Republic of the Philippines
Department of Environment and Natural Resources
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URGENT MEMORANDUM

MAR 0 1 2023

TO : **The Directors**
Policy and Planning Service
Legal Affairs Service
Administrative Service
Financial and Management Service
Human Resource Development Service
Climate Change Service
Knowledge and Information Systems Service
Strategic Communication and Initiatives Service

The Bureau Directors
Environmental Management Bureau
Mines and Geosciences Bureau
Biodiversity Management Bureau
Ecosystems Research and Development Bureau
Forest Management Bureau
Land Management Bureau

FROM : **The Assistant Secretary**
Finance, Information Systems and Mining Concerns and
Deputy Quality Management Representative

SUBJECT : **REQUEST FOR COMMENTS ON THE DRAFT DOCUMENTS REGULATORY QUALITY MANAGEMENT SYSTEM (RQMS) STANDARD**

In view of the letter of the Development Academy of the Philippines to the DENR dated 16 February 2023, for the inputs and comments on the draft Regulatory Quality Management System (RQMS) Standard, you are requested to submit to this office your respective comments on 08 March 2023, through the DENR Central Office QMS Secretariat, with email address at qmssecretariat@denr.gov.ph.

You may also download copy of the RQMS standard through the link bit.ly/3y2Wpri. For any clarification/question you may contact Mr. Antonio Bautista Jr. of the Information Systems Division through VOIP No. 1146 or direct line 8926-0507.

For information and compliance.

ENGR. NONITA S. CAGUIOA

MEMO NO. 2023 - 170

development academy of the philippines
The National Productivity Organization

16 February 2023

SEC. MARIA ANTONIA YULO LOYZAGA
Secretary
Department of Environment and Natural Resources
DENR Bldg. Visayas Avenue, Diliman, Quezon City Metro Manila

Dear **Secretary Loyzaga:**

Greetings from the Development Academy of the Philippines (DAP)!

The DAP's Modernizing Government Regulations Program (MGRP) is a regulatory reform initiative that aims to contribute to the national government's efforts to improve the ease of doing business in the country by developing mechanisms that would make regulations more relevant and coherent. One of the important initiatives being undertaken by the MGR Program is the crafting of a Regulatory Quality Management System (RQMS) which is a standard management guideline for developing regulations and improving regulatory services. The RQMS Standard is similar to the ISO 9001:2015 Quality Management System but is designed in the context of regulatory agencies and regulation-making.

As a recognized Standards Development Organization (SDO) partner of the Department of Trade and Industry-Bureau of Philippine Standards (DTI-BPS), the DAP is aiming for recognition of the RQMS as a Philippine National Standard (PNS) and has been coordinating with DTI-BPS for this purpose. Prior to the recognition of the RQMS as a PNS, DTI-BPS requires a broad-based consultation and formalization process with various stakeholders. It is for this reason that we would like to hear your comments and inputs on the draft RQMS. Attached for your reference are the Activity Brief and draft RQMS Standard for your perusal. You may send your comments and inputs through this link or through email at rqms@dap.edu.ph. We will also be conducting a series of focus group discussions and key informant interviews from March to April 2023; invitation links to these activities will be sent to you by email.

We hope to receive your inputs and comments on or before **15 April 2023**. Should you have any clarification about this matter, we can be contacted through the above email. Attention: Ms. Marbida L. Marbida, Program Manager.

Thank you and we look forward to your active participation in this worthwhile endeavor.

Best regards.

Very truly yours,

Engelbert C. Caronan

ATTY. ENGELBERT C. CARONAN, JR., MNSA
President and CEO

development academy of the philippines

REGULATORY QUALITY MANAGEMENT SYSTEM AS A PHILIPPINE NATIONAL STANDARD

ACTIVITY BRIEF

I. Background and Rationale

The DAP's Modernizing Government Regulations Program (MGRP) is a regulatory reform initiative that was created to contribute to broad-based improvements in national productivity and competitiveness by examining the regulatory environment of specific sectors and industries and identifying possible reforms in regulatory governance.[1] Existing regulations in the sectors and industries are reviewed with the end goal of streamlining unnecessary rules and processes, and reducing compliance costs borne by the government, businesses and citizens.

The MGR Program also aims to enhance the capacity of government agencies to improve the regulation-making process and effectively manage the delivery of regulatory services. Among regulatory agencies and even within an agency, however, there are different interpretations of processes. To achieve uniformity of quality in regulatory services, there is a need to ensure that all offices/bureaus within the agency have a uniform understanding of the regulations and the attendant processes required in formulating, implementing and evaluating them.

With this in mind, the MGR Program initiated the development of the Regulatory Quality Management System (RQMS) Standard to come up with minimum requirements in establishing a regulatory management system whose intent is to ensure the delivery of quality regulatory services to the general public. The RQMS Standard uses the ISO 9001:2015 Quality Management System (QMS) as its main reference.

Other ISO documents guided the formulation of the RQMS Standard. These include the ISO/IEC 17020:2012 Conformity Assessment – Requirements for the operation of various types of bodies performing inspection; ISO 14001:2015 Environmental Management System; and ISO 37001 Anti-Bribery Management System. The RQMS also referred to select literature on regulatory management and good regulatory practices of the Organization for Economic Cooperation and Development or OECD, Asia Pacific Economic Cooperation or APEC, Association of Southeast Asian Nations or ASEAN and various academic journals.

In addition to the use of secondary references, the formulation of the draft RQMS Standard was informed by a number of consultations with various stakeholders from the government, private sector and civil society groups. Since December 2017, the draft RQMS document has been subjected to consultation workshops with national and local government agencies such as the Department of Agriculture (DA)-Fertilizer and Pesticide Authority; DA-National Meat Inspection Service; Department of Health (DOH)-Bureau of Quarantine; DOH-Health Facilities and Services Regulatory Bureau; DOH-Office of Human Resources, and the Philippine Drug Enforcement Agency (PDEA), among other agencies.

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[1] Regulatory governance refers to the policies, tools, processes and institutions that are primarily concerned with developing, implementing, administering, enforcing new rules/decisions, and reviewing/revising regulations over time. It is the process of regulating regulations and regulators, and the rules that govern the establishment and operation of an organization. Regulatory Governance looks into the *processes* by which organizations make and implement decisions, and the *means* by which those decisions can be challenged or appealed.

Complementarity of RQMS and NPRMS

The DAP's RQMS initiative recognizes the National Policy on Regulatory Management System (NPRMS) developed by the Anti-Red Tape Authority (ARTA) as the macro system that will be implemented at the broader country level, while the RQMS Standard is for implementation as a tool to operationalize good regulatory practices at the micro level of the regulatory agency. The DAP's intention is to ensure the alignment of the RQMS with NPRMS so that DAP and ARTA can have a common framework that will be used to improve the Regulatory Management System in the Philippines. Since the RQMS Standard covers the agency level, it is a tool that regulatory agencies can use to comply with the policy and administrative guidance being developed by ARTA for the NPRMS. In essence, the RQMS will complement and assist the implementation of NPRMS. The DAP and ARTA agree that regulatory reform will be accelerated if both instruments (RQMS and NPRMS) are aligned as guidance for the regulatory agencies.[2]

II. Promulgation of the Regulatory Quality Management System as a Philippine National Standard

The Regulatory Quality Management System (RQMS) is a template and standard guideline to effectively develop, implement and evaluate regulations. The RQMS is similar to the ISO QMS standard but is designed in the context of regulatory agencies and regulation-making. Intended for use by regulatory agencies,[3] the RQMS outlines the regulatory management system and processes that need to be established, implemented, maintained and continuously improved in the regulated agencies in order to achieve their agency mandates and policy objectives.

As a recognized Standards Development Organization (SDO)[4] partner of the Department of Trade and Industry-Bureau of Philippine Standards (DTI-BPS), the DAP is aiming for recognition of the RQMS as a Philippine National Standard (PNS) and has been coordinating with DTI-BPS for this purpose.

One of the DTI-BPS's requirements prior to the recognition of the RQMS as a Philippine National Standard is the conduct of a broad-based consultation and formalization process with various stakeholders from within the Philippines. These stakeholders are composed of ISO QMS-certified LGUs, ISO QMS and RMS experts, oversight agencies, regulatory agencies, private sector, academe and civil society group representatives.

To prepare for the public consultation and the promulgation of the RQMS as a Philippine National Standard, a RQMS Technical Committee (TC) was formed to review and determine the draft RQMS document's readiness to be submitted for comments and feedback of the stakeholders during the consultations that will be conducted beginning 15 February until 15 April 2023. The RQMS TC is also tasked to approve the final RQMS draft and endorse it to the DTI-BPS for promulgation as a PNS.

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[2] Source: Minutes of the DAP-ARTA Meeting on the NPRMS, 20 September 2022.

[3] Including the offices of the Local Government Units who are developing and enforcing regulations at the local level.

[4] The DTI-BPS defines SDOs as "organizations that possess the necessary expertise, capacity and resources to develop standards."

III. Consultation Methodology and Platforms

The consultation participants will be engaged through key informant interviews, focus group discussions, survey questionnaire, and email communication exchanges. To reach its targeted stakeholders, the consultations will be using online media platforms such as *Zoom* teleconferencing; DAP, PDC, MGRP and DTI-BPS websites; postings in the MGRP *Facebook* page; and administration of a *SurveyMonkey* questionnaire.

IV. Target Stakeholders

Specifically, the following are the targeted stakeholders for the consultations:

- ISO-certified National Government Agencies/Regulatory Agencies - sourced from the 2020 database of the Department of Budget and Management - Government Quality Management Council
- ISO-certified LGUs - sourced from the DAP Government Quality Management Program; to be coordinated with the Department of the Interior and Local Government-Bureau of Local Government Supervision (DILG-BLGS)
- Oversight agencies - ARTA, DBM, DILG, DTI-BPS, National Economic and Development Authority (NEDA)
- Individual QMS and RMS experts
- Private sector representatives – e.g., business chambers and clubs
- Academe representatives

V. Next Steps

Upon completion of the required minimum 60-day consultation period, the RQMS TC Secretariat will collate the inputs, comments and feedback from the consultation participants and incorporate them in the draft RQMS document. The enhanced draft will then be reviewed and approved by the RQMS TC before its submission to the DTI-BPS for promulgation as a Philippine National Standard in May, 2023.

development academy of the philippines

Regulatory Quality Management System (RQMS) Standard

DRAFT FOR CONSULTATION

(Ver6 15Feb23)

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FOREWORD

Recognizing the need for a whole-of-government effort in the pursuit of regulatory reform, the Development Academy of the Philippines (DAP), as a recognized Standards Development Organization, developed this Regulatory Quality Management System (RQMS) to contribute to the operationalization of the National Policy on Regulatory Management System at the agency-level by providing a template that outlines the regulatory processes that need to be established, implemented, maintained and continuously improved in order to achieve agency mandates and policy objectives.

