ISO 9001 assessment process

CLIENT INFORMATION NOTE

Overview

This Client Information Note explains the main stages of our process for ISO 9001 Quality Management System assessment and certification.

The assessment process normally includes two visits to your site before we can recommend approval. We call these two visits:

- Stage 1 (document review and planning visit), and
- Stage 2 (initial assessment).

Once we have issued your approval certificate, we will carry out surveillance visits to maintain your approval.

At each visit, our assessors will be open and helpful, and will follow a practical approach. In this way we believe that we add value to the assessment process.

Before we visit, we will discuss and agree with you the visit dates, start and finish times, the assessment team members, how long the visit will last, and which parts of your business we will visit.

Visits will be carried out and reported in your national language unless otherwise agreed.

Stage 1 - Document review and planning visit

Purpose of the visit

We do this visit to:

- find out whether the management system processes and documents required by the standard are in place and put into practice so that a meaningful Stage 2 assessment can take place
- collect information about your company's organisation, processes and activities so that we can develop a plan for the Stage 2 assessment
- confirm the scope, assessment team requirements and timing for the Stage 2 assessment
- answer any questions you may have about our service.

The visit will identify any weaknesses or omissions in your system that may need to be put right before the Stage 2 assessment.

Carrying out the visit

The visit (which usually lasts for two days), starts with an opening meeting. The assessor will explain to your management team how we carry out assessments, and you will be able to introduce your company. The assessor will agree a plan for the visit with you.

The assessor will then:

- review the design and documentation of your system against the assessment standard, the context of the organisation and proposed assessment scope
- produce a detailed plan for the Stage 2 visit, and
- produce a focused report which describes both positive findings, and any issues requiring your attention before the Stage 2 visit takes place. The report will identify the grading of these issues as if they were findings outstanding at the end of the Stage 2 visit.

The assessor will usually need to review:

- Context of the organisation
- Interested parties
- quality policy

Main roles and responsibilities

- site activities – the assessor will, as appropriate, tour the site to:
- confirm the processes and products covered by the quality management system
- identify current controls and performance, and
- get to know the site ready for the Stage 2 assessment.
- The context of the organisation – Including identification of the needs and expectations of interested parties

- Identification of Risks and Opportunities
- product and statutory requirements - the assessor will look at any product and service performance or standards compliance claims that you make in your company literature. He or she will also check that any statutory or regulatory requirements, relating to your product or service, have been addressed in your management system.
- continual improvement – the assessor will look at your quality objectives and assess whether they reflect policy. He or she will also make sure that:
- objectives are established and support continual improvement
- appropriate planning has been conducted to achieve objectives, and
- measuring and reporting on performance have been dealt with.
- operational arrangements – the assessor will check that procedures are established to control your management system processes.
- monitoring and measurement – the assessor will check that an appropriate range of measuring and monitoring processes, including internal audit programmes and reports are in place to measure quality performance. He or she will also review how the management system performs, including your progress against objectives.

The assessor will then look at whether procedures are in place to deal with the following requirements:

- management system documentation
- corrective action
- internal audits – including a review of the audit programme and reports
- management review process – including a review of records.

The visit ends with a closing meeting to present the Stage 1 report and agree the next stage of the assessment process, including any health and safety, security and administrative issues.

The documentation reviewed during the Stage 1 visit will be used at future visits as a baseline. However, you should continue to amend system documents as a result of internal improvement activities. At each visit we will need to identify the changes between the latest issue and the baseline.

Stage 2 - Initial Assessment

Purpose of the visit

During this visit the assessor will focus on how your management system has been put into practice. The Stage 2 visit aims to confirm that:

- your policies, objectives, programmes and procedures are effectively put into practice
- there is a planned and systematic approach for improvement
- you are managing your processes effectively
- the management system meets all the requirements of the assessment standard.

Carrying out the visit

The assessment follows the plan prepared during the Stage 1 visit. Members of the assessment team will visit areas with guides who can witness the findings and help the assessment. The Stage 2 assessment usually includes a meeting with the representative of senior management with overall responsibility for the management system.

