


MSGQ
QUALITY MANAGEMENT SYSTEM MANUAL

according to standards

ISO 9001:2015/Amd 1:2024
ISO/IEC 80079-34:2018

Rev. 22 of 07/05/2024

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REV	DATA	DESCRIZIONE	PREPARATO	CONTROLLATO	APPROVATO
22	07/05/2024	Implementation of amendment 1 of 23/02/2024 of the ISO 9001:2015	G. Fava	S. Libiani	M. Stoto
21	12/10/2022	Separated the SGI manual from the Safety, Environment and Health part, deleted references from ISO 14001 & ISO 45001	G. Fava		M. Stoto

[1] Also for UKCA
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CONTENTS

0. PROCESSES APPROACH AND RISK ASSESSMENT (UNI EN ISO 9001:2015)

Biffi Italia (hereinafter "the Company") has updated, redesign and implemented its own Quality Management System in compliance with the new references mentioned above in the cover sheet and the Corporate Emerson requirements included in GLOBAL QUALITY MANAGEMENT SYSTEM MANUAL.

0.1 General

Redesigning and improving its own Quality Management System, the Company has evaluated:

- Its capacity to supply regularly products and services which satisfy Customer requirements and the applicable mandatory references;
- Risks and opportunities associated to the internal and external context;
- Customer and stakeholders needs and expectations;
- Product and service typologies offered;
- Processes complexity and the interactions of the same ones;
- Personnel skills;
- Its dimensions and organizational structure.

0.2 Quality Management System fundamentals

The Company Quality Management System is based on the following fundamentals:

- Customer focus;
- Leadership;
- People active involvement;
- Processes approach;
- Continuous improvement;
- Decision process based on objective evidences;
- Relationships management.

0.3 Processes approach

0.3.1. General

The Company has established a documented and maintained functional SGQ to ensure that products supplied are compliant to the explicit and implicit Customer requirements and to the achievement of a company continuous improvement.
To properly apply the System, the Company has:

- arranged a Quality Management System Manual citing SGQ procedures;
- identified processes necessary to SGQ;
- established consecutions and interactions among the processes and criteria and methods to ensure the operating effectiveness of the same ones through suitable procedures;
- implemented the SGQ applying documented procedures and instructions;
- defined work instructions;
- defined the necessary resources;
- measured, monitored, analyzed the processes and implemented the necessary actions to obtain the results expected and continuous improvement.

Furthermore, the Company has defined, described and highlighted its full process in "**DR 158** Flow Chart QA" document and employs Value Stream Map methodology, typical of Lean Management, for process management.
The business processes were analyzed from the point of view of safety in chapter 1 of the DVR while the environmental aspects are found in the environmental analysis.
These documents are constantly updated in order to act from the point of view of processes optimization, continuous improvement, risk management, monitoring of the full process and identification of development and improvement opportunities.

0.3.2. PDCA

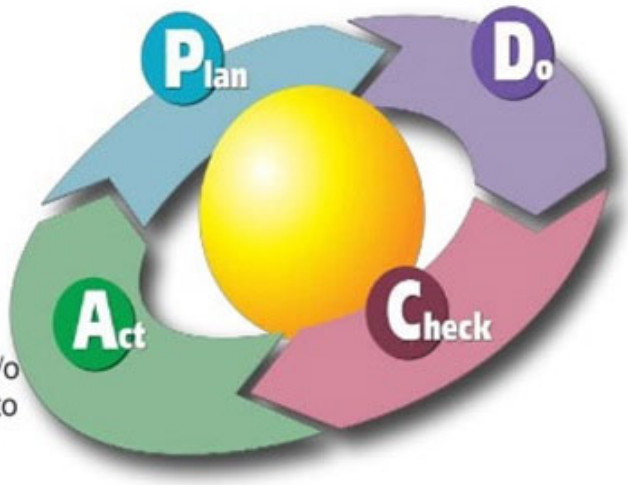
PDCA methodology, also as known as "Deming Wheel", is used for SGQ management and for particularly strategic processes also in a Kaizen optic (continuous improvement) and it follows the following method:

P - Plan. Pianificazione.

D - Do. Esecuzione del programma, dapprima in contesti circoscritti.

C - Check. Test e controllo, studio e raccolta dei risultati e dei riscontri.

A - Act. Azione per rendere definitivo e/o migliorare il processo (estendere quanto testato dapprima in contesti circoscritti all'intera organizzazione).



0.3.3. RISK ASSESSMENT – Risk-Based Thinking

Company SGQ aims to identify and manage risks and opportunities related to processes and resulting risks, to define the more suitable preventive and protective measures to eliminate and reduce to the minimum the risks.

0.3.4. RISK ASSESSMENT – Quality

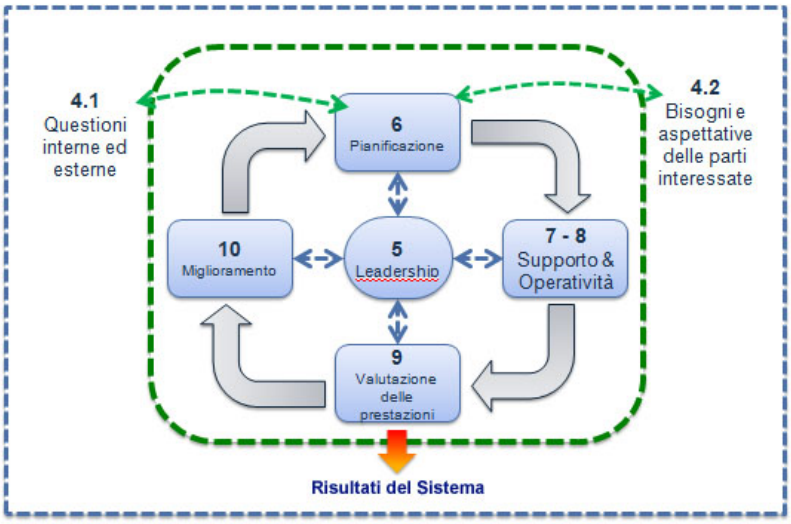
The Company, in accordance with **P-SGQ-03**, evaluates, with regard to Quality aspects:

- All the risks that may prevent Biffi from reaching its objectives (Risk Assessment);
- All the risks that can lead to a block of production (Business Contingency Plan).

The assessed risks are reported on the **DR 208**-Quality according to the criteria included in the document itself.

1. SCOPE AND SGQ APPLICABILITY

The Company, with the aim to unroll their own activities in the best way and in order to improve the environment in which it works, it decides to adopt a Quality Management System, in compliance with ISO 9001:2015 and ISO/IEC 80079-34:2018 reference standards.
SGQ adopted by the Company establishes management requirements which consent to express the company policy and establish goals which allows to obtain the continuous improvement of the company performances, as well as goals which permit to the organization to identify and manage company risks and improve performances.
SGQ establishes, documents, effects, maintains and improves continuously the company management system in accordance with International Reference Standards.
The following model shows the fundamental processes on which standards ISO 9001:2015 and ISO/IEC 80079-34:2018 are based:



This Manual and SGQ described in it are applicable to the activities of design, production, sales and after sales service for electric, pneumatic, hydraulic, gas-hydraulic and subsea actuators and the related control system respecting contractual and applicable standards requirements.
This Manual was realized to provide to stakeholders (internal and external from the Company) a clear and concise image of the company approach to quality, health&safety, environment management describing the principal aspects and the elements necessary to allow the reader to comprehend the way with which the Company has recognized and transferred in operating terms ISO 9001 and ISO/IEC 80079-34 standard requirements.
This document is one of the cornerstones of the commitment toward Customers and all the stakeholders, together with Integrated Policy.
The structure of this Manual is based on the voluntary standards applied.
These activities are carried out at Fiorenzuola d'Arda plant in Piacenza province (Strada Biffi,165).

