

1.0 Purpose/Scope

- 1.1 The purpose of this procedure is to ensure that the context of **Your Company** and the needs and expectations of interested parties are understood.
- 1.2 The procedure applies to the external and internal issues that can affect the Quality Management System (QMS).

2.0 Responsibilities and Authorities

- 2.1 The **President** has the prime responsibility and approval authority for this procedure.
- 2.2 **Top management** is responsible to determine the relevant external and internal issues that affect the ability to achieve the intended result(s) of the QMS and that can impact on the planning of the QMS.

3.0 References and Definitions

- 3.1 Reference: This document addresses clause 4 of the AS 9120 B standard covering, Context of the organization.
- 3.2 Definitions
- 3.2.1 Top management: Person or group of people who directs and controls an organization at the highest level.
- 3.2.2 Context of the organization: Combination of internal and external factors and conditions that can have an effect on an organization.

4.0 Resources

- 4.1 As outlined in the procedure P-710 for Resource management.

5.0 Instructions

- 5.1 To fully understand the organization and its context, **Your Company** determines the external and internal issues that are relevant and that affect its ability to achieve the intended outcomes of the QMS.
- 5.1.1 The external and internal issues include production and service conditions capable of affecting or being affected by the company.
- 5.1.2 Relevant internal and external Issues may include the:
- Business and quality management conditions related to the areas of **leadership, customer focus, engagement of people, process approach, improvement, evidence-based decision making and relationship management** that can either affect the company's purpose, or be affected by its decisions.
 - **External cultural, social, political, legal, regulatory, financial, technological, economic, natural, and competitive context, whether international, national, regional, or local.**

- Internal characteristics or conditions of the company, such as its activities, products and services, strategic direction, culture, risk-based thinking, and capabilities (people, knowledge, processes, systems).
- 5.1.3 In support of top management, the **Management representative / AS steering committee** are continually on alert for information that can impact the QMS.
- During the development and implementation phases of the QMS, the determination and tracking of relevant internal and external issues is followed up at the regular (weekly) AS steering committee meetings.
 - Notes or minutes of AS steering committee meetings provide the evidence that internal and external issues are addressed.
 - As required to document, follow up and update the identified relevant internal and external issues, the **Management representative** makes use of the relevant sections in the organizational context worksheet, F-440-002.
- 5.2 To completely understand the needs and expectations of interested parties, **Your Company** identifies the interested parties that are relevant to the QMS.
- 5.2.1 The interested parties are identified and their expectations and needs (requirements) are determined along with which of their requirements become regulatory requirements.
- 5.2.2 Interested parties can include person(s) and groups concerned with or affected by the quality performance and can be **customers, communities, suppliers, regulators, nongovernment companies, investors, employees.**
- 5.2.3 In support of top management, the **Management representative / AS steering committee** are continually on alert for information regarding relevant interested parties and how they can impact the QMS.
- During the development and implementation phases of the QMS, the identification of relevant interested parties and their requirements are followed up at the regular (weekly) AS steering committee meetings.
 - Notes or minutes of AS steering committee meetings provide the evidence that the needs of interested parties are addressed.
 - As required to document, follow up and update the identified relevant internal and external issues, the **Management representative** makes use of the relevant sections in the organizational context worksheet, F-440-002.
- 5.3 In support of **Top management**, the QMS documentation provides for an understanding of the requirements and of the international standard as a whole.
- 5.3.1 As related to this procedure, the following combines the relevant external and internal factors and conditions to complete an activity loop from leadership through continual improvement where:
- P-500 demonstrates leadership and commitment to the QMS
 - P-600 determines the issues that impact on the planning of the QMS