Our assessment team will report, as a minimum, any findings related to:

- follow-up of findings from the Stage 1 visit
- activities, products and services identified in the agreed scope for the assessment
- how effective the management system is at achieving your organisation's policy including continual improvement and customer satisfaction
- putting into practice the arrangements to manage the product realisation processes
- progress to achieve objectives through the management programme
- putting into practice the systems required by the management system, and maintaining appropriate records
- putting into practice monitoring and
- measurement arrangements to assess how the management system performs and whether objectives are achieved
- how involved in and committed to the management system, the senior management are, and
- how effective the internal audit, corrective action and management review processes are.

The assessment team will hold review meetings with you each day to discuss any findings. Appropriate staff should be present to confirm that you accept these findings. Please see below in the 'Reporting' section for how we define findings. We finalise the grade of findings at the end of the visit.

The visit ends with a closing meeting to present a summary of the findings, and to agree the next stage of the assessment process. The assessor will give a complete report to your management representative. If we have not reported any Major Nonconformities, and you have informed the assessor of your proposed corrective action for any Minor Nonconformities, the assessor will recommend approval to the assessment standard (although this depends on an independent technical review by our office.) However, if any Major Nonconformities have been reported, we will delay approval and carry out a follow up assessment to review corrective actions. Our team leader will agree with you the arrangements for this.

Surveillance visits

Purpose of the visit

Once we have certified your management system, we will begin a programme of surveillance visits (which normally take place at a minimum of every twelve months). The surveillance visits aim to confirm that the approved management system continues to:

- be maintained
- be in operation, and
- deliver continual improvements.

We also consider the implications of changes to the system. Such changes may have been carried out as a result of

changes in your activities, products or services.

We will then consider whether you continue to meet certification requirements.

Carrying out the visit

The scope of the surveillance visits will normally have been agreed with you at your previous visit. We will confirm the details with you at an opening meeting.

The areas chosen will allow us to review:

- Changes to the context of the organisation
- internal audit and management review processes
- progress in meeting quality objectives and improvement targets
- corrective action processes including customer satisfaction and complaints
- changes to your system and the effectiveness of their implementation, and
- how you manage changes relating to responsibilities and the authority of main staff.

We will also review any outstanding findings and how you use LRQA and accreditation logos.

If we report any Minor Nonconformities during a visit we will normally follow them up during your next visit, otherwise we will make arrangements with you for the follow up.

If we report a Major Nonconformity during a surveillance visit, we will arrange a special surveillance visit to follow up the necessary corrective action (normally within three months). This is the first phase of our suspension and withdrawal of approval process.

At the closing meeting, our assessor will report on the current visit and agree with you the theme for the next visit. If any Major Nonconformities have been reported, the assessor will also agree arrangements for follow-up of actions you will take.

Certificate renewal

Planning for the certificate renewal

We conduct certificate renewals on a three-yearly basis, planned at the previous surveillance visit and agreed with you.

The certificate renewal planning process contains three steps: Review, Preview and Planning.

Review

This step includes the review of past performance such as:

- trend information on complaints and other performance indicators
- system documentation improvements
- Improvement Log projects
- lessons learned from audits
- trends in our findings.

Based on this review of past performance, our assessor will identify any potential risks in the present management system regarding successful implementation of the strategies and objectives.

Preview

The aim of the preview is to align our assessment activities with your strategy and objectives. The assessor will use their conversation with senior management to understand your longer-term expectations, for example, strategy issues such as business and operational risks, competitive issues, changes to internal and external environment, etc. Our assessor will establish, through the interview, whether these expectations, objectives and strategies will impact your management system or the stakeholders of your organisation.

The preview stage will be used to identify further themes that can be used in the coming certificate renewal visit and for the next three-year cycle.

Planning

The next step in the visit is planning the certificate renewal. In this part of the visit, our assessor will:

- identify any aspects of the system that have not been appropriately addressed during the surveillance cycle, and plan how to review these
- use the information gained during the review and preview stages to support the planning process
- if appropriate, consider how best to give attention to any themes identified (including the improvement tracking log)
- identify the areas, departments, processes and activities to be assessed
- agree with you sensible durations for each of these, commensurate with risk
- try to identify the best use of resources, and avoid duplication
- add appropriate time for reporting, consolidating and presenting reports
- consolidate the information into a sensible visit plan.

