



# Scheme Requirements

ISO 9001 – Quality Management Systems – Requirements



## Name of Standards

The name of these standards is ISO 9001 – Quality Management System Requirements (referenced as ISO 9001).

The following is a summary of aspects of the ISO 9001 assessment process as detailed in requirements set by ISO in the International Standard ISO/IEC 17021 - Conformity assessment – Requirements For Bodies Providing Audit And Certification Of Management Systems and supporting requirements from the International Accreditation Forum [in particular (but not limited to): IAF: MD 1 - IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling and IAF: MD 5 - IAF Mandatory Document for Duration of QMS and EMS Audits]. Further details are available from HDAA on request.

## Process Requirements

The assessment includes an assessment of the ISO 9001 quality management standard selected by the client that HDAA is accredited to assess.

To enable the certification assessment to occur the client will at a minimum provide access to the following information:

- a) a copy of its documented policies and procedures relating to its services
- b) evidence of its internal processes.

Assessments shall be planned allow enough time and resources for the assessment activities to fully comply with the requirements of ISO 17021 and the relevant and required IAF mandatory documents.

The stage 1 assessment shall be performed to:

- a) assess the management system documentation
- b) evaluate the primary location and site-specific conditions and to determine the preparedness for the Stage 2 assessment review (including understanding of the requirements of the standard)
- c) confirming the scope of the management system, processes, and location(s)
- d) review resources for Stage 2 assessment and agree the details of the Stage 2 assessment
- e) gain an understanding of the management system and operations
- f) evaluate if internal assessments and management review are planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the Stage 2 assessment.

The Stage 1 assessment shall be documented and communicated, including identification of any areas of concern that could be classified as nonconformity during the Stage 2 assessment. The interval between Stage 1 and Stage 2 assessments will consider the need to resolve areas of concern identified at the stage 1 assessment. The Stage 1 assessment may result in the need to revise the arrangements for Stage 2

## Assessment planning and coordination

HDAA shall begin assessment planning as early as reasonably possible. HDAA will aim to provide the client with adequate time to arrange for meetings (e.g., with Top Management) and to prepare for the assessment.

As part of the assessment planning, HDAA shall inform the client of the names of the members of the assessment team who will carry out the assessment and this shall occur with enough notice to allow the client to appeal against the appointment of any team member.

HDAA shall take into consideration any information provided to us prior to and during an assessment, including any concerns may require special attention during the assessment.

An assessment plan will be developed that includes or refers to the following:

- a) the assessment objectives
- b) the assessment criteria
- c) the assessment scope, including identification of the organisational and functional units or processes to be assessed
- d) the dates and sites where the on-site assessment activities are to be conducted
- e) the expected time and duration of on-site assessment activities
- f) the roles and responsibilities of the assessment team.

The assessment includes an initial certification assessment which is completed in two stages as well as periodic maintenance and recertification assessments of the client's policies, procedures, and practices relating to its services. At the Stage 1 assessment, HDAA shall confirm among other things that relevant internal audits are completed and that management review occurs.

The Stage 1 assessment will generally occur on-site but may occur as a documentation review off-site. The Stage 2 assessment shall take place at the client's site(s) and or outlet(s) as applicable. During the Stage 2 assessment, HDAA shall at least evaluate information and evidence of conformity with all Stage 2 requirements.

At on-site assessments the assessment team shall hold a closing meeting with the client's management and any people who wish to be involved, prior to concluding the on-site assessment.

## Assessment report

Reports will have the (at a minimum) following content:

- a) the number of sites and a list of the sites sampled
- b) the number of staff as advised by the client
- c) a summary of evidence
- d) a separate summary of key findings
- e) any continuous improvement actions
- f) a comparison of performance across different sites and geographic locations where this is relevant
- g) the client's certification status.

Where applicable, reports of maintenance, recertification, or follow-up assessments shall also document close out of each improvement action revealed previously.

HDAA will use its best endeavour to provide the client with a written report, including agreed proposed improvement action (if applicable) within 20 working days of the completion of the assessment, even if the decision is not to certify.

Where the client does not meet the requirements of ISO 9001, HDAA will provide a description of the improvement action and confirm that the improvement action must be resolved within 6 months of written notification of the improvement action (usually the draft report).

Clients that meet certification requirements will be certified to the ISO 9001.

In the instance of a major nonconformity that does not place a person at risk of significant harm the client is required to provide evidence of a corrective action plan within 5 working days of the date of issue of the major nonconformity, and close out shall normally require a follow-up visit by HDAA within three months. For a certified service provider, failure to close out a major nonconformity within six months shall result in automatic suspension of certification. In the instance of a nonconformity:

- a) the nonconformity must be closed out before certification or recertification
- b) for a certified client, the nonconformity must be closed out within six months of the date of issue.

HDAA shall conduct at least annual maintenance assessments, to ensure that the client continues to meet the requirements of the standards during the service agreement cycle. HDAA may conduct an out of cycle assessment at any time if so determined.

