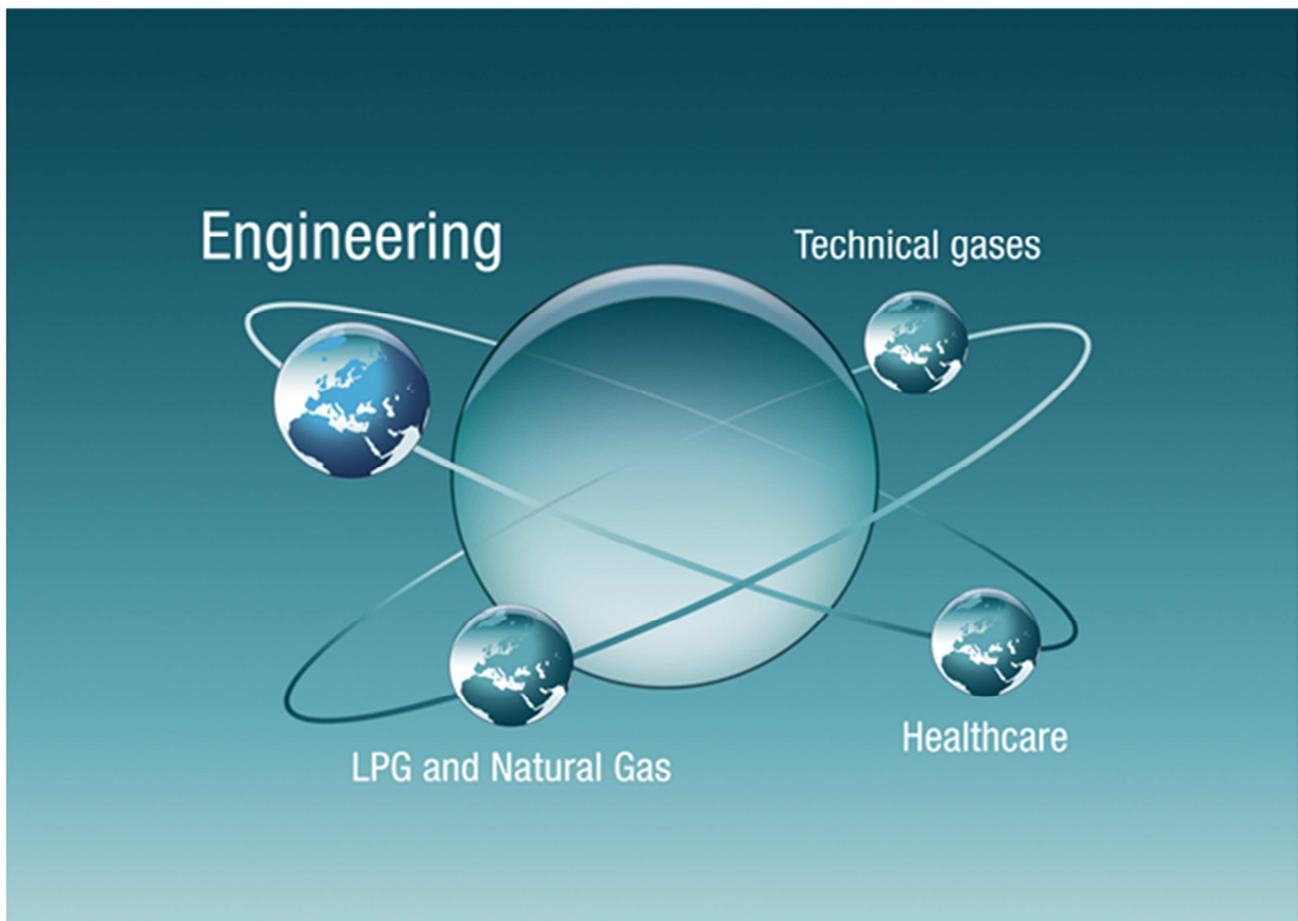


CORPORATE MANUAL OF INTEGRATED MANAGEMENT SYSTEM



SIAD Macchine Impianti, the Company leader of SIAD Group's Engineering

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INTRODUCTION

SIAD Macchine Impianti created in 1953 as SIAD S.P.A spin-off, is the Engineering dept. SIAD Group reference company.

