Chapter 10. Leadership Related

Contents:
0) Introduction
1) 5.1, 5.1.1 Leadership and Commitment (ISO9001)
2) 5.1.1.3 Process Owners (IATF16949)
3) 5.3 Organizational Roles, Responsibilities, and Authorities (ISO9001)
4) 5.3.1 Organizational Roles… supplemental (IATF16949)
5) 5.3.2 Responsibility and authority for product requirement and corrective actions (IATF16949)
6) 5.1.2 Customer Focus (ISO9001)
7) 9.1, 9.1.1 Monitoring, measurement, analysis and evaluation (ISO9001)
8) SIs & FAQs
9) Supplementary Notes
10) Exhibits

0) Introduction

There are many interrelated clauses in this chapter, but centering around top management. The responsibility for top management on QMS has been enlarged significantly in this new version. And Top Management needs to be orientated to this new requirements. This chapter helps to provide a useful guideline.

1) 5.1, 5.1.1 Leadership and Commitment (ISO9001)

(Clause Description-Paraphrase) Top management shall demonstrate leadership and commitment with respect to the quality management system by demonstrating accountability, establishing policy and objectives etc. The list of responsibilities are: a) taking accountability for effectiveness of the QMS, b) ensure Quality Policy and Objectives are established, compatible to contents and strategic direction, c) ensure integration of the QMS into the business processes, d) promote process approach, and risk-based thinking, e) provide resources needed for the QMS, f) communicating the importance of conforming to the QMS requirements, g) ensuring QMS achieve its intended results, h) engaging, directing, and supporting others to contribute to the effectiveness of QMS, i) promote improvement, and, j) support other leaders to lead in their respective areas of responsibilities.

(Highlights of the clause)
- (Ref to old Standards) There was a similar clause, 5.1.1 Management Commitment, in the previous version of ISO9001.
- Many of the requirements under this new clause are not new e.g. a) taking accountability of the effectiveness of the QMS, e) providing resources and i) driving continual improvement.
- There are however some new ones: (b, (c), (d) and (g).
- The QMS responsibility of Top Management therefore has increased significantly, with this change.

(Compliance Best Practice)

> **5.1, 5.1.1 Leadership and Commitment**
> 1. *To help compliance, a procedure should be prepared to guide top management in their new roles and responsibilities. See **Exhibit 10-1.***
> 2. *Management can also delegate some of these responsibilities and tasks, to a few key assistants, but still holding accountability*

2) 5.1.1.3 Process Owners (IATF16949)

(Clause Description-Paraphrase)

Top management shall identify process owners who are responsible for managing the organization's processes and related outputs. Process owners shall understand their roles and be competent to perform those roles.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- The heads of each process are now required to manage their processes and department/function independently.
- And they need to know their role and be competent at performing those roles.

(Compliance Best Practice)

3) 5.3 Organizational Roles, Responsibilities, and Authorities (ISO9001)

Clause Description-Paraphrase)

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. The primary roles involved are: (a) ensuring that the QMS conforms to the requirements of ISO9001:2015; (b) ensuring that the processes are meeting the objectives, (c) reporting on the process performances and on opportunities for improvement; (d) promoting customer focus throughout the organization; e) ensuring the continued integrity of the QMS when changes take place.

(Highlights of the clause)

- (Ref to old Standards). There has been a similar Clause 5.5, Responsibility, authority and communication, in the old version of ISO9001. In the previous version, the requirement was very simply stated i.e. responsibilities and authorities are defined and communicated.
- New requirement allows to appoint a few key persons to help manage QMS
  - They must ensure the QMS conforms to the requirements of ISO9001:2015
  - ensure that the processes are meeting the objectives
  - reporting on the process performances and on opportunities for improvement
  - ensuring the continued integrity of the QMS when changes take place
- Responsibilities and authorities for these key people are communicated and understood

(Compliance Best Practice)

4) 5.3.1 Organizational Roles… supplemental (IATF16949)

(Clause Description-Paraphrase)

Top management shall assign personnel with the responsibility and authority to ensure that customer requirements are met. These assignments shall be documented. This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards, and customer portals.

(Highlights of the clause)

- This clause moves down the line, to focus on a few responsibilities that have close connections with customer satisfaction
- Clear assignment of persons-in-charge is required for: selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards and customer portals.
- Assignments shall be documented.

