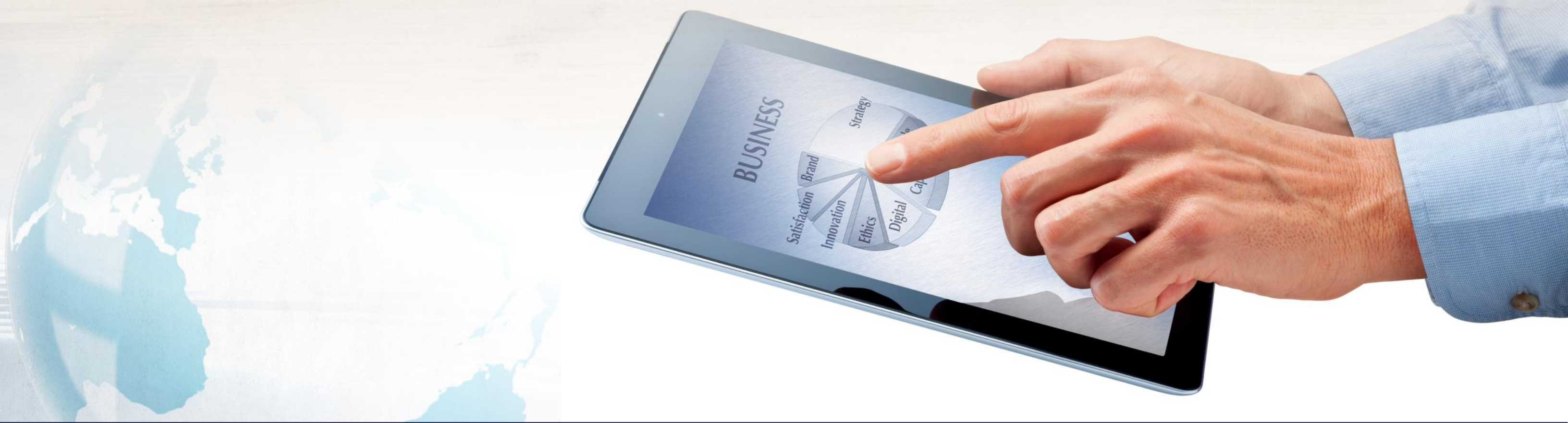
PERRY JOHNSON REGISTRARS, INC.



What To Expect During Your Stage 1 Audit

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Why Are Audits Split Into Two Stages?

A common question from those who are new to certification or are undergoing audits for the first time is why – "*why* does it take two separate audits to determine if an organization meets certification requirements?" The answer is surprisingly straightforward – Certification Bodies (CBs) such as Perry Johnson Registrars are held accountable to a number of requirements from the entities that accredit their services. Among these is the ISO 17021-1:2015, which states (in part): "The initial certification audit of a management system shall be conducted in two stages: stage 1 and stage 2."

While not initially apparent, the intent behind this approach is to ensure that only companies that are well and truly prepared for a certification assessment will be permitted to complete the "full" audit. Essentially, the stage 1 audit is a sort of preliminary check to make sure all systems are "go" for stage 2, which gets down to the final checks on requirements.

Setting the Stage: Before the Stage 1 Audit

Before an audit can be scheduled, let alone performed, an organization must be a contracted client. At PJR, we use a series of scope-specific applications called "F-1" to facilitate this process in an effective way. The F-1 series documents are complex. This is intentional, as their intent to gather as much information as possible about the organization seeking certification. The more information we gather up-front, the more competitive and accurate the quote for services will be without the need for later adjustments. Additionally, candid and honest responses can help clue PJR staff in to any unique or particularly challenging circumstances that might arise during the audit process.

Once all the documentation has been completed and the organization has signed a contract with PJR, an Audit Program Coordinator (aka a "scheduler") will be assigned. This individual will serve as the direct point of contact for any and all needs providing "cradle to grave client management." Your scheduler will assign an auditor that is qualified in your standard and is competent in the specific technical needs of your business. With PJR's diverse network of auditors located globally, the scheduler will also take into account geographical proximity of the auditor to minimize travel costs as much as possible.

During this pre-audit preparatory stage, clients are required to complete an attestation of readiness form – also referred to as an F-108 – this form confirms that each client has completed or prepared the following prior to their Stage 1:

- A scope analysis of the QMS, including consideration of exclusions and exemptions
- A firm determination of processes and an assessment of their interaction(s)
- A list of process measurables (KPIs) and associated performance data
- Internal audit documentation
- Internal auditor competency records
- Management review records
- Consideration (and control) of outsourced processes
- Consideration (and control) of statutory and regulatory requirements
- Required documentation (may vary by standard)

“Front to Back” – Analyzing the Stage 1 Audit

Once all of the documentation and preliminary legwork is complete, then what?

The typical stage 1 audit is conducted on-site at a client facility. Some exceptions can be made for very simplistic ISO 9001 management systems to be conducted off-site, but the savings in travel costs may be outweighed by the additional on-site time that would then occur in the stage 2.

