Internal Quality Auditor Training Standard

[Core]

1 General Provisions

1.1 Purpose

The purpose of this standard is to train Internal Quality Auditors to implement smooth and effective internal quality audits by defining basic requirements for training.

1.2 Scope

This standard applies to the training of Internal Quality Auditors who implement internal quality audits of quality management systems.

1.3 Definitions and Terms

Definitions of terms used in this standard are as follows:

| No. | Term | Definition | |
|-----|--------------------------|--|--|
| 1 | Internal Quality Auditor | A person who is appointed for the purpose of performing internal quality audits. | |

2 System

2.1 Management System

The management system for internal quality auditor trainings is described in Attachment 1 "Internal Quality Audit Training System".

2.2 Roles and Responsibilities

Roles of lead administrator, administrative section and instructors are as follows:

- 2.2.1 The lead administrator for internal quality auditor training is the Quality Representative. The quality representative appoints those who are qualified as Internal Quality Auditor.
- 2.2.2 The administrative section for internal quality auditor training is the administration section in charge of holding internal quality audits. It conducts training based on training plan and manages training records for each internal quality auditor in a log.

2.2.3 Instructors, who conduct in-house training for Internal Quality Auditors, implement training as stipulated in paragraph 3.3.

Instructors are those selected by the administrative section and approved by the Quality Representative.

3 Procedure

3.1 Planning the Training

The head of administrative section (including those who have been delegated by the head of administrative section; same for hereinafter) verifies records of the current year's training and draws up an internal quality audit training plan for the following year. They will then submit the plan to related sections after obtaining approval from the Quality Representative.

If, however, the training for the following year is found unnecessary from the current year's result, training may be cancelled.

3.2 Appointment of Internal Quality Auditor Candidate

In response to the request from administrative section, the head of sections concerned appoint candidates, who satisfy the following criteria as Internal Quality Auditor:

- (1) Understands quality control.
- (2) Understands the overall operations at its own facility.
- (3) Understands the general outline of quality assurance system of its own facility.
- (4) Has the ability to demonstrate leadership roles including organizational management and adequate correspondence.

3.3 Implementation of Training

- 3.3.1 The administrative section implements training for candidates for Internal Quality Auditors (hereinafter referred to as "initial training") based on internal quality auditor training plan.
- 3.3.2 Contents of initial training are as follows:

No. 1, 3 and 4 below can be replaced by seminars provided by external agencies.

| No. | Contents | | | |
|-----|--|--|--|--|
| 1 | Outline and requirements of ISO 9000 series | | | |
| 2 | Outline of G-HQS and facility quality control criteria. | | | |
| 3 | Outline of quality management system audit (including purpose and types, etc.) | | | |
| 4 | Implementation and techniques of internal quality audit. | | | |
| 5 | Examples trainings from internal quality audit findings | | | |
| 6 | Any other contents approved by the head of administrative section. | | | |

3.3.3 The administrative section keeps tracks of initial training records of each Internal Quality

Auditor candidate.

3.4 Appointment of Internal Quality Auditor

An Internal Quality Auditor candidate is qualified to become an auditor when the Quality Representative determines the candidate is able to perform audits and meets the following requirements:

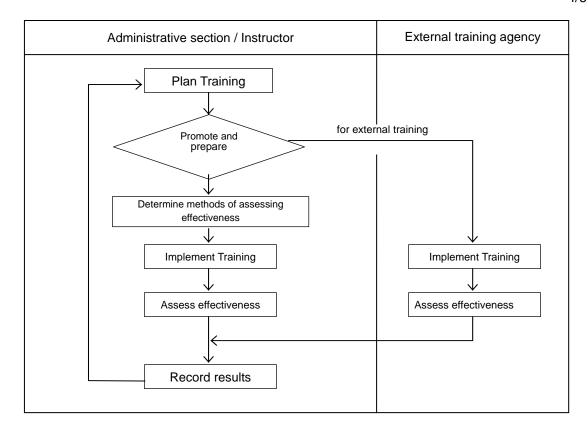
- (1) He/she has completed training listed in paragraph 3.3.
- (2) He/she satisfies either one or both of the following at least twice.
 - Experienced in participating in past internal quality audits as an assistant to Internal Quality Auditor, or being directly involved in an audit as an auditee.
 - Experienced in being directly involved in a review for ISO 9000 series examined by a third party.