(Compliance Best Practice)

5) 5.3.2 Responsibility and authority for product requirement and corrective actions (IATF16949)

(Clause Description-Paraphrase)

Top management shall ensure that: (a) persons are authorized to stop shipment and stop production to correct quality problems. (b) personnel with authority and responsibility for corrective action are informed promptly, and nonconforming product is not shipped to the customer, but contained and identified; (c) all production shifts are staffed with personnel in charge of, conformity to product requirements.

(Highlights of the clause)

- (Ref to old Standards). There has been a similar clause. 5.5.1.1 Responsibility for quality, in the old version of ISO/TS16949, It basically stated the same requirements, with clearer elaborations
- Total requirement is given in (a) to (c)
  a) authorise people to stop shipment and production when quality problem occurs
  b) product is cannot be shipped to the customer, but contained and identified
  c) This arrangement is to be for all operating shifts

(Compliance Best Practice)

> **5.3.2 Responsibility and authority for product requirement and corrective actions**
> 1. *If you are not running shifts, this clause is easy to handle. The full workforce and management is available during normal shifts, to manage quality issues. Just tell Auditor there is no night shifts.*
> 2. *If you are running shifts, then delegation must be done for the night shifts. The normal arrangement to stop production is delegated to the supervisor or shift leader. And they should be able to explain when asked.*

6) 5.1.2 Customer Focus (ISO9001)

(Clause Description-Paraphrase)

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that (a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; (b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; (c) the focus on enhancing customer satisfaction is maintained.

Author's note: For exact wordings, please refer to standard indicated after the clause title.

(Highlights of the clause)
   a) (Ref to old Standards). There had been a similar clause, 5.2 of the same title, in the old version of ISO9001.
   b) Like in the older version of IATF, Management shall ensure customer focus. It means focus on the important areas concerning customers
   c) There are new items to focus on: a) customer and statutory and regulatory requirements, b) risk and opportunities impacting customers, c) customer satisfaction
      .

(Compliance Best Practice)

> **5.1.2 Customer Focus**
> 1. *This is a concept clause, actual implementation will be carried out all departments and everyone in the company*
> 2. *You are only required to understand the intent and ensure compliance. There is generally no need to produce any additional documentation as evidence.*

7) 9.1, 9.1.1 Monitoring, measurement, analysis and evaluation (MMAV)

(Clause Description-Paraphrase)

The organization shall determine:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated. The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results. (no non-achievement actions)

(Highlights of the clause)

- There are 2 sets of people who needs to make MMAV decisions here, Top Management and QAQC.
- Top Management to set what KPI to monitor the entire processes.
- Process & QAQC decide on what needs to be control for products and process, and at what stages.

(Compliance Best Practice)

> **9.1, 9.1.1 Monitoring, measurement, analysis and evaluation**
> 1. *Auditors may likely be asking about KPI setting method, be prepared to explain the process of proposing and approving KPI.*
> 2. *Chapter 25 discusses about setting detail inspection items.*

8. SIs & FAQs

FAQ	IATF Clause	Questions and Answers
5	**5.3.1 Organizational roles, responsibilities, and authorities — supplemental**	**QUESTION:** Is the intent that responsibilities be assigned to the function (e.g. Quality), a specific title (e.g. Quality Director) or a named individual (e.g. Bob Smith)? **ANSWER:** Responsibilities are assigned to the role/position (i.e. specific title, Quality Director) within the organization. Although individuals may have those responsibilities in their roles, the responsibilities remain with the role (e.g. Quality Director). Therefore, top management will assign the responsibility and authority to the role, not to the individuals by name.

9. Supplementary Notes

Legend: HOC= Highlights of Clause, CBP= Compliance Best Practice, S&Q= SIs & FAQ, EXH= Exhibits

Clause	Section	Clarification Subjects
5.1, 5.11	CBP	**SN-10.1. How do we help Top Management to handle IATF Auditor, on their new QMS roles and responsibilities?**
5.1, 5.11	CBP	**SN-10.2. Will 3P auditor really ask the big boss on QMS details?**
5.1, 5.11	CBP	**SN-10.3. How should Management promote risk based thinking?**
5.1, 5.11	CBP	**SN-10.4. what does integration means and how to achieve this?**
5.1, 5.11	CBP	**SN-10.5. How does Top Management support lower-tiers in leadership?**
5.1, 5.11	CBP	**SN-10.6. Can we still maintain the QMR position, to relief the Top Management of extra burden?**
5.1.1.3	CBP	**SN-10.7. Management can still delegate in the new version. How is this best carried out so that no effectiveness is lost?**
5.3	CBP	**SN-10.8. How should a department QMS report for Management look like?**

