



MANAGEMENT REVIEW

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This procedure addresses the requirements of two ISO 9001 clauses, 5.4, Planning, and 5.6, Management review. Merging quality system planning (especially quality objectives) together with management reviews is the most efficient strategy, especially for a smaller company.

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for scheduling, conducting, and recording management reviews of the quality management system.

II APPLICATION

This procedure applies to all activities comprising the quality system, and in particular those named in Section 4, Review Input, of this procedure.

III PROCEDURE

1 Frequency and scheduling

Management reviews must be conducted at least once a year. More frequent reviews are often prescribed in the maturation phase of the quality system - typically in the first two years - as in Section 1.2.

The months of March and September are used here only as an example. Any schedule is ok, but it must be synchronized with the cycle for internal audits (8.2) and compilation of quality performance data (8.4).

If you need a wider timeframe for scheduling the review, you could set the schedule to be the first and the third quarters, for example, and thus give yourself a window of three months, instead of one.

1.1 Quality performance and the quality management system are reviewed at least once a year. The annual review is conducted in March.

1.2 For the first two years (i.e., through the maturation phase of the quality system), management reviews are conducted twice a year. The additional review is conducted in September. In response to changing or special conditions and events, the **<President>** may call for unscheduled extraordinary reviews.

2 Attendance

There are no specific requirements as to who must participate in the review, but the established interpretation is that, at a minimum, the top executive manager (the president, for example) and the function responsible for operating the quality system (the quality manager, for example) must always be present. Otherwise, there are no specific expectations to who else should participate.

The list of participants should be roughly the same as the group of managers that you designated as the top executive management in Section 5.5 of the quality manual.

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- 2.1 Management reviews are chaired by the <President> and are attended by <Quality>, <Sales>, <Customer Service>, <Engineering>, <Production Engineering>, <Purchasing>, <Production>, and <Human Resources>.

Delete any functions that are not applicable, e.g., do not exist in your company.

In a very small company, where all or most of the management functions (especially <President>, <Quality>, and <Production>) are performed by one person (usually the owner), the best strategy is to have everyone else who has any kind of managerial/supervisory responsibility attend the management review.

Whatever changes you make be sure to coordinate with QM Section 5.6.1.3.

- 2.2 Those managers who are unable to attend shall receive minutes of the review meeting and, after reviewing the minutes, may submit their input and comments to the <President> and/or <Quality>. No more than two managers may be absent from the meeting. The <President> and <Quality> must always attend.

If the functions of <President> and <Quality> are held by the same person name someone else as the second, "mandatory" participant. In a very small company where there is basically only one person responsible for all "management" functions there should still be someone else present at the review even if the additional person is just an employee or a family member working only part-time.

3 Agenda

- 3.1 The agenda for management review meetings covers at least all items listed in Section 4 of this procedure. The agenda is documented on the cover page of the Management Review Report (QF-56-01-1)

4 Management review input

Most of the items listed below are required in the standard in Clause 5.6. However, to get the most benefit from management reviews, this procedure also incorporates items that help to comply with other clauses. For example, presentation of data on the effectiveness of training is included to satisfy requirements of Clause 6.2.2.

Read item-specific notes to find out why a particular item needs to be included in the review input.

- 4.1 At a minimum, the following information and data are presented for review:

- **Follow-up actions from previous reviews:** <Quality> reports on the status of action items from the previous meetings. Actions which are not completed may be extended with a new due date, reassigned to another person/function, changed, or abandoned. Reasons for the failure to implement the action and any decisions regarding continuation of the action are recorded in the Management Review Report.
- **Process performance and product conformity:** <Quality> presents quality performance data. This includes rates of process and product nonconformities, on-time delivery performance, supplier quality performance and productivity data.

Edit the scope of the quality performance data as appropriate, and coordinate with QM Section 8.4, Analysis of Data.

- **Corrective and preventive actions:** <Quality> presents the most important corrective and preventive actions implemented through the period, and the status of pending actions.
- **Customer feedback and complaints:** <Customer Service> presents summaries of customer feedback and customer complaints, including analysis of trends.
- **Internal quality audits:** <Quality> presents results of internal quality system audits. This includes summaries of results for the cycle, the frequency of audit findings against particular elements of the quality system and discussion of significant findings.
- **Changes and quality system planning:** <Quality> highlights any product, process, capacity, or other operational or organizational changes that affect the quality system and proposes specific actions to update or modify the system in response to these changing circumstances.
- **Recommendations for improvement:** <Quality> concludes the input phase of the review with recommendations for improvement..

