risks and opportunities with assigned roles, responsibilities and authorities. The planned actions should include a framework for monitoring and evaluating the effectiveness of the actions taken. The NRA can choose the methods of risk management that suit its needs. Depending on the size, complexity and regulatory functions of the NRA, principles can be based on WHO Guidelines on Quality Risk Management [18] and ISO 31000 standard [19]. NRAs should establish quality objectives for relevant regulatory and administrative functions, for all levels and section of NRA and for all processes needed for the QMS. Where quality objectives are established for multiple levels within the NRA (e.g. directorate, department, unit or zone), the objectives should be consistent to ensure that all levels contribute towards achieving the overall expectations from legal mandates and of customers. The quality objectives should be integrated with business objectives to ensure that the QMS supports the consistency, effectiveness and efficiency of NRAs.

Quality objectives of NRAs should be consistent with its quality policy, should contribute to customer satisfaction, and should be relevant to the regulatory products and services as mandated by the national legal framework.

To the extent possible, quality objectives should be specific, measurable, attainable, realistic and time-bound (SMART). The QMS should provide the measures for NRA to communicate the objectives to designated audiences within NRA and the means to monitor and update the objectives.

QMS should include a plan to ensure that the set objectives will be met. The planning exercise includes determining the actions that will need to be taken, the resources that will be required (e.g. human and financial to purchase equipment and the required supplies), the responsibilities that will be assigned to staff for specific tasks, the timelines that will be defined for completion of each step and the means that will be used for monitoring and evaluating whether or not the objectives have been achieved.
The NRA should plan for changes to the QMS. The purpose of planning the change is to maintain the integrity of the QMS and ensure the NRA’s ability to provide conforming regulatory products and services during the change. For any change, the NRA should consider the availability of resources and necessary allocation or reallocation of responsibilities. This could be done by implementing an effective change management process within QMS. The need for changes can result from changing needs of customers and other relevant interested parties, for example, new products to be evaluated to grant market authorization, availability of new information and communication technologies (ICTs) for a service or process, a move to outsourcing of an important processes, departure of persons in key roles (e.g. due to retirement or job change), or a move to online service provision.

5.7 Support and resources

NRAs should determine and document resources which are needed to establish, implement, maintain and continuously improve the QMS. The determination should be done within the organisational context of the NRA and the scope of the legal mandates on the functions and activities. NRAs should also determine and document those technical and administrative resources which need to be provided by external providers (companies and individuals/experts).

NRAs should determine, provide and document the personnel and their required minimum competencies necessary for the effective implementation of the QMS and for the effective operation and control of its processes.

The competencies of the personnel should include a combination of appropriate education, professional training, experience and behavioural attitude as deemed necessary by the NRA. Where the assigned personnel with defined responsibilities and authorities do not have all the competencies, training plans should be developed and implemented with appropriate evaluation criterion for acquired competencies.

For consistency purposes of the QMS, NRA training plans for the rest of technical and administrative personnel and functions should be based on the competency framework or matrix and/or performance appraisal system coordinated by human resources departments. Records of evidence of an employee’s competence including diplomas or degrees, completion of training certificates, resumes, performance reviews, licenses and other documents should be retained.
The competency framework or matrix should be used in assigning official and non-official job function hierarchies and relationships (e.g. junior officer, senior officer, or head of unit). The framework should also include the procedure for designation or qualification of technical officers (e.g. Senior or Lead Assessor, Senior or Lead inspector, Senior or Lead Analyst); these should be supported by re-qualification procedures.

NRAs should determine, provide and maintain a documented list of infrastructures needed for technical and administrative processes in the execution of the legal mandates. Lists of the following should be maintained to allow for identification, location, type, quantities, versions, operational status (i.e. in use vs. not in use) and plans for qualification, validation, calibration, and maintenance (as applicable):

a) Buildings and associated utilities;
b) Technical (e.g., inspection and testing equipment) and administrative equipment (e.g., servers, computers, and printers), including hardware and software;
c) Transportation and logistical resources;
d) Information and communication technology.

NRAs should determine, provide and maintain the human and physical factors of work environment necessary for the operation of technical and administrative processes and activities within the context of organisational structure and national legislation. To the extent that it is practical, the environment should address social, psychological and physical (i.e. workspace) conditions to promote work-life balance. Depending on the activities of the NRA, applicable occupational, health and safety policies and procedures should be considered for implementation as provided in ISO 45001 Occupational Health and Safety [7].

NRAs and its units should implement and document a policy and procedure on the management of waste that is generated. The waste management should be conducted within the recommendations and applicable requirements of the current version of ISO 14001 [8]. NRAs should determine and document a list of monitoring and measuring resources and equipment used to ensure that the regulatory products and services meet the expected requirements. The equipment should be suitable for measurement activity to be undertaken and maintained to ensure continued fitness.

For the equipment including software that is used in technical measurements (e.g. inspection and laboratory equipment), NRAs should ensure that the results obtained from such equipment are valid and that the calibration of equipment is traceable to national or international measurement standards. The calibrated equipment should be identified with calibration status and safeguarded from adjustments, damage or deterioration.
In the event of measuring equipment found to be out of calibration, NRAs should evaluate and document the validity of previous measurement results obtained from the equipment and take appropriate actions.

The NRAs should consider how to determine and manage the organizational knowledge required to meet NRA’s present and future needs. Persons and their experience are the foundation of organizational knowledge. Capturing their experience and knowledge can generate synergies leading to the creation of new or updated organizational knowledge. In determining, maintaining and making organizational knowledge available, NRAs can benefit by a) learning from failures and successes, b) gathering knowledge from stakeholders, experts and partners, and c) capturing existing internal knowledge.

The tools for maintenance and distribution of organizational knowledge can include the intranet, libraries, awareness sessions, newsletters and others.

NRAs should ensure that all personnel (both full-time and part-time) have read and understood the quality policy and the relevant quality objectives that are relevant to their level in the organisation. This should be documented to verify that personnel understood their contributions to the effectiveness of the QMS and the benefits of improved performance. NRA personnel should be aware of the implications of not following policies and procedures established under QMS, for example, the release to customers of non-conforming regulatory products.

NRAs should determine, implement and document internal and external communication policies and procedures within the QMS. The policy should clearly describe “what” to communicate and define responsibilities and authorities for communication to the assigned competent personnel. Depending on the context, nature and intent of the communication, the policy should describe the level, audience and frequency of the communication including the format and medium (e.g. verbal, letter, mail, website, or intranet). Social media and mobile applications are additional tools for communicating with interested parties. The communication policy and procedure should be implemented within the legal framework of the NRA and related national (governmental) procedures and practices.
5.8 Operation

NRAs should ensure that planning of technical and administrative processes is done effectively as provided under 5.6 above for all operations within the scope of QMS.