While there are abundance of tools and references in making regulations coherent, the Development Academy of the Philippines (DAP) deems that modernizing regulations and the way they are developed entail a systematic and cohesive approach that start with an overarching policy framework that is the country's National Policy on Regulatory Management System or NPRMS as developed by Anti-Red Tape Authority and supported by a management system that operationalizes the concept and principles of regulatory management at the organization level.

A collaboration among like-minded institutions and individuals with their respective expertise in the areas of regulatory governance, quality management systems, policy development, among others, the RQMS is a document that standardizes regulation making in the country. It covers the important elements in regulation making from the context of the organization, to its leaders and stakeholders, supported by appropriate resources and guided by its operation and control mechanism. All these elements interact in a Plan Do Check Act (PDCA) cycle to ensure continual improvement.

With this, we are delighted to publish the first edition of the RQMS which is intended to be used by regulatory agencies and local government units particularly the units or offices with regulatory functions/mandates.

ACKNOWLEDGEMENT

The DAP would like to acknowledge the invaluable contributions of the members of the RQMS Technical Committee in the review and finalization of this Standard. The DAP's utmost gratitude goes to Usec. Carlos Bernardo O. Abad Santos of the National Economic and Development Authority (NEDA), Prof. Jonilo J. Del Rosario of the University of the Philippines Open University (UPOU), Dir. John Aries S. Macaspac of the Department of Budget and Management, Dir. Frances Rose E. Mamaril of the Department of Health, SVP Magdalena L. Mendoza of the DAP, Mr. Noel Edward S. Morales of the Local Government of Muntinlupa, Mr. Ruy Y. Moreno of the Management Association of the Philippines, Dir. Gerald Glenn F. Panganiban of the Bureau of Plant Industry, Dir. Debie T. Torres of the Department of the Interior and Local Government, and Ms. Emmaline C. Vitug.

The DAP would also like to acknowledge the support of Sec. Ernesto V. Perez of the Anti-Red Tape Authority for the finalization of the RQMS. The support of the ARTA is crucial, being the lead in the promotion of regulatory management, as well as the implementation of corresponding efforts and initiatives, consistent with Republic Act No.11032 or the Ease of Doing Business (EODB) and Efficient Government Service Delivery (EGSD) Act of 2018. Moreover, the eventual adoption of this standard will not be possible without the support and acceptance of the various regulatory agencies that provided their inputs and comments to further improve the content and enhance the suitability of this standard.

Last but not least, the DAP would like to thank Dir. Neil Catajay and Engr. Mario Gaudiano of the Department of Trade and Industry - Bureau of Philippine Standards for the guidance that has been extended to the DAP during the standardization process.

INTRODUCTION

0.1 General

It is critical for governments to maintain effective regulations in order to protect public interests and uphold developmental goals. In order to achieve this, an efficient and effective Regulatory Quality Management System (RQMS) should be in place to ensure regulatory quality and reduce unnecessary regulatory burden. A coherent regulatory framework leads to the attainment of desired regulatory objectives and reduction in the costs of doing business.

The potential benefits to a regulatory agency of implementing an RQMS are:

a. Ability to determine areas of control in the delivery of regulatory services;
b. Ability to achieve consistency of quality in regulatory services; and,
c. Provide mechanism/management template to allow continual regulatory process improvement.

This RQMS is intended to be used by regulatory agencies and not by the regulated entities. It focuses on how a regulatory agency will develop, implement, and evaluate regulations, and act on the corresponding nonconformities.

0.2 Objectives

0.2.1 Identify and review common and unique regulatory management approaches and practices;
0.2.2 Determine gaps and challenges in regulatory policy-making, administration and enforcement;
0.2.3 Develop a framework to effectively manage regulations and regulatory processes; and,
0.2.4 Formulate a common goal for action to advocate improvement in the delivery of regulatory services for public sector performance.

0.3 Regulatory management principles

This RQMS is based on literature on regulatory management and good regulatory practices of the Organisation for Economic Co-operation and Development, Asia Pacific Economic Cooperation, Association of Southeast Asian Nations and various academic journals. The RQMS is anchored on the following regulatory management principles:

0.3.1 Competency-based, evidence-based and risk-based regulation making

Regulatory agencies use the information that it holds, and require regulated entities to provide technical and general information as necessary to determine their competency and assess the relevant benefits and costs associated with a proposed or existing regulation. To ensure that they undertake their regulatory functions and that there is no harm to public health, safety or interest, regulatory agencies also need to assign its enforcement and monitoring activities at premises or entities that present the greatest risk, harm, or benefit to the citizenry. A principle of evidence-based policy-making, enforcement and inspections require that regulatory agencies' actions and their effectiveness should be regularly evaluated against a set of well-defined indicators, and based on reliable and trusted data.

0.3.2 Sound legal and empirical basis, consistency, proportionality, and targeting

Regulatory agencies need to ensure that regulations have sound legal and empirical basis and that they will only intervene when necessary (e.g. when the market cannot correct itself) and policy solutions are directed at the root cause of the perceived problem or risk. *Consistency* involves the review of regulations and policies to ensure that they are consistent with other regulations and regulators interpret and apply them consistently while *proportionality and targeting* involves ensuring government action does not 'overreach' or extend beyond addressing a specific problem or achieving the identified objective. This ensures that scarce public resources are employed efficiently, removing duplications of regulatory effort and improving effectiveness.

0.3.3 Benefit-oriented interventions

Activities of regulatory agencies need to be clearly focused on the underlying regulatory objectives, represent the course of action(s) to achieve these objectives effectively and efficiently, integrated and aligned (i.e., work towards common purposes and objectives), and flexible and innovative, achieving the best regulatory outcome.

0.3.4 Capacity-development interventions

Regulatory agencies need to ensure that enforcers, inspectors, licensing evaluators, analysts, middle management, and process owners are hired, selected, and/or appointed based on a set of competencies and are regularly trained and managed to ensure professionalism, integrity, consistency and transparency. The capacity-development interventions shall focus on building functional and behavioral competencies through training, coaching, and mentoring to help ensure that regulations are up-to-date with current practices and work towards innovation.

0.3.5 Transparency and accessibility

Regulatory agencies need to ensure that processes are comprehensible and transparent such that regulations are instinctive and can be easily interpreted; regulatory actions should provide certainty and assurance to regulated entities; and the process and basis for regulatory decision-making are documented, transparent and publicly available, e.g., regular updating and publication of the Citizen's Charter, in order to foster public trust and confidence. Regulatory authorities are accountable for the actions they take, and welcome scrutiny, comments, suggestions and/or recommendations from their stakeholders, general public and other sectors, including the regular reporting of performance evaluation so that businesses can seek explanation of decisions made by regulators, as well as appeal to them and there are probity provisions in order to maintain integrity.

0.3.6 Responsiveness and accountability

Following the Philippine Good Regulatory Practices, it is important to design 'fit-for-purpose' regulatory frameworks which will be able to address disruptive technologies, changes in consumer behavior, and evolving stakeholder preferences. Regulatory authorities need to have a guide that shall set the flexibilities and boundaries of authorities

while remaining responsive and considering full range of options available to them; tailoring their approach to account for the circumstances of each individual case; focusing on consistency of outcome; and, regularly reviewing their process/system and operational policy to ensure it is evidence-based, remains relevant and appropriate to changes in the sector. Regulatory agencies, as institutions, have an obligation to account for their activities, accept responsibility for them, and disclose the results in a transparent manner.

NOTE: The guide is specific to the context of the regulatory agency.

0.3.7 Partnership and cooperation

Regulatory agencies need to cooperate with other regulatory agencies, their regulated entities and the broader national and international community to provide opportunities to nurture a network of best practices, and create sustainable and resilient relationships to embrace change.

0.4 RQMS framework

The RQMS Framework below illustrates how the Sections 4 to 11 can be grouped in relation to the RQMS principles and the regulatory management cycle.

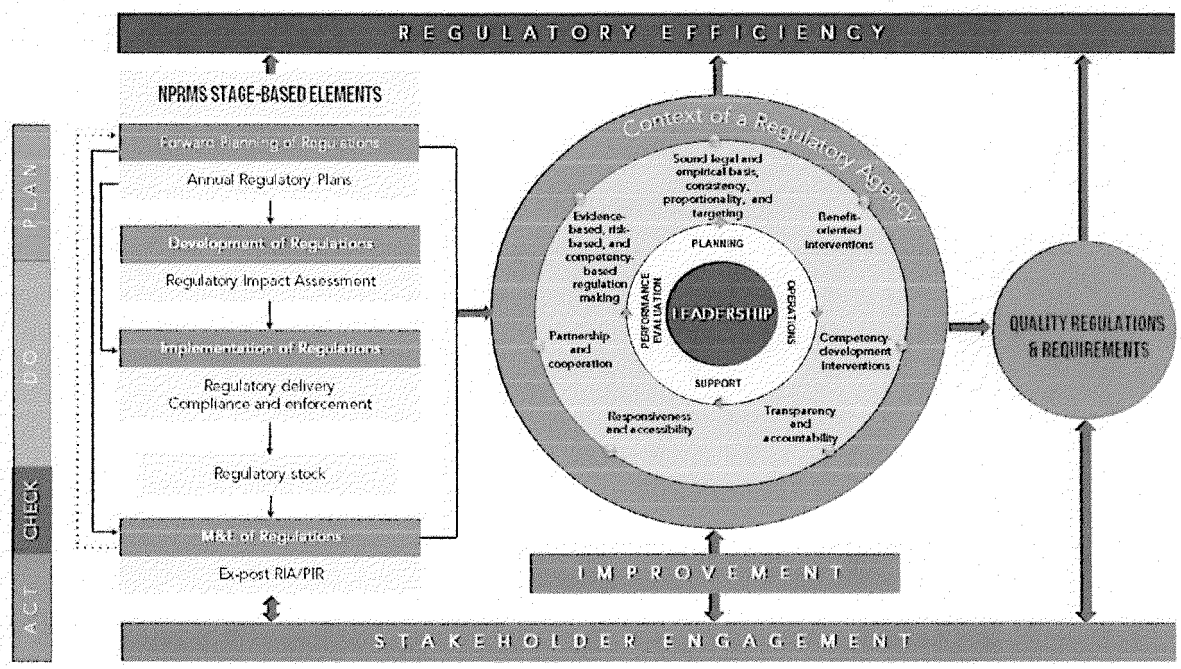

Figure 1: RQMS Framework

1. SCOPE

This Philippine National Standard specifies requirements for an RQMS when a regulatory agency:

a. Needs to demonstrate its ability to consistently provide products and services that meet client and applicable statutory and regulatory processes and regulations; and,
b. Aims to enhance regulatory quality through the effective application of the system, including processes for improvement of the system and the assurance of conformity to client and applicable statutory and regulatory processes and regulations.