Its activities are various and range from plants design (compressors, air separation units and gas treatment) to the global and continuous assistance services. Currently, the company designs, manufactures and installs, throughout the world: compressors for compressing all types of gases and mixtures; air separation units for industrial gases production; gas separation plants. Thanks to its Global Service Division, it also provides Assistance and Maintenance Services.

The SIAD Group is among the main industrial groups in Italy and Europe and its activity covers: industrial gases; Engineering; industrial goods; Healthcare and Services. Founded in Bergamo in 1927, SIAD has a strong tradition and a long standing experience. Over the recent decades, the company has succeeded in entering new markets and expand to other countries, while maintaining a flexible and dynamic organization and ensuring the highest quality, reliability and professionalism.

For additional details see the website <https://www.siadmi.com>

FOREWORD

SIAD Macchine Impianti challenge consists in punctually meeting requirements, facing needs and future expectations in an always more dynamic and complex scenario. For SIAD Macchine Impianti (hereinafter the Company), the adoption of an Integrated Management System represents a strategic decision helping to improve overall performance and a sound basis for sustainable development initiatives. The possible advantages resulting from its implementation according to the UNI EN ISO 9001 Standard, can be summarized as follows:

- Capability of duly providing products and services complying with applicable requisites;
- Encourage the opportunities to increase customer satisfaction;
- Risks resolution and opportunities identification, connected to its context and its objectives;
- Capability of showing compliance with voluntary and regulatory requirements.

The Integrated Management System (SGI), manages the range of regulatory requirements, codes, regulations and voluntary models that the Company Management has adopted and are listed in the Company Policy.

It is based on UNI EN ISO 9000 management principles:

- customer focus;
- leadership;
- engagement of people;
- process approach;
- improvement;
- evidence-based decision making;
- relationship management.

It's carried out by means of:

- the approach for processes, that ensures processes are properly provided resources and thus managed, improvement opportunities are established and relevant actions are duly taken to this purpose;
- the risk-based thinking, thanks to which it's possible to identify those factors that may deviate processes and its management system from already planned outcomes, to implement preventive checks to the purpose of lowering the negative effects and maximize opportunities when they arise.

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1. SCOPE

This manual describes the characteristics of the company Integrated Management System (SGI) in implementation of the Company Policy, with the purpose of:

- being the main operation reference guide for all those participating in its processes;
- demonstrating its ability to consistently provide products and services that meet customer and applicable legal (statutory and regulatory) requirements, and;
- being used by external parties to the company, including certification bodies, to assess its ability to meet the requirements of standards (and models) voluntarily adopted and company's own requirements;
- aiming to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable legal (statutory and regulatory) requirements.

2. REFERENCES

PASGI Company Policy of Integrated Management System
S000 Governance & Compliance

EN ISO 9001:2015 Quality management systems - Requirements

EN ISO 9000:2015 Quality management systems - Fundamentals and vocabulary

EN ISO 9004:2009 Managing for the sustained success of an organization

EN ISO 14001:2015 Environmental management systems

BS OHSAS 18001:2007 Occupational health and safety management systems

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

3. TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

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4. CONTEXT of the COMPANY

4.1. Understanding the company and its Context

The company has determined 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 Integrated Management System. The company periodically monitors and reviews information about these external and internal issues.

4.2. The Needs and Expectations of Interested Parties

Due to their effect or potential effect on its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the company has determined:

- a) the interested parties that are relevant to the Integrated Management System;
- b) the requirements of these interested parties that are relevant to the Integrated Management System;
- c) which of these needs and expectations become its compliance obligations.

The company monitors and review information about these interested parties and their relevant requirements.

4.3. The Scope of the Integrated Management System

The company has determined the boundaries and applicability of the Integrated Management System to establish its scope, in determining this scope the company has considered:

- a) the external and internal issues;
- b) the requirements of relevant interested parties;
- c) the products and services of the company;
- d) the compliance obligations;
- e) its authority and ability to exercise control and influence.

The company applies all UNI EN ISO 9001 requirements.

The scope of the corporate Integrated Management System is available and maintained as information documented in the Company Policy, types of products and services covered are declared.

4.4. The Integrated Management System and its Processes

The company has established, applies, maintains and continually improves an Integrated Management System, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The company has determined the processes needed for the Integrated Management System and their application throughout the company, and has:

- a) determined the inputs required and the outputs expected from these processes;
- b) determined the sequence and interaction of these processes;
- c) determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determined the resources needed for these processes and ensure their availability;
- e) assigned the responsibilities and authorities for these processes;
- f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) valued these processes and implemented any changes needed to ensure that these processes achieve their intended results;
- h) improved the processes and the Integrated Management System.