NRAs should ensure that there is a process of consistent communication with customers and stakeholders to collect their feedback, inputs and other inquiries that may be useful in reviewing the requirements for the offered regulatory products and services. The details of the regulatory products and services offered including contingency requirements (such as those applied during natural disasters or epidemics) should be communicated upfront (e.g. through the NRA website, pre-submission meetings, or scientific advice) in order for customers to understand the information they need to provide to NRA relating to regulatory products and services.

NRAs should ensure that the requirements and expectations for the products and services are determined and defined within the applicable national laws and regulations. To promote public transparency and accountability, the product and service requirements may include fee schedules and delivery timelines for product market authorisations, licences, permits and certificates. This information may be included in the national guidelines and guidance notes and should be publicly available to customers and stakeholders.

NRAs should ensure through a review process that requests for services received from customers are complete and in conformity with service requirements. A checklist used for such reviews should be documented. When there is a difference between the requirements for products or services as requested by customer and the requirements prescribed by NRA, the same should be communicated to the customer and resolved before processing the request. Any verbal request or change in the requirements, either by the NRA or by the customer, should be confirmed before service is processed.

When the requirements for products and services are changed due to any reason, NRAs should take measures to inform all relevant interested parties. NRAs should retain evidence of the results of the revisions to the requirements of products and services and any new requirements for the products and services that are provided.
When NRAs plan on implementing new regulatory function(s) due to the revision of the national legal framework or wish to introduce new regulatory products and/or services (such as through mobile phone application), the following process steps should be followed:

a) Determine and document the process(es) that will form part of the new function including the stages, steps and control measures needed through implementation roadmaps or projects. The determination should include expected reviews, verifications and validations that the processes are robust enough for the intended function. NRAs should also determine and document the competencies, responsibilities and authorities of the project development team. Where the NRA would not be able to provide all the required resources, the NRA should document those resources that will be externally sourced. NRAs should determine the need to involve customers, stakeholders and internal personnel to ensure that key inputs are collected. NRAs should also assess whether any of the existing requirements (e.g. timelines or schedule of fees) are applicable to the new regulatory function or whether there is a need to establish new ones. All documents used and generated out of these roadmaps should be retained in an appropriate format and medium.

b) Once the implementation roadmap has been completed, NRAs should determine and document the inputs such as performance indicators, national legal requirements for compliance, and codes of ethics and professional conduct, as well as the potential consequences of failure using a risk-based approach.

c) As defined in the implementation roadmaps, intermediate reviews (where practical and possible), verification steps (i.e. comparing the new application/process with a similar proven application/process) and validation exercises (i.e. testing under intended user conditions) should be conducted by NRAs to ensure that the resulting function or product meet the requirements for the intended use.

d) The expected outputs of design and development process will be in the form of standard operating procedures (SOPs) or service provision manuals that give the information necessary for all the processes required to provide intended products and services including information to be provided by the customers.

e) Where changes are to be made in the new application or to the developed products or process(s), these changes will be identified, reviewed and controlled. A risk-based change management procedure should be documented and implemented.
NRAs should ensure that externally provided products and services (e.g. subcontracted ICT support, purchased reference standards, or subcontracted quality control laboratory testing) required for technical and administrative functions and activities of the NRA, conform to the QMS requirements. Where national laws and regulations exist for managing use of public NRA funds in procurement, for example, a national public procurement Act with procedures based on amount thresholds for either single sourcing or open/closed bid competitions and decision levels (i.e. Director General, Council, or Board level), the QMS should not duplicate any procedures which are provided for public procurements; however, the NRA should ensure that the public procurement procedure conforms to the requirements given in the subsequent paragraphs below and should close gaps, if any. The NRA should also implement these requirements when it carries out direct procurement.

NRAs should ensure that competence criteria are defined, documented and implemented for the evaluation, selection, performance monitoring, and re-evaluation of external providers and suppliers (e.g. NRAs having documented, well-defined and transparent criteria for the selection and performance monitoring of external non-staff experts).

When NRAs must perform in-house pre-qualification of providers, there should be a documented procedure and policy on the competence criteria for evaluation, selection, performance monitoring, and re-qualification. The pre-qualification and re-qualification should focus on the competence of the individual persons and the institution or company to provide the products and/or services that meet applicable QMS requirements.

NRAs should implement measures for ensuring that the externally provided products and services do not adversely affect the organisation’s image and ability to consistently deliver the products and services to the customers.

The NRA should determine which specific controls are to be implemented for an external provider and for incoming products and services provided by them. Control activities that may be considered include inspections, certificates of analysis or testing, second party audits, evaluation of statistical data and KPIs.

NRAs should clearly communicate the requirements and controls to be applied to the external provider and both parties should agree as to what is required. This understanding of requirements is usually reflected in a technical service agreement or through a purchase order or contract. The NRA should ensure that the requirements communicated to the external providers are complete, clear and address any potential issues.
NRAs should carry out their technical and administrative functions for processing of requests for services under controlled conditions. The controlled conditions should include, as applicable:

a) Use of guidelines, policies and procedures that provide the requirements for the regulatory products and services including those for performance of activities.

b) NRAs should document and implement measures for reviewing (peer review or QA review), approving and releasing of output of intermediate processes to ensure that there are adequate controls for those activities that are involved in providing conforming products and services. For this purpose, the following guidelines should be considered for adoption and implementation as applicable and to the extent necessary:
   Where the NRA has a unit or site responsible for GxP inspections, recommendations and technical requirements: *WHO Quality Management Systems Requirements for National Inspectorates* [12].

c) As required, monitoring and measuring resources and equipment should be available and in use to ensure that the processes are effective and controlled. Where measuring equipment must be used in providing regulatory services of the NRA laboratory, technical requirements and recommendations from the following guidelines should be considered for adoption and implementation as applicable and to the extent necessary: *WHO Good Practices for Pharmaceutical Quality Control Laboratories* [13] for physico-chemical and *WHO Good Practices for Pharmaceutical Microbiology Laboratories* [14] for microbiological testing. These two WHO guidelines can be supported and complemented with current *ISO 17025 standard* [15] and *EDQM, Quality Management Documents* [16].

d) NRAs should ensure that the provided infrastructure and working environment are suitable for the operation of both technical and administrative processes and activities and for the performance of applicable regulatory functions.

e) NRAs should ensure that the appointment of personnel is based on the required competencies and qualifications and is described and documented in respective units. This should include the implementation of control measures to avoid or reduce human errors through peer and QA reviews.
NRAs should document and implement policies and procedures on the unique identification and traceability of released regulatory products and services. As far as practical and possible, these also should be supported by systematic measures to facilitate traceability of the products and services to the equipment, software, personnel and location used by the NRA.