5.3	CBP	**SN10.9. When delegating back to a function, is HOD the automatic choice?**
5.3.1	CBP	**SN10.10. Where is the main pitfall in this area 5.3.1?**
5.1.2	CBP	**SN10.11. How do we demonstrate customer focus, since there are no documentation to show as evidence?**
5.3.2	CBP	**SN10.12. What kind of evidence is required to show delegation of quality responsibilities for night shifts.**

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SN10.1. How do we help Top Management to handle IATF Auditor on their new QMS roles and responsibilities?

Top Management may be asked by IATF Auditor on their new responsibilities on the QMS. To assist them to understand this role, a 1-2 page information/ procedure should be prepared. they can continue to delegate out the real work, but they must be in the know.

SN10.2. Will IATF auditor really ask the big boss on QMS details?

Probably not much, unless the boss shows total ignorance. IATF Auditor's work is very tight, with 1/3 of the time already reserved for production audit. For top management, an auditor tends to enquire on the higher level stuff, e.g. strategic directions, market trends, KPI, target setting and continual improvement. They are less likely to pick on day-to-day operations with top management.

SN10.3. How should Management promote risk-based thinking?

Risk-based thinking is a new subject, that comes with the new version of ISO9001. During transition. training should have been conducted. In Chapter 2, clause 6.1.2.1 also suggested a documented procedure to respond to risks actually encountered, followed by recurrence prevention. Management just have to ensure this kind of response is undertaken, by asking pertinent questions.

SN10.4. What does integration mean, and how to achieve this?

Integration (5.1c) can save time and unify the business operations. It means we should stop thinking QMS being a separate set of management duties from the real business. It should not exist in isolation, but integrated into every sphere of the operations.

SN10.5. How does Top Management support lower-tiers in leadership?

As an operations gets more complex and sophisticated, subordinates need to be self-motivated and self-driven. Leaders should also change their thinking to suit the trend. They need to learn some management soft-skill rather than drilling further down the hard-skill lane. They should become more participative, and less commanding. Top Management is generally more skilful in this area, and can assist the lower-tier leaders to develop this flair.

SN10.6. Can we still maintain the QMR position, to relief the Top Management of extra burden?

The Standard does not say that QMR has to be scrapped. The word 'Management Representative' just disappeared from the document. Yes, you can keep the position. You can even keep the name, but the responsibility must change. Top Management is accountable but can delegate. The easiest way is to delegate responsibilities back to departments concerned. Top Management is finally the person in charge. He or she is no longer totally sheltered from audit by the QMR. He has to demonstrate that he is in the know. QMR can continue to assist the Top Management, but active duties and responsibilities are transferred to each function. QMR should only be in a coordinator or an advisory role. He/she now has a 'staff', rather than 'line' responsibility. **(Exhibit -10-2)**

SN-107. Management can still delegate in the new version. How is this best carried out so that no effectiveness is lost?

Yes, you need to think effectiveness in delegation. Sending an email with a new JD is not good enough. It will not be effective. You need a training to explain to them clearly the new duties and responsibilities. QMR's role now is only a coordinator or advisor. Finally give the assurance that ongoing support will be given. This support role is what QMR can do very well. Evidence to show in audits are: QMS team chart, samples of their regular reports to management.

SN-10.8. How should a department QMS report for Management look like?

Currently, most organizations are just submitting a KPI status report. Reporting can improve, if some other important headings can be added. such as, resources, safety and environment, changes in the process that can affect QMS and organization, changes in risk and opportunities, opportunity for improvement etc. See **Exhibit 10-4** for a specimen. However, the improved report is not mandatory, A face-to-face reporting is also acceptable.

SN10.9. When delegating back to a function, is HOD the automatic choice?