2. NORMATIVE REFERENCES

The Company has developed its own integrated management system according to:

- ISO 9000:2015 model – Quality management system – Basis and vocabulary;
- ISO 9001:2015 model – Quality management system – Requirements;
- ISO 9004:2009 model – How to manage an organization for durable success – Quality management approach;
- ISO/IEC 80079-34:2018 technical standard – Implementation of quality management system to produce equipment installed in potentially explosive atmospheres.
- Amendment 1 of 23/02/2024 relating to the update of the UNI ISO reference standards for the UNI EN ISO 14001:2015 and UNI ISO 45001:2018 standards

The binding product requirements can be traced in appropriate documents managed by Quality Office. The main directives that constitute the references for Biffi actuators are the following:

- machinery directive 2006/42/EC – UK SI 2008 No. 1597 (as amended);
- low voltage directive 2014/35/EU;
- electromagnetic compatibility 2014/30/EU – UK SI 2016 No. 1091(as amended);
- RE-D Directive 2014/53/EU – UK SI 2017 No. 1206(as amended);
- ATEX Directive 2014/34/EU – UK SI 2016 No. 1107(as amended);
- PED Directive 2014/68/EU (See P-SGQ-30) – UK SI 2016 No. 1105 (as amended)

with subsequent amendments and integrations.

3. TERMS, DEFINITIONS

See the Quality Management System procedure **P-SGQ-35** regarding “Documentation Management” for more information for Quality aspects.

Here are quoted the functional bodies abbreviations:

Abbreviation	Function
ACQ	Sourcing
AF	After Sales
AGQ	Quality Management System Employee
AM	Atex Manager
AMM	Administration
ASGSA	Environment, Health&Safety Management System Employee
CE	Emergency Coordinator
COM	Sales
DDL	Employer
DS/RD	Plant Manager / Management Representative
EHS	Environment, Health&Safety Office
ENG	Engineering
HR	Human Resources
LOG	Logistics
MC	Plant Physician
MKT	Marketing
NC	Non-compliance
PMG	Product Manager
PMO	Project Management

Abbreviation	Function
PPP	Production Planning
PRD	Production
QA	Quality Office
ODV	Supervisory body
RQ	Quality Management System Manager
RLS	Workers' Safety Representative
RSGSA	Environment, Health&Safety Management System Manager
RSPP	Prevention and Protection Service Manager
SAL	Sales
SGQ	Quality Management System
SPP	Prevention and Protection Service

The following abbreviations are cyclic in the text:

SGQ	Quality Management System
MSGQ	Quality Management System Manual
PGI	Integrated Management Procedure
P-SGQ	Quality Management System Procedure
IOA	Environmental Operating Instruction
I-SPP	Safety Operating Instruction
I-SGQ	Quality Management System Instruction
SW	Standard Work
DR	Recording Document

ISO 9001:2015
Terms and definitions used are those defined by standard ISO 9000:2015.

ISO/IEC 80079-34
Ex Component: *part of Ex equipment or a module (other than an Ex cable gland), marked with symbol "U", which is not intended to be used alone and requires additional consideration when incorporated into Ex equipment or systems for explosive atmospheres use.*
Ex Equipment: *machines, equipment, fixed or mobile devices, control components and instrumentation, as well as detection or prevention systems which, separately or jointly, are intended for the production, transport, storage, measurement, control, energy conversion and for the transformation of material and which are able to cause an explosion through their own potential sources of ignition.*
Ex certificate: *document that assures the conformity of a product with the specified requirements for explosive atmospheres.*
Manufacturer: *organization, situated at a stated location or locations, that carries out or controls such stages in the production, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance with the relevant requirements of the product and undertakes all obligations in that matter.*
Contract: *requirements forming an agreement between manufacturer and customer and transmitted by any appropriate means.*
Customer complaint: *written report or verbal statement made by a customer which concerns the identity, quality, durability, safety, security, conformity or performances of any equipment or protective system or component as defined in Ex certificate.*
Product: *Ex equipment, protective systems, safety devices, Ex Components and their combinations, as well as software and service as defined in 3.4.2 of ISO 9000:2015.*

Safety devices: *devices intended for use inside or outside explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the explosion risks.*
Schedule drawing: *drawing or document listed in the Ex certificate and/or test report.*
Related drawing: *drawing or document not listed in the Ex certificate but linked to the schedule drawing and used, for example, for detailed production of components.*
Technical documentation: *documentation that enables the conformity of a product with the requirements of the standard(s) to be assessed.*
Manufacturer's documentation: *documents required by a manufacturer but not subject to assessment by the body responsible for verification when it is carried out a request for a test report or an Ex certificate.*
Protection type: *specific measures applied to Ex equipment to avoid ignition of a surrounding explosive atmosphere.*
Body responsible for verification: *body which conducts documentation review and periodical audit as requested by the Directive.*

4. ORGANIZATION CONTEXT

Company specific data are the following:

Company name:	BIFFI ITALIA S.r.l.
Foundation year:	1955
Main markets:	Foreign countries 80%, National 20%
Production:	Actuators and Control systems
Social capital:	1.820.000 Euro
REA:	PC – 121628
VAT n° and tax code:	01018580330
Employees at 02/05/2024	**327** of which 294 Biffi employees and 33 temporary workers
ATECORI 2007 classification	Code: 26.51.29 – production of other measure and regulation equipment, design instruments, electricity, gas, water and other liquids meters, precision analytical balances (disconnected parts and accessories included) Importance: P - primary Company Register Code: 28.14 – production of other taps and valves Importance: S - secondary Company Register Code: 28.12.00 – production of fluid-dynamic equipments (Scope: classification declared for IVA)
R.S.P.P.	Cristina Santi

4.1 Internal and external relevant factors

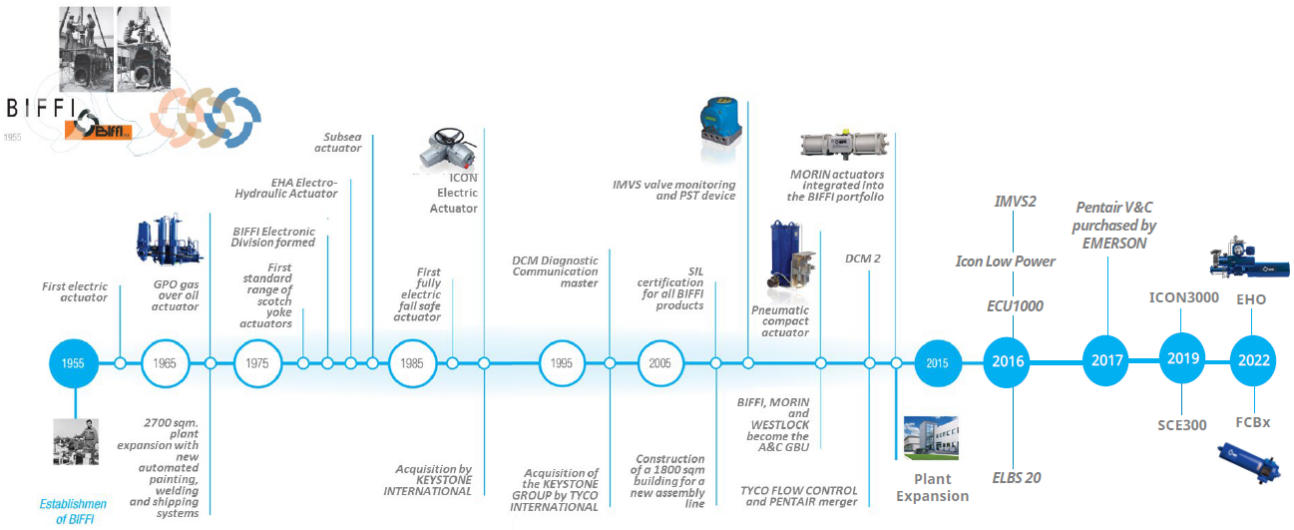
Company activities could be operated both in Italy and in foreign countries.