NRAs should implement measures to verify, protect and safeguard properties that belong to customers and stakeholders, including providers, and avoid their loss, damage and any effects that would make them unsuitable for use. This can include properties, for example, that may have been seized and quarantined or used as input for making regulatory decisions. Examples of property include marketing authorization product dossiers, quarantined products, samples for testing, intellectual property or personal data.

The NRAs should determine those products and services (e.g. seized drugs, drug samples collected for analysis, vaccines under release, licences, market authorisations, permits or certificates to be issued) that can deteriorate or degrade and implement appropriate preservation methods.

NRAs should document and implement practical procedures on release of regulatory products and services through all stages up to and including the customer. The release process includes defining responsibilities and authorities of the involved job functions. These processes should provide an internal QA procedure to ensure that the released products and services comply with all planned requirements.

NRAs should document and implement procedures for control of non-conformances and deviations that are observed or reported. Control actions include correcting the non-conformity or releasing product under suspension of due authorization. If the nonconformity is discovered after the product has been delivered to the customer, the NRA should take appropriate actions to prevent unintended use or undesired consequences and take measures such as issuing a recall or suspension. The QMS should not duplicate any existing procedures in technical units such as a laboratory or inspectorate.
5.9 Performance evaluation

NRAs should conduct monitoring, measurement, analysis and evaluation of all planned technical and administrative activities to determine whether the intended results, as defined in action plans, work plans or strategic plans, are being achieved. NRAs should define what needs to be monitored and measured (e.g. characteristics of processes, products, services and potential risks) and the methods to be used for monitoring, measurement, analysis and evaluation of the performance and effectiveness of the QMS. The monitoring, measurement, analysis and evaluation of the NRA performance should be linked to the planned KPIs (or simply indicators) as applicable. The establishment and implementation of the indicators should be as practical as possible to ensure that value is added through monitoring, measurement, analysis and evaluation activities. Therefore, the indicators or KPIs should have clear, relevant, economic, adequate and monitorable (CREAM) attributes. NRAs should determine and document the frequency of M & E of the indicators from the implemented action and activity plans as well as from the performance and evaluation of the QMS. NRAs should ensure that the M & E framework is consistent across different units, levels and functions of the organisation. The framework should be documented and aligned with the relevant quality objectives (strategic objectives) of the NRA.

The NRA should develop methods to seek feedback from a selected population of customers or from every customer at the end of a service provision. Means to obtain feedback is provided by social and published media such as web sites and message boards, opinion surveys and compliments or complaints. The NRAs should determine the degree of customer satisfaction after the results of feedback are analysed and evaluated and then act based on this information. NRAs should document, implement and publish comprehensive policies and procedures on handling of complaints in order to provide guidance to customers and stakeholders on complaint submission, investigation, resolution, appeal and communication within the national legal provisions. The procedures should define roles and responsibilities of a complainant and the NRA and specify timelines to effectively manage complaints related to regulatory products and services.
NRAs should analyse and evaluate monitoring and measurement data and information to determine summary performance results of the following:

a) Compliance of regulatory products (e.g., guidelines and software applications) to quality and validity requirements;
b) Compliance of regulatory services to quality and timeline commitments and requirements;
c) Degree of customer satisfaction;
d) Performance and effectiveness of the QMS for the overall NRA and/or the QMS for NRA units or functions and the need for improvements to the QMS;
e) Level of implementation of action or activity plans and strategic plans at the time of reporting;
f) Effectiveness of the actions taken to address risks and opportunities (such as strengths, weaknesses, opportunities and threats (SWOT) analysis);
g) Performance of external providers (including external technical experts).

NRAs should plan and conduct internal audits (at least once a year) to verify compliance to the QMS requirements across the organisation and to verify that the QMS is effectively implemented and maintained. An internal audit programme should have defined planning requirements, frequencies, methodologies, responsibilities, competencies and reporting. Each internal audit programme should take into consideration the importance and associated risks of the processes to be audited, the internal and external changes affecting the NRA, and the results of previous audits in order to:

a) Define the audit requirements for the criteria (QMS requirements) of compliance, scope (functions and departments to be audited) and methodology (interviews, examination of records, results, and trends) for each audit. The criteria for compliance may add and implement a scale for reporting observations (critical, major and minor) which should be clearly and objectively defined within the internal audit programme.
b) Select appropriately qualified and competent auditors who can conduct the audit objectively and impartially. The impartiality can be achieved by employing auditors that audit those processes in which they were not involved while serving in the NRA.
c) Ensure that the internal audit reports are submitted to TM for actions.
d) Take appropriate corrections and corrective actions without delay and within timelines defined by TM. Where corrective actions are delayed due to unavailability of required resources, appropriate risk management plans should be implemented and documented.
e) Retain records of internal audit programmes and internal audit reports including records of corrections and corrective actions.
Further technical guidance on managing internal audits can be adopted from the current version of ISO 19011 [17].

TM of NRAs should review the QMS at planned intervals (i.e. at least once a year) to ensure its suitability, adequacy, effectiveness and alignment with the strategic direction of the organisation as per strategic plans. Ideally, TM should review the QMS alongside the review of NRA’s business plans (activity, action or strategic plans). This will ensure that the QMS remains integrated into business processes effectively.

QMS reviews should consider inputs as provided in table 2 with the listed expectations of the outputs to come out in the minutes of the meeting (report).