To the extent necessary, the company:

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

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5. LEADERSHIP

5.1. Leadership and Commitment

5.1.1. General

Through its Managing Director, the company demonstrates leadership and commitment with respect to the Integrated Management System by:

- a) taking accountability for the effectiveness of the Integrated Management System;
- b) ensuring that the corporate policy and Integrated Management System objectives are established and compatible with the context and strategic direction of the company;
- c) ensuring the integration of the Integrated Management System requirements into the company's business processes;
- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the Integrated Management System are available;
- f) communicating the importance of effective Integrated Management System and of conforming to the Integrated Management System requirements;
- g) ensuring that the Integrated Management System achieves its intended results;
- h) engaging, directing and supporting persons to contribute to the effectiveness of the Integrated Management System;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2. Customer focus

Through its Managing Director and the Heads of Corporate Bodies, the company demonstrates leadership and commitment with regard to customer focus, and ensure 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.

5.2. Integrated Management System Policy

5.2.1. Establishing and Maintenance

Through its Managing Director the company establishes, implements and maintains a Company Policy that:

- a) is appropriate to the purpose and context of the company and supports its strategic direction;
- b) provides a framework for setting Integrated Management System objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the Integrated Management System;
- e) provides a commitment to the prevention of occupational accidents and diseases, to compliance with applicable legislation on safety and health at work;
- f) includes a commitment to the protection of the environment, including prevention of pollution and other specific commitments relevant to the context of the company.

5.2.2. Communication

The Company Policy is:

- a) available and maintained as documented information;
- b) communicated (through company notice-board, intranets, training, or other possible means), understood and applied within the company;
- c) available to relevant interested parties, as appropriate.

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5.3. Roles, Responsibilities and Corporate Authorities

Through its Managing Director the company ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the company. The Managing Director has assigned responsibility and authority for:

- a) ensuring that the Integrated Management System conforms to the requirements of International Standards and the models that the Company Management voluntary has adopted, listed in the Company Policy;
- b) ensuring that the processes are delivering their intended outputs;
- c) reporting on the performance of the Integrated Management System and on opportunities for improvement, in particular to Managing Director;
- d) ensuring the promotion of customer focus throughout the company;
- e) ensuring that the integrity of the Integrated Management System is maintained when changes to the system are planned and implemented.

6. PLANNING

6.1. Actions to address Risks and Opportunities

6.1.1. Determination of Risks and Opportunities

When planning the Integrated Management System, the company considers the scope of the system itself, the issues referred to in 4.1, the point 4.2 requirements, the activities referred to in 6.1.1.1 to 6.1.1.3, and determines the risks and opportunities that need to be addressed to:

- a) give assurance that the Integrated Management System can achieve its intended results;
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effect;
- d) achieve improvement.

6.1.1.1. Hazards identification, risk assessment and control determination

The company establishes and maintains procedures for the ongoing identification of hazards, assessment of risks and the implementation of the necessary control measures. The procedures include:

- a) ordinary and extraordinary activities;
- b) activities routine and non-routine of all personnel having access to work place;
- c) human behavior, ability and other human factors;
- d) the identified hazards which originated outside the workplace with the potential to cause harm to health and safety to people under the control of the company within the workplace;
- e) hazards generated near the workplaces by activities related to activities controlled by the company;
- f) infrastructure, facilities and materials of the workplace, company and third parties';
- g) changes or proposals for changes in the company, its activities or materials;
- h) changes to the integrated management system;
- i) any compliance obligation related to the risk assessment and implementation of the necessary control measures;
- j) the design of work areas, processes, installations, machinery/plants, operating procedures and work organization, including their adaptation to human capabilities.

The company ensures that the results of these assessments are considered also taking account the following intervention hierarchy to reduce risks:

- a) elimination;
- b) substitution;
- c) technological measures;
- d) evidence(s) and procedural controls;
- e) personal protection equipment.

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6.1.1.2. Environmental aspects

The company determines the environmental aspects of its activities, products and services that it can control and those that it can influence, and their associated environmental impacts, considering a life cycle perspective. When determining environmental aspects the company takes into account change and the abnormal conditions and reasonably foreseeable emergency situations.

