

White Paper: Dekra Certification (Pty) Ltd.

Title-Understanding the organization and its context.

Reference document-ISO 9001:2015

Extracts from the standard: ISO 9001:2015.

4.0 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.

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

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.

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.

4.4 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 the international standard if they are applicable within the determined scope of the 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 product and services covered, and provide justification for any requirement of the International Standard that the organization determines is not applicable to the scope of the quality management system.

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

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 the International Standard.

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 the processes;
- b) determine the sequence and interaction of these processes;
- c) determine and apply the criteria and methods (including monitoring, measurement's and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determine the resources needed for these processes and ensure their availability;
- e) assign the responsibilities and authorities for these processes;
- f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) improve the processes and the quality management system.

To the extent necessary, the organization shall:

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

Example: Putting the context of the organization into perspective, some examples follow.

A sole owner has decided to implement an ISO 9001:2015 quality management system and awaits a certification audit process to be carried out by Dekra Certification (Pty) Ltd.

The organization is registered under a trading name given as "Safeway Public Transport Services". The company operates from a house, located in a small

complex situated in the Northern suburbs of Johannesburg and wishes to supply the following services;

-transportation of groups of persons not exceeding fourteen (including the driver) to sporting events, tours, weddings, funeral's and transportation of school children to and from school.

The organization comprises the owner, who is also the vehicle driver and external service providers who look after financial and legal matters.

Company assets include;

- a dwelling house incorporating an office
- a desk top portal
- combined photo copier, fax and scanner
- double garage
- a Toyota fourteen seater mini bus (all seats fitted with safety belts, air conditioner, roll over protection, emergency exit and a first aid kit
- The owner holds a level three first aid certificate, is a licensed public service vehicle driver and holds an advanced drivers certificate.
- A jaguar vehicle used for transporting a maximum of four passengers for functions such as weddings.

During the quality management inception process, the owner arranged for a survey to be carried out by the external finance and legal support personnel.

The survey included the following aspects;

- the risks, opportunities and benefits of introducing an ISO 9001:2015 certified quality management system.
- costs and expected returns associated with introducing and managing a quality management system.
- expected revenue to be derived on a weekly, monthly and annual basis.
- possible threats from interested parties/competitors operating a similar service.
- determination of routes to be used locally and in the SADC region.
- Vehicle maintenance costs
- Expected market share
- Credit worthiness with the bank

- Costs of employing an additional driver.
- Legal compliance requirements and costs
- Vehicle insurance costs

Examples of documented information that an auditor may request, however, the list is not exhaustive;

- survey results
- the scope of the management system
- curriculum vitae of the owner
- customer requirements
- example of the risks and opportunities determined by the owner
- feedback from customers
- basis for hiring the financial and legal personnel
- process description and interaction with output results

A company carrying out marketing, sales, procurement, manufacturing and dispatch, associated with providing various components for the vehicle manufacturing industry has embarked on a programme to obtain ISO 9001:2015 certification.

The quality management system was developed with the aid of a consultant and has been operating for three months. One exclusion has been made associated with design and development, as all design requirements are provided by the various clients.

Several processes are administered by external providers, for example Information Technology Support, maintenance on plant and equipment and gardening services.

Internal processes include;

- Marketing
- Sales
- Manufacturing, including presswork, machine shop, spot welding and assembly
- Procurement
- Physical laboratory
- Painting

- Electro-plating
- Compliance
- Quality control
- Packing and dispatch

A capacity list is available and includes details of machining and metal finishing capabilities

The company has completed a management review and one full internal audit associated with their processes and await a document review from the certification body chosen, Dekra Certification (Pty) Ltd.

Interested parties include, customers, external service providers, neighbour's , the bank and environmental pressure groups.(Two complaints have been received relating to noise emanating from the press shop operations and paint fumes detected on one evening from paint spraying)

When the auditor is reviewing the organization and its context, the auditor can ask for the following details;

- a description of the needs and expectations determined for interested Parties
- review results of information derived from a review of interested parties
- identification of applicable legal requirements, for example local authority Regulations
- the scope of the quality management system
- information derived from process outputs

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