Table 2: Inputs and outputs for review meetings

<table>
<thead>
<tr>
<th>Inputs (to be reviewed)</th>
<th>Outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status of actions from previous reviews.</td>
<td>• Decisions and actions related to opportunities for improvements.</td>
</tr>
<tr>
<td>Changes in internal and external issues which are relevant to the QMS.</td>
<td>• Decisions and actions related to changes required to the QMS.</td>
</tr>
<tr>
<td>Information on performance and effectiveness of QMS, including trends in:</td>
<td>• Actions on additional resources needed to implement improvement initiatives and suggested changes in QMS and in other areas where resources (including human resources) are not adequate.</td>
</tr>
<tr>
<td>1. Customer satisfaction and feedback from stakeholders;</td>
<td>• Actions to implement for quality objectives achievement.</td>
</tr>
<tr>
<td>2. Extent to which quality objectives have been achieved;</td>
<td>• Responsibilities for follow up of actions on the decisions taken in the meeting.</td>
</tr>
<tr>
<td>3. Performance on compliance to commitments and requirements for regulatory products and services;</td>
<td>• Management review meeting minutes to be retained as records or reports and communicated appropriately to internal and external customers and stakeholders as per NRA communication policy.</td>
</tr>
<tr>
<td>4. Non-conformances and deviations, and status of implemented corrective actions;</td>
<td></td>
</tr>
<tr>
<td>5. Results of M &amp; E of indicators/KPIs;</td>
<td></td>
</tr>
<tr>
<td>6. Results of internal and external audits;</td>
<td></td>
</tr>
<tr>
<td>7. Performance of external providers (including external technical experts).</td>
<td></td>
</tr>
<tr>
<td>Adequacy of resources (financial, human, equipment and infrastructure).</td>
<td></td>
</tr>
<tr>
<td>Effectiveness of the actions taken to address risks and opportunities (such as SWOT or similar analysis).</td>
<td></td>
</tr>
<tr>
<td>Opportunities for improvements of QMS.</td>
<td></td>
</tr>
</tbody>
</table>
Management review agenda (inputs) and meeting minutes should be retained as records or reports and communicated appropriately to internal stakeholders as per NRA communication policy.

5.10 Improvement

There are different methods to conduct improvement, such as correcting existing nonconformities and deviations and taking actions to prevent recurrence, or conducting ongoing, small-step improvement activities based on opportunities identified either through risk analyses or breakthrough projects. These improvement activities can lead to innovation, to revision and/or improvement of existing processes or to the implementation of new processes. NRAs should implement and document measures to record and react to non-conformances and deviations by taking actions to control and correct them, including with related plans for managing related activities, if any. In addition, NRAs should conduct a root cause analysis (RCA) and evaluate the need to act in order to avoid recurrence of the non-conformances and deviations in the affected area as well as in any similar processes in the organisation in which such non-conformances or deviations could occur.

The steps involved in this process are:

a) Reviewing and analysing the non-conformance or deviation;
b) Determining, to the extent possible, the cause(s) of the non-conformance or deviation;
c) Determining if similar non-conformances exist or could potentially occur within the affected unit or function and/or other NRA units or functions having similar processes.

After implementing the corrective action, NRAs should review and document the effectiveness of the corrective action taken through practical means including during future internal audits which look for a recurrence of the same non-conformity. The results of the RCA and the implemented corrective actions should be used to update the risk and opportunity planning as applicable. Where corrective actions lead to changes to the process(es), NRAs should plan for similar changes to the QMS supported by a defined change management plan. NRAs should define the communication of non-conformances and corrective actions reports to internal and external customers as defined in the communication policy/procedures.

For technical and administrative processes, NRAs should ensure that the handling of conformances, deviations and corrective actions is consistent across the entire organisation. Non-conformances and deviations that are related to professional misconduct of NRA personnel should be handled in accordance with conditions of employment and service including related national legal provisions.
Improvement can include actions to reduce process variation, increase consistency of process outputs, products and services, and improve process capability. This should be done to enhance the NRA’s performance and give benefits to its customers and stakeholders. The results from performance monitoring and evaluation and management reviews should be used to decide which continual improvement actions should be implemented and what resources and support should be provided for their implementation by TM.

6 QMS IMPLEMENTATION METHODOLOGY

Full commitment of the head of NRA and the heads of technical, support, and administrative units (i.e. TM) is necessary for effective implementation and maintenance of the QMS in NRAs. This commitment should be supported by demonstrating leadership, management, commitment and customer focus through all stages of the implementation of QMS. The QMS should be designed to be integrated in business processes (i.e. not stand alone), supported with adequate resources (human, financial, equipment and infrastructure) and created to be simple enough to remain manageable with the available resources while being effective enough to support consistency, effectiveness and efficiency.

Potential mechanisms that can help in QMS implementation:

- Establishing strong coordination and communication mechanisms;
- Receiving high level support from TM for QMS implementation;
- Establishing high level ownership and commitment by TM for QMS implementation and maintenance;
- Including QMS implementation roadmaps in NRA strategic plans by TM when submitting to an oversight body (Council, board, committee or MOH) for approval as applicable;
- Including QMS implementation in NRA in the national health strategic plans;
- Including responsibilities and authorities for contributing to QMS in every staff job description and human resources (HR) performance appraisals;
- Creating and implementing training plans for QMS personnel based on NRA competence frameworks;
- Engaging all customers and stakeholders for communication and awareness;
- Implementing applicable ICT tools for internal and external implementation of QMS and communication of quality policy awareness;
- Imbedding assigned QMS personnel within business processes with dual responsibilities of business job functions and QMS responsibilities to support and maintain the QMS in the respective business unit.
Regardless of the size of NRA, the scope of regulatory functions and the NRA organizational model (i.e. discrete, centralised or decentralised), the recommendations in Appendix 1 for gap and situational analyses should be considered when implementing QMS and when planning for continuous improvement of a QMS that is already implemented. NRAs should first identify existing gaps and determine the level of implementation of the QMS with the use of Appendix 1 and self-benchmarking results.

Appendix 1 has categorised the key aspects of the QMS as:

a) **Non-existing QMS**: NRAs should focus on ensuring that processes and activities are performed consistently regardless of the personnel or location of execution. This may be covered for certain areas with automated systems (such as laboratory information management systems (LIMS) for laboratories or e-Performance appraisals for HR). NRAs should prioritise development and implementation of procedures for areas based on the related risks with respect to the products and services, the affected quality objectives and the availability of resources for maintenance of the procedures. This means that not every area should be prioritized at the same time for QMS development and implementation (for NRAs without implemented QMS).

b) **Existing QMS without implementation**: The focus at this stage should be on ensuring that consistent procedures are developed and implemented for the QMS to support business processes effectively. Careful consideration should be given at this stage to objectively addressing the activities for gap identification and validation; these steps would also be useful for NRAs that have already developed and implemented QMS. NRAs should ensure that the person(s) identifying the gaps have necessary competence and that TM fully supports the process. The review should be done to cover all areas in which the QMS has been implemented and the scope should be limited to records, reports or other means of verification that procedures have been implemented and are being used to the full extent as intended. The outcome of this review should be a RCA with proposed measures to implement; these measures should take into consideration of the availability of resources and associated risks of delayed implementation.