All the requirements of this RQMS Standard are generic and are intended to be applicable to any regulatory agency, regardless of its type or size, or the products and services it provides.

Note 1: In this RQMS Standard, the term 'products and services' only applies to regulatory services, intended for, or required by, a client.

Note 2: Statutory and regulatory processes and regulations requirements can be expressed as legal requirements.

2. NORMATIVE REFERENCES

The following documents, in whole or in part, are normatively referenced in this RQMS Standard and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

a. A Guide to Good Practice: Principles and Practices in Product Regulations and Market Surveillance by the International Organization for Standardization
b. Association of Southeast Asian Nations. (20--). Good Regulatory Principles.
c. Asia Pacific Economic Cooperation. (20--). Good Regulatory Practices.
d. Best Practice Principles on the Governance of Regulators. Organisation for Economic Co-operation and Development
e. Guidance on Regulatory Cost Model on Compliance Costs. Development Academy of the Philippines
f. Guide on Stakeholder Consultations. Development Academy of the Philippines.
g. Guidebook on Regulatory Impact Assessment for the Public Sector. Development Academy of the Philippines.
h. ISO 18091:2019 Quality management systems — Guidelines for the application of ISO 9001 in local government
i. ISO 9001:2015 Quality Management Systems - Requirements
j. ISO 9000:2015 Quality Management Systems - Fundamentals and Vocabulary
k. ISO 31000:2018 Risk Management
l. ISO 37001:2016 - Anti--bribery Management Systems - Requirements with Guidance for Use by the International Organization for Standardization
m. Government: Good or Bad by the International Organization for Standardization
n. Integrity Management Program Handbook - Building a Culture of Integrity. Office of the President and Office of the Ombudsman
o. Measuring Regulatory Performance: The Economic Impact of Regulatory Policy: A Literature Review of Quantitative Evidence - David Parker and Colin Kirkpatrick
p. National Policy on Regulatory Management System. Anti-Red Tape Authority [unsigned]
q. Philippine Good Regulatory Principles (PGRP). Anti-Red Tape Authority and Department for Business, Energy, and Industrial Strategy - UK Government

r. Regulatory Impact Assessment Manual. (2021). Anti-Red Tape Authority and UPPAF RESPOND.
s. Revised Philippine Government Internal Audit Manual through DBM Circular Letter No. 2020-8 dated 26 May 2020
t. The Financial Audit Manual, Commission on Audit. (2003).

3. TERMS AND DEFINITIONS

For the purposes of this RQMS Standard, the following terms and definitions apply:

	Terms	Definitions
3.1	Accountability	being responsible for decisions and activities of the regulatory agency to its governing and oversight bodies, legal authorities and, more broadly, relevant stakeholders
3.2	Activity	smallest identified object of work in a project
3.3	Adequate	sufficient for a specific purpose or requirement
3.4	Audit	systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled
3.5	Audit criteria	set of applicable rules and regulations, policies, procedures or requirements used as a reference against which objective evidence is compared
3.6	Audit evidence	records, statements of fact or other information, which are relevant to the audit criteria and verifiable
3.7	Audit findings	results of the evaluation of the collected audit evidence against audit criteria
3.8	Audit plan	a document that provides the main guidance of the whole audit process in order to achieve the audit objective in an efficient and effective way. It provides an integrated description of the auditee and the audit by serving as a guide for the whole audit.
3.9	Audit scope	is the framework or limits of the audit. It is normally defined by stating what the audit intends to cover and the relevant timeframes.
3.10	Audit team	two or more persons conducting an audit, one of whom will be appointed as audit leader, supported if needed by technical experts
3.11	Auditor	person who conducts an audit which possesses technical skills and upholds audit principles.
3.12	Behavioral competency	behaviors, attributes, and values that drive success in regulatory agencies
3.13	Citizen	general public
3.14	Client	those who comply with regulations
3.15	Client satisfaction	client's perception of the degree to which the client's expectations have been fulfilled
3.16	Client service	interaction of the regulatory agency with the client throughout the life cycle of a product or a service
3.17	Competence	ability to apply knowledge and skills to achieve intended results
3.18	Complaint	expression of dissatisfaction made to a regulatory agency related to its regulatory services or the complaints-handling process itself,

	Terms	Definitions
		wherein a response or resolution is explicitly or implicitly expected in a timely manner, based on relevant government directives.
3.19	Compliance	conformity with audit criteria related to statutory or regulatory requirements or other policy requirements
3.20	Concession	permission to use or release a product or service that does not conform to specified requirements
3.21	Conformity	fulfillment of a requirement
3.22	Consultation	structured public engagement which involves seeking, receiving, analyzing, and responding to feedback from relevant stakeholders
3.23	Context of the regulatory agency	combination of internal and external issues that can have an effect on a regulatory agency's approach to developing and achieving its objectives
3.24	Continual improvement	a recurring activity that aims to enhance performance and standards
3.25	Correction	action to eliminate a detected nonconformity
3.26	Corrective action	action to eliminate the cause of a nonconformity and to prevent recurrence
3.27	Data	facts about an object used as a basis for reasoning, planning and decision making process
3.28	Dependability	ability to perform as and when required
3.29	Design and development	set of processes that transform requirements for an object into more detailed requirements for that object
3.30	Documented information	information required to be controlled, maintained, and/or retained by an agency and the medium by which it is controlled
3.31	Effectiveness	achievement of objectives through an assessment of the outcomes of the regulatory agency's programs and outputs which accrue to the public, measured in terms of performance measures or targets
3.32	Efficiency	optimum utilization of resources by delivering a given quantity and quality of outputs with minimum inputs or maximizing outputs with a given quantity and quality of inputs
3.33	Enforcement	process of ensuring compliance with regulations to attain policy objectives
3.34	Engagement	involvement in, and contribution to achieve shared objectives
3.35	Feedback	opinions, comments and expressions of interest in a product, a service or a complaints-handling process
3.36	Fitness check	comprehensive evaluation of a policy area that usually addresses how several related legislative acts have contributed (or otherwise) to the attainment of regulatory objectives. Fitness checks are particularly well-suited to identify overlaps, inconsistencies, synergies and the cumulative impacts of legislation
3.37	Functional competency	specific competencies which are considered essential to perform any job in the organization within a defined technical or functional area of work
3.38	Improvement	activity to enhance performance
3.39	Information	Knowledge concerning objects, such as facts, events, things, processes, or ideas, including concepts, that within a certain context has a particular meaning.

	Terms	Definitions
3.40	Innovation	new or changed object realizing or redistributing value
3.41	Inspection	determination of conformity to specified requirements
3.42	Integrity	the faithful and consistent application of generally accepted public values and norms in the daily practice of public sector institutions; the proper use of powers, authorities, assets, resources and funds according to the official purpose for which they are intended, with the end in view of promoting public welfare.
3.43	Involvement	taking part in an activity, event or situation
3.44	Management	coordinated activities to direct and control a regulatory agency
3.45	Management system	set of interrelated or interacting elements of a regulatory agency to establish policies and objectives, and processes to achieve those objectives
3.46	Measurement	process to determine a value
3.47	Measuring equipment	measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a measurement process
3.48	Measurement process	set of operations to determine the value of a quantity
3.49	Mission	regulatory agency's purpose for existing as expressed by top management
3.50	Monitoring	determining the status of a system, a process, a product, a service, or an activity
3.51	Noncompliance	nonconformity with audit criteria related to statutory and regulatory requirements or other requirements, is sometimes referred to as non-compliance
3.52	Nonconformity	non-fulfillment of a requirement
3.53	Objective	results to be achieved
3.54	Output	result of a process
3.55	Performance	measurable result
3.56	Policy	intentions and direction of a regulatory agency as formally expressed by its top management
3.57	Procedure	specified way to carry out an activity or a process
3.58	Process	set of interrelated or interacting activities that use inputs to deliver an intended result
3.59	Products of a regulation	output of a regulatory agency that can be produced without any transaction taking place between the regulatory agency and the client
3.60	Project	unique process, consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources

	Terms	Definitions
3.61	Project management	planning, organizing, monitoring, controlling and reporting of all aspects of a project, and the motivation of all those involved in it to achieve the project objectives
3.62	Project management plan	document specifying what is necessary to meet the objective(s) of the project
3.63	Proportionality analysis	appropriate level of resources to invest in gathering and analyzing data for analysis.
3.64	Quality	degree to which a set of inherent characteristics of an object fulfills requirements
3.65	Quality objective	measurable goals and targets established for regulatory processes and regulations relevant to enhancing client satisfaction and should be consistent with the regulatory agency's quality policy, if any
3.66	Quality requirement	requirement related to quality
3.67	Record	document stating results achieved or providing evidence of activities performed
3.68	Regulated entity	members of a sector or market that are expected to comply with regulations
3.69	Regulation	government-endorsed rules with a mandatory requirement for compliance or an expectation of compliance
3.70	Regulatory agency	any government entity or instrumentality with regulatory functions which include, but are not limited to, local government units
3.71	Regulatory agency/ organizational knowledge	knowledge specific to the regulatory agency; it is generally gained by experience. It is information that is used and shared to achieve the regulatory agency's objectives
3.72	Regulatory capture	a type of government failure that occurs when a regulatory agency, which was created in the public interest, ends up advancing the political or commercial concerns of the people, companies or entities it is supposed to be regulating.
3.73	Regulatory compliance cost assessment	a systematic approach in identifying and assessing compliance costs of regulations
3.74	Regulatory failure	an imperfection in government performance which occurs when government intervention in the economy or society causes an inefficient allocation of resources and a decline in economic welfare.
3.75	Regulatory framework	context of the sector
3.76	Regulatory impact assessment	tool used to help a regulatory agency make better regulatory decisions based on information and empirical analysis about the potential positive and negative consequences of government action
3.77	Regulatory improvement objective	measurable targets established to promote the modification of the regulation in order to optimize the performance, effectiveness and quality of the formalities required by the government seeking always to ensure maximum social welfare
3.78	Regulatory objective	measurable targets specified in enabling issuance or legislation
3.79	Regulatory processes and regulations	obligatory requirement specified by an authority mandated by a legislative body
3.80	Regulatory quality plan	specification of the procedures and associated resources to be applied when and by whom to a specific object

