



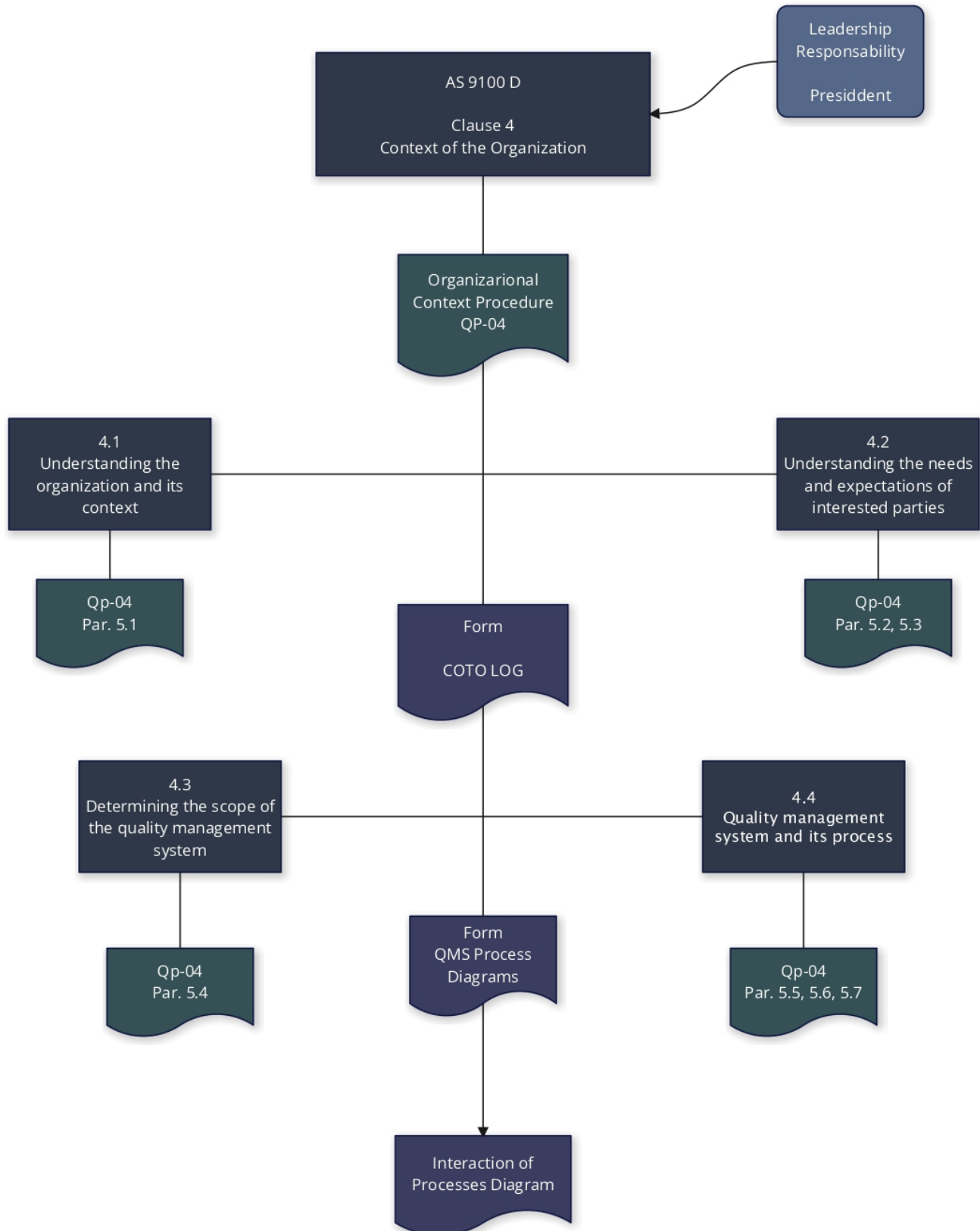
### Document # QP-04

CONTEXT OF THE ORGANIZATION	
<b>Procedure Title</b>	Context of the Organization
<b>Document Number</b>	QP-04
<b>Standard</b>	AS 9100 D: 2016
<b>Scope</b>	4.1, 4.2, 4.3, 4.4
<b>Process Owner</b>	Hasten Applied CNC CONTEXT OF THE ORGANIZATION
<b>Related Forms/Records</b>	<ul style="list-style-type: none"> <li>F-420-001 Inter. Parties risk list.</li> <li>F-620-004 External Risk</li> <li>F-620-003 Internal Risk</li> <li>F-930-001 QM Management Review Agenda</li> <li>COTO LOG 4100</li> <li>(Record retention Min 7 Years)</li> </ul>
<b>Related Work Instructions</b>	None
<b>Related Procedures</b>	<ul style="list-style-type: none"> <li>QP-06 Planning</li> <li>QP-09 Performance Evaluation</li> </ul>

APPROVAL AND REVISION HISTORY			
DATE	REVISION	DESCRIPTION	APPROVED BY
01/26/22	<b>A</b>	Context of the Organization	R.H.