c) **Ineffective QMS**: Addressing this stage is considered useful once the first two stages are addressed for the respective processes and activities. This stage focuses on the main objectives of the QMS, namely, to ensure that the NRA is being effective in supporting business processes and activities, providing regulatory products and services, and achieving strategic objectives. Therefore, it is important that QMS is simple and manageable enough in its implementation and maintenance to avoid diverting NRA time and resources on QMS instead of delivering regulatory products and services to the customers as provided by national legal mandates. Increasing effectiveness and efficiency of the QMS may also involve the adoption and implementation of IT to remove human errors while promoting consistency, reducing time for implementation and recording, and providing long-term cost reductions.
6.1 Gap analysis for developing a roadmap for QMS Implementation

The information in table 3 can be used to identify gaps and to define activities to be done for QMS implementation based on the recommendations of the guideline. The planning, prioritisation and implementation should be as practical as possible and be determined by the NRA taking into consideration the availability of resources and priorities for the provision of regulatory products and services.

Table 3: Gap analysis

<table>
<thead>
<tr>
<th>Guideline chapter</th>
<th>Existing system</th>
<th>Stage 1 (non-existing QMS)</th>
<th>Stage 2 (existing QMS without implementation)</th>
<th>Stage 3 (ineffective implementation of QMS)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Needed documents for consistency</td>
<td>Implemented evidence (by records, reports)</td>
<td>Effectiveness &amp; efficiency</td>
</tr>
<tr>
<td>Introduction</td>
<td>Linking and integration of overall QMS to quality systems and (automated) software for:</td>
<td>NRAs should perform an organisational wide review for consistency of practice by different staff using the same processes and the existing system. This review can be used to identify a consistency gap for QMS intervention and document development. Once the reviews are completed and gaps established, reviews should be done to determine if the existing systems and/or software have operational interfaces between one another when they all contribute towards achieving the same objective; these reviews can help to identify operational gaps in interfaces. QMS should be used to link the processes and activities between systems and/or software by providing documents.</td>
<td>Where consistency and operational interfaces have been implemented and supported under QMS, NRAs should conduct reviews to identify gaps in the level of implementation of the QMS documents. This should be evaluated by reviewing records and reports generated from the systems and/or software to establish consistency and operational linkages for same objectives. Where gaps are found to exist, NRAs should perform RCA and implement changes as appropriate to stage 1 QMS interventions.</td>
<td>NRAs should conduct reviews to identify gaps in effectiveness and efficiency of the QMS interventions with respect to the achievement of the intended objectives based on evidence from stage 2 outputs. When gaps have been identified, NRAs should revise the QMS implementation documents to ensure that they are effective and efficient in contributing towards the achievement of the objectives.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scope of the QMS</td>
<td>Documented statement defining the scope of the regulatory functions, physical locations, processes, regulatory products and services of the NRA</td>
<td>To identify gaps in scope of QMS, NRAs should review for the existence of consistent documented scope statements which includes all areas, locations and processes.</td>
<td>NRAs should review the level of implementation of the QMS across all units (including administrative) and locations to identify gaps in the implementation of the scope.</td>
<td>When identifying gaps for QMS revision, NRAs should review the effectiveness and efficiency of the scope of QMS in facilitating the provision of required products and services.</td>
</tr>
<tr>
<td>Organisational context of NRA</td>
<td>Adequate description and mandates of NRAs in terms of: • ability to define internal and external issues and customers and stakeholders</td>
<td>NRAs should review and identify gaps in the consistency of how issues for planning are determined among different units of the organisation. QMS documents should be developed and implemented to establish consistency.</td>
<td>NRAs should review the planning reports and records from different units to identify gaps in implementation of QMS documents. Where gaps are identified, RCA should be performed to ensure that procedures are implemented.</td>
<td>NRAs should review the contribution of QMS documents in making the planning to be more effective and efficient to identify gaps. Identified gaps should be addressed by implementing changes to QMS documents.</td>
</tr>
<tr>
<td>Leadership, management and organization</td>
<td>Adequate description and mandates of NRAs in terms of: • ability to develop and implement organisational structure • ability to develop and implement quality policy and customer focused initiatives • ability to assign QMS responsibilities and authorities to personnel</td>
<td>NRAs should review the consistency of supervisory and reporting structures, consistency in developing and implementing quality objectives, and consistency of assigned QMS responsibilities and authorities across units and locations to identify gaps in leadership, management or organisation. QMS procedures should be implemented to ensure that leadership, management and organisation processes are done consistently in implementation of QMS</td>
<td>NRAs should review the level of implementation of existing QMS procedures to ensure consistency in organisational structures, job titles, reporting lines, quality policies, QMS responsibilities and authorities across the units and locations to identify gaps in implementation of procedures. RCA should be done to determine changes that would improve implementation levels of QMS procedures.</td>
<td>NRAs should review the effectiveness and efficiency of the procedures in supporting leadership, management and organisation processes to identify gaps in existing QMS. Procedures should be revised to ensure that they are effective and efficient in supporting NRA and all its units in having leadership, management and organisation that is able to deliver on the regulatory products and services.</td>
</tr>
<tr>
<td>Document and data management</td>
<td>Documents under the QMS that are internally generated or from external origins for: • Regulations • Guidelines • Policies • Notes and guidance • Procedures (SOPs/Work instructions) • Lists, Registers, , Logbooks • Databases and spreadsheets • Templates, Forms • Application documents (dossiers, files) • Financial, accounting.</td>
<td>NRAs should identify gaps by reviewing the consistency in the development, review, approval, version and access control, distribution, storage, retrieval and disposition of documents as applicable across all units and locations of the organisation. Where gaps exist, procedures should be implemented to ensure that documents are managed consistently across all units and locations of the NRA.</td>
<td>NRAs should review the records in units and locations to identify gaps in the implementation of existing procedures for management of documents. RCA should be done to determine measures to promote implementation of existing procedures.</td>
