Annex 13

WHO guideline on the implementation of quality management systems for national regulatory authorities

Abbreviations

CREAM	clear, relevant, economic, adequate and monitorable
EDQM	European Directorate for the Quality of Medicines and HealthCare
GBT	*WHO Global Benchmarking Tool* (*4*)
GRP	good regulatory practices
ICT	information and communication technology
IT	information technology
ISO	International Organization for Standardization
M&E	monitoring and evaluation
NRA	national regulatory authority
PDCA	plan–do–check–act
QA	quality assurance
QMS	quality management system
RCA	root cause analysis
SMART	specific, measurable, attainable, realistic and time-bound
SWOT	strengths, weaknesses, opportunities and threats
WHO	World Health Organization

1. Background

Implementation of the Thirteenth World Health Organization (WHO) General Programme of Work (2019–2023) (*1*), as adopted by the Seventy-first World Health Assembly (2018), and the WHO Leadership priorities (*2*), 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 resolutions, including WHA67.20 (2014) (*3*), mandate WHO to provide support to its Member States 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" (*3*).

Accordingly, to facilitate access to these products, WHO's vision is for all Member States to have an effective 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 the safety, quality and efficacy of medical products within their respective Member States; demonstrating that the services they provide consistently meet legal and regulatory requirements; delivering effective and efficient services; evaluating performance; and making improvements. An effective quality management system (QMS) can help to 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 continued 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) (*4*). This tool assists WHO and regulators worldwide in evaluating the maturity and performance of regulatory systems and related functions. The GBT includes one indicator that assesses the NRA's level of development with respect to a QMS (*4*). Benchmarking results of low- and middle-income countries indicate that the majority of NRAs need to establish and implement a QMS or, if already established, enhance and maintain the QMS.

QMS implementation is challenging for NRAs, owing to the diversity of NRA legal mandates and organizational structures; the different levels of NRA development; and the number of regulatory functions that need to be implemented. WHO has developed this guideline to respond to requests by Member States for an international guideline on implementation of QMSs by NRAs.

2. Objectives

The aim of this guideline is to assist NRAs to develop, implement and improve their QMSs, based on principles from International Organization for Standardization (ISO) document ISO 9001 standard requirements (*5*). It provides recommendations on what NRAs should implement and maintain under each 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 harmonization, mutual reliance and recognition mechanisms among Member States.

Therefore, the objectives of the guideline are as listed next.

1. Describe principles for implementing a QMS to support planning, execution, monitoring and evaluation (M&E) of the performance of all applicable functions and activities of an NRA.
2. 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 an NRA.
3. 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.

3. Scope

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 other health technologies under the responsibility of an implementing NRA. All other existing or future guidelines for QMSs for specific regulatory functions will complement this guideline.

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

This guideline on QMS implementation can also be used for all models of NRA. NRAs can be legally, organizationally and operationally structured as follows:

- **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 and another one within the same country for licensing establishments' regulatory function);
- **decentralized:** one NRA with full legal mandates to enforce national laws and regulation of medical products within the country. A legally defined amount of enforcement, authority and operations is executed in localized zones or geopolitical zones of the country, while the rest is enforced at country level. This model exists in Member States with a federal governance system where laws and regulations are enforced at state/province and national levels; and

- **centralized:** 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 guideline is equally applicable to small, medium and large NRAs, as the principles and intended results of a QMS remain the same, regardless of the complexity of NRA. Therefore, this guideline describes the requirements that 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. The guideline can be utilized by institutions that are responsible for single or multiple specific regulatory functions related to medical products.

Although the use of this guideline is voluntary, NRAs are encouraged to use it to facilitate implementation of their QMS. The implemented QMS should be demonstrated by documented evidence to have systematic processes that are controlled, maintained and evaluated for continuous improvement. NRAs are free to use any appropriate national or international standard or guideline on QMSs as a basis for the implementation.

Where different units within the NRA have already implemented a QMS for specific regulatory functions (such as laboratory testing and/or regulatory inspection), this guideline could be used by the NRA for those functions and processes that have not been addressed by the management systems already implemented. This is to avoid duplications and overlaps of management systems. It is expected that NRAs will gradually integrate all existing management systems within the overall QMS of the NRA. The implementing NRA could determine the extent to which this guideline should be implemented, without omitting 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 a QMS. However, as part of the regulatory systems strengthening programme, WHO will conduct the benchmarking of the Member State's regulatory system and functions, including QMS-related processes, using the GBT (*4*) to determine the strengths and gaps, if any, for capacity-building and continuous improvement. This guideline should be implemented to cover regulatory functions that are part of the GBT, and other functions and activities of the NRA that are addressed by national laws and regulations but that are not part of the GBT. References to GBT revision VI (*4*) provides a linkage between GBT indicators and the relevant sections of this guideline (see Appendix 1).

The QMS using this guideline should be implemented on the foundation of the principles and recommendations on *Good regulatory practices* (GRP) (*6*). The implementation of the QMS should ensure that the GRP 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 that 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 ensure 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 an NRA include individuals or parties who receive or could receive and use products and services that are provided and offered by the NRA. These parties include the general public, patients, manufacturers, distributors, health practitioners, researchers, the ministry of health and other individuals and institutions that rely on the NRA's 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 of 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 QMS with the specific purpose of improvement. An internal audit should be conducted by an independent (i.e. of the function to be audited) team of competent auditors as designated by the management for this purpose.

process. A set of interrelated or interacting activities that use inputs to deliver an intended result. In the context of NRAs, the production and service provision processes should coincide with basic regulatory functions.