	Terms	Definitions
3.81	Regulatory quality management (RQM) framework	translated the NPRMS framework to principles that can be used in operationalizing it at the agency level
3.82	Regulatory quality management system (RQMS) framework	operationalization of the RQMS at the specific agency level (it differs depending on the regulatory agency)
3.83	Requirement	need or expectation that is stated, generally implied or obligatory
3.84	Risk	effect of uncertainty
3.85	Service	output of a regulatory agency with at least one activity necessarily performed between the regulatory agency and the client
3.86	Specification	document stating requirements
3.87	Stakeholder	person or regulatory agency that can affect, be affected by, or perceive itself to be affected by a decision or activity
3.88	Statutory requirement	obligatory requirement specified by a legislative body
3.89	System	set of interrelated or interacting elements
3.90	Technical expert	person who provides specific knowledge or expertise to the audit team
3.91	Top management	person or group of people who directs and controls a regulatory agency at the highest level
3.92	Traceability	ability to trace the history, application or location of an object
3.93	Transparency	openness about decisions and activities that affect society, the economy and the environment, and willingness to communicate these in a clear, accurate, timely, honest and complete manner
3.94	Unambiguous	clear
3.95	Unnecessary regulatory burden	The costs imposed on clients due to compliance to regulations that are problematic, duplicative and/or inconsistent.
3.96	Validation	confirmation, through the provision of objective evidence, that the output is capable of meeting intended use or application.
3.97	Verification	confirmation, through the provision of objective evidence, that the output is capable of fulfilling or has fulfilled the specified requirements.
3.98	Vision	aspiration of what a regulatory agency would like to become as expressed by top management

4. CONTEXT OF A REGULATORY AGENCY

Abstract: This section focuses on understanding the purpose, management system and relevant stakeholders of the regulatory agency. It allows the agency to identify external and internal issues that are relevant to its purpose and its strategic direction. It is important that relevant stakeholders are engaged to establish the context of a regulatory agency. The section comes before all the other requirements and will serve as an input to the process of creating the scope of the RQMS.

4.1 Understanding the regulatory agency *and its context*

The regulatory agency shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its RQMS. These issues will include, without limitation, the following factors:

a. The size, structure and delegated decision-making authority of the regulatory agency;
b. The locations and sectors in which the regulatory agency operates or anticipates operating;
c. The nature, scale and complexity of the regulatory agency's activities and operations;
d. The regulatory agency's service process;
e. The entities over which the regulatory agency has control and entities which exercise control over the regulatory agency;
f. The regulatory agency's jurisdiction over the other regulatory agencies;
g. The nature and extent of interactions with other government agencies; and,
h. Applicable compliance obligations.

The regulatory agency shall monitor and review information about these external and internal issues.

Note 1: Regulatory agency covers national and subnational government organizations or units that perform regulatory functions and/or uses regulations to effect or achieve developmental goals. For example, to promote innovation in the sector, a regulatory agency may design, develop, and implement a regulation--for instance, stringent Standards for product performance, safety, and environmental impact--which may create pressures for firms to innovate to improve quality and upgrade technologies.

Note 2: Issues can include positive and negative factors or conditions for consideration.

Note 3: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, economic, technostructural, and behavioral environments, whether international, national, regional or local.

The fourth element is the Technostructure that is composed of planners, analysts, and trainers who perform the intellectual work. This element provides the advice for the other parts and it is to be noted that they do not do any work but function in an advisory capacity.

Note 4: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the regulatory agency.

Note 5: A regulatory agency has control over another regulatory agency if it directly or indirectly controls the management of the regulatory agency (see A.13.1.3)

Note 6: Compliance obligations are legal requirements that a regulatory agency has to comply with and other requirements that a regulatory agency has to or mandatory and statutory requirements. Compliance obligations can arise from mandatory requirements, such as applicable laws and regulations, or voluntary commitments, such as regulatory agency and industry standards, contractual relationships, codes of practice and agreements with community groups or non-governmental agencies.

4.2 Understanding the needs and expectations of relevant stakeholders

The regulatory agency shall determine:

a. The stakeholders that are relevant to the RQMS;
b. The needs and expectations of these relevant stakeholders that are relevant to the RQMS; and,
c. which of these needs and expectations become its compliance obligations.

The regulatory agency shall monitor and review information about these relevant stakeholders and their relevant requirements.

Note: In identifying the requirements of relevant stakeholders, a regulatory agency can distinguish between mandatory requirements and the non-mandatory expectations of, and voluntary commitments to, relevant stakeholders.

4.3 Determining the scope of RQMS

The regulatory agency shall determine the boundaries and applicability of the RQMS to establish its scope. When determining this scope, the regulatory agency shall consider:

a. the internal and external issues referred to in 4.1;
b. the requirements of relevant stakeholders referred to in 4.2;
c. the compliance obligations referred to in 4.2;
d. its regulatory agency unit (s), function (s), and physical boundaries;
e. enforcement and inspection activities; and,
f. its authority and ability to exercise control and influence.

The regulatory agency shall apply all the requirements of this RQMS if they are applicable within the determined scope of its RQMS.

The scope of the regulatory agency's RQMS shall be available and maintained as documented information. Conformity to this RQMS may only be claimed if the requirements determined as not being applicable do not affect the regulatory agency's ability or responsibility to ensure the conformity of its regulatory services and the enhancement of regulatory outcomes. The scope shall state the legal bases and the types of regulatory services covered, and provide justification for any requirement of this RQMS that the regulatory agency determines not applicable to the scope of its RQMS.

4.4 RQMS and its processes

4.4.1 The regulatory agency shall establish, implement, maintain and continually improve a RQMS, including the processes needed and their interactions, in accordance with the requirements of this RQMS.

The regulatory agency shall determine the processes needed for the RQMS and their application throughout the regulatory agency, and shall:

a. Determine the inputs required and the outputs expected from these processes;
b. Determine the sequence and interaction of these processes;
c. Determine and apply the criteria and methods (including monitoring, measurement and related performance indicators) needed to ensure the effective operation and control of these processes;
d. Determine the resources needed for these processes and ensure their availability;
e. Assign the responsibilities and authorities for these processes;
f. Address the risks and opportunities as determined in accordance with the requirements of 6.1;

g. Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; and,
h. Improve the RQMS and its processes.

4.4.2 To the extent necessary, the regulatory agency shall:

a. Maintain documented information to support the operation of its processes; and,
b. Retain documented information to have confidence that the processes are being carried out as planned.

To achieve the intended outcomes, including enhancing its regulatory performance, the regulatory agency shall establish, implement, maintain and continually improve the RQMS, including the processes needed and their interactions, in accordance with the requirements of this RQMS Standard.

The regulatory agency shall consider the knowledge gained in 4.1 and 4.2 when establishing and maintaining the RQMS.

4.5 Regulatory risk analysis

4.5.1 The regulatory agency shall undertake regular regulatory risk analysis, which shall:

a. Identify the regulatory risk the regulatory agency might reasonably anticipate, given the factors listed in 4.1 and the activities that are vulnerable to integrity risks;
b. Analyze, assess and prioritize the identified regulatory risks, including risks in administering regulations; and,
c. Evaluate the suitability and effectiveness of the regulatory agency's existing controls to mitigate the assessed regulatory risks.

4.5.2 The regulatory agency shall establish criteria for evaluating its level of regulatory risk, which shall take into account the regulatory agency's policies and objectives.

4.5.3 The regulatory agency shall monitor and review the information related to the results of Risk Analysis

a. On a regular basis so that changes and new information can be properly assessed based on timing and frequency defined by the regulatory agency; and,
b. In the event of a significant change to the structure or activities of the regulatory agency.

4.5.4 The regulatory agency shall maintain and retain documented information that demonstrates that the regulatory risk analysis has been conducted and used to design or improve the RQMS.

5. LEADERSHIP

Abstract: This section highlights the importance of having the regulatory agency's leadership actively taking accountability of the effectiveness of the regulatory agency's RQMS. It espouses the need for top management to create a working environment that motivates employees to deliver their functions and ensure regulatory quality.

5.1. Leadership and accountability

The RQMS shall be led by the regulatory agency's leadership. The regulatory agency shall determine its accountability to both its citizens and clients.

5.1.1 Governing Body and Top Management

The regulatory agency leadership may emanate from its governing body and/or top management.

Note: The relationship between the top management and governing body, wherever applicable, will be defined based on the context of the regulatory agency that will use the RQMS standard.

5.1.1.1 Governing Body

When the regulatory agency has a governing body, that body shall demonstrate leadership and accountability with respect to the RQMS by:

a. Approving the agency's regulatory commitment;
b. Ensuring that the regulatory agency's strategy and regulatory commitment are aligned;
c. At planned intervals, receiving and reviewing information about the content and operation of the agency's RQMS;
d. Requiring that adequate and appropriate resources needed for effective operation of the RQMS are allocated and assigned; and,
e. Exercising reasonable oversight over the implementation of the agency's RQMS by top management and its effectiveness.

5.1.1.2 Top management

Top management shall demonstrate leadership and accountability with respect to the RQMS by:

a. Taking accountability for the effectiveness of the RQMS;
b. Ensuring that the regulatory commitment and regulatory objectives are established for the RQMS and are compatible with the context and strategic direction of the agency;
c. Ensuring the integration of the RQMS requirements into the agency's regulatory processes;
d. Promoting the use of the process approach and risk-based thinking;
e. Ensuring that the resources needed for the RQMS are available;
f. Communicating internally and externally regarding the regulatory quality;
g. Communicating internally the importance of effective RQMS and of conforming to the RQMS requirements;
h. Ensuring that the RQMS is appropriately designed to achieve its objectives;
i. Ensuring that the RQMS achieves its intended results;
j. Engaging, directing, and supporting employees to contribute to the effectiveness of the RQMS;
k. Promoting continual improvement;
l. Supporting other relevant regulatory management roles to demonstrate their leadership as it applies to their areas of responsibility;
m. Encouraging the use of reporting procedures for integrity risks;

n. Ensuring that no personnel will suffer retaliation, discrimination or disciplinary action for reports made in good faith, or on the basis of a reasonable belief of violation or suspected violation of the agency's regulatory quality policy, or for avoiding integrity risks; and,
o. At planned intervals, reporting to the governing body (if any) on the content and operation of the RQMS and of allegations of integrity risks.

