

Great Western Registrar LLC



ISO Client Program and Audit Manual

Based on the requirements of ISO17021 and Associated
ANAB Accreditation Rules

04/02/2018

Created and Approved by: Karey S. Yates, President/Owner

Uncontrolled if printed

Section 1

Application Review & Quote Process:

Potential Client submits application for initial certification or transfer of current certification.

A Client workbook is created according to work instruction found in the work book.

Application review is conducted including determination of audit time (see below). Criteria for acceptance of application is found on the application review form.

- a. If transfer, the review is to include, contacting current CB for certificate information and conduct desk review and determine the time needed to conduct an on-site visit of the client's site if necessary.

Process for Determination of client audit time:

GWR will conduct an initial review of a potential client application and provide a baseline of audit time. This baseline will be used for quoting purposes only, and may be revised during subsequent scheduling activities, should GWR receive a contract from the client.

GWR will determine the time needed to plan and accomplish a complete and effective audit of a client's management system.

GWR will consider the following, at a minimum, when determining audit time.

- What standard the client has implemented.
- Complexity of the client and its management system.
- Language used by the client.
- Regulatory or Technology context.
- If the client outsources any activities included in the client scope of management system.
- Results of any prior audits.
- Size of sites and number of sites (Must have a multi-site form completed).
- Geographical locations and logistics complexity.
- The risks associated with products, processes, services or other activities of the organization.
- Combined or integration of systems.
- Length of time the client has been in business.

Additional factors may be used in calculation of audit time based on application and CIU review. (see scheduling of audits in subsequent sections of this manual)

The starting point for determining audit time shall be found in IAF MD5.

Audit duration may be increased or decreased appropriately, based on risk analysis. GWR will not reduce audit time by more than 30% from the required MD5 time.

Each client file will be assigned a workbook that contains all of the calculations for determining audit time and will be kept current throughout the life of the contract with GWR.

A copy of the agreement and applicable workbook pages are sent to the potential client.

During the application review (or CIU review), if it is determined that the scope of the client QMS includes more than one site, GWR will determine the sampling to be used. GWR will develop a sampling program to ensure proper audit of the management system over the 3-year certification cycle. GWR will record the rationale for the sampling plan.

Legally Enforceable Agreements:

Great Western will have, on file, legally enforceable agreements with each client. This agreement outlines the responsibilities for GWR and its certification activities and the client responsibilities for maintaining a quality management system that meets the requirements of GWR and the standards for which they are seeking certification.

Process for Transfer of a Certification:

GWR conducts transfer process according to IAF MD5.

Receive signed contract and update the client workbook with appropriate information.

Send signed contract to document control. Document control personnel sets up a new client folder on the GWR server and sends welcome email.

GWR management conducts a desk review and completes a Transfer Review report. If management concludes that certification can be transferred, and an on-site review is necessary, the visit will be scheduled. The appropriate program manager is notified to schedule the next audit according to program. It is not required that a Stage1/Stage2 audit be conducted for ISO9001 transfers at re-certification.

GWR personnel create a certificate and sends to the new client.
The appropriate audit is then scheduled according to certification program.

Section 2

Scheduling:

Initial Certification Process:

Receive signed contract.

Send signed contract to document control. Document control personnel sets up a new client folder on the GWR server and sends welcome email.

Send CIU (client information update) form to client and request any updates to client information or implemented QMS including identification of QMS processes.

Receive completed CIU from client and update the client register and client workbook with current information

Determine if calculated audit time is correct in the client workbook. Make changes, if necessary. Identify by initialing and date of the changes.

Inform ISO scheduling personnel that the client is ready to have an audit scheduled.

Scheduling personnel selects a competent audit team and communicates to the auditor/s regarding anticipated audit timeframes.

Scheduling personnel creates an NOA (Notification of Audit) and sends to client for acceptance.

Once client accepts the audit, the scheduling personnel creates an NOA (Notification of Assignment) and sends to auditor/s. Scheduling personnel also sends the client audit program document.

- a. If the auditor identifies a conflict of interest, the auditor is expected to contact GWR immediately so other auditor arrangements can be made. GWR cannot certify clients where in which consulting activities have taken place within 2 years by the assigned auditor.
- b. It is acceptable for the Stage 1 and Stage 2 audits to be scheduled during this activity.

- c. GWR personnel are required to inform the client of the potential risks associated with scheduling the Stage 1 and Stage 2 audits in conjunction with each other.

Once the audit team has been assigned, the identified Lead auditor is to create and send the Stage 1 audit plan to the client.

Audit team conducts the Stage 1 audit and sends reports to GWR.

Client resolves areas of concern (if applicable).

Lead Auditor and client confirm dates for the Stage 2 audit. This confirmation is to include the confirmation of audit team if it will differ from the Stage 1 audit team.

Lead Auditor creates Stage 2 audit plan utilizing the client audit program and sends to the client no less than 2 weeks prior to the scheduled audit.

Audit team conducts Stage 2 audit and sends reports to GWR.

Client resolves any NCR activity and Lead Auditor verifies implementation of corrective action.

GWR personnel conduct a pre-review of the audit records to ensure required reports are available for certification decision makers.

If there are missing records, pre-review personnel will contact the Lead auditor for the appropriate records.

Pre-Review personnel then sends reports to a competent certification decision maker (Review Board Members) to conduct a final review for certification decision.

If the review board member concludes that certification be granted, a certificate of registration is created with justification of scope and issued to the client.

Audit program document and workbooks are updated appropriately.

If the review board member concludes that certification cannot be granted, the member informs the President of Great Western Registrar to conduct an additional investigation on why the certificate cannot be granted. It is the responsibility of the President to inform the client that certification cannot be granted.