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 that 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 that 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. 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 an organization at the highest levels and who have the authority and responsibility to mobilize resources within the organization. In NRAs, the terms "senior management" or "top management" can be used interchangeably.

services. Output of an organization with at least one activity necessarily performed between the organization and the customer. Services of NRAs are also called regulatory services in this guideline. This includes, for example, activities such as evaluation of applications for market authorizations, inspections of facilities, testing of health product samples, etc.

5. Quality management system requirements for national regulatory authorities

5.1 Quality management system concepts

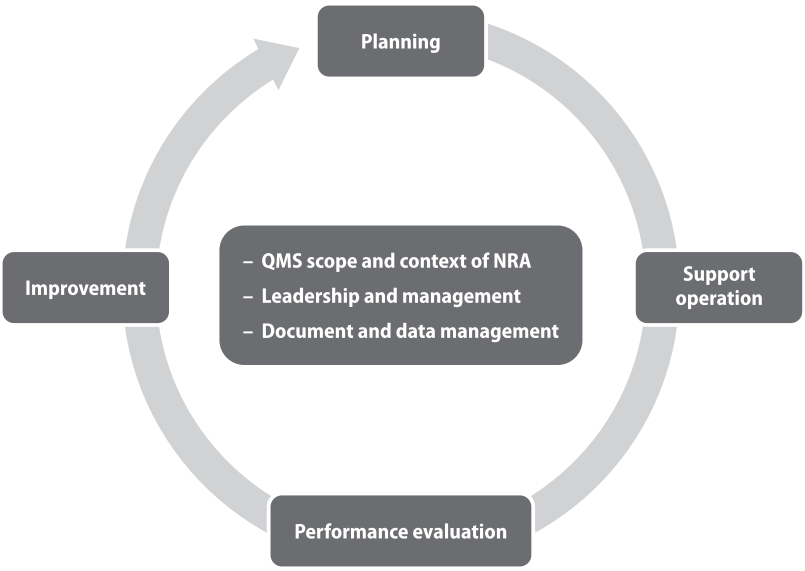
NRAs should implement a QMS that is supported by the process approach concept, plan–do–check–act (PDCA) cycle and risk-based thinking. NRAs should ensure that the implemented QMS meets its needs without making it unnecessarily complex, to avoid a negative effect on the NRA's effectiveness and efficiency. The QMS should be simple, fit for purpose and understandable.

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 Fig. A13.1. The ISO 9001 standard (*5*) provides a brief description of the PDCA as follows:

- **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.

Fig. 1
Applied PDCA cycle

NRA: national regulatory authority; PDCA: plan–do–check–act;
QMS: quality management system.



The scope of the QMS and context of the NRA 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. Top management 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.

Applying risk-based approaches (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 that 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 organization 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, transparent and reliable results in the regulation of medical products.

The QMS requirements that are described in this guideline are based upon the quality management principles presented next, as provided in ISO 9000 (*7*).

- **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, health-care practictioners, manufacturers, researchers and procurers, by providing regulatory products and services that 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 valued services.
- **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 that are based on individuals within the NRA.
- **Improvement:** successful organizations have an ongoing focus on improvement. The NRA should ensure that it strives continously to improve its processes, products and services and the QMS.
- **Evidence-based decision-making:** decisions based on the analysis and evaluation of data and information are more likely to produce the desired results. This requires NRAs to implement measures for monitoring, analysing and evaluating the collected data, to assess whether the processes are delivering the desired results.
- **Relationship management:** for sustained success, organizations should manage their relationships with relevant interested parties. Implementing an effective QMS requires the NRA to ensure that its relationships are managed strategically for continous 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.

5.2 Quality management system requirements

The QMS requirements described in the subsequent subsections describe what NRAs should implement as part of their overall QMS. Table A13.1 provides a summary and focus for each subsection.

Table A13.1
Summary of quality management system requirements for each subsection

Subsection	Summary of requirements for implementation of a quality management system
5.2.1 Introduction	The requirements of this subsection focus on the NRA describing and documenting the setup of its QMS. The setup includes: • legislative mandates and scope (functions) of the NRA; • standards and guidelines used in QMS implementation; • QMS implementation history; • 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, ministry of health policies and strategic action plans; • identification of the functions and processes that are already covered by other QMSs.
5.2.2 Scope of the quality management system	This subsection describes the 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. Implementation can be done at once or in phases.
5.2.3 Organizational context of the national regulatory authority	The focus of this subsection is to provide guidance regarding what should be indicated when describing and documenting the setup of the NRA with its regulatory system, functions and activities within the QMS. This extends to the model type (discrete, decentralized or centralized) and to the relationships with other institutions providing regulatory services for medical products and other health 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).
5.2.4 Leadership, management and organization	This subsection describes requirements for what should be expected from top management for effective implementation of the QMS. It also includes the roles, responsibilities and authorities that should be part of the implemented QMS.