In most cases yes. But there may be exceptions. An example is production. We will automatically think of the production manager as the chosen one. However, if he/she oversees 3 factories, an operations spanning from injection moulding, to blow-moulding, to secondary processes and the assembly, he is too high up to be an effective process owner. He can remain the overall process owner, but the section-in-charge to each production unit should be identified as the co-process owners. The responsibility to identify the roles and training should be a cross-functional team consisting of the HOD, QMR and HR.

SN10.10. Where is the main pitfall in this area 5.3.1?

If the process owner cannot demonstrate knowledge on this area, or worse he/she doesn't even realise he/she is appointed one, it becomes a finding, if. A case in point was the planner of an organization 'appointed' the process owner for tracking customer portal. She maintained she is not the person, but someone else in HQ was. The audit had to take another direction, in which a remote location has just surfaced, and an onsite audit has to be done on the remote. This is an expensive experience because the HQ is situated in another country.

SN10.11. How do we demonstrate customer focus, since there are no documentation to show as evidence?

IATF Auditors are unlikely going to ask a direct question on this clause, but will pick up on the response and attitude demonstrated on important customer issues such as complaint handling, preventing risks to customers etc, and also matters listed as a) to c) in the clause.

SN10.12. What kind of evidence is required to show delegation of quality responsibilities for night shifts?

If you are running shifts, then the arrangement must be done for the night shifts. The normal arrangement to stop production is delegated to the supervisor or shift leader. Your supervisor/ leader in-charge should explain how do they handle a reject situation. Example, how they will alerting higher-up people, how decisions are made to stop the machine, and activities to contain the lot and identification.

Exhibit 10-1. Procedure to Guide Top Management

Procedure on Leadership

PIC	Flow Diagram	Key Notes
MD	**5-02 (1)** Assumes Accountability	**5-02 (1)** • taking accountability for the effectiveness of the quality management system • where physically not feasible, or due to time constraints, active involvement via assigned process owners needs to be demonstrated • ensuring that the resources needed for the QMS are available; • ensuring that the quality management system achieves its intended results
MD/QMR asst	**5-02 (2)** Ensure Quality Policy and Objectives are Established/Reviewed	**5-02 (2)** • ensuring that the quality policy and quality objectives are established/reviewed annually • ensuring Policy and Objectives are compatible with the context and strategic direction of the organization;
MD/QMR Asst	**5-02 (3)** Integrates QMS Requirements into the Business Processes	**5-02 (3)** • ensuring QMS requirements are integrated into the organization's business processes
MD/QMR Asst	**5-02 (4)** Promotes Process Approach & Risk-Base Thinking	**5-02 (4)** • promoting the use of the process approach and risk-based thinking;
MD/QMR Asst		**5-02 (5)** • communicating the importance of effective quality management and of conforming to the QMS requirements
MD/QMR Asst	**5-02 (5)** Communicates the Importance of Effective Quality Management & Conforming to QMS Requirement	• promoting continual improvement
MD/QMR Asst	**5-02 (6)** Supports Lower-Tier Leaders	**5-02 (6)** • engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; • supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Remarks given in here explain on the exhibit. Do not include them as part of the document
- This procedure is to help Top Management to understand their roles and responsibilities as defined by ISO/IATF
- It is good for QMR to do a briefing for Top Management and retain that as a training record