Biffi Italia S.r.l. is located near Fiorenzuola d'Arda on the way for Castell'Arquato. It designs and produces electric, pneumatic, gas-hydraulic and subsea actuators necessary for the functioning of different type of valves (butterfly, ball, etc.) installed in oil plants, gas pipelines, power and hydraulic plants, chemical plants, water systems located in every part of the world and related control systems.

Biffi is a leader in its sector for the production and design of electric and gas-hydraulic actuators customized and designed according to worldwide Customer requirements and needs.
It was born in 1955 as a family business by Magni brothers who have created a company believing strongly in their ideas and projects with solid foundations and a team of expert, motivated and creative people so closely that it became attractive to several multinationals that later bought it.

The following scheme represents the various ownership changes of the Company:

- It has been a Magni property until 1989;
- In 1989 it was sold to an American multinational Keystone International Inc.;
- In 1997 it has been sold by an American multinational Tyco, Flow Control division;
- From 2012 October 1st is become part of Pentair Group, Actuation & Controls division;
- From April 2017 has become part of Emerson group together with all Pentair Valves & Control and Actuation & Control. Biffi has become part of Actuation and Technologies division;
- From 2019, Biffi produces actuators with Emerson, Bettis and Fisher trade-mark.

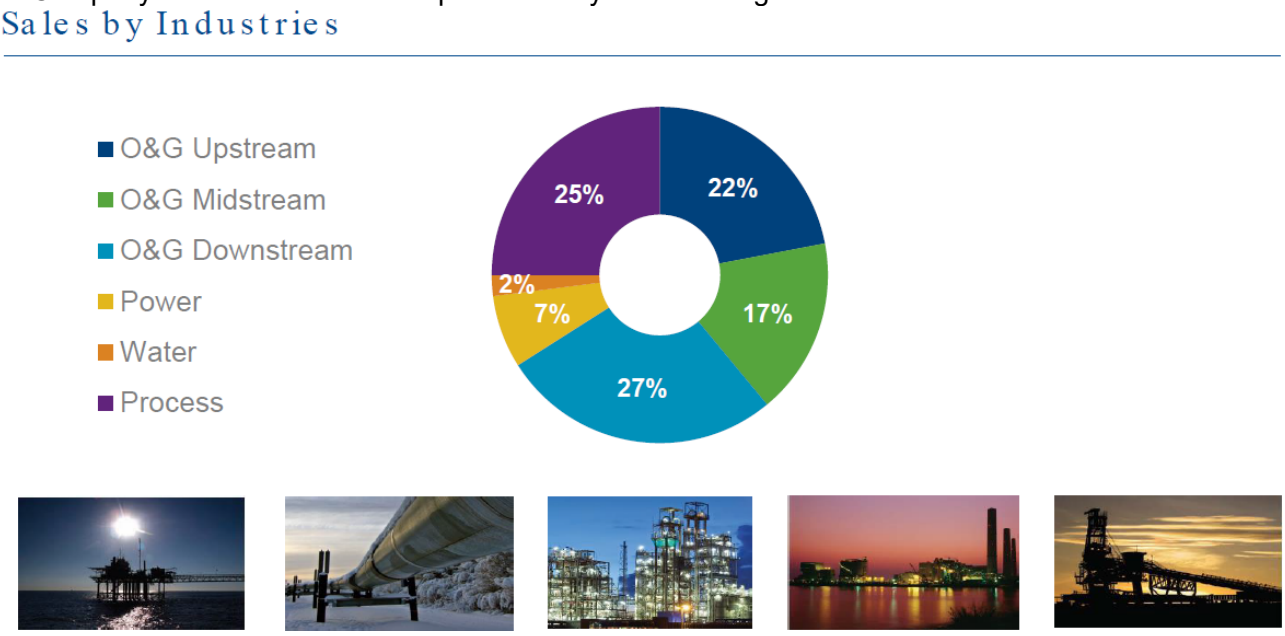


After a first expansion in 1969 which involved the relocation to the current plant, the establishment was substantially enlarged in 1978.
A new 2.715 m2 building was built in 1996 to host an automated equipment for painting. In 2007 building 2 was enlarged with a part of the shed used for assembly and testing of greater dimensions gas-hydraulic actuators and a part of the new Shipping Department with the related Administration Offices for invoicing. Every year some operational department were reorganized applying Lean methodology. In 2014 a new 3 floor building was built for Management Offices, Marketing, Sales, PMO, Reception, etc. and the cafeteria has been renovated.

As of November 2023, the new photovoltaic system of about 900 Kwatt of power built on the new canopies of the employee parking lot (300 parking spaces) came into operation.
Today the Company has a 63.988 m2 area.

The company has a modern establishment equipped with modern equipment, where the Industrial Engineering and Application departments use a fully automated IT system for design, and the engineers of the Research and Development department constantly develop technical innovations that are able to allow the company to be an actor of prime reference for the sector, thanks also to the application and development of the most recent technologies. The Company Technical and Sales Offices are always available to satisfy any Customer request.

The Company reference market is represented by the following sectors.



Productive cycle (active on average for 220 days/year) is organized through “Value Streams” and follows the following main operational phases:

- Raw material acquisition;
- Warehouse;
- Production planning;
- Carpentry;
- Machining;
- Deburring;
- Washing;
- Primer painting;
- Assembly;
- Intermediate testing;
- Final painting;
- Finishing;
- Final testing;

- Touch up;
- Packing;
- Shipping;
- Technical assistance to client companies

Phases are widely described in Risk Assessment Document.

Based on these considerations, it can be assumed that the internal and external factors taken into consideration are the following:

External factors:

a) Cultural, social, legal, financial, technological, economic and market factors and environmental.

b) Influence of new competitors, contractors and all types of suppliers.

c) New technologies, laws and new knowledge on products and processes and their effect on safety and health at work and environment.

d) Relevant factors and trends relating to the specific industry or sector.

e) Relations with interested parties and their perceptions.

f) Influence of climate change on products and processes.

Internal factors:

- Governance, organization, roles and responsibilities.
- Policies, objectives and strategies.
- Resources, knowledge and skills (eg, capital, time, human resources, processes and technologies).
- Introduction of new products and services.
- Relations with the workforce, with suppliers and contractors and with outsourced suppliers.
- Hours and working conditions.

4.2 Needs and expectations of interested parties

Public Administration (Municipality/ASL/Local societies/Customs/INAIL/ARPA/VV.FF./etc.): it is expected that standards, regulations and directives in effect should be satisfied and respected, in terms of legal, fiscal, environmental and of safety and prevention.

Territory and Neighborhood: they wish that the potential pollution sources produced by the company (atmosphere emissions, acoustic pollution, etc.) are kept to a minimum and do not affect the comfort and wellness linked to the quality of life.