Note: Reference to "business" in this RQMS Standard can be interpreted broadly to mean activities that are core to the purposes of the regulatory agency's existence, whether it be a line/attached agency or a government owned and controlled corporation.

5.2 Citizen and client focus

Top management shall demonstrate leadership and commitment with respect to citizen and client focus by ensuring that:

a. Citizen, client, and applicable statutory requirements and regulatory processes and regulations are determined, understood and consistently met;
b. The risks and opportunities that can affect the ability to enhance citizen and client satisfaction are determined and addressed; and,
c. The focus on enhancing citizen and client satisfaction is maintained.

Note: The "citizen" (population) is the object of regulation while "client" (regulatee) is the subject of regulation. Clients have different but related needs, requirements and expectations.

5.3 Regulatory quality policy

5.3.1 Establishing the regulatory quality policy

Top management shall establish, implement and maintain a regulatory quality policy that:

a. Requires coherence with the mandate of the regulatory agency;
b. Is appropriate to the purpose and context of the regulatory agency and supports its strategic direction;
c. Provides a framework for setting RQMS objectives;
d. Includes a commitment to satisfy applicable requirements;
e. Encourages raising concerns in good faith, or on the basis of a reasonable belief in confidence, without fear of reprisal;
f. Includes a commitment to continual improvement of the RQMS;
g. Includes commitment to promote integrity and ensure fair administration of regulation; and,
h. Explains the consequences of not complying with regulatory quality policy.

Note 1: If the regulatory agency has an existing quality policy for its Quality Management System, it shall be reviewed, analyzed and where necessary, enhanced to ensure integration and alignment with its identified regulatory outcome.

5.3.2 Communicating the regulatory quality policy

The regulatory quality policy shall:

a. Be available and maintained as documented information;
b. Be communicated, understood, and applied within the regulatory agency; and,
c. Be available to relevant stakeholders.

5.4 Regulatory agency roles, responsibilities and authorities

Top management shall have overall responsibility for the implementation of, and compliance with, the RQMS.

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the regulatory agency.

Managers at every level shall be responsible for requiring that the RQMS requirements are applied and complied within their regulatory agency or function.

The governing body, top management, and all other personnel shall be responsible for understanding, complying with, and applying the RQMS requirements, as they relate to their role in the regulatory agency.

Top management shall assign the responsibility and authority for:

a. Ensuring that the RQMS conforms to the requirements of this document;
b. Ensuring that processes are delivering their intended outputs;
c. Reporting on the performance of the RQMS and on opportunities for improvements in particular to top management;
d. Ensuring the promotion of citizen and client focus throughout the regulatory agency; and,
e. Ensuring the integrity of the RQMS is maintained when changes to the RQMS are planned and implemented.

5.4.1 Regulatory Compliance Function

Top management shall assign to a regulatory compliance function the responsibility and authority for:

a. Overseeing the design and implementation of the RQMS by the regulatory agency;
b. Providing advice and guidance to personnel on the RQMS and issues relating to quality regulations;
c. Ensuring that the RQMS conforms to the requirements of this document;
d. Reporting on the performance of the RQMS to the top management and other compliance functions, as appropriate;
e. Ensuring the promotion of stakeholder focus throughout the regulatory agency; and,
f. Ensuring the integrity of the RQMS is maintained when changes to the RQMS are planned and implemented.

The regulatory compliance function shall have adequate resources and be assigned to a person(s) who has the appropriate competence, status, authority and independence.

The regulatory compliance function, lodged in existing regulatory units within the regulatory agency, shall have direct and prompt access to the governing body and top management in the event that any issue or concern needs to be raised in relation to quality regulations or RQMS.

Note 1: There are existing institutional mechanisms, such as, but not limited to, the Committee on Anti-Red Tape within regulatory agencies, that are tasked to ensure that the agency complies with the provisions of Republic Act 11032, its Implementing Rules and Regulations (IRR), and with the subsequent issuances by ARTA.

6. PLANNING

Abstract: This section highlights the importance of determining risks and opportunities that need to be addressed to provide confidence that the RQMS can attain its intended outcomes and achieve continual improvement.

6.1 Actions to address risks and opportunities

6.1.1 When planning for the institutionalization of the RQMS, the regulatory agency shall consider its internal and external context including the issues referred to in 4.1; the needs and expectations of the relevant stakeholders referred to in 4.2; and, the identified regulatory risks referred to in 4.5 which need to be addressed, to:

a. give assurance that the RQMS can achieve its intended results of delivering regulatory and development functions in the context of regulation-making;
b. promote integrity and ensure the fair administration of regulations;
c. prevent or reduce unnecessary regulatory burdens of the existing regulations;
d. ensure and enhance desirable effects of the proposed and existing regulations; and,
e. achieve improvement.

6.1.2 The regulatory agency shall plan:

a. actions to address regulatory risks and opportunities; and,
b. how to:
    1. integrate and implement appropriate actions to address the identified regulatory risks and opportunities into its RQMS processes; and,
    2. monitor the effectiveness and evaluate the impact of the proposed and existing regulations.

The actions taken to address regulatory risks and opportunities shall be proportionate to the potential impact of the regulations.

Note 1: Options to address risks can include: a) avoiding the risk; b) taking the risk in order to pursue an opportunity; c) eliminating the risk source; d) changing the likelihood or consequences; e) sharing the risk; and, f) retaining the risk by informed decision.

Note 2: Opportunities can lead to the amendment or formulation of new regulation, alternative options, and other desirable and viable possibilities to address the needs and expectations of the agency and its clients.

6.2 RQMS objectives and planning to achieve them

6.2.1 The regulatory agency shall establish objectives at relevant functions, levels, and processes for the RQMS.

The RQMS' objectives shall:

a. be consistent with the regulatory agency's quality policy;
b. be measurable;
c. take into account applicable factors referred in 4.1 (context of the regulatory agency), 4.2 (needs and expectations of the relevant stakeholders), and 4.5 (relevant risks and opportunities identified);
d. be monitored;
e. be communicated; and,

f. be updated and regularly reviewed.

The regulatory agency shall maintain documented information on the RQMS objectives.

6.2.2 When planning how to achieve its RQMS objectives, the regulatory agency shall determine:

a. what will be done;
b. what resources will be required;
c. who will be responsible;
d. when it will be completed; and,
e. how the results of the planning will be monitored and evaluated.

The regulatory agency shall retain documented information on the planning of the RQMS objectives.

6.3 Planning of changes

When the regulatory agency determines the need for changes to the RQMS, the changes shall be carried out in a planned manner (See 4.4 RQMS and its processes).

The regulatory agency shall consider:

a. the purpose of the changes and their potential consequences;
b. the integrity of the RQMS;
c. the availability of resources; and,
d. the allocation or reallocation of responsibilities and authorities.

Planned changes to the RQMS are subject to management review and approval before implementation.

7. STAKEHOLDER ENGAGEMENT

Abstract: This section highlights the importance of identifying and classifying stakeholders that are relevant to the mandate of the regulatory agency and following a process in engaging relevant stakeholders. It is important for the regulatory agency to work together with relevant stakeholders including other government entities to support regulatory cooperation at all levels of government.

7.1 General

The regulatory agency shall ensure that stakeholder engagement is integrated in the processes of the RQMS; such as in planning, operations, support, performance evaluation, and improvement.

Note: Stakeholder Engagement is an overarching source and basis of expectations, issues, policy alternatives, and decision-making which may impact both the regulatory agency and the regulated entities. It promotes accountability and transparency to the regulatory agency as well as demonstrates respect for the stakeholder interests.

7.2 Stakeholder Engagement Process

When engaging the relevant stakeholders, the regulatory agency shall:

7.2.1 Identify the objectives of the stakeholder engagement

The regulatory agency shall clearly state the objectives that it wants to achieve during the engagement.

The objectives shall also be properly and effectively communicated to the relevant stakeholders as this will guide the relevance of the responses that the relevant stakeholders will provide to the activity.

7.2.2 Identify the relevant stakeholders

The regulatory agency shall make sure that the impacts (positive and negative) of the policy/initiative have been identified, assessed and so that the relevant stakeholders that may be affected by these will be consulted. The regulatory agency shall also consider consulting the relevant stakeholders that will implement the policy/initiative and groups with the knowledge and expertise that may contribute toward polishing the strategies to be used to implement the policy/initiative.

7.2.3 Preparation of the Consultation Documented Information

The regulatory agency shall prepare documented information for the engagement activity that contains the rationale for doing such activity, the objective and expected output of the consultation, targeted stakeholders, and important assumptions about the topic. The documented information is expected to be free of jargons and easy to understand regardless of the educational background of the reader/stakeholder. The material should provide the relevant stakeholders a good background of the topic to be consulted.

7.2.4 Generate awareness on the engagement

Let the relevant stakeholders be aware that the agency is conducting an activity that intends to generate their comments and inputs. Among the ways to publicize the activities are, among others, placing announcements in relevant publications, notification through appropriate channels (e.g., the Philippine Business Regulations Information System), agency websites and social media pages, and directly contacting relevant stakeholders through phone, email or snail mail. This is also where the limitations are drawn. Stakeholder Engagement does not mean letting them decide what to do but is hearing them on what they have to say and consider them in the decision making as the agency tries to weigh in the

514 factors on what is best for the relevant stakeholders, the public while staying aligned to the mandate of
515 the regulatory agency.

516 ***7.2.5 Launch the engagement exercise***

517 The engagement shall reach as many concerned relevant stakeholders as possible. Regulatory agencies
518 may introduce platforms for the relevant stakeholders to provide their comments (e.g., online surveys
519 and polls, through the phone, mobile app, etc.). The most appropriate tools depend on the objectives of
520 the engagement exercise, the identified stakeholders, the nature of the initiative as well as required time
521 and resources.