In addition to the topics listed above, the management review may also consider such issues as cost of quality and non-quality; integration of the quality system with other operations and activities; market and customer response to the quality effort; and any other such issues related to the quality management system.

4.2 Following each presentation, the participants discuss the issues, compare their status and performance with preceding periods, and identify areas where improvement is required.

5. Quality objectives and quality policy

ISO 9001 Clause 5.4.1 requires that quality objectives must be consistent with the quality policy, be established at all relevant functions and levels within the organization, and be measurable. The most common compliance problem is that quality objectives are not measurable and/or are not measured. Behind every objective there must be a system for measuring performance and systematically collecting the data. Objectives cannot be a list of aspirational wishes or marketing slogans.

From compliance point of view, the most efficient strategy is to establish objectives in the areas where performance data are already available, either because recording the data is required by the ISO 9001 standard, or because the data have been collected before and are available. The types of data that are required by ISO 9001 and could be used are: customer complaints – the objective could be to decrease their number; product and process nonconformities – the objective could be to decrease their number overall, or for specific processes, products or types of nonconformities; corrective actions – the objective could be to decrease the time it takes to implement a corrective action (decreasing the number of corrective actions is not necessarily a measure of improvement); and so forth.

In fact, any time you can easily extract some performance data from a record that is systematically maintained, you have a candidate for an objective. Other popular objectives tied to performance that can be easily tracked are product returns, scrap

rates, rework, inventory turn-over, set-up cycle, warranty cost, on-time delivery, machine down time, etc.

In service industries, typical objectives are to reduce customer waiting time, decrease customer use of technical support, increase ration of repeat customers (customer loyalty), increase scoring for specific questions on customer satisfaction surveys, and so forth.

Be sure that the choice of your objectives is closely aligned with the system for collecting and analyzing quality performance data required in Clause 8.4 of the ISO 9001 standard. To comply with this clause you must collect certain types of data, so why not use the same data to monitor your objectives.

Auditors will expect you to have about four to seven objectives. Anything less than three or more than ten will be viewed with suspicion and provoke questioning that may lead to a finding.

- 5.1 An important role of management reviews is to establish quality objectives and to review progress toward achieving the objectives and fulfilling the quality policy. Quality objectives are established to improve performance and/or the quality system and thus fulfill the quality policy and other organizational goals and aspirations.
- 5.2 At the end of the meeting, <Quality> presents the status of quality objectives established by the previous review (those objectives are documented on the title page of the Management Review Report); and records their status in the *Status Next Mngmt Review* column.
- 5.3 When an objective is not achieved, the participants decide whether to drop the objective, reduce its target value, or extend the target due date. Objectives that have been achieved may be discontinued or be retained with a higher target value.
- 5.4 Any quality objectives that are carried on into the next period and any new objectives established by the review meeting are documented in the Quality Objectives Matrix on the title page of the Management Review Report.
- 5.5 The principal quality policy is reviewed to ensure its continuing suitability. The policy is changed when the goals expressed in the policy have been achieved, or when changes within or outside the company render the policy inadequate or inappropriate.

6 Management review output

The scope of the review output defined below is pretty much dictated by the standard, and there is not much room for change. The strategy here is to credit improvement actions as quality objectives (5.4.1) and as evidence of satisfying requirements for continual improvement (8.5.1).

- 6.1 Management reviews are concluded with actions related to:
 - Improvement of the quality management system,
 - Improvement of quality performance, and
 - Improvement of products and/or services to better meet customer requirements and increase customer satisfaction.

6.2 These improvement actions are defined implemented as

- **Management review actions:** Documented in the Management Review Report (QF-56-01-1) in the *Actions, Assigned to, and Due Date* columns. This type of action is most suitable for minor improvements that can be quickly implemented, and which are not directly related to product or process conformity.
- **Corrective or preventive actions:** Documented in the Corrective Action Request (CAR) form (QF-85-03-1) and processed in accordance with procedure QOP-85-03, Corrective and Preventive Actions. CARs are normally used for improvements related to specific actual or potential product or process nonconformities.
- **Quality objectives:** Documented on the title page of the Management Review Report (refer to Section 6 of this procedure). This method is most suitable for implementing long term improvement goals.

6.3 Resource needs for implementing improvement actions are identified. This include assignment of responsibility, time frame, and allocation of human, equipment, technical knowledge, and other necessary resources.

8 Record

Management review records must be as comprehensive as possible. They will be the sole evidence that the agenda of the review was completely covered, and that the review was concluded with appropriate decisions and actions.