Shareholders/owners: they want to maximize the business with a development and continuous sustainable improvement point of view to obtain the performances defined in the budget and in the short, medium, long term goals. This is the reason why, first of all, they have decided to implement SGQ. Their interest in SGQ is related to the company's ability to satisfy the requirements and to avoid penalty or uncover possibility of cost savings thanks to improvement obtained through SGQ, the correct planning and the continuous improvement that allow, among other things, the fight and contrast of emergencies (environmental, health, natural disasters, safety, etc.).

Customers: they wish that the delivery of the products realized by the Company will not be delayed due to defects, planning mistakes or major unforeseen as well as natural disasters. They wish a competitive and sustainable product sales price in the face of quality products and with an extremely low defect index.

Suppliers/partners: they want an adequate remuneration for the product/service supplied, being paid on time, to be able to realize their product/service in a planned way with a delivery time suited to the required complexity in order to limit planning errors or unforeseen events of majeure such as natural disasters or accidents at work, and with a precise and clear definition of the requirements and specifications agreed. All this from a partnership, growth and mutual business development point of view.

Employees: they want to work in a company where they can be proud of their contribution, can grow professionally and work in a planned way without possible emergencies related to planning problems, supplier delivery and defectiveness/lack of materials, components and/or products defects. They want to spend their working hours in a healthy, safe, sustainable and friendly environment and to work in synergy with their colleagues establishing personal relationships based on respect, transparency and trust, reaching the goals shared with the company.

Head company: they wish to have the certainty of the application of the legislative obligations related to the specific country. It provides support based on its own experience and that of the other companies in the group in order to raise awareness of the development and production of increasingly sustainable products by encouraging the use of new technologies with a lower environmental impact and increasingly safer from the point of view of safety. It requires the application of group rules to allow a homogeneous management of common aspects.

Workers' representatives, trade unions and employers: they want to have all the information available about the obligations put in place by the company so that they can verify and make workers aware of the provisions of the legislation and other requests.

Visitors: they want the workplaces to which they have access, the equipment and the working environment in general to guarantee everyone the best possible standard of health and safety and the environment for everyone.

Relatives and relatives of workers: they want the workplace, equipment and in general the working environment to guarantee everyone the best possible standard with a view to prevention and continuous protection of workers, satisfaction and fulfillment of the workers themselves.

In addition, they want the potential sources of pollution produced by the company (emissions into the atmosphere, noise pollution, etc.) to be reduced to a minimum and not affect the comfort and well-being related to the quality of life of the workers and their families.

Industrial associations, non-governmental organizations (NGOs), media: they want to be made aware of all the information required in order to monitor the situation and provide updated information to their interlocutors.

ODV: compliance with regulations and maintenance of the measures necessary for compliance with Legislative Decree 231/2001.

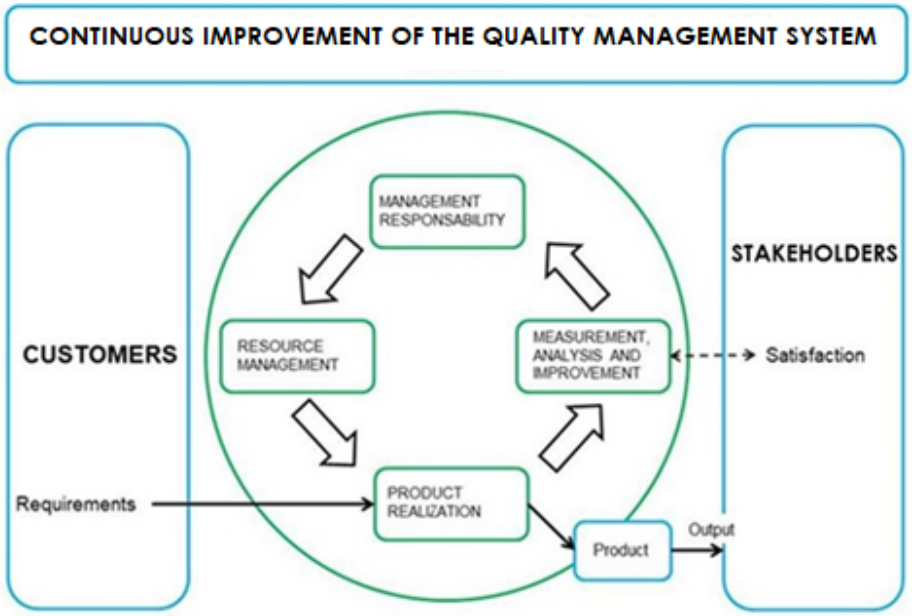
4.3 Applicability

BIFFI ITALIA S.r.l. is in Fiorenzuola d'Arda and performs activities of design, production, sales and after sales service of actuators and related control systems for Oil & Gas, power, water and processes sectors considering the external and internal factors reported in point 4.1 and the requirements or relevant stakeholders reported in point 4.2.

Quality Management System was planned to satisfy all the requirements contained in ISO 9001:2015/Amd 1:2024, ISO 14001:2015, ISO 45001:2015 and ISO/IEC 80079-34:2018 standards.

4.4 Quality Management System requirements and its processes

The implemented SGQ allows to identify the processes that impact on the company's functionality, to establish the correct flow and its interactions, managing them through appropriate controls and indicators. The interaction between the improvement and the support processes for implementation and general control and is total; it concerns all the business processes in general and is set as illustrated in the following flow.



The mapping of the Biffi processes is represented in **DR 158.**

5. LEADERSHIP

Responsibilities related to the following MSGQ chapter are evident from the responsibilities contained in the reference procedures.

The Company choses to act according to a work logic based on empowerment because Management believes that a model based on a slim and horizontal asset will be more effective in terms of personnel motivation.

In order to guarantee the effective functioning of SGQ roles, responsibilities, duties and mutual relations of all the personnel who manages, unrolls and controls the activities which impacted on products and services of the products, on environment, health, safety are identified.

The management also identifies the participation of workers as a fundamental value for maintaining a good corporate organizational level.

See **Organizational Chart.**

5.1 Leadership and Commitment

Fundamental values on which the Company work is based are the following:

- Loyalty, transparency and respect towards superiors, colleagues and employees, customers and internal and external suppliers;
- Ability to respond quickly and comprehensively to superiors, colleagues, employees, customers and internal and external suppliers;
- Operational methods in line with the procedures and ability of the Company and of the individuals to take in charge their responsibilities;
- Willingness to favor managerial and staff development practices (continuous training);
- Specific attention to environmental;
- Punctuality and reliability;
- Operational methods aimed at achieving objectives and continuous improvement (See P-SGQ-01).

Company management has chosen to keep the Quality Management System active using PDCA methodology and:

- planning activities and modifications (Plan);
- introducing changes in located areas and/or through master plan (Do);
- verifying the activities and changes effectiveness through documented evidences (Check);
- extending success activities and changes on a large scale (Act).

The Management is constantly committed to develop, maintain, and improve continuously:

- their responsibility for SGQ effectiveness;
- integration of the SGQ into the business and definition of goals in line with company strategies and its context;
- awareness raising and risk-based thinking approach (See **P-SGQ-03**);
- the availability of the necessary technical and human resources;
- communication and disclosure at all levels of the importance of SGQ requirements.

It also undertakes to:

- ensure that the SGQ achieves its goals;
- involve, guide, and support the people who contribute to the effectiveness of the SGQ;
- provide support to other managerial roles in demonstrating their leadership.