<td>NRAs should review the effectiveness and efficiency of the procedures in identifying gaps in the management of documents. Procedures should be revised to ensure that they are more effective and efficient in the management of documents of the NRA. NRAs can consider the use of IT in the management of documents depending on the availability of resources, size of NRA and complexity of documents to be managed.</td>
</tr>
</tbody>
</table>
| **procurement and HR records**  
| Reports, letters, emails, permits, licences, certificates, others |
| **Planning** | Linking and integration of planning in quality systems and (automated) software for objectives in:  
| Technical activities  
| Support and administrative activities  
| Monitoring and evaluation |
| NRAs should review the consistency in the planning, monitoring and evaluation of technical and administrative, and support activities with associated risk and change management plans to identify gaps across all units and locations. QMS procedures should be implemented to ensure that all planning, monitoring and evaluating of technical and support activities are done consistently and with related risk and change management plans. |
| NRAs should review the level of implementation of procedures for consistency in planning, monitoring and evaluating of technical and support activities. To identify gaps for QMS revision, the review should evaluate the consistency in implementation of risk and change management plans based on existing records and reports. RCA should be done to ensure that procedures are implemented. |
| To identify gaps with existing procedures, NRAs should review the effectiveness and efficiency of the QMS procedures in support of planning, monitoring and evaluating of activities, risks and changes. QMS procedures should be revised or replaced with automated systems based on the complexity and size of the NRA and its planning activities. |
| **Support and resources** | Adequate and quality resources for:  
| Personnel and competencies  
| Organisational knowledge management  
| ICT  
| Work environment  
<p>| Communication and awareness |
| NRAs should review the consistency in the allocation of personnel, training in QMS, knowledge sharing, use of ICT and communication of QMS requirements to identify gaps for QMS implementation. Procedures should be implemented to ensure consistency across all units and locations in allocation of personnel, training of staff in QMS implementation, use of intranets and other ICT tools and communication. |
| NRAs should review the records to identify gaps in levels of implementation of existing procedures for QMS personnel, competencies, knowledge management, ICT, work environment and communication across all units and locations. RCA should be done to ensure procedures are implemented. |
| To identify gaps for QMS revisions, NRAs should review the effectiveness and efficiency of the procedures in ensuring that there are adequate and quality personnel, QMS competencies, knowledge management, ICT, workspace, communication and awareness of QMS implementation. Procedures should be revised to ensure that they are effective and increase efficiency in their implementations. |
| <strong>Operation</strong> | Process approach focused on the regulatory products and services and on NRA quality objectives |
| To identify gaps for QMS implementation, NRAs should review the consistency in the conduct of technical and administrative activities in providing products, services, and operational interfaces or linkages among processes that contribute to the same product, service or quality objective. Where gaps exist, procedures should be implemented to ensure consistency and operational linkages of processes. |
| NRAs should review the records from technical and administrative units and locations to identify gaps in the implementation of existing procedures. RCA should be performed, and measures should be put in place to ensure full implementation of procedures across all affected units and locations. |
| NRAs should review and identify gaps in the effectiveness and efficiency of the implemented procedures and quality systems in facilitating the provision of products and services that meet requirements and support the achievement of the objectives. Procedures and systems should be revised to ensure that they are effective and increase efficiency in the processes for providing products and services and for supporting the achievement of NRA objectives. |</p>
<table>
<thead>
<tr>
<th>Performance evaluation</th>
<th>M &amp; E framework with performance indicators for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Products and services requirements</td>
<td></td>
</tr>
<tr>
<td>• Quality objectives</td>
<td></td>
</tr>
<tr>
<td>• Customer complaints</td>
<td></td>
</tr>
<tr>
<td>• QMS</td>
<td></td>
</tr>
<tr>
<td>• Resources (human, financial, ICT, equipment and infrastructure)</td>
<td></td>
</tr>
<tr>
<td>• Risk and opportunity management</td>
<td></td>
</tr>
<tr>
<td>NRAs should review and determine gaps in consistency in the M &amp; E activities across all units and locations for QMS implementation. Where gaps in consistency are identified, procedures should be implemented to ensure that all M &amp; E of performance indicators are done consistently across different units and locations of NRAs.</td>
<td></td>
</tr>
<tr>
<td>NRAs should review and identify gaps in the level of implementation of existing procedures and systems of the QMS for the M &amp; E framework. RCA should be done to inform revised measures for the implementation of procedures and systems across all affected NRA units and locations.</td>
<td></td>
</tr>
<tr>
<td>NRAs should review and identify gaps in the effectiveness and efficiency of the implemented QMS procedures and systems used for M &amp; E. These procedures and systems should be evaluated to ensure that their output provides evidence useful for planning of continuous improvements. Where gaps exist, NRAs should revise the procedures and systems to ensure that they are more effective and efficient in supporting M &amp; E of performance indicators across all units and locations of the organisations.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Improvement</th>
<th>Evidence based improvements</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRAs should review and identify gaps in the consistency of handling and prioritisation of improvements across the entire organisation. Where there are inconsistencies, procedures should be implemented to ensure that all proposals for improvements are submitted with evidence and evaluated with respect to priorities and availability of resources. Procedures for improvement should define responsibilities and authorities for handling, planning and implementation of improvements.</td>
<td></td>
</tr>
<tr>
<td>NRAs should review and identify gaps in levels of implementation of QMS procedures for handling and implementing improvements across all units and locations of the organisation. Where gaps are identified, RCA should be done with revised measures for the implementation of the procedures.</td>
<td></td>
</tr>
<tr>
<td>NRAs should review and identify gaps in the effectiveness and efficiency of the procedures in facilitating timely implementation of improvements. Procedures should be revised to ensure that they are more effective and efficient in facilitating timely implementation of improvements.</td>
<td></td>
</tr>
</tbody>
</table>
The QMS roadmap for NRAs will depend on the respective stages of implementation. The roadmap will be used to identify activities to be done, required resources, competencies of personnel, responsibilities and authorities, timelines (timeframe) and prioritisation based on the needs of the NRA with respect to the regulatory products and services as mandated by national laws and regulations. Table 4 summarises the steps in the development and implementation roadmap for QMS.