522 The regulatory agency shall consider the following in the selection of the most appropriate tool:
523 a. proportionality in terms of the impact of the policy/initiative;
524 b. degree of interactivity needed (e.g. written consultation versus stakeholder events/ online
525 discussion fora/ other internet based tools);
526 c. accessibility considerations (e.g language, disability, etc.); and,
527 d. timing requirements.

528 ***7.2.6 Feedback***

529 The regulatory agency shall acknowledge the receipt of the comments given by the relevant
530 stakeholders through responses to communications, website postings, among others; and, to level
531 expectations, let them know the process that it will undergo and its limitations. The careful and
532 transparent treatment of contributions received establishes a good basis for preserving constructive
533 cooperation and fruitful relations with relevant stakeholders.

534 ***7.2.7 Processing***

535 The regulatory agency shall process and analyze the data and inputs gathered from relevant
536 stakeholders. Processing may be through triangulation using multiple methods, data sources, observers,
537 or theories in order to gain a more complete understanding of the stakeholder contributions being
538 analyzed.

539 ***7.2.8 Update on the progress***

540 The regulatory agency shall keep the relevant stakeholders updated, in a timely manner, on the progress
541 on the issue/decision or proposed policy. As part of the process, feedback of the progress of the
542 consultation in a timely manner shall be made available covering the results of the different engagement
543 activities completed.

544 ***7.2.9 Improvement on stakeholder engagement***

545 The regulatory agency shall identify and act on areas for improvement in stakeholder engagement. The
546 regulatory agency shall continually upgrade on the latest methodology so that relevant stakeholders are
547 updated with the regulatory agency's decision.

8. SUPPORT

8.1 Resources

8.1.1 General

The regulatory agency shall determine and provide the resources for the establishment, implementation, maintenance and continual improvement of the RQMS.

Note: Resources needed depend on factors such as the size of the regulatory agency, its mandate, the nature of its operations, and the integrity risks it could encounter. Examples of resources include the following:

a. Financial resources: There should be a sufficient budget included, for the RQMS to function effectively and,
b. Technological resources: There should be sufficient information and communications technology resources available for the RQMS to function effectively.

The regulatory agency shall consider:

a. the capabilities of, and constraints on, existing internal resources; and,
b. what needs to be obtained, if any, from external providers.

8.1.2 People

The regulatory agency shall determine and provide competent and qualified persons necessary for the effective implementation of its RQMS and for the operation and control of its processes. There should be sufficient personnel who are able to apply sufficient time to their relevant RQMS to function effectively.

8.1.3 Infrastructure

The regulatory agency shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve and maintain conformity with regulatory processes and regulations. Physical resources must be available in the regulatory agency for the RQMS to function effectively.

Note: Infrastructure can include:

a. Buildings and associated utilities;
b. Equipment, including hardware and software;
c. Transportation resources; and,
d. Information and communication technology.

8.1.4 Environment for the operation of processes

8.1.4.1 The regulatory agency shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve, maintain and improve conformity to regulatory objectives.

Note 1: A suitable environment can be a combination of human, physical and technological factors, such as:

a. Social (e.g., non-discriminatory, calm, non-confrontational);
b. Psychological (e.g., stress-reducing, burnout prevention, emotionally protective); and

c. Physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the regulations administered.

8.1.4.2 The regulatory agency shall also determine, provide and maintain the environment necessary to promote transparency and minimize unwarranted discretion while ensuring accountability under relevant rules and regulations.

8.1.5 Monitoring and measuring resources

8.1.5.1 General

The regulatory agency shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity with regulatory processes and regulations.

The regulatory agency shall ensure that the resources provided:

a. Are suitable for the specific type of monitoring and measurement activities being undertaken; and,
b. Are maintained to ensure their continuing suitability for their purpose.

The regulatory agency shall retain appropriate documented information as evidence of fitness for the purpose of monitoring and measurement.

8.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the regulatory agency to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a. Identified in order to determine their status;
b. Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to national or international measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; and
c. Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The regulatory agency shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose and shall take appropriate action as necessary.

8.1.6 Regulatory agency knowledge

The regulatory agency shall determine the knowledge necessary for the operation of its processes to achieve conformity with regulatory processes and regulations and regulatory administration.

This knowledge shall be maintained and be made available to stakeholders as may be appropriate.

When addressing changing needs and trends, the regulatory agency shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates including the impact, if any, on ongoing operations and personnel.

Note 1: Regulatory agency knowledge is generally gained by experience. It is information that is captured or documented, retained, used and shared to achieve the regulatory agency's objectives.

Note 2: Regulatory agency knowledge is based on:

a. Internal sources (e.g., intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience, the results of improvements in processes and services); and,
b. External sources (e.g., standards; academic research; conferences; gathering knowledge from clients or external providers).

8.2 Regulatory Competence

The regulatory agency shall determine the necessary skills and capabilities required to support effective regulatory policy-making and administration. Specifically, the regulatory agency shall:

a. Determine the necessary functional and behavioral competencies of person(s) doing work under its control that affects the performance and effectiveness of the RQMS;
b. Ensure that these persons are competent on the basis of appropriate education, training, or experience;
c. Determine training needs associated with its RQMS, including risk-based and integrity enhancement approaches;
d. Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; and,
e. Retain appropriate documented information as evidence of competence.

Note: Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of personnel; or the hiring or contracting of competent persons.

8.3 Awareness

The regulatory agency shall ensure that persons doing work under the regulatory agency's control are aware of:

a. The regulatory policy and relevant regulatory objectives;
b. Their contribution to the effectiveness of the RQMS, including the benefits of improved performance; and,
c. The integrity management and risk-based policy and procedures, and their duty, responsibility, and accountability to comply.
d. The implications of not conforming with the RQMS requirements and the potential damage to them and the regulatory agency which can result from 'manifestation of integrity risks.'

Note: Manifestation of integrity risks can include bribery, conflict of interest, regulatory capture

The regulatory agency shall maintain and retain documented information on the training procedures, the content of the training, and when and to whom it was provided.

8.4 Communication

8.4.1 General

The regulatory agency shall determine the internal and external communications relevant to the RQMS, including:

a. On what it will communicate;
b. When to communicate;
c. With whom to communicate;
d. How to communicate;
e. Who will communicate;
f. The languages in which to communicate; and,
g. The effectiveness of the message and means of communications.

The regulatory agency shall retain documented information as evidence of its communications, as appropriate.

8.4.2 Internal communication

The regulatory agency shall:

e. Internally communicate information relevant to the RQMS among the various levels and functions of the regulatory agency, including changes to the RQMS, as appropriate; and,
f. Ensure its communication process(es) enable(s) personnel doing work under the regulatory agency's control to contribute to continual improvement.

8.4.3 External communication

The regulatory agency shall externally communicate information relevant to the RQMS to its relevant stakeholders, as established by the regulatory agency's communication process(es) and as required by its compliance obligations.

8.5 Documented information/regulatory instruments

8.5.1 General

The regulatory agency's RQMS shall include:

a. documented information required by this RQMS;
b. documented information determined by the regulatory agency as being necessary for the effectiveness of the RQMS, such as (but not limited to):
    - Documentary review procedures related to accreditation, permitting and licensing;
    - Determination of competency;
    - Inspection, testing, assessment and review methods and procedures;
    - Handling inspection items and samples;
    - Inspection records;
    - Inspection reports and certificates; and,
    - Complaint and appeals.
c. documented information on managing data and information gathered from regulated entities, it should be consistent with the regulatory agency's data protection policy.

Note: The extent of documented information for a RQMS can differ from one regulatory agency to another due to:

- The size of regulatory agency and its type of activities and processes;
- The need to demonstrate fulfillment of its compliance obligations;
- The complexity of processes and their interactions; and,
- The competence of persons doing work under the regulatory agency's control.

8.5.2 Creating and updating

When creating and updating documented information, the regulatory agency shall ensure appropriate:

a. Identification and description (e.g., a title, date, time, author, or reference number);
b. Format (e.g., language, software version, graphics) and media (e.g., paper, electronic); and,
c. Review and approval for suitability and adequacy.

8.5.3 Control of documented information/regulatory instruments

8.5.3.1 Documented information required by the RQMS and by this document shall be controlled to ensure:

a. It is available and suitable for use, where and when it is needed; and,
b. It is adequately protected (e.g., from loss of confidentiality, improper use, and loss of integrity).

8.5.3.2 For the control of documented information/regulatory instruments, the regulatory agency shall address the following activities, as applicable:

a. Distribution, access, retrieval and use;
b. Storage and preservation, including preservation of legibility;
c. Control of changes (e.g., version control); and,
d. Retention and disposition.

Documented information of external origin determined by the regulatory agency to be necessary for the planning and operation of the RQMS shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from alterations.

Note: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

9. OPERATIONS

Abstract: This section provides the framework for the regulatory agency's process of designing, monitoring and administration of regulatory processes and regulations. It defines the type and extent of control needed to ensure the regulatory agency's ability to consistently enforce regulation and its regulatory services and ensure regulatory quality.

9.1 Operational planning and control

The regulatory agency shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of regulations and/or regulatory services, and to implement the actions determined in Section 6.1 by:

a. establishing criteria for the processes and the acceptance of regulations and/or regulatory services;
b. implementing control of the processes in accordance with the criteria;
c. determining, maintaining and retaining documented information, to the extent necessary, to have confidence that the processes have been carried out as planned and to demonstrate the conformity of the regulations and/or regulatory services to applicable requirements; and,
d. the determination of resources needed to achieve conformity to the regulations and/or regulatory service requirements

The processes shall include specific controls referred to in 9.2 to 9.7

The output of this planning shall be suitable for the regulatory agency's operations.

The regulatory agency shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The regulatory agency shall ensure the outsourced processes are controlled (see 9.7).

9.2 Requirements for regulations and regulatory services

9.2.1 Client Communication

Communication with clients shall include:

a. providing information relating to the purpose and the requirements to comply with the regulation through consultation, among others;
b. handling enquiries and requests for regulatory services, including changes;
c. obtaining client feedback relating to regulatory processes and regulations, including client complaints through consultation, among others;
d. handling or controlling client property; and,
e. establishing specific requirements for contingency actions, when relevant.

9.2.2 Determining the process for preparation, compliance to, and review of new/existing regulatory processes and regulations

When deciding to regulate, the regulatory agency shall:

a. determine how the regulation and /or regulatory services are prepared, adopted, and reviewed to ensure effectiveness;

b. assess the need and impact on society of the regulations through the use of Regulatory Impact Assessment (RIA);
c. ensure the greatest degree of compliance through the identification of compliance strategies;
d. ensure consultation with all parties affected by the regulation; and,
e. conduct fitness check to the technical regulations.