5.1.1. General

In this way, the Company has set up a Management committee (which makes available departments all the resources necessary for the management, execution and verification of work activities to the company, activating the appropriate communication processes within the organization), implemented a corporate **Lean War Room**, defined a competencies / skill matrix for each department, which is kept updated by RQ, and acts to make sure that the collaborators:

- receive timely and continuous information on organizational performance;
- can learn the appropriate knowledge and skills to contribute to organizational goals;
- can make significant decisions based on documented evidences (Safety, Quality, On Time Delivery, Cost);
- can understand the meaning and impact of the activities according to the organization's results (Lean Gemba Walk, 5S Plant Overview, PDCA).

In addition, the Management establishes specific goals, committing itself to providing support and security to its employees involved in first person in addressing the major organizational challenges as well as daily issues, in an atmosphere of openness also favorable to experimentation (KPIs).

5.1.2. Customer focus

The Company's High Management is committed to spread the importance of satisfying Customer's requirements at all company levels.
It considers a priority and imperative need to provide its customers with quality products that fully meet the implicit and explicit needs and expectations of the same ones.
In this regard, it established a process of monitoring and measuring of customer satisfaction, subjected to periodic review by the Management.

5.2 Quality Management System policy

High Management has defined the general principles on which the Policy for the Quality Management System is based in accordance with the requirements included in Corporate Emerson Policy, which acts as an engine for its organization, setting guidelines, goals and commitments. The policy is appropriate and compatible with strategic direction.

5.2.1. Policy definition

Every year the Management presets specific goals during the Review and assesses whether the contents of the policies are still adequate to achieve these goals within the pre-established times.
SGQ policy and its related goals arise from a careful and objective analysis of internal situation, results achieved and future objectives, as well as the external environment and stakeholder requests.

5.2.2. Policy communication

Policy is formalized by the Management in the document called **“Quality Policy”**, spread and illustrated to all Company personnel during the start year company meeting. It is available to all the interested

functions, posted on a company notice board, saved in a folder shared with all company staff and published on company website.

5.3 Roles, responsibilities and organization authorities

To make that a system works, the involved functions must be fully aware of their role. The Management ensures that the most relevant responsibilities and authorities are unequivocally defined and that anyone involved is clear about their role. This is to optimize planning by ensuring that awareness is achievable through communication and training.

Each Team Leader (or area) is responsible for their employees, plans their activities, and has complete visibility on the components of his team in terms of production and performance, through evidences documented in the management system.
It also provides for the enhancement and professional growth of its employees, also after Management requests, in order to pursue the development of knowledge and continuous improvement.

Company roles and main tasks are indicated in the company ***organization chart***. All the information are available on Biffi Intranet company portal.

As for Atex directive, the ATEX Manager is responsible for:
- effectively coordinate the activities for equipment intended for use in explosive atmospheres;
- communicate with the body that issues the Ex certificate in relation to any proposed modification to the technical documentation and the project contained in the Ex certificate;
- maintain the connection with the body responsible for the verification of the quality system;
- authorize the initial approval process and modifications to drawings when necessary;
- authorize the concessions;
- review the Ex-certificate and the technical documentation, identifying any changes that may affect the conformity of the product with the certificate.

6. PLANNING (Plan – Do – Check – Act)

The Company has started a risks recognition process and opportunities relevant to the management system's purpose and defined actions, objectives and plans to be faced up.

6.1 Actions to address risks and opportunities

In recognizing risks and opportunities, the organization has considered the context and process inputs and expectations of internal and external stakeholders.
Furthermore, it has created, compiled and continuously managed **DR 208** Risk Management, which provides data useful for the effective management of risks and opportunities in relation to different issues. Methods are described in paragraphs 0.3.3 and 0.3.4 of this Manual.

6.2 SGQ objectives and planning to achieve them

The SGQ specific goals are defined annually during Review by the Management and are quantified and measurable through specific targets, which allow to verify the level reached and identify the improvement areas.

The goals consider the SGQ policy, the company needs and the market in which the company operates, and they are defined for the whole company organization and assigned to the various managers, within the relevant activities.

Quality planning is documented and meets the company's operational needs to meet the requirements set for contracts, products and controls.
The Manual, Procedures, Instructions, data and reports are an integral part of SGQ planning and constitute the set of activities and plans that develop the processes to be performed, the assignment of responsibilities, the tests and the improvement activities for SGQ implementation.
If, in presence of a specific contractual request and/or a product there are no documents already prepared, a specific plan is issued in compliance with all System requirements indicating the necessary additional requirements related to the activities planning of the specific product.

The reference procedure is **P-SGQ-01**.

6.3 Planning of changes

To ensure that the changes necessary for the management system will be planned, the possible consequences are considered, and the availability of resources and the definition of roles and responsibilities are ensured, proposals for changes to the management system are collected in the improvement plan, reported in the management review and managed as a **PDCA** project.
If extraordinary changes to the management system are required (as in case of company acquisitions, introduction of new products or services, stock exchange listing, etc.), a specific PDCA project will be implemented.

7. SUPPORT

The specific resources to keep SGQ active and effective and to allow its continuous improvement has been determined and made available by the Management on the basis of the Management Review and planned in the improvement plan, also for possible management of contracts and/or specific projects, both in terms of human resources and in logistic and/or procedural terms.

7.1 Resources

The Management undertakes to identify the resources necessary to maintain SGQ effectiveness and increase customer satisfaction and interested parties in compliance with the requirements.

During Review, the Management evaluates which resources are necessary for goals achievement, and endeavors to acquire them.

The staff is considered as a very important resource, given the close connection between the quality of the system and staff professionality.

In this sense, the motivation of the staff and individual awareness are an absolute priority for the Management both for the achievement of the preset goals and for the continuous improvement of system performances. Training and continuous updating are considered essential for ensuring staff growth and motivation.

Protection of working environment, natural environment, prevention of accidents and safety of workers during their activities are guaranteed by a periodic review of the fulfilments dictated by the standards adopted.

The Company pays particular attention to the management of resources and work environment through:

- Assignment of clear and well-defined tasks;
- Staff involvement in all company activities;
- Plant management and maintenance;
- Definition of security and fire prevention plans;
- Definition of emergency procedures
- Employee training on safety for personal protection devices use;
- Identification and use of appropriate measures to incentivize staff and involve them in the improvement;
- Involvement of all personnel to be aware of the importance of their activities and their contribution to achieving the goals set by the Management.

For this reason, it has defined and maintained the necessary infrastructures and work environment to ensure product compliance with the requirements.

Ordinary maintenance of the infrastructures is designed to keep them efficient and to avoid interruptions of service due to breakages or anomalies.

If an infrastructure needs extraordinary interventions (due to fault, anomaly, lack of reliability, etc.) the person in charge contacts the Management and the internal maintenance service signaling the need to take action to solve the problem.

The definition of intervention intervals, methods of execution and verification of the maintenance interventions both for the infrastructures and for the work environments are in charge of the Management and the maintenance service.

Work environments have been analyzed in detail in the Environmental Analysis (for environmental aspects) and in the Corporate Risk Assessment Document (for aspects related to health and safety).

It is also remembered that BIFFI ITALIA is careful to the aspects of energy consumption, keeping the goal of reducing them as a priority.

Company's staff, who work within the Integrated Management System, are competent and able to perform their duties, and are supported by adequate equipment and infrastructures, including the company's buildings, hardware and software and means of transport.