Table A13.1 *continued*

Subsection	Summary of requirements for implementation of a quality management system
5.2.5 Document and data management	This subsection 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.
5.2.6 Planning	This subsection focuses on planning requirements for achieving the set objectives, managing risks and opportunities across the NRA, and planning changes to the QMS for continuous improvement.
5.2.7 Support and resources	This subsection includes requirements for input resources (technical and non-technical), personnel and infrastructure needed for effective implementation of the QMS.
5.2.8 Operation	This subsection addresses the requirements for QMS implementation in core processes and activities that are within the mandates of the NRA. It also provides guidance on documenting operational linkages of processes and systems for effective and efficient QMS implementation.
5.2.9 Performance evaluation	This subsection provides methodologies and 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.
5.2.10 Improvement	This subsection presents requirements for NRAs to implement in the QMS to support continuous improvements based on collected, analysed and evaluated data.

5.2.1 Introduction

NRAs should have documented, available and accessible legislative laws and regulatory policies on medical products that 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 *Compendium of quality management system (QMS) technical documents for harmonization of medicine regulation in the East African Community* (*8*)).

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 regulatory processes, to ensure that it helps the NRA to achieve its legal mandates and functions.

The NRA should identify the functions and processes that are already covered by other QMSs. 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 M&E. The management systems for specific technical and administrative functions and processes are described in the next subsections.

5.2.2 Scope of the quality management system

This guideline aims to provide guidance on implementing a sustainable and effective QMS based on adapted ISO 9001 standard (*5*) 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 facilities 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 that are provided in the current version of the GBT (*4*). 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 collaboration, to improve and strengthen coordination between institutions. The QMS should also include the technical and administrative functions and processes that 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 a relevant national legal framework and by current best practices of the affected functions and processes.

5.2.3 Organizational context of the national regulatory authority

5.2.3.1 Understanding the national regulatory authority organization and its context

The NRA should demonstrate that it understands its organizational and operational context within the country's regulatory framework as part of national health system. The organization should understand the context under which it provides the regulatory products and services, which may be through using a discrete, decentralized or centralized type of organizational structure. This understanding facilitates the identification and management of internal and external issues relevant to its ability to achieve the objectives as defined in the NRA's 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 that are part of its routine operations.

The documented context of the NRA should clearly indicate the technical and administrative areas that 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 regulatory 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 laws or regulations, or procurement, 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 organizational context at planned intervals, and whenever there are changes to the legal framework or when there are organizational 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 the 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 other stakeholders) for the regulatory products and services that are provided. Where customers and other stakeholders are defined in the national laws and regulations, this would be sufficient, as long as all outputs and services provided by the NRA are addressed. 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 categorized, along with their respective needs and expectations of 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.

5.2.3.2 Quality management system processes

NRAs should ensure that inputs and resources that are required to perform the processes and functions covered in the QMS scope, with expected outputs, are determined, documented and provided. NRAs should document the sequences and interactions of regulatory processes, together with related measures and criteria for their control (e.g. key performance indicators). The level and type of controls that are applied to the regulatory processes should be determined and documented with a risk-based approach and should utilize the available opportunities. The QMS should provide procedures for evaluating the 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 regulatory functions and processes, to ensure that the personnel who are assigned with responsibilities and authorities in performing regulatory and administrative activities have the required competencies.

5.2.4 Leadership, management and organization

5.2.4.1 Commitment of top management

Top management of the NRA 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 top management with respect to a QMS:

- providing needed resources for the implementation of an effective QMS that is consistently implemented across the NRA units, functions and processes;

- integrating QMS requirements into the regulatory processes and aligning the quality policy and quality objectives with the strategic plans of NRAs;
- implementing a QMS that incorporates a risk-based approach and that is based on functions and processes rather than being built around individual personnel or specific activities;
- communicating the importance of the QMS, to maintain consistency in NRA functions and to improve the effectiveness and efficiency of the QMS;
- 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; and
- reviewing the performance of the QMS and promoting improvements.

Top management 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. Top management should also ensure that the 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.

5.2.4.2 Quality policy

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

- take into consideration the organizational context and strategic directions and plans and provide a framework for setting quality objectives;
- include a commitment to comply with applicable national legislation, as well as regional and global regulatory requirements and best practices;
- include a commitment to continual improvement of the QMS; and
- include a commitment to adopt and implement GRP, as provided in the *WHO good regulatory practices: guideline for national regulatory authorities for medical products* (*6*).

Top management 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 available to customers and stakeholders, through established document control procedures as per QMS requirements.

5.2.4.3 Roles, responsibilities and authorities

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

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

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

5.2.5 Document and data management

NRAs should have the 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 that are used in the 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 and version control, retrieval and use), retaining and disposing of internally generated documents. QMS documents of external origin (e.g. regulations, standards, pharmacopoeia 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 regulatory 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.

5.2.6 Planning

5.2.6.1 Quality management system planning

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

5.2.6.2 Action to address risks and opportunities

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 the WHO guidelines on quality risk management (*9*) and the ISO 31000 standard (*10*).

5.2.6.3 Quality objectives and planning to achieve them

NRAs should establish quality objectives for relevant regulatory and administrative functions, for all levels and sections of the 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 regulatory objectives, to ensure that the QMS supports the consistency, effectiveness and efficiency of the NRA.

Quality objectives of the NRA 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 the NRA to communicate the objectives to designated audiences within the NRA and the means to monitor and update the objectives.

The 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.

5.2.6.4 Planning of changes

The NRA should plan for changes to the QMS. The purpose of planning changes is to maintain the integrity of the QMS and ensure the NRA's ability to provide conforming regulatory products and services during any changes. 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 the 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 important processes; departure of persons in key roles (e.g. due to retirement or job change); or a move to online service provision.