9.2.2.1 The regulatory agency shall retain documented information, as applicable, on the results of the review.

9.2.3 Changes to requirements for regulations and regulatory services

The regulatory agency shall ensure that relevant documented information is amended, and that relevant stakeholders are made aware of the changed requirements, when the requirements for regulations and/or regulatory services are changed.

9.3 Design and development of regulations and regulatory services

9.3.1 General

The regulatory agency shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent administration and enforcement of regulations.

9.3.2 Design and development of regulations and regulatory services

In determining the stages and controls for the design and development of regulations and its services, the regulatory agency shall consider:

a. The nature, duration and complexity of regulatory design and development activities;
b. The required process stages, including applicable regulatory design and development reviews;
c. The required regulatory design and development verification and/or validation activities;
d. The responsibilities, accountabilities, and authorities involved in the regulatory design and development process;
e. The internal and external resource needs for the design and development of regulations and regulatory services;
f. The need to control interfaces between or among people involved in the regulatory design and development process;
g. The need for involvement of citizens, clients and other relevant stakeholders in the regulatory design and development process;
h. The requirements for subsequent implementation and enforcement of regulations and regulatory services, including the identification of measures to encourage preventive and corrective measures in the course of implementing and enforcing regulatory processes and regulations;
i. The level of control expected for the regulatory design and development process by regulated entities and other relevant stakeholders; and,
j. The documented information needed to be retained, to demonstrate that regulatory design and development requirements have been met.

Note 1: Verification can be the results of an inspection or other forms of determination and methods to identify fulfillment of requirements such as performing calculations, reviewing of documents, use of checklist, visual checks, etc.

Note 2: Validation can be the results of testing or other forms of determination under a real or simulated condition such as testing, simulation, reviewing of documents, alternative calculations, etc.

9.3.3 Design and development inputs

9.3.3.1 The regulatory agency shall determine the requirements essential for the specific types of regulatory processes and regulations to be designed and developed. The regulatory agency shall consider:

a. Functional and performance requirements;
b. Information derived from previous similar design and development activities;
c. Applicable client, stakeholder, contract/agreement, and statutory and regulatory processes and regulations;
d. Standards or codes of practice that the regulatory agency has committed to implement; and,
e. Results of risk analysis and/or potential consequences of failure due to the nature of regulatory processes and regulations.

9.3.3.2 The regulatory agency shall also determine the critical inputs (statistics, related issuances, etc.) to adequately perform regulatory impact assessment (see Figure 2). The regulatory agency shall consider:

a. Result of proportionality analysis;
b. Result of the analysis of regulatory problem;
c. Identification of regulatory alternatives;
d. Result of impact assessment;
    i. Results of cost analysis
    ii. Results of benefit analysis
    iii. Results of alternative approaches
    iv. Results of lenses
    v. Comparison of costs and benefits
e. Result of implementation, monitoring, and evaluation planning; and,
f. Result of consultation.

Note: Consultation may be conducted at any stage of the RIA process, as deemed necessary and beneficial to all relevant stakeholders.

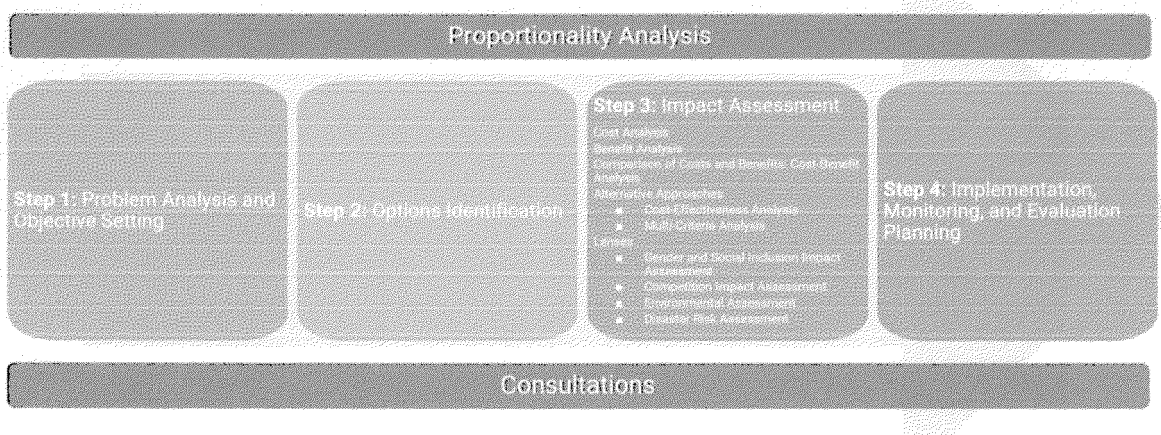

Figure 2: Regulatory Impact Assessment (RIA) Steps

Inputs shall be adequate, complete and unambiguous for the design and development purposes.

Conflicting design and development inputs shall be resolved by relevant authorities of the regulatory agency.

The regulatory agency shall retain documented information on regulatory design and development inputs.

9.3.4 Design and development controls

The regulatory agency shall apply controls to the regulatory design and development process to ensure that:

a. The results to be achieved are clearly identified and defined;
b. Reviews are conducted to evaluate the ability of the results of regulatory design and development outputs meet the input requirements;
c. Verification activities are conducted to ensure that the resulting regulations meet the requirements for the specified application or regulatory objective;
d. Any necessary actions are taken on problems determined during the reviews, or verification and validation activities; and,
e. Documented information of these activities are retained.

Note: Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as it is suitable for the regulations of the regulatory agency.

9.3.5 Design and development outputs

The regulatory agency shall ensure that regulatory design and development outputs:

a. Meet the regulatory input requirements determined in 9.3.3;
b. Are adequate for the subsequent processes for the administration and enforcement of regulations;
c. Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; and,
d. Specify the characteristics of the regulations that are essential for their intended purpose and their fair and proper administration and enforcement.

The regulatory agency shall retain documented information on regulatory design and development outputs.

9.3.6 Design and development changes

The regulatory agency shall identify, review and control changes made during, or subsequent to, the design and development of regulatory processes and regulations, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The regulatory agency shall retain documented information on:
a. Design and development changes;
b. The results of reviews;
c. The authorization of the changes; and,
d. The actions taken to prevent adverse impacts.

9.4 Administration and Enforcement of regulatory processes and regulations

9.4.1 Control of enforcement and inspections

The regulatory agency shall perform administration and enforcement of regulatory processes and regulations under controlled conditions.

Controlled conditions shall include, as applicable:

a. The availability of documented information that defines the results to be achieved;
b. Characteristics of the regulatory processes and regulations to be provided or the activities to be performed;
c. The availability and use of suitable monitoring and measuring resources and adequate information to effectively assess application for regulatory compliance;
d. The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for regulations and/or regulatory services have been met;
e. The use of suitable infrastructure and environment for the operation of processes;
f. The appointment of competent persons, including any required qualification;
g. The validation, and/or periodic revalidation as necessary, of the ability to achieve planned results of the processes for administration and enforcement of regulatory processes and regulations where the resulting output cannot be verified by subsequent monitoring or measurement;
h. The implementation of actions to prevent human error and to ensure fair and ethical practices; and,
i. The implementation of release, delivery and post-delivery activities.

9.4.2 Identification and Traceability of regulation and its regulatory services

The regulatory agency shall use suitable means to identify outputs of the regulation and its regulatory services when it is necessary to ensure the conformity of the regulation and its regulatory services.

The regulatory agency shall identify the status of the outputs of the regulation and its regulatory services with respect to monitoring and measurement requirements throughout the process of the regulation and its regulatory services.

The regulatory agency shall control the unique identification of the outputs of the regulation and its regulatory services when traceability is a requirement and shall retain documented information necessary to enable traceability.

9.4.3 Property belonging to clients or external providers

The regulatory agency shall exercise care with property belonging to the clients or external providers while it is under the regulatory agency's control or being used by the regulatory agency.

The regulatory agency shall identify, verify, protect and safeguard clients, or external providers' property provided for use or incorporation into the regulatory processes and regulations.

When the property of a citizen, client or external provider is lost, damaged or otherwise found to be unsuitable for use, the regulatory agency shall report this immediately to the citizen, client or external provider and retain documented information on what has occurred.

Note: A client or external provider's property can include infrastructure, materials, tools and equipment, premises, intellectual property, personal data and information.

9.4.4 Preservation of regulation and its regulatory services

The regulatory agency shall preserve the outputs during the process of development of the regulations up to the provision of its regulatory services to the extent necessary to ensure conformity to requirements.

Note: Preservation could include identification, handling and management of communication and information.

9.4.5 Post-delivery Activities for regulation and regulatory services

The regulatory agency shall meet requirements for post-delivery activities associated with the regulation and its regulatory services.

In determining the extent of post-delivery activities that are required, the regulatory agency/organization shall consider:

a. statutory and regulatory requirements;
b. the potential undesired consequences associated with the regulation and its regulatory services;
c. the nature, use and intended validity of the regulation and its regulatory services;
d. citizens and regulated entities' requirements; and,
e. feedback from citizens and regulated entities.

Note: Post-delivery activities can include handling of complaints such as actions against violations related to warranty provisions and regulatory obligations such as rectification and/or supplemental services or technical assistance, etc.

9.4.6 Control of changes in the regulation and its regulatory services

The regulatory agency shall review and control changes for regulation and its regulatory services to the extent necessary to ensure continuing conformity with regulatory requirements.

The regulatory agency shall retain documented information describing the results of the review of changes, the relevant authorities authorizing the change, and any necessary actions arising from the review.

9.4.7 Release of regulatory services

The regulatory agency shall implement planned arrangements, at appropriate stages, to verify that the regulatory requirements have been met.

The release of regulatory services to the regulated entity shall not proceed until planned arrangement for the regulation and its regulatory services have been satisfactorily completed, unless otherwise approved by relevant authorities and, as applicable, by the regulated entity.

The regulatory agency shall retain documented information on the release of regulatory services to the regulated entity to evidence conformity with the acceptance criteria and traceability to the person(s) authorizing the release.

9.4.8 Management of regulatory performance

The regulatory agency shall implement procedures and controls with respect to:

a. Outcomes and administrative priorities;
b. Risk-based approach to administration and enforcement of regulation and/regulatory services;
c. Effective stakeholder relationships;
d. Effective information management;
e. Transparency and accountability; and,
f. Ensuring regulatory quality and coherence.