HDAA will reassess certification to ISO 9001 every three years.

## Assessment Sampling

Sampling will be determined based on the Service Description provided and the Scheme sampling rules. It is important that the Service Description directly aligns with scope of services to be assessed, as services not included in the Service Description cannot be included in the scope of certification.

Sampling will include sites and or outlets representing service activities and the complexity of the activities undertaken. HDAA will consider the client's structure when determining the sample.

A condition of sampling is that HDAA shall apply sampling in line with the IAF and ISO 17021 requirements as follows:

- a) All the sites must be substantially of the same kind and must be operated to similar methods and procedures
- b) Business is conducted through linked processes in different locations
- c) The management system is centrally controlled and subject to central management review
- d) All the relevant sites (including the central office) are subject to the organisation's internal audit program have been internally audited prior to the start of the stage 1 audit
- e) The central office has established a management system in accordance with ISO 9001
- f) The ability to collect and analyse data from all sites initiate organisational change for the following is in place:
  - system documentation and system changes
  - management review
  - complaints
  - evaluation of corrective actions
  - internal audit planning and evaluation of the results
  - different legal requirements.

The sample may be extended where site sampling is inappropriate to gain enough confidence in the effectiveness of the management system under audit. Extensions to sampling may occur because of:

- a) the scope of activities based on an assessment of risks or complexity associated the activity
- b) size of sites eligible for multi-site audit
- c) variations in the local implementation of the management system such as the need to address different activities or different contractual or regulatory systems
- d) use of temporary sites.

At least 25% of the sample will be selected at random. The minimum number of non-central office sites and or outlets to be visited per assessment is:

- a) initial certification assessment: not less than the square root of the total number of full-time and part-time sites and/or outlets ( $y=\sqrt{x}$ ), rounded to the upper whole number
- b) maintenance assessment: not less than the square root of the total number of full-time and part-time sites and/or outlets with 0.6 as a coefficient ( $y=0.6\sqrt{x}$ ), rounded to the upper whole number

- c) re-certification assessment: the size of the sample is the same as for an initial assessment or where the management system has proved to be effective over a period of three years, the size of the sample may be reduced by a factor 0.8, i.e.:  $(y=0.8\sqrt{x})$ , rounded to the upper whole number.

In all assessments, the central office shall be visited at least once, in addition to the sites and/or outlets sampled. Where there is a hierarchical system of branches (e.g. head (central) office, national offices, regional offices, local branches), the sampling model for initial audit as defined above applies to each level.

The size of the sample shall be increased where there are special circumstances such as might apply to any of the site and/or outlet selection criteria.

Where a certified client with multiple sites and or outlets wishes to include new sites and or outlets in the scope of its certification, the client will provide enough information to demonstrate that its policies, procedures and practices have been fully implemented at the new sites to meet the requirements of the standards. Each new group of sites is considered as an independent set to determine the sample size, with those chosen for assessment to be included during the next scheduled assessment activity. After inclusion of the new group in the certificate, the new sites will be cumulated to the previous ones for determining the sample size for future maintenance or recertification audits.

## Information and Communication Technology Auditing (MD4:2018)

HDAA is authorised to complete assessments to MD4:2018 which enables a greater use of information and communication technologies (ICT) in the auditing activities. ICT is the use of technology for gathering, storing, retrieving, processing, analysing and transmitting information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others. The use of ICT may be appropriate for auditing both locally and remotely. The use of ICT during audits may include but is not limited to:

- Meetings; by means of teleconference facilities, including audio, video and data sharing,
- Audit of documents and records by means of remote access, either synchronously (in real time) or asynchronously (when applicable),
- Recording of information and evidence by means of still video, video or audio recordings,
- Providing visual/audio access to remote or potentially hazardous locations.

The use of ICT shall be mutually agreed upon with you by HDAA prior to the audit commencing. HDAA and the service provider shall ensure that security and confidentiality is maintained throughout audit activities and activity is in accordance with information security and data protection measures and regulations before ICT is used for audit purposes. In the event systems to be used, security and or data protection measures are not able to be fulfilled or agreed the assessment will be conducted on site.

## Assessment Duration

HDAA will identify the assessment duration for the Stage 1 and Stage 2 initial assessment, maintenance assessments, and re-certification assessments (this information is contained in this Service Agreement). The duration includes the duration of an initial assessment (stage 1 + stage 2) as relevant.

Duration is based on the effective number of personnel, then adjusted for the significant factors applying to the client and attributing to each factor an additive or subtractive weighting to modify the base figure. The basis for the establishment of assessment duration including adjustments will be recorded.

The number of days per site, including the central office, will be calculated for each site using the most recently published IAF document for the calculation of assessment days. Reductions may be applied and reasons for the justification of such reductions shall be documented by HDAA. The total time is the total sum of the time spent at each site plus the central office and will not be less than that which would have been calculated for the size and complexity of the operation if all the work had been undertaken at a single site.