The Company has determined which type of monitoring and measurements to take, verifying that it is carried out with correct and reliable equipment, which are regularly calibrated and maintained with the related documented information retained. For this reason, it organizes and manages the monitoring, maintenance and calibration of monitoring and measurement equipment, for objective credibility of read values and to demonstrate the product conformity with the specified requirements.

The company has prepared documented procedures and instructions, which clearly describe how its organization implements the monitoring, maintenance and calibration of monitoring and measuring equipment, which can affect the quality of the product.

This activity includes not only the final testing control devices, but also those related, where applicable, to product development, raw material control, control and regulation of the production process.

The equipment identification information is clearly highlighted on the same equipment by permanent marking and, where possible, by an adhesive label which shows the calibration status, which is also recorded in the specific management software application. Unsuitable tools are segregated to prevent their use. The data recorded in the software database are related to:

- identification of the equipment;
- date of last calibration;
- date of subsequent calibration;
- location of the equipment;
- Organization responsible for calibration.

Everything is detailed in **P-SGQ-18** procedure.

Business planning, in addition to the analysis of availability and requirements of materials and labor, includes the management of scheduled maintenance, to ensure that the production cycle organized over several shifts is continuous. For planned maintenance and other work tools such as forklifts, means of transport, telecommunications and information systems, is all detailed in the procedure related to scheduled maintenance **PGI 14-07**.

Needs related to organizational knowledge by employees are defined and planned in the company's "**Competencies / Skill matrix**".

The Company has defined responsibilities, criteria and methods for identifying training personnel needs who carry out activities that have an influence on quality and provide training by registering their performance and qualification and personnel assigned to particular tasks annually assessing the performance of all staff. Training activities are managed in the **VULSUB ITALIA.01** procedure.

To define the hierarchical-functional relationships, the Company has an updated **organization chart**.

7.2 Competence

To determine the competence, the relative criteria are established for each function that affects the SGQ, in order to evaluate the existing competence and determine the future needs. If the criteria are not satisfied, the Company carries out training plans aimed at overcoming the lack of competence/knowledge, including recruitment, training and job change programs.

The training activities are managed in human resources management procedure **VULSUB ITALIA.01.**

7.3 Awareness

Personnel must be aware of their activities importance, their contribution to achieving the SGQ objectives and the effectiveness of the management system and the consequent performance of the organization. For this purpose, regular training programs and company meetings occurred.

7.4 Internal and external communication

An effective two-way communication is essential for the company to have an efficient and performing management system and it must concern what you want to communicate, but also what has been understood; in other words, what has been planned and what has been reached up.
Management, RQ, RSGSA, RSPP are committed to the disclosure and involvement of all staff in the management of that, adopting appropriate tools such as:

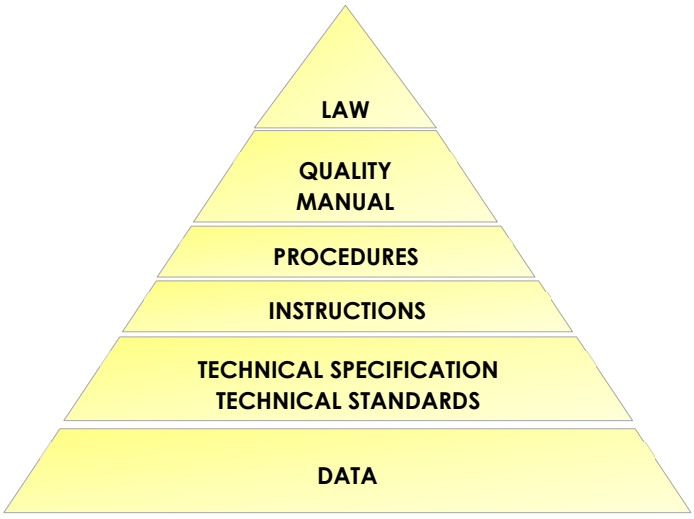
- Regular registered meetings and training sessions with staff
- Disclosure of policies and SGQ goals;
- Documentation disclosure (Procedures, Instructions, Standard Work);
- Written communications;
- Applying projects, performance indicators, PDCA plans, Value Stream Maps, etc. inside War Room;

The management criteria relating to the communication activity are described in the **P-SGQ-34**.

7.5 Documented information

The Company has expressed the need to maintain or preserve documented information to concretize, clarify and demonstrate the fact that SGQ is updated and effective.
For this reason, it has maintained its own Quality Management System Manual and all the existing documentation, also integrating it with other documented information, including data from the management system.

The SGQ document structure has been conformed to the operative reality of the Company and therefore includes the documents necessary to ensure the effective functioning and control of the processes.
Quality Management System (SGQ) document structure is shown in the following figure:



Quality management system documents are subdivided into:

- Quality Management policy
- Quality Management System Manual;
- Procedures (P-SGQ);
- Operating instructions (I-SGQ, IOA, SW);
- Modules (Mod.), Registrations (DR);

- Documents of external origin (laws, regulations, standards);
- Data and evidences of the management information system;
- Visual Management practices.

The documentation is kept under control according to the procedures indicated in the **P-SGQ-35**.
The documents, approved by Management, are managed electronically on company servers.
The communication to the staff at the time of publication and/or modification of the documents is done by e-mail.

7.5.1. SGQ Manual

The manual is the main document to describe or recall topics such as:

- integrated policies and Corporate Emerson Policy;
- the company organizational structure;
- the responsibilities attributed to the various organizational positions;
- the identification of processes and description of their interactions;
- recall of management system procedures;
- any definitions of the specific terms used.

The responsibility for the development of the SGQ Manual contents belongs to the Management together with the process managers, to guarantee credibility and effectiveness in their application.

RQ has a fundamental role in the development of the Manual, making use of the collaboration of all the aforementioned functions to ensure that they comply with the requirements of the relevant standards, contractual aspects and Company policy.

Copies of the Manual can be distributed to all the company functions involved and to Customers, when requested.

RQ manage the distribution of copies of the Manual or its revised sections.

7.5.2. Documents and data

This section describes the measures that the Company has adopted to keep under control the documents and data considered as fundamental for the definition and satisfaction of the contract and for SGQ management, including, as far as applicable, the documents coming from the outside (rules, binding laws, drawings of the customer, etc.).

Before issuance, SGQ documents and/or data are verified, for the purpose of their adequacy, approved and signed by authorized personnel, becoming operational following approval by signature, the specific Manager and the Management.

Every modification and/or revision concerning the documentation follows the same procedure as the original one.

7.5.3. Control of documented information

Documents and records relevant to SGQ, with which it is possible to evaluate the opportunity to implement improvement interventions, are identified, collected and stored in order to demonstrate the effective application and achievement of the objectives.

The records, whether they are general or specific documents, are cataloged in such a way as to be quickly traceable, allowing also the correlation between the same registrations and the product and/or the activity to which they refer to.

All documentation is stored on the company server and/or in the management application system.

Details are defined in the **P-SGQ-35**.

8. OPERATION

Generally operating activities are traceable through transactions in SAP.

8.1 Operational planning and control

These tools allow to manage the correct development of activities under controlled conditions by means of a sequence of predefined operations linked together such as:

- documented procedures or instructions, which define the various stages of the production process;
- training of production and control personnel on the process and on the equipment to be used;
- monitoring and control of process parameters to ensure that the specified requirements are met;
- definition of the conditions for keeping the process parameters and product characteristics under control, in the ways and at the times defined, establishing where and how to make the measurements, etc.;
- identification of the limits and/or tolerances within which to maintain the process regulation parameters;
- assurance that corrective actions and the relative approvals are implemented, in the manner and within the defined times;
- updating, methodically, of any changes to the documentation in strict correlation with the evolution of the product and / or technologies;
- issuance of corrective actions whose statistically consolidated results make operative instructions and/or procedures that improve the reliability of the process and therefore of the product.