Prior to the auditor's arrival, they should contact management at least one to two weeks in advance. The auditor should also provide an Audit Plan, which is crucial to review well before the auditor's arrival. If there is incorrect information reflected on the Audit Plan, the auditor should be made aware so that adjustments can be made. This could include a change in the number of employees or number of shifts. To avoid any confusion, changes of this nature should be conveyed to your scheduler in advance so they can be taken into account.

Once the auditor arrives on-site, the audit will begin with an opening meeting. This is the perfect time to confirm any last-minute changes in details and to inform the auditor of any critical information, such as personnel availability for interview purposes, or whether any other visitors are expected. From there, the audit will proceed according to the plan laid out by the auditor. During their execution of the audit, the auditor will use a PJR stage 1 workbook document to record the results of their assessments. This workbook offers two options for each item the auditor reviews – “conforms” or “concern.”

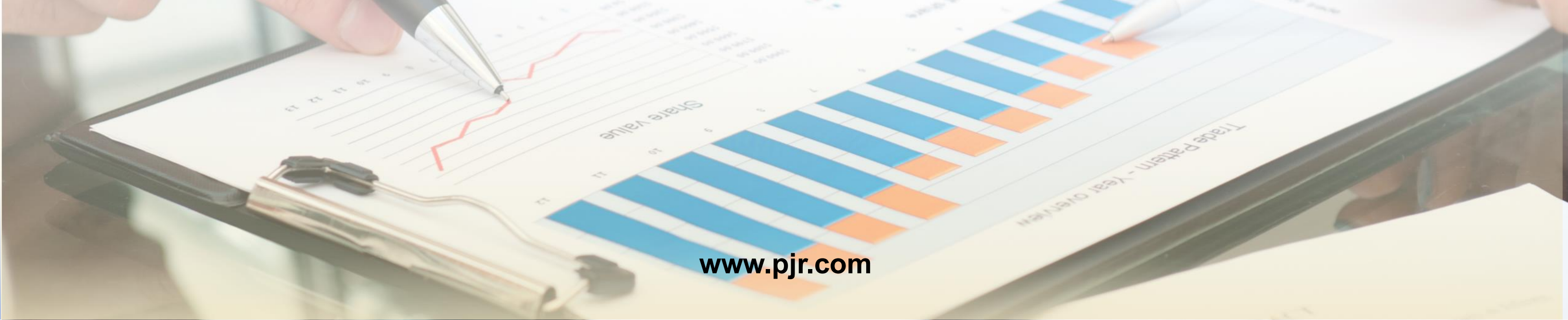
After the review of the required materials has been completed, the auditor will take some time to prepare their audit report. While there are no nonconformances issued during a stage 1 audit, the items marked as “concerns” in the audit workbook will be taken into account for the auditor to determine one of three possible outcomes during the closing meeting: recommending a continuance to stage 2 with no concerns, recommending a continuance with concerns, or recommending a repeat of the stage 1 audit.

The client will be asked to sign an acknowledgment of the stage 1 results and will receive a copy of the completed audit report. (Due to travel circumstances and other possible delays, it may take a few days before the finalized audit report is received.)

Pump the Brakes: What Can Put a Hold on the Stage 2 Audit?

There are a number of factors that may cause the auditor to recommend that the stage 2 not proceed. These include:

- Inadequate or inappropriate interaction of processes
  - As the interaction of processes is the single best indicator of an organization's understanding of ISO 9001's process approach, having an inadequate or unoriginal document should be avoided
- Inadequate process measurables (KPIs) or process performance data
- Inadequate internal audits
- Inadequate internal auditor competency records
- Inadequate management review



An important factor to note regarding the conclusions of a stage 1 audit report is that all such documents are subject to review by a member of the PJR executive committee to ensure that the decisions reached are appropriate and fair. Clients are also encouraged to issue a dispute or appeal of an auditor's decision if they disagree with the assessment. (This process is outlined in PJR's PRO-10, available at **www.pjr.com**).

If, at the end of the day, the recommendation handed down is to repeat the stage 1 audit, then the organization should work from the audit report provided to shore up the issues raised. Continued contact with the auditor and PJR's Executive Committee is permitted to discuss remedial actions and to ensure that clients are on the right path; PJR *wants* you to succeed!

Stage 2 Readiness

If the recommendation derived from the audit report is to continue on to stage 2, then congratulations! In the ideal situation, there will be approximately 60-75 days between the stage 1 and stage 2 audits. This will allow for proper preparation and the addressing of any concerns noted in the stage 1 audit report; back-to-back audits are discouraged, and almost always lead to trouble. Failure to address items raised as a concern in the stage 1 audit may result in those items being noted as nonconformities during the stage 2.

The care taken during the pre-stage 1 phase is crucial to the ultimate success of both stages. PJR encourages all clients to take full advantage of the support offered by your scheduler, auditor(s), and the PJR Executive Committee to help make the entire process as seamless as possible.

If you have lingering questions about the audit process, or would like more information in general, visit our website at **www.pjr.com** or call us at **(248) 358-3388**.