3.5 Implementation of Supplementary Training

- 3.5.1 In order to ensure proper implementation of operation and to improve auditor competence, the administrative section conducts supplementary training sessions that covers the following:
 - (1) Outline and requirements of ISO 9000 series (including updates and revisions)
 - (2) Outline of G-HQS and facility quality control standards (including new establishment and updates).
 - (3) Example training from internal quality audit findings.
 - (4) Any other training sessions that have been approved by the head of the main audit section.
- 3.5.2 The administrative section manages supplementary training of Internal Quality Auditor.

3.6 Assessing the effectiveness of Internal Quality Audit Training

- 3.6.1 The administrative section assesses the effectiveness of the implemented training.
- 3.6.2 Methods of assessing the effectiveness of implemented training are by the followings:
 - (1) Employing methods such as comprehension exams or mock audits that show a clear indication of whether or not the training results have reached a target level.
 - (2) Timing of initiating assessment is determined based on the training objectives.
 - (3) Results of assessment will be used as a reference for upcoming trainings.
 - (4) The administrative section manages the assessed effectiveness results.
 - (5) The basic system of assessing effectiveness is as follows:



3.7 Management of Internal Quality Auditor

The administrative section keeps track of each internal quality auditor in a log that manages the following:

- (1) Name and affiliated organization.
- (2) Date of appointment as an internal quality auditor.
- (3) History of training (contents, date and duration of initial training sessions, results of assessed effectiveness, records with internal quality audits or with an examining third party agency and contents, date and duration of supplementary training sessions).
- (4) History of implemented audit
- (5) History of modified affiliated organization

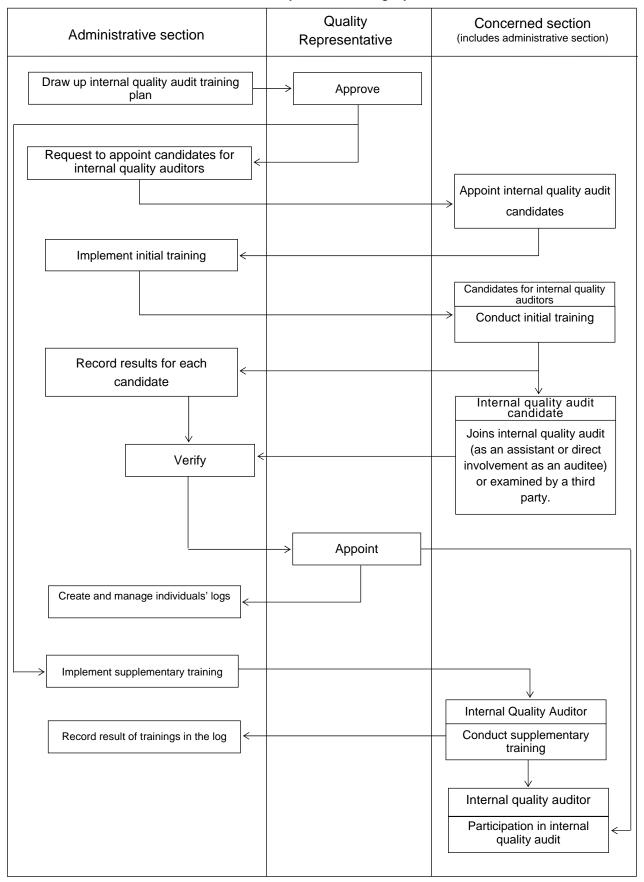
Supplementary Provision

4.1 Application of the Standard

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

Attachment -1 (related to paragraph 2.1)

Internal Quality Audit Training System



Establishment and Revision

| Date of Establishment, Revision or Enactment (MM/DD/YYYY) | | | Description (MM/DD/YYYY) | Approved by: |
|---|------------------|--------------------------|--|--------------------------------------|
| 0 | Estab. Enact. | 04/02/2010 05/01/2010 | First issue. This document becomes effective as of 05/01/2010. | T. Sonoda (Signed on original) |
| 1 | Estab. Enact. | 12/26/2011 01/01/2012 | Revised to correct wording. | T. Sonoda (Signed on original) |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |