

# DEKRA Business Assurance

*Understanding Context of the Organization*



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## What We Do

Certification and assessment services that help our customers:

- Meet their stakeholder requirements
- Develop new markets
- Reduce or mitigate risk
- Create a culture of continuous improvement.

## CERTIFICATION

### Quality, Environmental, Health, and Safety:

- > ISO 9001: Quality Management
- > ISO 14001: Environmental Management
- > OHSAS 18001: Occupational health & safety
- > IATF 16949: Automotive
- > AS9100: Aerospace
- > ISO 13485: Medical
- > TL 9000: Telecom

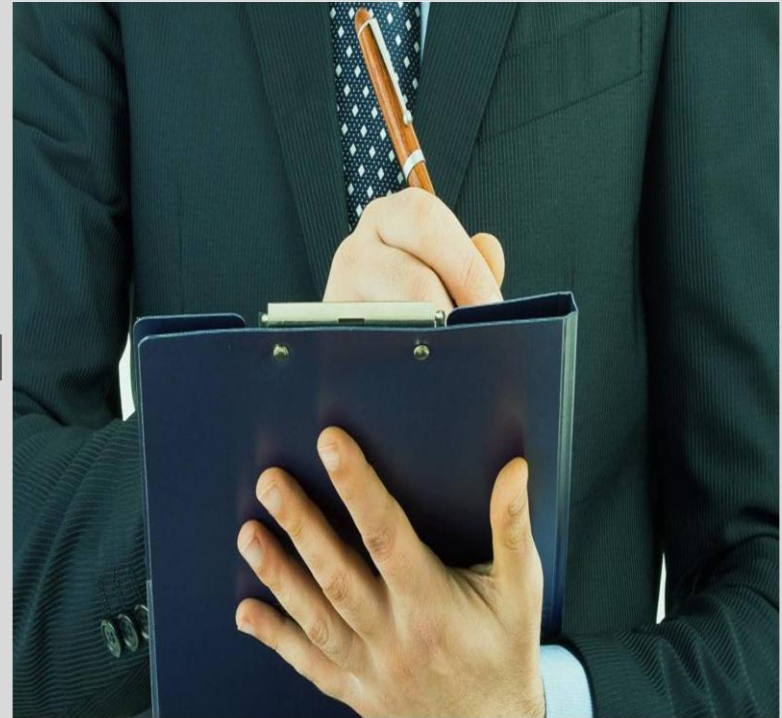
### Energy, Sustainability, and Risk:

- > ISO 50001: Energy
- > ISO 22301: Business continuity
- > ISO 27001: Information security
- > ISO 20001: Information technology
- > ISO 26000: Corporate social responsibility
- > ISO 55000: Asset management

## 2015 Revisions: Major Changes - QMS

Risk-based Focus

Process orientation Emphasized



## 2015 Revisions: Major Changes - EMS

Strategic Environmental Management  
Environmental Performance  
Protecting the Environment  
Lifecycle Thinking