The company communicates its significant environmental aspects among the various levels and functions of the organization, and maintains documented information of its environmental aspects and associated environmental impacts, the criteria used to determine them and the significant environmental aspects.

6.1.1.3. Compliance obligations

The company determines the compliance obligations related to its environmental aspects and the application procedure, takes them into account when establishing, implementing, maintaining and continually improving its environmental management system.

6.1.2. Activity Planning

The company plans:

- a) actions to address these risks and opportunities, the environmental aspects and the compliance obligations;
- b) how to:
 - 1) integrate and implement the actions into its Integrated Management System processes (see 4.4);
 - 2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

6.2. SGI Objectives and Planning to achieve them

The company establishes objectives at relevant functions, levels and processes needed for the Integrated Management System. The system's objectives:

- a) are consistent with the Company Policy;
- b) are measurable;
- c) take into account applicable requirements;
- d) are relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) are monitored;
- f) are communicated;
- g) are updated as appropriate.

The company maintains documented information on the Integrated Management System objectives

In planning how to achieve its SGI's objectives, the company determines:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

6.3. Planning of Changes

When the company determines the need for changes to the Integrated Management System, the changes shall be carried out in a planned manner (see 4.4).

The company considers:

- a) the purpose of the changes and their potential consequences;
- b) the integrity of the Integrated Management System;
- c) the availability of resources;
- d) the allocation or reallocation of responsibilities and authorities.

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7. SUPPORT

7.1. Resources

7.1.1. General

The company determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the Integrated Management System.

The company considers:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

7.1.2. People

The company determines and provides the persons necessary for the effective implementation of its Integrated Management System and for the operation and control of its processes.

7.1.3. Infrastructure

The company determines, provides and maintains the necessary infrastructure (including as applicable: buildings and their associated utilities, equipment (hardware and software included), transport resources, information technology and communication) for the operation of its processes and to achieve conformity of products and services.

7.1.4. Environment for the Operation of Processes

The company determines, provides and maintains the necessary environment (understood as a combination of human and physical factors: social, psychological, physical) for the operation of its processes and to achieve conformity of products and services.

7.1.5. Monitoring and Measuring Resources

7.1.5.1. General

The company determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The company ensures that the resources provided:

- a) are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) are maintained to ensure their continuing fitness for their purpose.

The company retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2. Measurement Traceability

When measurement traceability is a requirement, or is considered by the company to be an essential part of providing confidence in the validity of measurement results, measuring equipment are:

- a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- b) identified in order to determine their status;
- c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The company determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.1.6. Organizational Knowledge

The company determines the necessary knowledge for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and made available to the extent necessary.

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When addressing changing needs and trends, the company considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2. Competence

The company:

- a) determines the necessary competence of persons doing work under its control that affects the performance and effectiveness of the Integrated Management System;
- b) ensures that these persons are competent on the basis of appropriate education, training, or experience;
- c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) retains appropriate documented information as evidence of competence.

7.3. Awareness

The company ensures that persons doing work under its control are aware of:

- a) the Integrated Management System Company Policy;
- b) relevant Integrated Management System objectives;
- c) their contribution to the effectiveness of the Integrated Management System, including the benefits of improved performance;
- d) the significant environmental aspects and related actual or potential environmental impacts associated with their work;
- e) the health and safety consequences, real and potential, of their work activities, of their behaviour, and of the health and safety benefits deriving from the improvement of personal services;
- f) the implications of not conforming with the Integrated Management System requirements.

7.4. Communication

The company determines the internal and external communications relevant to the Integrated Management System, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

When establishing its communication processes, the company takes into account its compliance obligations, and ensures that environmental information communicated is consistent with information generated within the environmental management system, and is reliable.

7.5. Documented Information

7.5.1. General

The Company's Integrated Management System includes:

- a) documented information required by the International Standards and the models voluntarily adopted through Company Policy;
- b) documented information determined by the company as being necessary for the effectiveness of the Integrated Management System.

7.5.2. Creating and Updating

When creating and updating documented information, the company ensures appropriate:

- a) identification and description;
- b) format and media;
- c) review and approval for suitability and adequacy.