With regard to the planning and controls carried out in the Quality area, please refer to the procedures **P-SGQ-20 and P-SGQ-31**.

8.2 Products and services requirements

The Company has identified the activities for the correct determination of the product requirements, whether they are specified by the Customer that are implicit and/or binding. The requirements are defined in the economic offer that is sent to the customer.

8.2.1. Customer Communication

The company takes great care in communication with the customer, as it is considered the basis for establishing an active collaboration and therefore an added value, in the production process with a view to continuous improvement.
Communication with the Customer is mostly taken care of by SALES and PMO through:

- commercial documentation sending (offers, confirmations, price lists);
- technical documentation sending for a better definition of the product (e.g. datasheet, drawings);
- communications, by SALES and/or PMO, in case of problems in the execution of the supply or any delays;
- reception and response to Claims by AFTER SALES.

This Manual paragraph is defined in Product Supply Management Procedure **P-SGQ-02**, **P-SGQ-16**, **P-SGQ-17, P-SGQ-32**.

8.2.2. Definition of the requirements for products and services

Before submitting an offer and/or accepting an order, SALES and PMO verify that the content of the Customer's proposal gives clear and complete information, to assess if what is required and feasible and

that all the requirements related to the product are clearly defined, then proceed with the issue of its confirmation.
Before formalizing the offer, all the requirements related to:

- definition of the product to be supplied;
- identification of the type of material needed;
- technical documentation of the Customer with reference standards (national and/or international);
- definition of delivery terms;
- definition with the customer of any changes to be made to obtain the product to be manufactured;
- any legal obligations;
- any mandatory, explicit and implicit requirements.

8.2.3. Review of the requirements for product and services

Activities related to the Review of the contract and/or any changes to it are all documented; in this way the documentation is also used as registration of the control.

8.2.4. Changes to requirements for product and services

Upon receipt of any changes to the order, SALES and/or PMO carry out a careful verification of the same ones, so that there are no impacts on what has already been programmed, communicating as abovementioned to the involved functions.
In case of modification acceptance, SALES proceeds with the issue of the relative order confirmation or the revision of the original order confirmation.

8.3 Design and development of product and services

Start designing a new product can be decided on the acquisition of a customer order or on the decision by the Management based on analysis of the market prospects.
The development phase involves the execution of a preliminary study and the drawing up of drawings, BOMs, preliminary schemes as well as the execution of calculations where necessary. The first test specifications can also be developed and the requirements for obtaining specific process qualifications (welding, non-destructive tests, etc.) are verified.
For projects for which SIL certification is required, the Safety Plan is applied.
During development, the designers interface with the corporate bodies involved (Production, Quality, Purchasing, etc.) so as to be able to consider their needs already under development.
The design is described in the procedure for designing and developing of new products **P-SGQ-22**.
The management of design changes is described in the procedure **P-SGQ-14.**

8.4 Control of externally provided processes, products and services

The Company controls the procurement processes and the supply from the outside of materials to be used for production. The description of these processes is contained in **P-SGQ-19** and **P-SGQ-29**.

8.4.1. General

In particular, control is carried out in relation to:

- purchased details of new design;
- materials and/or services for checking details and/or products;
- all products and/or services that may influence safety, environment and the quality of the final product.

8.4.2. Type and extent of control

The function of products from outside checking is to ensure that these products are not used or put into production, without first having ascertained their compliance with the requirements specified in the order.

The acceptance of the product takes place as a result of checking and comparing the characteristics of the same ones with the references specified in the purchase order (test certificate, drawing, specifications, measurements, quality, quantity, product status, etc.).

It can also happen that a product from the outside can be placed, for reasons of urgency and prior authorization of RQ, directly in production, but it is still checked during subsequent checks. In the event that non-conformities are found with respect to what is required, the product is replaced and non-conformity is managed.

Proofs, checks and materials tests upon receipt are planned and described in a specific operating instruction.

All materials and/or services necessary for the realization of the product which may influence its quality or with potential effects on the environment, are compulsorily ordered from previously qualified Suppliers periodically checked and retrained by the Company.

The qualification of a Supplier is based on the ability of the Supplier to satisfy the requirements to the standards defined by the Company, such as:

- supplier's certification SGQ issued by recognized certification bodies (national and/or international);
- self-assessment questionnaire;
- preventive assessment by the Supplier through an audit;
- assessment of the qualitative constancy of supplies.

Supplier qualification responsibility is of RQ with regards to Quality aspects.
The manager update the documentation certifying the successful qualification and revise the list of qualified Suppliers, following the redevelopment of the same and sending a copy to ACQ for the update on the centralized information system.
The purchase document contains all the information which clearly describes the product to be ordered.
Before an order is issued, ACQ is responsible for:

- request an offer to the qualified Supplier and evaluate it economically;
- issue and manage the purchase order, clearly specifying all the requirements related to the product ordered;
- propose to RQ new suppliers to be qualified;
- submit any derogation proposals to RQ and ENG.

In presence of material not corresponding to the order, RQ issues a non-compliance with the Supplier segregating the material in a specific area and awaiting a solution.

This section of the Manual is defined in the following System Procedures:
P-SGQ-33 Evaluation of Suppliers for Quality aspects;
P-SGQ-19 Purchase management – Strategical Buyer;
P-SGQ-29 Purchase management – Tactical Buyer.

Furthermore, the Company has taken steps to:

- perform an adequate methodology to measure and monitor the main business processes and environmental performance, in order to demonstrate its ability to achieve the expected results. The management shall take appropriate corrective actions if the pre-set results are not achieved.
- implement a specific control system in order to verify that the product requirements are fully met. Controls based on acceptability criteria are performed both in acceptance and in production to facilitate coordination with production processes.

This allows to have documented evidences of the completed tests, freeing the product for subsequent processing or final testing.

Suppliers are classified by product families and subsequently identified those that provide special processes, outsourced and critical from an ATEX and PED point of view. For each category, the qualification criteria are defined and the trend of supplies is monitored.

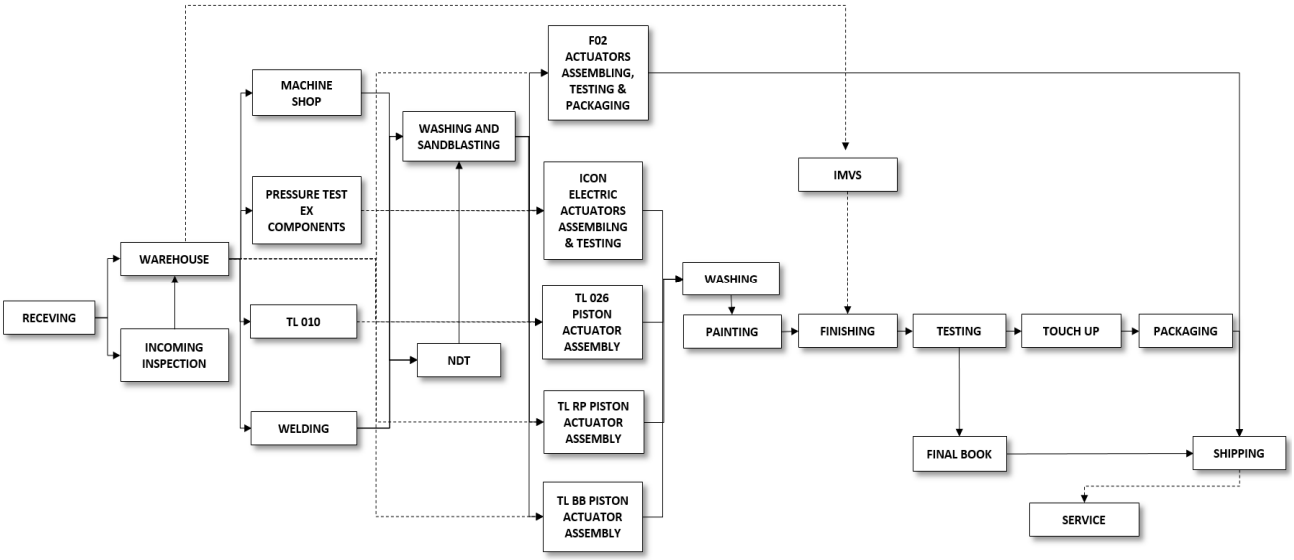
8.4.3. Information for external providers