Our assessor will allow time for discussion with all relevant managers and for a review of records for all relevant departments.

Conducting certificate renewal visits

We conduct the certificate renewal visit similarly to a Stage 2 assessment. In addition, we include a review of your system documentation to ensure that it:

- continues to suit your company, and
- complies with the certification requirements and the scope of certification, including continual improvement.

Changes to your approval

For any increase or decrease in your certificate of approval, please submit a formal request for the change. LRQA will review the request to consider:

- additions or changes to competency requirements for the visit team(s)
- additions or reductions in visit duration requirements

and you will be notified of any changes by an amended contract.

If the change requested has meant a major change or addition to your documented system, we will undertake a separate document review visit (Stage 1).

We will conduct the change to approval visit in line with our process for Stage 2 assessment visits, although we do not normally produce a formal visit plan. If we did not need to conduct a document review (Stage 1), we will allow time during the visit for the team leader to review relevant documentation and to agree a plan for the visit.

Change to approval visits may be carried out as separate visits or may be combined with a scheduled (Surveillance or Certificate Renewal) visit.

LRQA will issue an amended certificate(s), using the same expiry date as on the current certificate.

Reporting

The reporting process for all our visits is similar. We fill in visit reports to record assessment findings, progress against the assessment plan, positive comments, and also points of clarification or interpretation. We record assessment and identify them as Major Nonconformity or Minor Nonconformity. We define these gradings as follows:

Major Nonconformity: The absence of, or the failure to implement and maintain, one or more management system elements, or a situation which would, on the basis of the available objective evidence, raise significant doubt of the management to achieve:

- the policy, objectives or public commitments of the organisation
- compliance with the applicable regulatory requirements
- conformance to applicable customer requirements
- conformance with the audit criteria deliverables.

Generally, a major nonconformity will be a system failure that:

- is already affecting system effectiveness or deliverables
- puts at risk the capability of the management system
- requires immediate containment
- requires immediate root cause analysis and corrective action.

Our team leader will make arrangements with you for follow up.

Minor Nonconformity: A finding indicative of a weakness in the implemented and maintained system, which has not significantly impacted on the capability of the management system or put at risk the system deliverables, but needs to be addressed to assure the future capability of the system.

Generally, a minor nonconformity will be a weakness in an internal facing process or procedure; or a finding where any further deterioration of control could reasonably be considered likely to result in the system becoming ineffective. Requires root cause investigation and corrective action.

If raised at a visit that results in a certificate being issued, then the assessor will ask you to indicate the corrective action that you will take. This corrective action plan will form part of the independent review by our office before your certificate is issued. If raised at a surveillance visit, although you need to take corrective action within an appropriate time after the visit, you do not normally need to provide us with details of the action until we next visit you.

In both cases, at the next visit the assessor will review the action you have taken and fill in the corrective action review section in the report.

Please keep copies of all our visit reports for three years. In exceptional circumstances, we may ask you to provide copies of previous reports.

Suggestions for improvements that could be made to a compliant management system that would improve the efficiency of the processes undertaken we will record in either:

- the executive summary, for strategic improvement suggestions, or
- the body of the report, for improvement suggestions that relate to a particular area.

Sampling

It is important to remember that even though a problem may not have been identified in an area of activity, it does not necessarily mean that there are no problems. As assessment work is based on sampling techniques, statistically there is always a possibility that issues will not be identified during an assessment. Please consider this when you audit your own management system.

Confidentiality

We will not pass on any of the information we gather about your organisation (including the contents of reports) to any other person or organisation without your permission (except as required by the accreditation body).

Further information

To find out more about how LRQA can help you to increase performance and reduce risk, please visit our website www.lrqa.com. From here you can also visit one of our country specific websites to find out about LRQA in your country.

Get in touch

Visit **www.lrqa.com** for more information

LRQA
1 Trinity Park
Bickenhill Lane
Birmingham
B37 7ES
United Kingdom

YOUR FUTURE. OUR FOCUS.

CIN038 - Version November 2021