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7.5.2.1. Participation and Consultation

The company establishes, implements and maintains procedures for employee participation through:

- a) The correct involvement in hazard identification, risk assessment and control definition;
- b) The correct involvement in the investigation of accidents;
- c) The involvement in the development and revision of health and safety policies and objectives;
- d) Consultation where there are changes that affect health and safety;
- e) Workers' representatives for safety.

The company ensures consultation of stakeholders when appropriate in the area of health and safety at work and consultation with suppliers when there are changes that affect health and safety at work.

7.5.3. Control of Documented Information

Documented information required by the Integrated Management System is kept under control to ensure:

- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected.

For the control of documented information, the company addresses the following activities, as applicable:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes;
- d) retention and disposition.

Documented information of external origin determined by the company to be necessary for the planning and operation of the Integrated Management System is identified as appropriate, and kept under control.

Documented information retained as evidence of conformity is protected from unintended alterations.

8. OPERATION

8.1. Operational Planning and Control, Emergency

The company plans, implements and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

- a) determining the requirements for the products and services;
- b) establishing criteria for:
 - 1) the processes;
 - 2) the acceptance of products and services;
- c) determining the resources needed to achieve conformity to the product and service requirements.
- d) Implementing control of the processes in accordance with the criteria;
- e) determining, maintaining and retaining documented information to the extent necessary:
 - 1) to have confidence that the processes have been carried out as planned;
 - 2) to demonstrate the conformity of products and services to their requirements.

The output of this planning is suitable for the company's operations.

The company identifies the operations and activities that are associated with the identification of the hazards for which it is necessary to apply the control measures to govern the risks of health and safety at work.

The company controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Consistent with a life cycle perspective, the company:

- a) establishes controls to ensure that its environmental requirements are addressed in the design and development process for the product or service, considering each life cycle stage;
- b) determines its environmental requirement for the procurement of products and services, as appropriate;
- c) communicates its relevant environmental requirements to external providers, including contractors;
- d) considers the need to provide information about potential significant environmental impacts associated with the transportation or delivery, use, end-of-life treatment and final disposal of its products and services.

The company ensures that outsourced processes are controlled (see 8.4).

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8.1.1. Emergency preparedness and response

The company establishes, implements and maintains the process needed to prepare for and respond to potential emergency situations.

The company:

- a) prepares to respond by planning actions to prevent or mitigate adverse environmental impacts from emergency situations;
- b) responds to actual emergency situations;
- c) takes action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential environmental impact;
- d) periodically tests the planned response actions, where practicable;
- e) periodically reviews and revises the process and planned response actions, in particular after the occurrence of emergency situations or tests;
- f) provides relevant information and training related to emergency preparedness and response, as appropriate, to relevant interested parties, including persons working under its control.

8.2. Requirements for products and services

8.2.1. Customer Communication

Communication with customers includes:

- a) the provision of information relating to products and services;
- b) handling enquiries, contracts or orders, including changes;
- c) obtaining customer feedback relating to products and services, including its complaints;
- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.

8.2.2. Determining the Requirements for Products and Services

In determining the requirements for the products and services to be offered to customers, the company ensures that:

- a) the requirements for the products and services are defined, including:
 - 1) any applicable statutory and regulatory requirements;
 - 2) those considered necessary by the company;
- b) the company can meet the claims for the products and services it offers.

8.2.3. Review of the Requirements for Products and Services

The company ensures that it has the ability to meet the requirements for products and services to be offered to customers. The company conducts a review before committing to supply products and services to a customer, including:

- a) requirements specified by the customer, including requirements for delivery and post-delivery activities;
- b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c) requirements specified by the company;
- d) statutory and regulatory requirements applicable to the products and services;
- e) contract or order requirements differing from those previously expressed.

The company ensures that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the company before acceptance, when the customer does not provide a documented statement of their requirements.

The company retains documented information, as applicable:

- a) on the results of the review;
- b) on any new requirements for the products and services.

8.2.4. Changes to Requirements for Products and Services

The company ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

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8.3. Design and Development of Products and Services

8.3.1. General

The company establishes, implements and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2. Design and Development Planning

In determining the stages and controls for design and development, the company considers:

- a) the nature, duration and complexity of the design and development activities;
- b) the required process stages, including applicable design and development reviews;
- c) the required design and development verification and validation activities;
- d) the responsibilities and authorities involved in the design and development process;
- e) the internal and external resource needs for the design and development of products and services;
- f) the need to control interfaces between persons involved in the design and development process;
- g) the need for involvement of customers and users in the design and development process;
- h) the requirements for subsequent provision of products and services;
- i) the level of control expected for the design and development process by customers and other relevant interested parties;
- j) the documented information needed to demonstrate that design and development requirements have been met.