### Table 4: Development of QMS implementation roadmap

<table>
<thead>
<tr>
<th>Steps</th>
<th>Activity</th>
<th>Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Assign resources (personnel, financial, equipment and infrastructure).</td>
<td>TM</td>
</tr>
<tr>
<td>2</td>
<td>Use Appendix 1 and results from self-benchmarking to determine the status of the QMS and submit report to TM, noting activities and areas that require actions.</td>
<td>Assigned staff/Consultant</td>
</tr>
<tr>
<td>3</td>
<td>Prioritise activities based on availability of resources (internal and external), risks of non-implementation and regulatory products and services as mandated by national laws and regulations.</td>
<td>TM</td>
</tr>
<tr>
<td>4</td>
<td>Allocate responsibilities and authorities with timelines for development, review, approval, implementation, M &amp; E of prioritised QMS requirements.</td>
<td>TM &amp; Assigned staff/Consultant</td>
</tr>
<tr>
<td>5</td>
<td>Validate the prioritisation of QMS requirements, timelines, responsibilities and authorities with NRA staff through collection of input and feedback to promote ownership of QMS implementation.</td>
<td>TM &amp; Assigned staff/Consultant</td>
</tr>
<tr>
<td>6</td>
<td>Consolidate the feedback and input into an activity/action plan as a roadmap for QMS implementation for the NRA.</td>
<td>Assigned Staff/Consultant</td>
</tr>
<tr>
<td>7</td>
<td>Integrate the QMS roadmap (activity/action plan) into the NRA organisational activity/action plans, the NRA strategic plans and the MOH health strategic plan/policy as applicable.</td>
<td>TM</td>
</tr>
</tbody>
</table>
## Appendix 1: Activity plan for QMS implementation with effectiveness and performance indicators

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Ref sub chapters</th>
<th>Effectiveness and performance indicators</th>
<th>Responsibility within the NRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Appointment of QMS focal person(s) or lead(s)</td>
<td>6.4</td>
<td>Official letters of appointment with defined responsibilities and authorities in QMS</td>
<td>Head of the NRA</td>
</tr>
<tr>
<td>2.</td>
<td>QMS focal person(s) understand the QMS requirements</td>
<td>6.4 &amp; 6.7</td>
<td>• Competency matrix for QMS focal person(s)/lead(s)</td>
<td>TM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Training plans for competency gaps in QMS implementation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Training records of QMS focal person(s)/lead(s)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Training/orientation records in development and implementing QMS documents (Quality manual, SOPs and/or forms and templates)</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>QMS focal person(s)/lead(s) conducts a gap analysis of current system based on tables 3 and 4 of the guideline and develops a QMS action plan (as part of strategic plan)</td>
<td>7.1</td>
<td>• Documented gap or situation analysis report</td>
<td>TM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Documented roadmap with resources, timelines and responsibilities (part of NRA strategic and action plans)</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>QMS focal person(s)/lead(s) conducts orientation and awareness sessions for NRA employees on QMS development and implementation (with roles and responsibilities)</td>
<td>6.7</td>
<td>Accessible and available QMS orientation and awareness sessions records and materials in appropriate format</td>
<td>QMS focal person(s)/lead(s)</td>
</tr>
</tbody>
</table>
| 5. | • Establishment of NRA current context (SWOT analysis), if already available.  
• Determining comprehensiveness of the legal provisions (Acts and regulations) in describing interested parties relevant to QMS  
• Identification of QMS processes, sequences, linkages and interdependencies  
• Determining scope of QMS and relationships of its processes | 6.1, 6.2 & 6.3 | • Documented official organisational chart covering NRA governance and TM and internal and external operational relationships  
• Documented description of internal and external issues including SWOT analysis of the NRA (with defined customers and stakeholders based on legal provisions)  
• Documented description of internal and external customers and stakeholders with their respective needs and expectations (if not adequately described in the national legislations)  
• Documented statement of scope for the QMS  
• Documented flowcharts, process maps and their operational linkages for all processes under the scope of QMS with related products and services | • TM  
• QMS focal person(s)/lead(s) |
|---|---|---|---|---|
| 6. | Documenting Quality Policy within the context and strategic direction of NRA | 6.4 | Documented, accessible (publicly), and available quality policy understood by NRA staff | • TM  
• QMS focal person(s)/lead(s) |
| 7. | Use information from step 5 above, as input, to determine risks and opportunities and develop risk and opportunity management plans | 6.6 | • Documented and controlled registry of assessed and categorised risks and opportunities (from SWOT analysis)  
• Risk and opportunity responsibility matrix (based on responsible, accountable, consulted and informed (RACI principles) | • TM  
• QMS focal person(s)/lead(s) |
<table>
<thead>
<tr>
<th></th>
<th>Develop and document SMART quality objectives including plan for M &amp; E with related required resources</th>
<th>6.6</th>
<th>Documented quality objectives (and their short and long term targets), resources, responsibilities (ideally in NRA’s strategic plan) and M &amp; E indicators</th>
<th>TM</th>
</tr>
</thead>
</table>
| 8. |                                                                                                                                                          | 6.7 | Documented and implemented procedures for:  
  - staff recruitment (based on defined competency framework for different levels and positions, training and re-training based on established gaps as per organisational competency framework  
  - management and maintenance of measuring equipment as applicable in making regulatory decisions (laboratory and/or inspection equipment  
  - management of organisational knowledge (e.g., retirements, resignations, and new knowledge acquisition)  
  - management of internal and external communication of regulatory decisions, products, services and other engagements with customers and stakeholders  
  - use of IT in technical and administrative processes including management of templates used in the software or equipment or in other procedures needed to manage resources as described in the guideline |  
  - TM  
  - QMS focal person(s)/lead(s) |
<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10.</td>
<td>Develop new or harmonize with existing procedures for all processes in technical and administrative units of NRA</td>
<td>6.8</td>
<td>Documented and implemented procedures for all applicable technical and administrative processes within NRA and that contain the appropriate level of detail based on the complexity of the processes and associated risks. The procedures should address all activities which are involved in provision of products and services as mandated by national legislations</td>
</tr>
</tbody>
</table>
| 11. | Develop procedures for monitoring of customer satisfaction, internal audit, management review, and complaints handling, and put them in practice. | 6.9 | • Documented and implemented procedures for customer complaints and satisfaction along with publications of guidance to the public on the procedures and communication  
• Documented and implemented internal audit programs  
• Documented and implemented regular reviews of QMS implementation and performance by TM | TM/QMS focal person(s)/lead(s) |
| 12. | Develop procedures for corrections, corrective actions, and improvements, and put them in practice | 6.10 | Documented and implemented procedures for corrective actions and change management, along with a link for updating risk and opportunity management plans | TM/QMS focal person(s)/lead(s) |
**Abbreviations**

*NOTE: This section will be updated in the final stages of guideline development.*