5.2.7 Support and resources

5.2.7.1 Resources

NRAs should determine, document and provide the resources that are needed to establish, implement, maintain and continuously improve the QMS. The determination should be done within the organizational 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 that need to be provided by external providers (companies and individual experts).

5.2.7.2 Personnel

NRAs should determine, provide and document the personnel and their required minimum competencies necessary for effective implementation of the QMS and for effective operation and control of its processes. A focal person or lead may be appointed to coordinate and monitor the implementation of the QMS at appropriate levels and functions.

The competencies of all 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 criteria for acquired competencies.

For the purposes of consistency of the QMS, NRA training plans for the rest of the 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 educational diplomas or degrees; completion of training certificates; resumés; performance reviews; licences; 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 requalification procedures.

5.2.7.3 Infrastructure and work environment

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 versus not in use) and plans for qualification, validation, calibration and maintenance (as applicable):

- buildings and associated utilities;
- technical (e.g. inspection and testing equipment) and administrative equipment (e.g. servers, computers, and printers), including hardware and software;
- transportation and logistical resources; and
- ICT.

NRAs should determine, provide and maintain the human and physical factors of the work environment necessary for the operation of technical and administrative processes and activities within the context of the organizational 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 (*11*).

The NRA 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 (*12*).

5.2.7.4 Monitoring and measuring resources and equipment

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 the 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 its calibration status and safeguarded from adjustments, damage or deterioration.

In the event of measuring equipment being 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.

5.2.7.5 Organizational knowledge management and awareness

The NRAs should consider how to determine and manage the organizational knowledge required to meet the NRA's present and future needs. Individuals

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 (i) learning from failures and successes; (ii) gathering knowledge from stakeholders, experts and partners; and (iii) 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 quality objectives that are relevant to their level in the organization. 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 the QMS, for example, the release to customers of non-conforming regulatory products.

5.2.7.6 Internal and external communication

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.

5.2.8 Operation

NRAs should ensure that planning of technical and administrative processes is done effectively, as provided under Section 5.2.6 for all operations within the scope of the QMS.

5.2.8.1 Customer communication and review of the regulatory products and services requirements

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 for reviewing the pertinence of 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 publicised (e.g. through the NRA website, pre-submission meetings, or scientific advice), so that customers are aware of the requirements for submissions to the 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 authorizations, licences, reference standards (e.g. pharmacopoeia), 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 the customer and the requirements prescribed by the NRA, this 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 services are processed.

When the requirements for products and services are changed for any reason, NRAs should take measures to inform all relevant interested parties. They 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.

5.2.8.2 Design and development of new products and services

When NRAs plan on implementing new regulatory function(s) due to 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:

1. 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 sufficiently robust 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 additional ones. All documents used and generated out of these roadmaps should be retained in an appropriate format and medium.

2. 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.
3. 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 meets the requirements for the intended use.
4. The expected outputs of the design and development process will be in the form of standard operating procedures 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.
5. 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.

5.2.8.3 Externally provided products and services

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 the 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 that are provided for public

procurements. However, the NRA should ensure that the public procurement procedure conforms to the requirements described in the subsequent paragraphs of this subsection and should close gaps, if any. The NRA should also implement these requirements when it performs 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 prequalification of providers, there should be a documented procedure and policy on the competence criteria for evaluation, selection, performance monitoring, and requalification. The prequalification and requalification 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 organization'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 key performance indicators.

The NRA 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 and clear and address any potential issues.

5.2.8.4 Service provision

NRAs should carry out their technical and administrative functions for processing requests for services under controlled conditions. The controlled conditions should include, as applicable, the points listed next:

- use of guidelines, policies and procedures that provide the requirements for the regulatory products and services, including those for performance of activities;
- NRAs should document and implement measures for reviewing (peer-review or quality assurance [QA] review), approving and releasing the 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:

  - for technical processes involving review of application documents for marketing authorization for the assurance of quality, safety and efficacy, procedures and recommendations this includes, among others: *Good review practices: guidelines for national and regional regulatory authorities* (*13*); *Regulation and licensing of biological products in countries with newly developing regulatory authorities* (*14*) and *WHO guidelines on evaluation of similar biotherapeutic products (SBPs)* (*15*);
  - where the NRA has a unit responsible for good practices inspections, recommendations and technical requirements: WHO *Quality management systems requirements for national inspectorates* (*16*);

- 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* (*17*) for physicochemical testing and *WHO good practices for pharmaceutical microbiology laboratories* (*18*) for microbiological testing. These two WHO guidelines can be supported and complemented with the current ISO/IEC 17025 standard (*19*) and the European Directorate for the Quality of Medicines and HealthCare (EDQM) *Quality management documents* (*20*);
- 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; and
- 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 should also be supported by systematic measures to facilitate traceability of the products and services to the equipment, software, personnel and location used by the NRA.

5.2.8.5 Property belonging to customers or external providers

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 and personal data.

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

5.2.8.6 Release and compliance control of products and services

NRAs should document and implement practical procedures on the release of regulatory products and services through all stages up to and including the customer. The release process includes defining the 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 nonconformances and deviations that are observed or reported. 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.

5.2.9 Performance evaluation

5.2.9.1 Monitoring and measurement

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, workplans 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 key performance indicators (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 key performance indicators 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 organization. The framework should be documented and aligned with the relevant quality objectives (strategic objectives) of the NRA.