8.3.3. Design and Development Inputs

The company determines the requirements essential for the specific types of products and services to be designed and developed. The company considers:

- a) functional and performance requirements;
- b) information derived from previous similar design and development activities;
- c) statutory and regulatory requirements;
- d) standards or codes of practice that the company has committed to implement;
- e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved.

The company retains documented information on design and development inputs.

8.3.4. Design and Development Controls

The company applies controls to the design and development process to ensure that:

- a) the results to be achieved are defined;
- b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
- e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- f) documented information of these activities is retained.

8.3.5. Design and Development Outputs

The company ensures that design and development outputs:

- a) meet the input requirements;
- b) are adequate for the subsequent processes for the provision of products and services;
- c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The company retains documented information on design and development outputs.

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8.3.6. Design and Development Changes

The company identifies, reviews and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The company retains documented information on:

- a) design and development changes;
- b) the results of reviews;
- c) the authorization of the changes;
- d) the actions taken to prevent adverse impacts.

8.4. Control of Externally Provided Processes, Products, Services

8.4.1. General

The company ensures that externally provided processes, products and services conform to requirements. The company determines the controls to be applied to externally provided processes, products and services when:

- a) they are intended for incorporation into the company's own products and services;
- b) they are provided directly to the customers by external providers on behalf of the company;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by the company.

The company determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The company retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.2. Type and Extent of Control

The company ensures that externally provided processes, products and services do not adversely affect the company's ability to consistently deliver conforming products and services to its customers. The company:

- a) ensures that externally provided processes remain within the control of its Management System;
- b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) takes into consideration:
 - 1) the potential impact of the externally provided processes, products and services on the company's ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2) the effectiveness of the controls applied by the external provider;
- d) determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3. Information for External Providers

The company ensures the adequacy of requirements prior to their communication to the external provider.

The company communicates to external providers its requirements for:

- a) the processes, products and services to be provided;
- b) the approval of:
 - 1) products and services;
 - 2) methods, processes and equipment;
 - 3) the release of products and services;
- c) competence, including any required qualification of persons;
- d) the external providers' interactions with the company;
- e) control and monitoring of the external providers' performance to be applied by the company;
- f) verification or validation activities that the company, or its customer, intends to perform at the external providers' premises.

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8.5. Production and Service Provision

8.5.1. Control of Production and Service Provision

The company implements production and service provision under controlled conditions.

Controlled conditions include, as applicable:

- a) the availability of documented information that defines:
 - 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 - 2) the results to be achieved;
- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria or control of processes or outputs, and acceptance criteria for products and services, have been met;
- d) the use of suitable infrastructure and environment for the operation of processes;
- e) the appointment of competent persons, including any required qualification;
- f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g) the implementation of actions to prevent human error;
- h) the implementation of release, delivery and post-delivery activities.

8.5.2. Identification and Traceability

The company uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The company identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The company controls the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

8.5.3. Property belonging to Customers or External Providers

The company exercises care with property belonging to customers or external providers while it is under the company's control or being used by the company.

The company identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the company reports this to the customer or external provider and retain documented information on what has occurred.

8.5.4. Preservation

The company preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

8.5.5. Post-Delivery Activities

The company meets the requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the company considers:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback.

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8.5.6. Control of Changes

The company reviews and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The company retains documented information describing the results of the review of changes, the person authorizing the change, and any necessary actions arising from the review.

8.6. Release of Products and Services

The company implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The company retains documented information on the release of products and services. The documented information includes:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person authorizing the release.

8.7. Control of Nonconforming Outputs

The company ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The company takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

The company deals with nonconforming outputs in one or more of the following ways:

- a) correction;
- b) segregation, containment, return or suspension of provision of products and services;
- c) informing the customer;
- d) obtaining authorization for acceptance under concession.

Conformity to the requirements is verified when nonconforming outputs are corrected.

The company retains documented information that:

- a) describes the nonconformity;
- b) describes the actions taken;
- c) describes any concessions obtained;
- d) identifies the authority deciding the action in respect of the nonconformity.