QUALITY MANAGEMENT SYSTEM  
CLAUSE 4 - CONTEXT OF THE ORGANIZATION



## 4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

## 4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

- a) the interested parties that are relevant to the quality management system;
- b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

### Hasten Applied CNC "INTERESTED PARTIES"

Our "Interested parties" are the stakeholders who receive our Products and who may be impacted by them, or those parties who may otherwise have a significant interest in Hasten Applied CNC. The interested parties applicable Hasten Applied CNC are listed in a COTO Log, along with the reason for their inclusion. This includes both internal and external parties.

### ISSUES OF CONCERN

- For each interest party, the related issues of concern are identified in the COTO Log. These issues may reflect direct concerns of the party (for example, customers are concerned about quality of products) or they may be indirect concerns. Such concerns may impact on the interested party or may be concerns derived from the party that impacts Hasten Applied CNC.
- Issues may be either internal or external, depending on whether the interested party is internal or external. In addition, a certain type of party may have both internal and external concerns.
- When attempting to identify internal concerns, Hasten Applied CNC considers technological or employee concerns etc.
- When attempting to identify external concerns, Hasten Applied CNC may consider concerns arising from competition, society and culture, labor relations, statutory and regulatory issues, supply chain, economic issues, etc.

### RISKS AND OPPORTUNITIES

- Management will then identify risks and opportunities related to the issues of concern within the COTO Log.
- Within the COTO Log, each risk and opportunity will be noted, along with the primary process involved, priority, and a bias. The "bias" identifies if the issue is a risk, an opportunity, or some blending of the two.
- Management will then determine a treatment method for each risk or opportunity. Risks are managed to reduce their likelihood and consequence, while opportunities are managed to

increase their likelihood and consequence. Blended issues may require more complex treatment.

- Where a risk is determined to be treated via a risk assessment style treatment, these must then be entered into the Risk Register tab within the COTO Log.
- Opportunities are managed via the Opportunity Register tab within the COTO Log.

### **4.3 Determining the scope of the quality management system**

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

- a) the external and internal issues referred to in 4.1;
- b) the requirements of relevant interested parties referred to in 4.2;
- c) the products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

- Hasten Applied CNC has determined defined and documented the scope of its QMS in this document. (QMS-001)

### **4.4 Quality management system and its processes**

**4.4.1** The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

- a) determine the inputs required and the outputs expected from these processes;
  - The QMS processes are documented in QMS-001 that show inputs required and expected outputs.
  - **The QMS shall also address customer & applicable statutory & regulatory QMS requirements.**
- b) determine the sequence and interaction of these processes;

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- See Appendix B (Interaction of Processes Diagram) of the QMS-001 Document
- c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
  - See Process in QMS-001
- d) determine the resources needed for these processes and ensure their availability;
  - Hasten Applied CNC Leadership reviews resource requirements at Management review meetings and assigns relevant parties to ensure resources are made available.
- e) assign the responsibilities and authorities for these processes;
  - See Appendix "C" Organizational Chart in QMS-001 and Section 5.3 of QP-05.
- f) address the risks and opportunities as determined in accordance with the requirements of 6.1
  - Risks and Opportunities are addressed in the COTO log and are addressed at Management Review meetings.
- g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
  - Processes are evaluated on an ongoing basis and during Management Review meetings through a review of measurement and monitoring records and performance indicators for each process.
  - These reviews identify opportunities to improve QMS processes, use of resources, and product quality.
- h) improve the processes and the quality management system.
  - See QP-09 (Performance Evaluation)

### **4.4.2 To the extent necessary, the organization shall:**

- a) maintain documented information to support the operation of its processes;
- b) retain documented information to have confidence that the processes are being carried out as planned.

Hasten Applied CNC shall establish and maintain documented information that includes:

- a general description of relevant interested parties;
- the scope of the quality management system, including boundaries and applicability.
- a description of the processes needed for the quality management system and their application throughout the organization;
- the sequence and interaction of these processes;
- assignment of the responsibilities and authorities for these processes.
  - See Maintained Documented Procedures listed in Hasten Applied CNC QMS-001, and Retained documents referenced in the body of text for each QP.
  - Information contained within these retained documents are evidence of processes being carried out as planned by the QMS
  - *A general description of Hasten Applied CNC interested parties is listed in the COTO Log.*
  - *The "Scope" of the QMS, including boundaries and applicability appears in the Scope Statement of the QMS-001*



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- *A "Description of the process needed for the QMS, the sequence & interaction of the processes and assignment of responsibilities for these processes and their application throughout the organization appears in the QMS-001, Appendix B, Page 5, 6, 7, 8, 9, 10 of the QMS-001A.*