5.2.9.2 Monitoring of customer satisfaction

The NRA should develop methods to systematically seek feedback from a selected population of customers, or from every customer at planned intervals. Means to obtain feedback is provided by social and published media such as websites and message boards, opinion surveys and compliments, suggestions 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 legislations. The procedures should define the roles and responsibilities of a complainant and the NRA and specify timelines to effectively manage complaints related to regulatory products and services.

5.2.9.3 Analysis and evaluation

NRAs should analyse and evaluate monitoring and measurement data and information, to determine summary performance results of the following:

- compliance of regulatory products (e.g. guidelines and software applications) to quality and validity requirements;
- compliance of regulatory services to quality and timeline commitments and requirements;
- degree of customer satisfaction;

- 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;
- level of implementation of action or activity plans and strategic plans at the time of reporting;
- effectiveness of the actions taken to address risks and opportunities (such as strengths, weaknesses, opportunities and threats (SWOT) analysis); and
- performance of external providers (including external technical experts).

5.2.9.4 Internal audit

NRAs should plan and conduct internal audits (at least once a year), to verify compliance to the QMS requirements across the organization 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:

- 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;
- select appropriately trained, 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 are not involved while serving in the NRA;
- ensure that the internal audit reports are submitted to top management for actions;
- take appropriate corrections and corrective actions without delay and within timelines defined by top management. Where corrective actions are delayed due to unavailability of required resources, appropriate risk management plans should be implemented and documented; and

- retain records of internal audit programmes and internal audit reports, including records of corrections and corrective actions.

Further technical guidance on managing and performing internal audits can be adopted from the current version of ISO 19011 (*21*).

5.2.9.5 Management review

Top management 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 organization as per strategic plans. Ideally, top management should review the QMS alongside the review of the NRA's regulatory plans (activity, action or strategic plans). This will ensure that the QMS remains integrated into regulatory processes effectively.

QMS reviews should consider inputs as provided in Table A13.2, with the listed expectations of the outputs to be presented in the minutes of the meeting (report).

Table A13.2
Inputs and outputs for review meetings

Inputs (to be reviewed)	Outputs
Status of actions from previous reviews Changes in internal and external issues that are relevant to the QMS Information on the performance and effectiveness of the QMS, including trends in: • customer satisfaction and feedback from stakeholders; • the extent to which quality objectives have been achieved; • performance on compliance to commitments and requirements for regulatory products and services; • nonconformances and deviations, and the status of implemented corrective actions; • results of M&E of indicators/key performance indicators; • results of internal and external audits; and • performance of external providers (including external technical experts) Adequacy of resources (financial, human, equipment and infrastructure)	• Decisions and actions related to opportunities for improvements • Decisions and actions related to changes required to the QMS • Actions on additional resources needed to implement improvement initiatives and suggested changes in the QMS and in other areas where resources (including human resources) are not adequate • Actions to implement for achievement of quality objectives • Responsibilities for follow-up of actions on the decisions taken in the meeting

Table A11.1 *continued*

Inputs (to be reviewed)	Outputs
Effectiveness of the actions taken to address risks and opportunities (such as SWOT or similar analysis) Opportunities for improvements of the QMS	• 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

M&E: monitoring and evaluation; NRA: national regulatory authority; QMS: quality management system; SWOT: strengths, weaknesses, opportunities and threats.

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.

5.2.10 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, 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 nonconformances 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 nonconformances and deviations in the affected area, as well as in any similar processes in the organization in which such nonconformances or deviations could occur. The steps involved in this process are:

- reviewing and analysing the nonconformance or deviation;
- determining, to the extent possible, the cause(s) of the nonconformance or deviation; and
- determining whether similar nonconformances exist or could potentially occur within the affected unit or function and/or other units of the NRA or functions that have 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 that look for a recurrence of the same nonconformity. 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 reports on nonconformances and corrective actions to internal and external customers, as defined in the communication policy/procedures.

For technical and administrative processes, NRAs should ensure that the handling of nonconformances, deviations and corrective actions is consistent across the entire organization. Nonconformances 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 the 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 top management.

6. Quality management system implementation methodology

6.1 Supporting factors for quality management system implementation

Full commitment of the head of the NRA and the heads of technical, support and administrative units (i.e. top management) 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 the QMS. The QMS should be designed to be integrated in regulatory processes (i.e. not standalone); 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 support QMS implementation include:

- establishing effective coordination and communication mechanisms;

- receiving high-level support from top management for QMS implementation;
- establishing high-level ownership and commitment by top management for QMS implementation and maintenance;
- including QMS implementation roadmaps in NRA strategic plans by top management when submitting to an oversight body (council, board, committee or ministry of health) for approval, as applicable;
- including QMS implementation by the NRA in the national health strategic plans;
- including responsibilities and authorities for contributing to the QMS in every staff job description and human resources performance appraisal;
- 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;
- embedding assigned QMS personnel within regulatory processes, with the dual responsibilities of regulatory job functions and QMS responsibilities to support and maintain the QMS in the respective regulatory unit.

6.2 Situational analysis of quality management system implementation status in the national regulatory authority

Regardless of the size of NRA, the scope of regulatory functions and the NRA organizational model (i.e. discrete, decentralized or centralized), the recommendations in Table A13.3 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 2, Table A13.3 and self-benchmarking results. Table A13.3 categorizes the key aspects relevant to the different stages of the QMS, as listed next.