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9. PERFORMANCE EVALUATION

9.1. Monitoring, Measurement, Analysis and Evaluation

9.1.1. General

The company determines:

- 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;
- e) the criteria against which the company evaluates its environmental performance, and appropriate indicators;
- f) reactive measures for the control of occupational diseases, accidents and other historical evidence of the lack of health and safety at work performance.

The company evaluates the performance and the effectiveness of Integrated Management System.

The company ensures that calibrated or verified monitoring and measuring equipment is used and maintained, as appropriate.

The company retains appropriate documented information as evidence of the results.

9.1.2. Customer Satisfaction

The company monitors the customers' perceptions of the degree to which their needs and expectations have been fulfilled. The company determines the methods for obtaining, monitoring and reviewing this information, for example through customer surveys, customer feedback on delivered products and services, meetings with customers, market-shares analysis, compliments, warranty claims and dealer reports.

9.1.3. Analysis and Evaluation

The company analyses and evaluates appropriate data and information arising from monitoring and measurement. The results of analysis are used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the Integrated Management System;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the Integrated Management System.

9.1.4. Evaluation of compliance

The company establishes, implements and maintains the process needed to evaluate fulfilment of its compliance obligations: determines the frequency that compliance will be valued, evaluates compliance and takes action if needed, maintains knowledge and understanding of its compliance status.

9.2. Internal Audit

The company conducts internal audits at planned intervals to provide information on whether the Integrated Management System:

- a) conforms to the company's own requirements for its Integrated Management System;
- b) is effectively implemented and maintained.

The company:

- a) plans, establishes, implements and maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the importance of the processes concerned, changes affecting the company, and the results of previous audits;
- b) defines the audit criteria and scope for each audit;

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- c) selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensures that the results of the audits are reported to relevant management;
- e) takes appropriate correction and corrective actions without undue delay;
- f) retains documented information as evidence of the implementation of the audit programme and the audit results.

9.3. Management Review

9.3.1. General

The SGI function manager reviews the Company's Integrated Management System, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the company.

9.3.2. Management Review Inputs

The management review is planned and carried out taking into consideration:

- a) the status of actions from previous management reviews;
- b) changes:
 - 1) in external and internal issues that are relevant to the Integrated Management System;
 - 2) the needs and expectations of interested parties, including compliance obligations;
 - 3) its significant environmental aspects;
 - 4) risks and opportunities;
- c) the extent to which environmental objectives have been achieved;
- d) the progress of investigations into dangerous events, corrective actions and preventive actions;
- e) information on the performance and effectiveness of the Integrated Management System, including trends in:
 - 1) customer satisfaction and feedback from relevant interested parties;
 - 2) the extent to which Integrated Management System objectives have been met;
 - 3) process performance and conformity of products and services;
 - 4) nonconformities and corrective actions;
 - 5) monitoring and measurement results;
 - 6) audit results;
 - 7) the performance of external providers;
- f) the adequacy of resources;
- g) relevant communications from interested parties, including complaints;
- h) the effectiveness of actions taken to address risks and opportunities (see 6.1);
- i) opportunities for improvement.

9.3.3. Management Review Outputs

The outputs of the management review include decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the Integrated Management System;
- c) resource needs.

The company retains documented information as evidence of the results of management reviews.

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10. IMPROVEMENT

10.1. General

The company determines and selects opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

- a) improving products and services to meet requirements as well as to address future needs and expectations;
- b) correcting, preventing or reducing undesired effects;
- c) improving the performance and effectiveness of the Integrated Management System.

10.2. Nonconformity and Corrective Action

When a nonconformity occurs, including any arising from complaints, the company:

- a) reacts to the nonconformity and, as applicable:
 - 1) takes action to control and correct it;
 - 2) deals with the consequences;
- b) evaluates the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - 1) reviewing and analysing the nonconformity;
 - 2) determining the causes of the nonconformity;
 - 3) determining if similar nonconformities exist, or could potentially occur;
- c) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) updates risks and opportunities determined during planning, if necessary;
- f) makes changes to the Integrated Management System, if necessary.

Corrective actions are appropriate to the effects of the nonconformities encountered.

The company retains documented information as evidence of:

- a) the nature of the nonconformities and any subsequent actions taken;
- b) the results of any corrective action.

10.3. Continual improvement

The company continually improves the suitability, adequacy and effectiveness of the Integrated Management System.

The company considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

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