9.4.9 Monitoring compliance

The regulatory agency shall implement procedures and controls with respect to:

a. Adopting and promoting a risk-based approach to compliance monitoring;
b. Implementing the strategy; and,
c. Evaluating monitoring strategy and effectiveness of compliance activities.

9.4.10 Managing Nonconforming outputs of the regulation and its regulatory services

9.4.10.1 The regulatory agency shall ensure that outputs of the regulations and regulatory services that do not conform to applicable requirements are identified, and controlled to prevent unnecessary difficulties and/or regulatory burden.

The regulatory agency shall determine and retain documented information that defines/states the regulatory objective or purpose of regulations and regulatory services. This shall also apply to nonconforming products and services detected after administration and enforcement of regulatory processes and regulations.

9.4.10.2 The regulatory agency shall implement procedures and controls by:

a. Developing a set of graduated responses to address nonconformities;
b. Applying correction to the nonconformity and corrective action to the detected causes of the nonconformity.
c. Addressing risks; and,
d. Remediation and monitoring regulated entities' return to compliance.

9.4.10.3 The regulatory agency shall maintain and retain documented information that:
a. Describe the nonconformity;
b. Describe the actions taken;
c. Describe any concession obtained; and,
d. Identify the authority deciding the action in respect of the nonconformity.

Note: Concession is generally limited to the delivery of regulations and regulatory services that have nonconforming characteristics within the specified limits and is generally given for a limited quantity of regulatory services or a period of time, and for a specific use.

9.5 Addressing adverse events or regulatory failure

The regulatory agency shall ensure that procedures and controls are in place in case of adverse events or regulatory failure. The regulatory agency shall determine that the following processes are implemented:

a. Event notification or identification;
b. Risk-based management;
c. Response management;
d. Management of actions to address the effect of the event or regulatory failure; and,
e. Post-implementation review.

Note: Actions to adverse events or regulatory failure can include the communication of the status and results of action to the client, citizen and relevant stakeholders.

9.6 Implementation of integrity controls

The regulatory agency shall implement integrity procedures and controls over regulatory agencies under its control as well as its regulated entities.

Note: Integrity procedures and controls to be applied by the regulatory agency are guided by the requirements of COA and ARTA.

9.7 Control of externally provided regulatory processes and regulatory services

9.7.1 General

The regulatory agency shall ensure that externally provided regulatory processes and services conform to requirements.

The regulatory agency shall determine the controls to be applied to externally provided regulatory processes and services when:

a. Services from qualified/accredited external providers are intended for incorporation into the regulatory agency's own regulations and/or regulatory services;
b. Services and products are provided directly to the client(s) by external providers on behalf of the regulatory agency; and,
c. A process, or part of a process, is provided by an external provider as a result of a decision by the regulatory agency.

The regulatory agency shall determine and apply criteria for the selection, monitoring, and evaluation of performance, and re-evaluation of external providers, based on their ability to provide processes, products and/or services in accordance with applicable requirements. The regulatory agency shall retain documented information of these activities and any necessary actions arising from the evaluations.

9.7.2 Type and extent of control

The regulatory agency shall ensure that externally provided processes, products and services do not adversely affect the regulatory agency's ability to consistently perform the administration and enforcement of the regulation and its regulatory services to the regulated entities.

The regulatory agency shall:

a. Ensure that externally provided processes remain within the control of its RQMS;
b. Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
c. Take into consideration:
    1. The potential impact of the externally provided regulatory processes and services on the regulatory agency's ability to consistently meet client and statutory and regulatory requirements;

2. The effectiveness of the controls applied by the external provider; and,

e. Determine the verification, or the other activities, necessary to ensure that the externally provided processes and services meet requirements.

9.7.3 Information for external providers

The regulatory agency shall ensure the adequacy of requirements prior to their communication to the external provider.

The regulatory agency shall communicate to external providers its requirements for:

a. The processes and services to be provided;
b. The approval of services, methods, processes and equipment, including release of regulatory services;
c. Competence, including any required qualification of persons;
d. The external providers' interactions with the regulatory agency, citizen and regulated entity;
e. Control and monitoring of the external providers' performance to be applied by the regulatory agency; and,
f. Verification or validation activities that the regulatory agency, or its client, intends to perform at the external providers' premises.

10. PERFORMANCE EVALUATION

Abstract: This clause represents the 'check' step in the PDCA cycle and emphasizes the need for monitoring, measurement analysis, internal audits, performance evaluation through citizen and client satisfaction, and management reviews to determine if the regulatory agency's RQMS is functioning properly.

10.1 Monitoring, measurement analysis, and evaluation of RQMS performance

The regulatory agency shall retain appropriate documented information as evidence of the monitoring, measurement, analysis, and evaluation results.

10.1.1 General

The regulatory agency shall determine:

a. what needs to be monitored and measured;
b. who is responsible for monitoring and measuring;
c. when the monitoring and measuring shall be performed;
d. when the results from monitoring and evaluated measurement shall be analyzed;
e. to whom and how such information shall be reported.
f. the methods for monitoring, measurement, analysis, and evaluation, as applicable, to ensure valid results; and,
g. the criteria against which the regulatory agency will evaluate its performance, and appropriate indicators.

10.1.2 Evaluating the effectiveness of the regulation

The regulatory agency shall monitor clients' perceptions of the degree to which their needs and expectations have been fulfilled. The regulatory agency shall determine the methods for obtaining, monitoring and reviewing this information

NOTE: Examples of monitoring client perceptions can include client surveys, client feedback, feedback from newspaper or broadcast and/or other social media platforms.

10.1.3 Analyses and Evaluation

The Regulatory Agency shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

1. Compliance to regulatory processes and services;
2. Degree of Client satisfaction;
3. Performance of external providers;
4. The effectiveness of actions taken to address risks and opportunities;
5. Performance and effectiveness of the RQMS; and,
6. The need for improvements to RQMS.

10.2 Internal audit

The regulatory agency shall conduct internal audits at planned intervals to provide information on whether the RQMS Standard:

a. conforms to:

1. the regulatory agency's own requirements for its RQMS;
2. integrity controls; and,
3. the requirements of this RQMS Standard.

b. is effectively implemented and maintained.

The regulatory agency shall

a. plan, establish, implement, and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the regulatory agency, and the results of the previous audits;
b. define the audit criteria and its scope for each audit;
c. select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
d. ensure that the results of the audit are reported, in a timely manner, to relevant management;
e. maintain and retain appropriate documented information as evidence of the implementation of the audit program and the audit results; and,
f. take appropriate correction and corrective actions without undue delay.

10.3 Management review

The regulatory agency shall periodically review regulations to ensure conformance to policy objectives and planned outcomes. Such reviews shall determine the effectiveness of the regulations being administered and the efficiency and effectiveness of the regulatory agency's administration.

10.3.1 General

Top management shall review the regulatory agency's RQMS, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the regulatory agency.

10.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

a. the status of actions from previous management reviews;
b. information on the performance and effectiveness of the RQMS, including;
    1. Data on regulatory compliance;
    2. Monitoring report on the accrued benefits as stated in conducted RIA for enforced regulations;
    3. Trends in Client satisfaction and feedback from relevant stakeholders;
    4. Trends in the performance of external providers;
    5. The effectiveness of actions taken to address risks and opportunities;
    6. The results of review of results of regulatory risk analysis;
    7. Results of periodic review;
c. changes in:
    1. external and internal issues that are relevant to the RQMS;
    2. information on the performance and effectiveness of the RQMS, including trends in:
        -the needs and expectations of relevant stakeholders including their feedback;
        -nonconformities and corrective actions;
        -monitoring and measurement results;
        - audit results;
        -integrity results;
        -risks and opportunities;
        -extent to which the policy/regulatory objectives have been met; and,

-process performance and conformity of regulatory services;

d. the adequacy of resources;
e. relevant communications from relevant stakeholders, including complaints; and,
f. opportunities for continual improvement.

10.3.3 Management review outputs

The outputs of the management review shall include:

a. conclusions on the continuing suitability, adequacy and effectiveness of the RQMS;
b. conclusions on the alignment with the strategic direction of the regulatory agency as part of the management review outputs;
c. decisions and actions related to continual improvement;
d. decisions and actions related to any need for changes to the RQMS, including resources;
e. decisions and actions, if needed, when objectives have not been achieved;
f. opportunities to improve integration of RQMS with other management systems, if needed; and,
g. any implications for the strategic direction and thrust of the regulatory agency.

The regulatory agency shall retain documented information as evidence of the results of management reviews.

11. IMPROVEMENT

Abstract: This section highlights the need for the regulatory agency to identify/correct nonconformities and also determine/identify opportunities for improvement.

11.1 General

The regulatory agency shall determine (see 11.1, 11.2 and 11.3) and select opportunities for improvement and implement any required actions to achieve the intended outcomes of the regulation and sustain its RQMS including meeting client requirements and enhancing client satisfaction.

These shall include:

a. improving regulations and regulatory management to achieve the intended regulatory outcomes and meet requirements as well as to address future needs and expectations;
b. correcting, preventing or reducing unnecessary regulatory burdens; and,
c. improving regulatory performance and effectiveness of the RQMS.

Note: Examples of improvement can include continual improvement, breakthrough change, and innovation.

11.2 Nonconformity and corrective action

11.2.1 When nonconformity occurs, including any arising from complaints, the regulatory agency shall:

a. respond promptly to the nonconformity and, as applicable:
    1. take action to control and correct it;
    2. deal with the consequences, including mitigating adverse impacts;
b. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order for it not to recur or occur elsewhere, by:
    1. reviewing and analyzing the nonconformity;
    2. determining the causes of the nonconformity;
    3. determining if similar nonconformities exist, or could potentially occur;
c. implement any action needed;
d. review the effectiveness of any corrective action taken;
e. update risks and opportunities as a result of the application of corrective actions; and,
f. make changes to the RQMS, if necessary.

11.2.2 The regulatory agency shall retain documented information as evidence of:

a. the nature of the nonconformities and any subsequent actions taken; and,
b. the results of any corrective action.

11.3 Continual improvement

The regulatory agency shall continually improve the suitability, adequacy and effectiveness of the RQMS to improve regulatory performance.

The regulatory agency shall consider the results of the analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities to be addressed as part of continual improvement.