- **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 for laboratories or e-performance appraisals for human resources). NRAs should prioritize 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 an implemented QMS).

- **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 regulatory 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 a QMS. NRAs should ensure that the person(s) identifying the gaps have the necessary competence and that top management 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 root cause analysis with proposed measures to implement; these measures should take into consideration the availability of resources and associated risks of delayed implementation.
- **Ineffective implementation of 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 regulatory processes and activities; providing regulatory products and services; and achieving strategic objectives. Therefore, it is important that the QMS is uncomplicated/unsophisticated and manageable enough in its implementation and maintenance to avoid diverting NRA time and resources on the QMS instead of delivering regulatory products and services to the customers as provided by national legal mandates. Increasing the effectiveness and efficiency of the QMS may also involve the adoption and implementation of ICT to remove human errors while promoting consistency; reducing time for implementation and recording; and providing long-term cost reductions.

6.3 Gap analysis for developing a roadmap for quality management system implementation

The information in Table A13.3 can be used to identify gaps and define activities to be done for QMS implementation, based on the recommendations of this guideline. The planning, prioritization 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 A13.3
Gap analysis

Guideline section	Existing system	Stage 1 (non-existing QMS)	Stage 2 (existing QMS without implementation)	Stage 3 (ineffective implementation of QMS)
		Needed documents for consistency	Implemented evidence (by records, reports)	Effectiveness and efficiency
5.2.1 Introduction	Linking and integration of overall QMS to quality systems and (automated) software for: • registration and market authorization • laboratory inspections and licensing • vigilance • market surveillance and control • clinical trials oversight • lot release • environmental (waste) management • occupational health and safety • finance and accounting • e-procurement • planning, monitoring and evaluation • human resource performance appraisal, training and staff/talent retention • others	NRAs should perform an organization-wide review for consistency of practice by different staff using the same processes and the existing system. This review can be used identify a consistency gap for QMS intervention and document development. Once the reviews are completed and gaps established, reviews should be done to determine whether 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. The QMS should be used to link the processes and activities between systems and/or software by providing documents.	Where consistency and operational interfaces have been implemented and supported under the 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 the same objectives. Where gaps are found to exist, NRAs should perform RCA and implement changes as appropriate to stage 1 QMS interventions.	NRAs should conduct reviews to identify gaps in the 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.

Table A13.3 *continued*

Guideline section	Existing system	Stage 1 (non-existing QMS)	Stage 2 (existing QMS without implementation)	Stage 3 (ineffective implementation of QMS)
		Needed documents for consistency	Implemented evidence (by records, reports)	Effectiveness and efficiency
5.2.2 Scope of the QMS	Documented statement defining the scope of the regulatory functions, physical locations, processes, regulatory products and services of the NRA	To identify gaps in the scope of the QMS, NRAs should review for the existence of consistent documented scope statements, which includes all areas, locations and processes.	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.	When identifying gaps for QMS revision, NRAs should review the effectiveness and efficiency of the scope of the QMS in facilitating the provision of required products and services.
5.2.3 Organizational context of the NRA	Adequate description and mandates of NRAs in terms of: • ability to define internal and external issues and customers and stakeholders	NRAs should review and identify gaps in the consistency of how issues for planning are determined among different units of the organization. QMS documents should be developed and implemented to establish consistency.	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.	NRAs should review the contribution of QMS documents in making the planning more effective and efficient to identify gaps. Identified gaps should be addressed by implementing changes to QMS documents.

Table A13.3 *continued*

Guideline section	Existing system	Stage 1 (non-existing QMS)	Stage 2 (existing QMS without implementation)	Stage 3 (ineffective implementation of QMS)
		Needed documents for consistency	Implemented evidence (by records, reports)	Effectiveness and efficiency
5.2.4 Leadership, management and organization	Adequate description and mandates of NRAs in terms of: • ability to develop and implement organizational structure • ability to develop and implement quality policy and customer-focused initiatives • ability to assign QMS responsibilities and authorities to personnel	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 organization. QMS procedures should be implemented to ensure that leadership, management and organization processes are carried out consistently in implementation of the QMS	NRAs should review the level of implementation of existing QMS procedures, to ensure consistency in organizational 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 levels of implementation of QMS procedures.	NRAs should review the effectiveness and efficiency of the procedures in supporting leadership, management and organization processes to identify gaps in the existing QMS. Procedures should be revised to ensure that they are effective and efficient in supporting the NRA and all its units in having leadership, management and organization that is able to deliver on the regulatory products and services.

Table A13.3 *continued*

Guideline section	Existing system	Stage 1 (non-existing QMS)	Stage 2 (existing QMS without implementation)	Stage 3 (ineffective implementation of QMS)
		Needed documents for consistency	**Implemented evidence (by records, reports)**	**Effectiveness and efficiency**
5.2.5 Document and data management	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, procurement and HR records • reports, letters, emails, permits, licences, certificates, others	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 organization. Where gaps exist, procedures should be implemented to ensure that documents are managed consistently across all units and locations of the NRA.	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.	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 NRA documents. 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.