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CREAM</td>
<td>Clear, Relevant, Economic, Adequate and Monitorable</td>
</tr>
<tr>
<td>GBT</td>
<td>Global Benchmarking Tool</td>
</tr>
<tr>
<td>HR</td>
<td>Human Resources</td>
</tr>
<tr>
<td>ICT</td>
<td>Information and Communication Technology</td>
</tr>
<tr>
<td>IT</td>
<td>Information Technology</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standardisation Organization</td>
</tr>
<tr>
<td>KPI</td>
<td>Key Performance Indicator</td>
</tr>
<tr>
<td>LI</td>
<td>Licensing Establishments</td>
</tr>
<tr>
<td>LIMS</td>
<td>Laboratory Information Management System</td>
</tr>
<tr>
<td>MA</td>
<td>Marketing Authorization</td>
</tr>
<tr>
<td>M &amp; E</td>
<td>Monitoring and Evaluation</td>
</tr>
<tr>
<td>MC</td>
<td>Market Surveillance and Control</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MS</td>
<td>Member States</td>
</tr>
<tr>
<td>NRA</td>
<td>National Regulatory Authority</td>
</tr>
<tr>
<td>PDCA</td>
<td>Plan, Do, Check and Act</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>QMS</td>
<td>Quality Management System</td>
</tr>
<tr>
<td>RACI</td>
<td>Responsible, Accountable, Consulted and Informed</td>
</tr>
<tr>
<td>RCA</td>
<td>Root Cause Analysis</td>
</tr>
<tr>
<td>SMART</td>
<td>Specific, Measurable, Attainable, Realistic and Time-bound</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>SWOT</td>
<td>Strengths, Weaknesses, Opportunities and Threats</td>
</tr>
<tr>
<td>TM</td>
<td>Top Management</td>
</tr>
<tr>
<td>VL</td>
<td>Vigilance (one of GBT regulatory functions)</td>
</tr>
<tr>
<td>WHA</td>
<td>World Health Assembly</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
References


[18] WHO Guidelines on Quality Risk Management.

**References to the GBT VI**

The WHO GBT is used to assess the level of implementation of QMS in NRA. The QMS indicator consists of 14 sub-indicators that are used to identify the degree of QMS implementation and the existing gaps across the NRA.

<table>
<thead>
<tr>
<th>Chapter in QMS guideline</th>
<th>GBT VI – QMS sub–indicators</th>
<th>Related GBT VI sub – indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>RS05.06</td>
<td></td>
</tr>
<tr>
<td>Scope of the QMS</td>
<td>RS05.02</td>
<td>RS01.01, RS01.02, VL01.01, MA01.01, MC01.01, LI01.01, RI01.01, LT01.01, CT01.01, LR01.01</td>
</tr>
<tr>
<td>Organisational context of NRA</td>
<td>RS05.06, RS05.08</td>
<td>RS02.04, RS03.04, RS07.04</td>
</tr>
<tr>
<td>Leadership, management and organization</td>
<td>RS05.01, RS05.02, RS05.03, RS05.04</td>
<td>RS02.01, RS04.01, VL02.01, VL03.02, MA02.01, MA03.02, MC02.01, MC03.02, LI02.01, LI03.02, RI02.01, RI03.02, LT02.01, LT04.02, CT02.01, CT03.02, CT04.04, LR03.02</td>
</tr>
<tr>
<td>Document and data management</td>
<td>RS05.07</td>
<td>RS01.04, RS01.05, RS01.08, RS09.06, RS09.08, VL03.04, VL04.01, VL04.02, VL04.03, MA03.04, MA04.01, MA04.02, MA04.03, MA04.10, MA05.02, MA06.01, MC03.04, MC04.01, MC04.02, MC04.03, MC04.05, MC04.07, MC04.08, MC05.01, MC05.02, LI03.04, LI04.01, LI05.01, LI06.01, RI03.04, RI04.01, RI04.02, RI04.04, RI04.05, RI04.06, RI05.01, RI05.02, LT03.02, LT03.04, LT04.04, LT06.02, LT06.03, LT08.01, CT03.04, CT04.05, CT04.06, CT04.07, CT06.01, LR01.02, LR03.04, LR04.03</td>
</tr>
<tr>
<td>Category</td>
<td>Code 1</td>
<td>Code 2</td>
</tr>
<tr>
<td>--------------------</td>
<td>--------</td>
<td>--------</td>
</tr>
<tr>
<td>Planning</td>
<td>RS05.02</td>
<td>RS03.03, RS04.05, VL04.04, VL04.08, MA01.12, MA04.06, MA04.07, MA06.02, MC04.04, MC05.03, LI04.03, LI05.02, RI04.03, RI05.05, LT03.01, LT08.04, CT06.02, CT06.04, LR06.04</td>
</tr>
<tr>
<td>Support and resources</td>
<td>RS05.04, RS05.14</td>
<td>RS02.02, RS06.01, RS06.02, RS08.01, RS08.02, RS08.04, RS09.03, RS09.07, RS09.09, VL02.02, VL03.01, VL03.02, VL03.03, VL06.01, VL06.02, VL06.03, MA02.02, MA03.01, MA03.03, MA05.01, MA05.03, MA05.04, MC02.02, MC03.01, MC03.03, MC06.01, MC06.02, MC06.03, LI02.02, LI03.01, LI03.03, LI06.02, RI02.02, RI03.01, RI03.03, RI06.01, RI06.02, RI06.03, RI06.04, LT03.03, LT04.01, LT04.03, LT05.01, LT05.02, LT06.05, LT07.01, LT09.01, LT09.02, LT09.03, CT02.02, CT03.01, CT03.03, CT05.02, LR02.02, LR03.01, LR03.03, LR05.01, LR05.02, LR06.01</td>
</tr>
<tr>
<td>Operation</td>
<td>RS05.06, RS05.09</td>
<td>RS02.03, RS04.02, RS04.03, RS06.03, RS06.04, RS09.05, RS09.07, VL04.05, VL04.06, VL04.07, MA01.09, MA01.10, MA01.11, MA01.13, MA04.05, MA04.08, MA04.09, MA04.10, MC01.06, MC01.07, LI01.04, LI04.02, LI04.04, RI01.04, RI05.03, LT02.02, LT06.01, LT06.04, LT10.01, CT01.09, CT01.10, CT04.01, CT04.02, CT04.03, CT05.01, LR04.01, LR04.02</td>
</tr>
<tr>
<td>Performance evaluation</td>
<td>RS05.10, RS05.11, RS05.12, RS05.13</td>
<td>RS01.09, RS10.01, RS10.02, VL05.02, MA04.06, MA06.02, MC04.06, MC05.03, LI05.02, RI05.04, RI05.05, LT08.02, LT08.03, LT08.04, CT06.02, CT06.04, LR06.02, LR06.04</td>
</tr>
<tr>
<td>Improvement</td>
<td>RS05.05</td>
<td>LR06.02</td>
</tr>
</tbody>
</table>

***