Surveillance Process:

GWR scheduling personnel are to determine client on-site audit cycle as appropriate.

- a. The 1st surveillance of client certified management system is to be conducted prior to the 1-year date of initial certification decision.
- b. All other surveillance activity is to be conducted once per year, except in re-certification years.

Send CIU (Client Information Update) form to client and request any updates to client information or implemented QMS.

Receive completed CIU from client and update their workbook with current information.

Determine if calculated audit time is correct in the client workbook. Make changes, if necessary. Identify review by initialing and date of the changes.

Inform ISO scheduling personnel that the client is ready to have an audit scheduled.

Scheduling personnel selects a competent audit team and communicates to the auditors regarding anticipated audit timeframes.

Scheduling personnel creates an NOA (Notification of Audit) and sends to client for acceptance.

Once client accepts the audit, the scheduling personnel creates an NOA (Notification of Assignment) and sends to auditor/s. Scheduling personnel also sends the client audit program document. If the auditor identifies a conflict of interest, the auditor is expected to contact GWR immediately so other auditor arrangements can be made.

Lead Auditor creates the surveillance audit plan using client audit program and sends to client no less than 2 weeks prior to the scheduled audit.

Audit team conducts the surveillance audit and sends audit reports to GWR.

Client resolves any NCR activity and Lead Auditor verifies implementation of corrective action or accepts corrective action plan.

GWR personnel conduct a pre-review of the audit records to ensure required reports are available for certification decision makers.

If there are missing records, pre-review personnel contact the Lead auditor for the appropriate records.

If Major NCRs are recorded, Pre-Review personnel sends audit reports/records to competent certification decision makers (Review Board Members) to conduct a final review.

No Certification decision is made during this type of review; however, the review is conducted to identify changes and provide a review of the work of the audit team.

Once the review member completes the appropriate review, they inform GWR personnel whether or not the cert is to be maintained.

Re-Certification Process:

The same process for Surveillance activities is to be followed for maintaining certification with the exception of the following:

1. Lead Auditor is to verify the implementation of any corrective action identified as Major NCR.
2. Recertification Review is conducted and if NCR trends are identified, the president of GWR and the lead auditor are made aware for planning purposes.
3. Review Board members are to make a certification decision.

If the review board member concludes that certification be re-issued/renewed, a certificate of registration is created and sent to the client utilizing the existing certification cycle.

Should an ISO certification expire due to NCR activity, the President will suspend the certification for no more than 6 months, or as appropriate, so that effective implementation of corrective action can be verified. If the verification provides evidence that the QMS is in good standing, the certification will be restored. Should this occur, the previous certification cycle expiry will remain in effect.

Section 3 :

Suspension or Withdrawal of Client Certification:

It may, at times, become necessary to either suspend or withdraw a client certification. Below are the conditions that may require suspension or withdrawal.

Suspension:

- Client fails to provide corrective action evidence within agreed time frame.
- Client management system persistently fails to meet certification requirements.
- Client does not allow surveillance or re-certification audits to be conducted at the required frequencies including non-response to requested information for scheduling.
- Client fails to pay for services according to terms of contract (the Accounting Manager has the authority to suspend the certification based on financial justification).
- Client requests voluntary suspension.
- Client intentionally misrepresents their certification.

In most cases, the suspension will remain in effect until the situation that resulted in suspension has been resolved. In cases where the client has not met their financial responsibility the suspension will remain in effect for 60 days. If the client has not fulfilled their financial responsibility after 60 days, the cert may be withdrawn. If the suspension is due to the client QMS not meeting requirements or the client has not scheduled their required audit the suspension will remain in effect for no more than 180 days. Client cert can be re-instated and brought into good standing once applicable fees have been paid and the situation has been resolved.

Withdrawal of certification:

- Client has not met the requirements for re-instatement of certification.

(Due to ALL standards being process based, GWR does not have a process for reduction of scope).

The President, Operations Manager and/or Strategy and Planning manager have the authority to make decisions regarding suspension or withdrawal.

Should these decisions indicate a potential risk to impartiality or conflict of interest, GWR management may enlist the input of the AIB (Advisory Impartiality Board).

Section 4

Use of Marks and Certificates:

(GWR is under agreement with the ANAB for the use of their mark in association with the GWR mark and those requirements are included in GWR policy).

All clients with GWR certificated management systems are authorized to use the GWR registered mark to identify and communicate the certification.

The following rules apply for the use of the GWR mark:

- The mark must be traceable back to Great Western Registrar LLC.
- There shall be no ambiguity, in the mark or accompanying text, as to what has been certified and which certification body has granted the certification.
- The mark shall not be used on product nor product packaging, nor in any other way denoting product conformity.
- The mark cannot be used or applied by certified clients on laboratory tests, calibration or inspection reports or certificates.

Statements of certification may be used by certified clients in the following ways:

- On product packaging that can be removed without the product disintegrating or being damaged (typed labels or id plates are considered part of the product).
- Statements shall in no way imply that the product is certified.
- Statement shall include reference to identification of the certified client, type of management system and applicable standard and the name Great Western Registrar LLC.

The contract between GWR and its clients is the agreement that is legally enforceable that provides for the control of the policies and instructions contained in this document.

It is required that clients:

- Conform to the requirements of this document when making reference to certification status in all communication media.
- Do not make or permit any misleading statements regarding certification.
- Upon withdrawal of certification, discontinue its use of all advertising matter that contains reference to certification.
- Do not imply that the certification applies to activities and sites that are outside the scope of certification.
- Do not use its certification in such a manner that would bring GWR and /or the certified system into disrepute and lose public trust.

Should GWR management or GWR representatives identify non-conformance with regard to the above policies, GWR reserves the right to take appropriate action, including requests for corrective action.