Table A13.3 *continued*

Guideline section	Existing system	Stage 1 (non-existing QMS)	Stage 2 (existing QMS without implementation)	Stage 3 (ineffective implementation of QMS)
		Needed documents for consistency	Implemented evidence (by records, reports)	Effectiveness and efficiency
5.2.6 Planning	Linking and integration of planning in quality systems and (automated) software for objectives in: • technical activities • support and administrative activities • M&E	NRAs should review the consistency in the planning, monitoring and evaluation of technical, 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.

Table A13.3 *continued*

Guideline section	Existing system	Stage 1 (non-existing QMS)	Stage 2 (existing QMS without implementation)	Stage 3 (ineffective implementation of QMS)
		Needed documents for consistency	Implemented evidence (by records, reports)	Effectiveness and efficiency
5.2.7 Support and resources	Adequate and quality resources for: • personnel and competencies • organizational knowledge management • ICT • work environment • 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.

Table A13.3 *continued*

Guideline section	Existing system	Stage 1 (non-existing QMS)	Stage 2 (existing QMS without implementation)	Stage 3 (ineffective implementation of QMS)
		Needed documents for consistency	Implemented evidence (by records, reports)	Effectiveness and efficiency
5.2.8 Operation	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.

Table A13.3 *continued*

Guideline section	Existing system	Stage 1 (non-existing QMS)	Stage 2 (existing QMS without implementation)	Stage 3 (ineffective implementation of QMS)
		Needed documents for consistency	Implemented evidence (by records, reports)	Effectiveness and efficiency
5.2.9 Performance evaluation	M&E framework with performance indicators for: • products and services requirements • quality objectives • customer complaints • QMS • resources (human, financial, ICT, equipment and infrastructure) • risk and opportunity management	NRAs should review and determine gaps in consistency in the M&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&E of performance indicators is done consistently across different units and locations of NRAs.	NRAs should review and identify gaps in the level of implementation of existing procedures and systems of the QMS for the M&E framework. RCA should be done to inform revised measures for the implementation of procedures and systems across all affected NRA units and locations.	NRAs should review and identify gaps in the effectiveness and efficiency of the implemented QMS procedures and systems used for M&E. These procedures and systems should be evaluated to ensure that their output provides evidence that is 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&E of performance indicators across all units and locations of the organizations.

Table A13.3 *continued*

Guideline section	Existing system	Stage 1 (non-existing QMS)	Stage 2 (existing QMS without implementation)	Stage 3 (ineffective implementation of QMS)
		Needed documents for consistency	Implemented evidence (by records, reports)	Effectiveness and efficiency
5.2.10 Improvement	Evidence-based improvements	NRAs should review and identify gaps in the consistency of handling and prioritization of improvements across the entire organization. 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.	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 organization. Where gaps are identified, RCA should be done with revised measures for the implementation of the procedures.	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.

HR: human resources; ICT: information and communication technology; IT: information technology; M&E: monitoring and evaluation; NRA: national regulatory authority; QMS: quality management system; RCA: root cause analysis; SOP: standard operating procedure.

6.4 Quality management system development and implementation roadmap

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 (time frame); and prioritization based on the needs of the NRA with respect to the regulatory products and services as mandated by national laws and regulations. Table A13.4 summarizes the steps in the development and implementation roadmap for QMS.

Table A13.4
Development of quality management system implementation roadmap

Steps	Activity	Responsible
1	Assign resources (personnel, financial, equipment and infrastructure).	Top management
2	Use Table A13.3 and results from self-benchmarking to determine the status of the QMS and submit report to top management, noting activities and areas that require actions.	Assigned staff/ consultant
3	Prioritize 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.	Top management
4	Allocate responsibilities and authorities with timelines for development, review, approval, implementation, and monitoring and evaluation of prioritized QMS requirements.	Top management and assigned staff/ consultant
5	Validate the prioritization of QMS requirements, timelines, responsibilities and authorities with NRA staff, through collection of input and feedback to promote ownership of QMS implementation.	Top management and assigned staff/ consultant
6	Consolidate the feedback and input into an activity/ action plan, as a roadmap for QMS implementation for the NRA.	Assigned staff/ consultant
7	Integrate the QMS roadmap (activity/action plan) into the NRA organizational activity/action plans, the NRA strategic plans, and the ministry of health strategic plan/policy, as applicable.	Top management

NRA: national regulatory authority; QMS: quality management system.

6.5 Activity plan for quality management system implementation

Appendix 1 provides a typical action plan for the systematic development and implementation of a QMS. The plan provides a linkage between the section/subsections of this guideline and includes examples of documents and records to be established to demonstrate adequate implementation of the QMS.

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Appendix 1

References to the *WHO Global Benchmarking Tool*, revision VI

The *WHO Global Benchmarking Tool* (GBT) (*4*) is used to assess the level of implementation of a quality management system (QMS) in a national regulatory authority (NRA). The QMS indicator, RS05, consists of 14 subindicators that are used to identify the degree of QMS implementation and the existing gaps across the NRA.