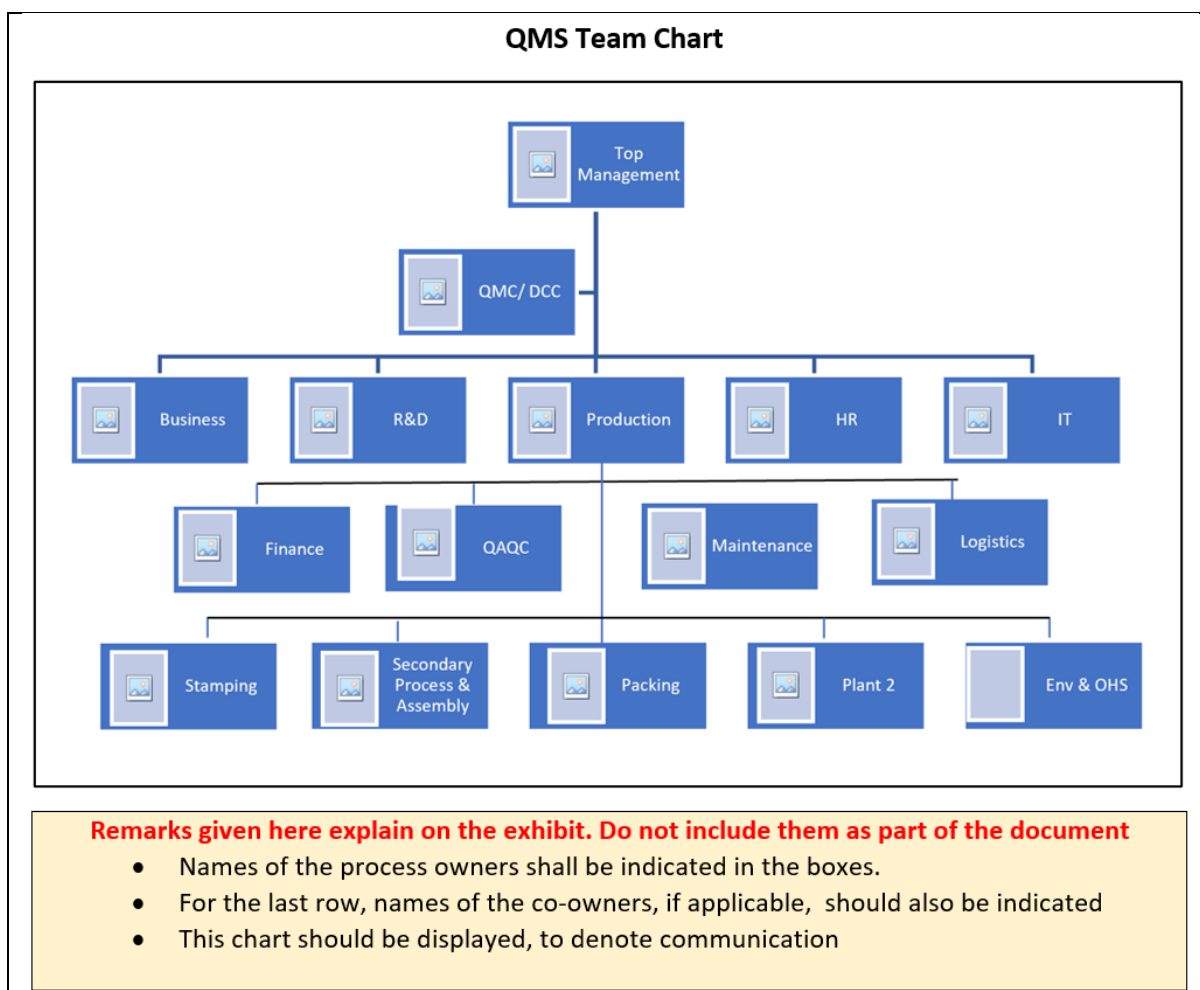Exhibit 10-2. Full Delegation Chart

QMS Team Chart

Exhibit 10-3. Customer Satisfaction Responsibilities

Customer Satisfaction responsibilities Chart

Rev No	Effective Date	Compiled by	Approved by
01	11 Jun 2019	QMR	MD

No	Customer Satisfaction Activities	Responsibility
1	Selection of Special Characteristics	APAP Team
2	Setting KPI	Various HOD, asst by QMR
3	Setting KPI related training	Various HOD, HR, asst by QMR
4	RFQ handling	Business Development (BD)
5	Customer satisfaction survey	Business Development (BD)
6	Scorecards/ Customer portal	Planner, QA
7	Customer complaints	QA, Asst by BD
8	Product Design and Development	R&D
9	Order Processing/ Production Planning	Planner
10	Capacity analysis	Planner, Production
11	Logistics Information	Planner, storekeeper

Remarks here explain on the exhibit. Do not include them as part of the document
- For total delegation, a QMS Team chart is used. **See Exhibit 10.2.**
- This list is not the total delegation chart. This is only part of it, as per Clause 5.3.1, the specific areas, which affect customer satisfaction

Exhibit 10-4. QMS Monthly Report

Department	Month	Date	Reported by

A: KPI performance & Achievement

KPI	Target/Expected	Actual	Judgement

Remarks:

B: Safety & Environment

B: Resources

C: Changes that can affect process, or the organization

D: Risks and Opportunities changes in this area

E: Other Remarks

>> End of Chapter 10 <<>>