Although it is ok to classify management review records as confidential, you cannot refuse to show these records to certification auditors. You could, however, deny access to anyone else auditing your system, on the basis that the records have been already audited by your registrar.

8.1 Management review output is documented in the Management Review Report based on form QF-56-01-1. The report is prepared by <Quality> and is distributed to the attending and, if any, absent participants. The location and retention period for management review records are specified in Operational Procedure QOP-42-02, Control of Records.

IV REFERENCED DOCUMENTS

- Form QF-56-01-1, Management Review Report
- Operational Procedure QOP-42-02, Control of Records
- Operational Procedure QOP-85-03, Corrective and Preventive Action

V ASSOCIATED RECORDS

- **Management Review Report:** Record of the management review meeting, to include presented and discussed topics and issues; conclusions, policies and changes; and any actions initiated to implement the conclusions and policies. Documented using form QF-56-01-1, Management Review Report.

Auditors may also ask for copies of reports, charts, overheads and other such materials presented at the management review meeting. But lack of such records would not necessarily be a noncompliance, especially in a smaller company. The



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presentations may be verbal.

- **Quality Objectives Matrix:** Record of established quality objectives. Documented on the title page of the Management Review Report (QF-56-01-1).





INTERNAL QUALITY AUDITS

This procedure represents a classic and well-established approach to internal auditing.

If internal auditing is new in your company and you don't have any established practices, you should incorporate this procedure without too many changes, and then review it, say, a year later when you get your own experience with operating this system.

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for conducting internal audits of the quality management system.

II APPLICATION

This procedure applies to all processes and activities of the quality management system, and to all areas where the quality system is implemented.

III PROCEDURE

1 Audit plan

1.1 Planning of internal audits is based on the Quality System Process Map diagram and the Quality System Process Matrix documented in the Quality Manual Section 4, and on the Internal Audit Checklist documented in form QF-82-02-3. The process map, matrix and the audit checklist define all major quality system processes, and for each process specify:

- Sequence and interrelation between the processes (process map),
- Process purpose, owners and sub-processes (process matrix),
- QMS requirements (audit checklist),
- Questions to ask and auditing techniques (audit checklist)
- Relevant sections and clauses in the ISO 9001 standard (audit checklist).

1.2 **<Quality>** is responsible for planning and scheduling internal audits of the quality system, manufacturing processes and products. Audit frequency is based on the status and importance of the processes, products and areas to be audited, as well as results of previous audits, internal/external nonconformities, and customer complaints. Each quality system process is audited at least once a year.

An audit plan where all processes and activities are audited with the same frequency (for example, annually) is not acceptable. There must be some variation in audit frequency to demonstrate that audits are scheduled on the basis of the status and importance of the audited area or activity.

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- 1.3 Internal audits cover all quality management system processes and sub-processes; are conducted in all relevant departments, functions and areas; and cover all relevant shifts.

Be sure that your audit plan reflects this requirement for covering all shifts.

- 1.4 Quality system audit plan and schedule is documented in a matrix, a model of which is provided in form QF-82-02-1, Internal Audit Plan. The vertical side of the matrix lists processes of the quality system to be audited and the horizontal side lists audit dates and assigned auditors. More detailed scope and reference for the audit, to include relevant sub-processes, procedures, areas/functions and reference clauses of ISO 9001 standard, are provided in the Quality System Process Map diagram (QM 4.1.1), the Quality System Process Matrix (QM 4.1.1), and the Internal Audit Checklist (form QF-82-02-3).

Note that QF-82-02-1 is actually just the schedule component of the internal audit plan. The actual scope and reference for the internal auditing program are defined in the Quality System Process Map diagram, the Quality System Process Matrix, and the Internal Audit Checklist.

- 1.5 Internal audit plans and cycles are synchronized with management reviews of the quality system (refer to Operational Procedure QOP-56-01, Management Review), so that complete results from the full auditing cycle are available in time for the management review meeting.

2 Audit team

- 2.1 <Quality> is responsible for qualifying, training and assigning internal auditors. Personnel assigned to carry out internal audits are independent of those having direct responsibility for the audited activity.

Edit this as appropriate to your company, but be sure to clearly communicate the requirement for objectivity and impartiality of the auditor.

- 2.2 Internal auditors are qualified on the basis of their education, experience and training. Minimum requirements are:

- **Education:** High School graduation
- **Experience:** Two years in the industry
- **Training:** 16 hours external or in-house training

The training can be by an external course or seminar provided by a qualified institution (such as a registrar, accredited training organization, etc.), or in-house training provided by a qualified consultant/trainer. If training is provided in-house, the trainer must have documented qualifications as a Lead Auditor.