## 2015 Revisions: Major Changes - All

Leadership

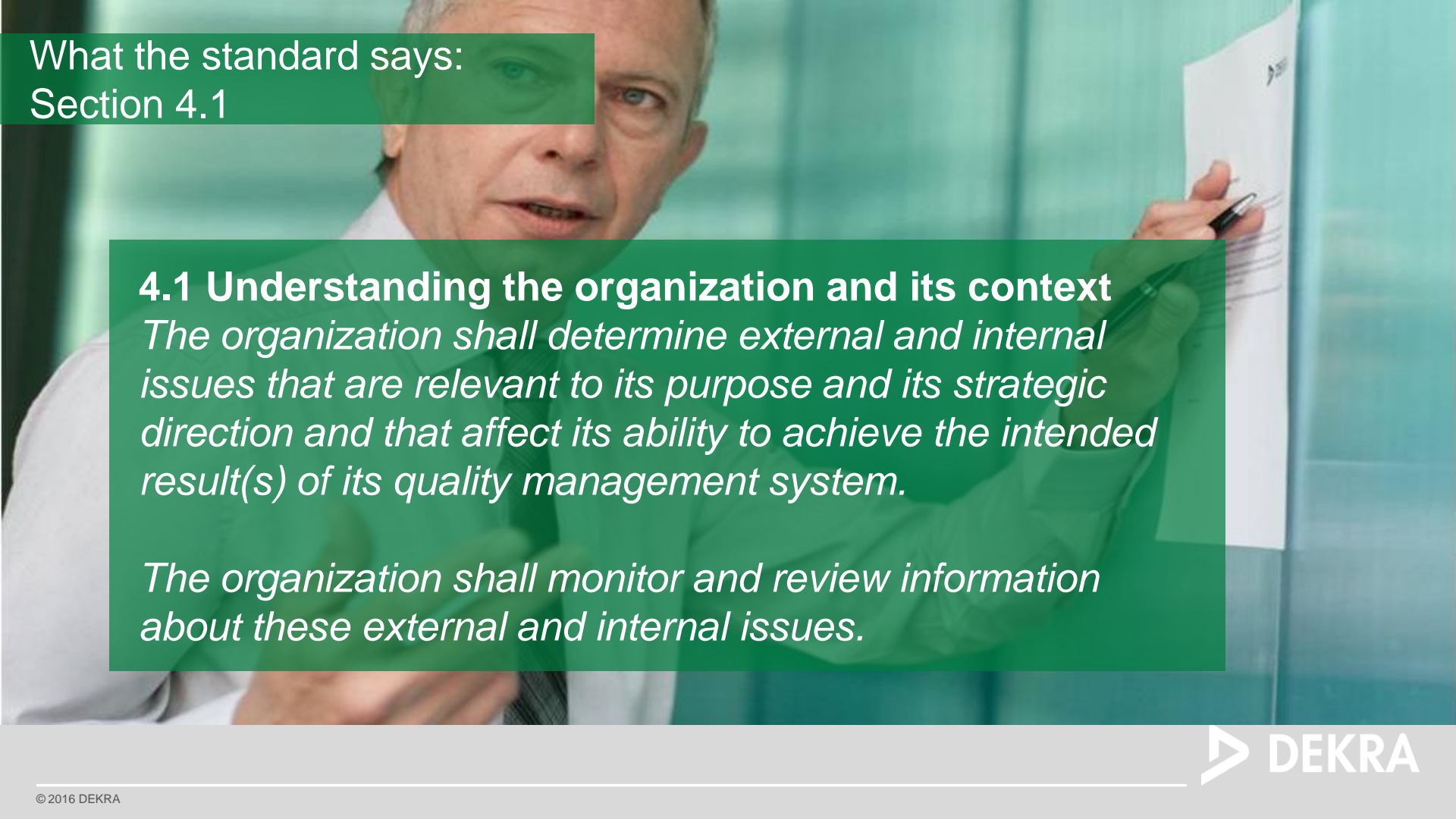
Communication

Documentation

**Context of the Organization**





A man in a white shirt and tie is pointing at a document on a glass wall. The document is partially visible on the right side of the image. The background is a blurred office setting with a window.

## What the standard says: Section 4.1

### **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.*

*The organization shall monitor and review information about these external and internal issues.*


## 4.1 Continued

*NOTE 1 Issues can include positive and negative factors or conditions for consideration.*

*NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.*

*NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.  
(Taken from ISO 9001:2015 (E))*





## What the standard says: Section 4.2

### **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." (Taken from ISO 9001:2015 (E))*



## Needs and Expectations: Annex A.3

*Subclause 4.2 specifies requirements for the organization to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties.*

*However, 4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.*

## Annex A.3 Continued

*There is no requirement in this International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the organization to decide. (Taken from ISO 9001:2015 (E))*



## Importance

Clauses 4.1 and 4.2 are the very first clauses after the introduction, coming before the requirement to determine the scope. Therefore they are logically required as part of the process to create the scope and the system itself.

Equally logical, they are therefore key underpinnings of the new standard. They are the required start to identifying the risks and opportunities for the organization. The simple reality is that for many organizations, these only exist in the brains of various people in the company. This clause requires they be more explicit

## Context of the organization

Provide a **high-level understanding** of the **issues that can affect**, either positively or negatively, the way the organization **manages its responsibilities** in relation to the management system for persons working under its control.

Issues can include conditions, characteristics or changing circumstances that can affect the system.



## Context: Internal Issues

governance

organizational  
structure

roles and  
accountabilities

policies,  
objectives, and  
strategies

resource and  
knowledge  
capabilities

new products  
and equipment

organizational  
culture

standards and  
guidelines



## Example: Internal Issues

### STRENGTHS:

- Long term employees with deep skills and loyalty
- Deep expertise in our processes

### WEAKNESSES:

- Debt after recent equipment purchases is higher than normal
- Too many positions with employees ready to retire without trained replacements

Machining Company  
supplying multiple  
industries

### OPPORTUNITIES:

- Increased capacity due to equipment purchase means we can pursue more business
- Apprentice program with local community college is under consideration

### THREATS:

- Building is very old and requires extensive and expensive work to bring back to a condition that will attract new customers and new employees

Context:  
External Issues

cultural

social

political

legal

financial

economic

market  
competition

key drivers  
and trends

## Example: External Issues

### STRENGTHS:

- Strong local economy has available suppliers, employees and training
- Strong partnerships with all critical suppliers

### WEAKNESSES:

- Strong competition for employees
- Increasing transportation costs
- Increasing raw material costs

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### OPPORTUNITIES:

- Neighboring building is for sale. Larger structure would enable move without need for extensive repairs and would enable us to redo the process flow for increased efficiencies

### THREATS:

- Increasing regulatory environment
- Increasing local housing costs make it difficult for our employees to find affordable housing nearby

## Examples of Context



*Issues that are relevant to its purpose and its strategic direction and that affects its ability to achieve the intended result(s) of the QMS*

Intersection = sustainable position.

Breakdowns can be devastating

## Context: Other Interested Parties



Requirements/expectations from interested parties become obligatory requirements for an organization if that organization chooses to adopt them.

### Other Interested parties can include:

Legal and regulatory authorities

Parent organizations

Suppliers and external providers

Owners, shareholders, clients,  
visitors, & local community

Customers



Relevant to it's purpose

## What is the organization's purpose?

To create the existing service or a product.

Strategic direction

"that affects its ability to achieve the intended result(s) of the QMS "

The QMS exists to enable the organization to create the service or product efficiently and effectively.

## What does this mean for my organization?

- **The organization needs to broaden its traditional look at itself.**
  - Look at your internal processes
  - Look at your customers
  - Look at your market
- **Organizations may choose to include areas required in other standards in their QMS context:**
  - Environmental impact
  - Societal or culture of their company, community, & workforce.


# Summary

Leadership needs to examine:

- The organization's context
- The associated interested parties
- Set up the strategic direction
- Determine scope & boundaries

Use this context to ensure the quality policy and quality objectives are:

- Compatible with the context
- Compatible with the strategic direction



**Determining the organization's context and interested parties enables the leadership to ensure the QMS is more effective and efficient at delivering what the interested parties need & expect.**



Thank You

*If you need anything please  
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*or go to*

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