

[Quality Management Organization Standard]

[Core]

1 General Provisions

1.1 Purpose

The purpose of this standard is to ensure effective implementation of quality management practices by defining basic requirements for organizations, responsibility, authority, and quality assurance system in performing quality management activities.

1.2 Scope

This standard applies to a facility's organizations which engage in quality management activities.

1.3 Definitions of Terms

Definitions of terms used in this standard are as follows:

No.	Term	Definition
1	Responsibility	Task to be carried out based on the duties assigned to each position. <ul style="list-style-type: none">• Responsibility in performing duties.• Responsibility for achievements against assigned duties.• Responsibility for reporting or communicating the results achieved in performing assigned duties.
2	Authority	Scope of discretion in exercising rights in performing assigned duties. <ul style="list-style-type: none">• Authority to formulate a plan and seek approval of the plan.• Authority to deliberate.• Authority to make decisions at one's own discretion.• Authority to instruct or direct immediate subordinates, and have them follow.• Authority to give advice or suggestions based on one's own professional or technical expertise.• Authority to request a report or information.
3	Quality Representative	A person with responsibility and authority as top quality executive of a facility.
4	Management Representative	A person with responsibility and authority to establish a quality management system of a facility and to verify that the system is properly implemented and maintained.

2 Organization

2.1 Formulation of Organization

- 2.1.1 Organizations performing quality management activities of a facility are listed in the organization chart developed and issued by the head of the facility.
- 2.1.2 Each head of an organization (hereinafter referred to as “organization head”) listed in the organization chart developed and issued by the head of its own facility forms its business units taking into account compliance with legal requirements.
- 2.1.3 The business units are established systematically and operated with channels in issuing instructions and orders identified.

2.2 Management of Business Units

The organization head continuously and properly monitors fulfillment of roles, responsibilities and authority of business units under its own management in such a manner that the business units are effectively operated and managed.

3 Responsibility and Authority

3.1 Responsibility and Authority

- 3.1.1 The organization head assigns roles and responsibilities to each position as duties per business unit and supervise those to whom duties are assigned.
- 3.1.2 The organization head defines and clarifies responsibilities for each position, delegates authority necessary to complete assigned duties, and supervise those to whom authority is given.
- 3.1.3 The quality representative of the facility is a person nominated and appointed as a quality representative by the head of the facility.
- 3.1.4 The head of the facility delegates authority to the quality representative as necessary to implement duties as quality representative of the facility, and ensures the duties are implemented.
- 3.1.5 The quality representative appoints a management representative who is responsible for the quality management system of the facility, or may serve as management representative of the facility itself.

3.2 Delegation of Authority

- 3.2.1 If any person with responsibilities and authority delegates any part of its roles and responsibilities for operational or other reasons, delegate the authority necessary to perform the roles and responsibilities with duties being delegated clearly identified.
- 3.2.2 The person with delegated duties as set out under paragraph 3.2.1., reports progress of the duties in a timely manner.

4 Quality Assurance System

4.1 Quality Assurance System

- 4.1.1 The principles of the quality assurance system of a facility are described in “Quality Assurance System” of “Quality Manual”.
- 4.1.2 The organization head clarifies the quality assurance system of its own for improving operational effectiveness.

5 Supplementary Provision

5.1 Application of the Standard

Matters relating to establishment, revision and implementation of this standard are outlined in G-HQS [Quality Management Standards Control Standard]

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