

Great Western Registrar LLC



AS&D Client Program and Audit Manual

Based on ISO 17021, AS9104, Associated ANAB
Accreditation Rules & ICOP Resolutions

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

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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 according to 17021-1 requirements and download appropriate documents and certificate from OASIS.
- b. Review of OASIS database to determine current certification status.
- c. Determine the time needed to conduct an on-site visit of the client site.

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 site/s 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 (Must have an integration form completed).
- 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 AS9104.

Audit duration may be increased appropriately, based on risk analysis. The base audit time found in AS9104 will not be decreased.

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 structure of the organization utilizing the definitions provided in AS9104.

Total audit time will be calculated based on structure and time requirements given in AS9104. If it is determined that the client has a multi-site structure the following will apply:

Annual Surveillance – Years 1 and 2

Year 1 – Central function and approximately 50% of sites. Year 2 – Central function and remaining sites not audited in Year 1.

Recertification – Year 3

Central function and all sites.

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 managements system that meets the requirements of GWR and the standards for which they are seeking certification.

Process for Transfer of a Certification:

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. This review is to include a review of the client OASIS information. A feedback to the previous CB is put into OASIS requesting information on the validity of the certification and will include a plan for transfer from the previous CB.

Should information be provided that the certification can be transferred, the appropriate scheduling manager is informed to schedule an on-site visit (special audit) by a competent auditor. The completed transfer audit is recorded in OASIS and GWR personnel create a certificate and send to the new client. OASIS database is updated to move the client certification to GWR.

The appropriate audit is then scheduled according to certification cycle.

Should the auditor provide justification that the certification cannot be accepted and transferred to GWR, the President of GWR is notified and it is the responsibility of the President to contact the client.

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.

A CIU (Client Information Update) form is sent to client to request any updates to client information or implemented QMS. This includes a request for the client to identify their QMS processes.

GWR OASIS administrator or designee logs into OASIS and requests an OIN for the new client. GWR OASIS administrator or designee sends client an e-mail through OASIS requesting a supplier admin be assigned.

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 by initialing and date of the changes.

Inform AS&D 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. Once a date is agreed upon by the auditor and client, scheduling personnel creates an NOA (Notification of Audit) and sends to client for formal acceptance. This is considered the binding agreement for audit.

Once client accepts the audit, the scheduling personnel creates an NOA (Notification of Assignment) and sends to auditor/s. Once the assigned auditor signs the NOA, it is a binding agreement. Scheduling personnel also sends the client audit program document to the Lead Auditor during this activity.

- a. If any 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 by the auditor within 2 years.
- b. It is acceptable for the Stage 1 and Stage 2 audits to be scheduled during this activity, however, these audits cannot be scheduled on back to back days.
- 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.
- d. GWR personnel sets up the audit in OASIS according to instruction.

Once the audit team has been assigned, the identified Lead auditor is to create and send the Stage 1 audit plan to the client no less than 2 weeks prior to the scheduled audit.

Audit team conducts the Stage 1 audit and records the appropriate information on AS9101 Form 1 in OASIS and according to the GWR Process Manual for Conducting Audits and Maintaining Competencies and inputs the audit information into OASIS.

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 according to Process Manual for Conducting Audits and Maintaining Competencies and utilizing the required and appropriate AS9101 forms and updates OASIS with the audit information.

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

GWR personnel conducts an Admin Review of the audit records in OASIS to ensure required reports are available for certification decision makers.

If there are missing records or information, the Admin Reviewer rejects the audit.

Once all report issues are resolved, personnel then verifies the report and a Technical Reviewer is notified that a certification decision is needed. A competent certification decision maker (Review Board Members) conducts a final review for certification decision.

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

The required audit reports and certificate/s are accepted on OASIS and the cert is published.

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. The President is to conduct an additional investigation as to the reasons 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 at least once per year except in re-certification years.

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

GWR receives completed CIU from client and updates the client 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 AS&D 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.

GWR personnel sets up the audit in OASIS according to instructions.

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 enters the appropriate audit information in OASIS.

Client and Lead Auditor resolve any NCR activity within the required timelines and Lead Auditor verifies implementation of corrective action or accepts corrective action plan.

GWR personnel conducts an admin review of the audit records to ensure required reports are available.

If there are missing or incomplete records, review personnel will reject the audit in OASIS. The Lead auditor updates and/or revises the records in OASIS. Once the Admin Reviewer verifies and accepts the audit, a Technical Reviewer is notified. The Technical Reviewer (Review Board Member) is to either conduct a final review in the case where Major NCRs were identified, or to close the audit if a positive recommendation is made with no follow up activity required.

No Certification decision is made during this type of review, however, the review is conducted to identify changes to client program. This review also provides record of evaluation of auditor performance and provides a review of the work of the audit team.

Re-Certification Process:

A re-certification audit is conducted on-site for maintaining certification. The same process for surveillance audits is to be conducted 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 required 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.

The OASIS documents are downloaded to client file for the control of the records after each audit.

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. The suspension will be identified in OASIS. 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, Accounting 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.