The standard explicitly requires that internal auditors must be qualified, but does not state any particular qualification criteria. The criteria defined in this clause are just an example.



3 Preparing for audit

3.1 Auditors prepare for an audit by:

- Reviewing the Quality System Process Map diagram, the Quality System Process Matrix (documented in the Quality Manual Section 4), and the Internal Audit Checklist (documented in QF-82-02-3);
- Refreshing their knowledge of the quality manual and relevant operational procedures;
- Reviewing nonconformity reports, customer complaints, and corrective action files; and
- Customizing and augmenting (as necessary) the Internal Audit Checklist.

4 Conducting and reporting the audit

4.1 The manager responsible for the area scheduled for audit is contacted at least one week in advance with the proposed audit date. The manager responds with a confirmation, or proposes an alternative date.

4.2 In conducting the audit, auditors generally follow the Internal Audit Checklist (QF-82-02-3). The checklist defines the minim scope criteria (requirements) for the audit and provides examples of relevant questions and auditing techniques. The checklist is also used for referencing reviewed evidence and keeping audit notes.

4.3 When a nonconformity is noted, it is brought to the attention of, and discussed with, the responsible manager. Before the end of the audit each noted nonconformity is documented using the Audit Nonconformity Report form (a model of the form is provided in QF-82-02-2, Audit Nonconformity Report). Auditors fill out only the first part of the form, describing the noted nonconformity. The form is then handed over to the responsible manager who uses its second part to propose a corrective action.

5 Corrective action and follow up

In this procedure, the process for requesting and implementing corrective actions resulting from audit findings is incorporated into the Audit Nonconformity Report form. Thus, the general Corrective and Preventive Action procedure and form do not apply to audits. While, in theory, the general Corrective and Preventive Action system could be used for internal audit findings, it is not a good idea. Audit findings must always be addressed as a priority, and within a specified time frame; because an open finding means that the quality system is technically in default.

5.1 Once a nonconformity is identified and documented, further processing of the nonconformity report is similar to the corrective action requests (Operational Procedure QOP-85-03, Corrective and Preventive Action). Upon receiving the report, the responsible manager investigates the cause of the problem noted as a nonconformity, proposes a corrective action to be taken, and indicates the date by which the corrective action will be fully implemented. The auditor reviews and

approves the proposed action.

- 5.2 On, or immediately after the due date for implementation of corrective action, the auditor follows up with an inquiry or an audit to determine if the corrective action has been implemented and if it is effective. When there is objective evidence that the corrective action is effective, the nonconformity report is closed out. If more work is needed to fully implement the action, a new follow-up date is agreed upon.

6 Documentation and records

- 6.1 The scope of the audit, references to objective evidence and general audit notes are documented in the Internal Audit Checklist (QF-82-02-3).
- 6.2 Nonconformities, implementation of resulting corrective actions, and follow-up audits are documented using the Audit Nonconformity Report form, a model of which is provided in Form QF-82-02-2, Audit Nonconformity Report.
- 6.3 The first block of the form contains a description of the nonconforming condition, the second block contains the proposal for a corrective action, and the third block is reserved for the follow-up audit and close-out of the report.
- 6.4 Pending nonconformity reports are kept by the auditor who initially issued the report. Closed-out nonconformity reports are kept by <Quality>.
- 6.5 At the end of an auditing cycle, all nonconformity reports established during the cycle are compiled and analyzed, and are presented at the management review meeting (refer to Operational Procedure QOP-56-01, Management Review).

IV ASSOCIATED DOCUMENTS

- QM Section 4.1.1, Quality System Process Map diagram
- QM Section 4.1.1, Quality System Process Matrix
- Form QF-82-02-1, Internal Audit Plan
- Form QF-82-02-2, Audit Nonconformity Report
- Form QF-82-02-3, Internal Audit Checklist
- Operational Procedure QOP-42-02, Control of Records
- Operational Procedure QOP-56-01, Management Review
- Operational Procedure QOP-85-03, Corrective and Preventive Action

V ASSOCIATED RECORDS

- **Internal audit plans:** Plans for quality management system audits. Based on Form QF-82-02-1, Internal Audit Plan.
- **Internal Audit Checklists:** Checklist filled out with comments and references noted by auditors during the audit. Established using form QF-82-02-3, Internal



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Audit Checklist.

- **Audit Nonconformity Reports:** Reports with audit findings and records of corresponding corrective actions. Established by auditors using Form QF-82-02-2, Audit Nonconformity Report.