Subsection in QMS guideline	GBT VI – QMS subindicators (*4*)	Related GBT VI subindicators (*4*)
5.2.1 Introduction	RS05.06	
5.2.2 Scope of the QMS	RS05.02	RS01.01, RS01.02 VL01.01 MA01.01 MC01.01 LI01.01 RI01.01 LT01.01 CT01.01 LR01.01
5.2.3 Organizational context of the NRA	RS05.06, RS05.08	RS02.04, RS03.04, RS07.04
5.2.4 Leadership, management and organization	RS05.01, RS05.02, RS05.03, RS05.04	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

Table *continued*

Subsection in QMS guideline	GBT VI – QMS subindicators (*4*)	Related GBT VI subindicators (*4*)
5.2.5 Document and data management	RS05.07	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
5.2.6 Planning	RS05.02	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
5.2.7 Support and resources	RS05.04, RS05.14	RS02.02, RS06.01, RS06.02, RS08.01, RS08.02, RS08.03, 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

Table *continued*

Subsection in QMS guideline	GBT VI – QMS subindicators (*4*)	Related GBT VI subindicators (*4*)
5.2.8 Operation	RS05.06, RS05.09	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
5.2.9 Performance evaluation	RS05.10, RS05.11, RS05.12, RS05.13	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
5.2.10 Improvement	RS05.05	LR06.02

GBT: *WHO Global Benchmarking Tool* (*4*); NRA: national regulatory authority; QMS: quality management system.

Appendix 2

Activity plan for quality management system implementation

Step	Activity	Subsection of QMS guideline	Recommendations of documents and records to be established	Responsibility within the NRA
1.	Appointment of QMS focal person(s) or lead(s)	5.2.4.3	Official letters of appointment with defined responsibilities and authorities in the QMS	Head of the NRA
2.	QMS focal person(s) understands the QMS requirements	5.2.7.2	• Competency matrix for QMS focal person(s)/ lead(s) • Training plans for competency gaps in QMS implementation • Training records of QMS focal person(s)/lead(s) • Training/orientation records in development and implementation of QMS documents (quality manual, standard operating procedures and/or forms and templates)	Top management
3.	QMS focal person(s)/lead(s) conducts a gap analysis of the current system based on Tables A13.3 and A13.4 of the guideline and develops a QMS action plan (as part of the strategic plan)	6.1	• Documented gap or situation analysis report • Documented roadmap with resources, timelines and responsibilities (part of NRA strategic and action plans)	• Top management • QMS focal person(s)/ lead(s)

Table A11.1 *continued*

Step	Activity	Subsection of QMS guideline	Recommendations of documents and records to be established	Responsibility within the NRA
4.	QMS focal person(s)/lead(s) conduct(s) orientation and awareness sessions for NRA employees on QMS development and implementation (with roles and responsibilities)	5.2.7.5	Accessible and available QMS orientation and awareness sessions records and materials in appropriate format	QMS focal person(s)/ lead(s)
5.	• Establishment of NRA current context (SWOT analysis), if already available • Determination of the comprehensiveness of the legal provisions (Acts and regulations) in describing interested parties relevant to the QMS • Identification of QMS processes, sequences, linkages and interdependencies • Determination of the scope of the QMS and relationships of its processes	5.2.3.1	• Documented official organizational chart covering NRA governance and top management 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 the QMS, with related products and services	• Top management • QMS focal person(s)/ lead(s)

Table A11.1 *continued*

Step	Activity	Subsection of QMS guideline	Recommendations of documents and records to be established	Responsibility within the NRA
6.	Documentation of a quality policy within the context and strategic direction of the NRA	5.2.4.2	Documented, accessible (publicly) and available quality policy understood by NRA staff	• Top management • 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	5.2.6.2	• Documented and controlled registry of assessed and categorized risks and opportunities (from SWOT analysis) • Risk and opportunity responsibility matrix (based on responsible, accountable, consulted and informed [RACI] principles)	• Top management • QMS focal person(s)/ lead(s)
8.	Development and documentation of SMART quality objectives, including a plan for M&E with related required resources	5.2.4.2	Documented quality objectives (and their short- and long-term targets), resources, responsibilities (ideally in NRA's strategic plan) and M&E indicators	Top management

Table A11.1 *continued*

Step	Activity	Subsection of QMS guideline	Recommendations of documents and records to be established	Responsibility within the NRA
9.	Development of new or harmonization with existing procedures for control of measuring equipment, organizational knowledge management, personnel training and communication	5.2.7.4	Documented and implemented procedures for: • staff recruitment (based on a defined competency framework for different levels and positions), training and retraining based on established gaps as per organizational competency framework • management and maintenance of measuring equipment, as applicable in making regulatory decisions (laboratory and/or inspection equipment) • management of organizational 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	• Top management • QMS focal person(s)/ lead(s)

Table A11.1 *continued*

Step	Activity	Subsection of QMS guideline	Recommendations of documents and records to be established	Responsibility within the NRA
10.	Development of new or harmonization with existing procedures for all processes in technical and administrative units of the NRA	5.2.8	Documented and implemented procedures for all applicable technical and administrative processes within the 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 that are involved in provision of products and services as mandated by national legislations	• Top management • QMS focal person(s)/ lead(s)
11.	Development of procedures for monitoring of customer satisfaction, internal audit, management review and complaints handling, and put them into practice	5.2.9	• 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 programmes • Documented and implemented regular reviews of QMS implementation and performance by top management	• Top management • QMS focal person(s)/ lead(s)
12.	Development of procedures for corrections, corrective actions and improvements, and put them into practice	5.2.10	Documented and implemented procedures for corrective actions and change management, along with a link for updating risk and opportunity management plans	• Top management • QMS focal person(s)/ lead(s)

IT: information technology; M&E: monitoring and evaluation; NRA: national regulatory authority; QMS: quality management system; SMART: specific, measurable, attainable, realistic and time-bound; SWOT: strengths, weaknesses, opportunities and threats.