Suppliers and their qualifications are registered in **DR 124** qualified suppliers list (which also includes classification), in Supplier Database **DR 252** and in the management system.
For the qualification of a new supplier, the periodic evaluation and the treatment of specific problems with the involved supplier to the **P-SGQ-33**.

The dialogue with external suppliers is continuous and constant, since they are considered by the Company as strategic partners. All correspondence and the exchange of information is done by e-mail, and when necessary, by sending technical specifications and/or drawings.

8.5 Production and Service provision

Production process is represented in **DR 158** and summarized as follows:



8.5.1. Production and services provision control

The company plans production activities according to what is contractually agreed with the customer. ENG, once received the contractual documentation from PMO, starts study actuator phases and personalization, thus completing the technical base of the same.
During the phase of personalization completion, the activities of supplying products through orders to the suppliers can be started, according to productive planning and deliveries agreed with the Customer, or activities can be started to realize the parts to be assembled in-house.
In this second case, Manufacturing Engineering identifies the most appropriate equipment, verifies the availability of instructions, controls plan or anything else that may be useful to ensure the conformity of the parts produced. Furthermore, with the support of QA, all monitoring and measurement activities deemed necessary for the fulfillment of contractual requirements are implemented.

Once the articles are received, they are loaded into warehouse by LOG, making them available for assembly and testing activities. PPP Office can act in three different ways: purchase, internal production, processing production. The methods for obtaining details are made in batches or single pieces according to the needs.

8.5.2. Identification and traceability

BIFFI ITALIA identifies all the products within the production cycle through markings when provided or identification codes applied on the packaging of the products.
When traceability is an explicit requirement of the Customer or of national and international laws, directives and regulations, the Company keeps the components and products under control with the relevant registrations (see, in this regard, the documents **I-SGQ-76, I-SGQ-38, I-SGQ-81**).

Identification and traceability of materials and finished products is ensured through documented operating procedures and practices, from receiving and during all the process phases related to handling, testing and delivery.

8.5.3. Customer or external providers' properties

Customer's properties that can be found at the Company are actuators in repair and/or components that are sent by the customer to be mounted on the actuators that are identified as described in the reference procedures or instructions. The specifications or the documentation that the customer transmits to the Company in support of the contract are managed and stored according to the rules established by PMO service and it can be found in specific instructions. This documentation is kept for the duration of the contract by the direct managers involved and it is not returned unless explicitly requested by the Customer at the end of the order.

The Company is responsible for verifying the compatibility of the product supplied to the customer with the requirements mentioned in the certificate.

Returns management is regulated by **P-SGQ-32** and **PTC-13.**

8.5.4. Preservation

All products are managed and stored in ways that prevent damage. There are also different manners of handling, packaging, storage and delivery, also in relation to the specifications of the individual customers. For further details on the activities, refer to the support instructions, see **I-SGQ-36** and **I-SGQ-40**.

8.5.5. Post-delivery activities

After-sales assistance provides the management of reports of any kind on the product sold (for example any defects found, presumed non-compliance, etc.) through a prompt complaints analysis and an appropriate activation of the corrections necessary to obtain a better Customer satisfaction.
Furthermore, it is available for periodic maintenance and other paid interventions.
The Company only guarantees the responsibility for the product, therefore no warranty management is necessary, as the product does not provide it.

8.5.6. Control of changes

Cycle phases are standardized. If it is necessary to change production processes, we proceed by applying the PDCA methodology (see **P-SGQ-14**).

8.6 Products and services release

At the end of the development phases and after the design validation, which gives rise to the final documentation release, the Management authorizes the launch of the product on the market.

8.7 Control of nonconforming outputs

The activity is carried out according to the **P-SGQ-36**.
Anyone within the company is responsible for identifying and reporting anomalies and non-conformities found:

- *on materials and products:* identification of anomalies that makes it unsafe or doubtful use, incorrect coding, damage, expired or damaged products, use beyond the warranty period, etc.;

- *on SGQ:* failure to comply with the rules and regulations contained in this manual and in the procedures, errors and inaccuracies in the specific Operating Instructions, documentation not updated or not available, omitted or incomplete records, etc.;
- *following Customer's notification:* anomalies can be reported on the products used as a result of an assembling or delivery to the end user; damage and possible replacement evaluation is subject to AF evaluation;
- *on machinery and vehicles:* malfunctions, failures from the point of view of safety, overheating, etc.;
- *near miss and dangerous situations;*

It is responsibility of those who find a non-conformity to identify and segregate it, as applicable.
QA function analyze the reported non-compliance and consult the company departments concerned to identify the actions to be taken and the application methods and times.
Following the analysis of the causes of non-compliance, for particularly serious or recurrent non-conformities, QA may require the involved company departments to take corrective action aimed at eliminating the cause of a non-compliance in order to avoid recurrence.
Any exceptions to what was initially agreed must be managed in compliance with **I-SGQ-88**.

9. PERFORMANCE EVALUATION

The company has established rules to plan the monitoring, measurement, analysis and improvement needed to demonstrate product compliance, to ensure SGQ compliance and to continuously improve its effectiveness.
For these activities applicable methods and indicators have been identified, which are examined during the Review. The reference procedure is **P-SGQ-01.**

9.1 Monitoring, measurement, analysis and evaluation

Therefore, they are defined:

- Significant process variables (indicators, monitored by **DB**);
- Definition of the control system (frequency, responsible);
- Reference conditions and acceptance criteria values;
- The records and data used to provide evidence of these monitoring activities.

If the results are not achieved, necessary corrective actions will be taken.
The results of monitoring and measurements are summarized in the Management Review Report (and related annexes), examined in the periodic meetings.
The health and safety measurements identified are related to injuries, occupational diseases, accidents and organizational well-being.

9.1.1. General

The Company considers the satisfaction of its Customers one of the objectives to be achieved and for this reason, it constantly provides for measuring and analyzing it.

9.1.2. Customer satisfaction

During periodic meetings, information about customers are collected and commented regarding satisfaction with the product delivered and the service provided: general observations, complaints, suggestions. The findings are used to make improvements to company services and subject to specific

monitoring. These monitoring are analyzed in the subsequent periodic meetings and during Management Review.

QA and Management function, as part of the Management Review, define the company targets that, properly calculated and monitored, allow to assess how the company meets the explicit and implicit requests and needs of its Customers.

To define the parameters that contribute to customer satisfaction, some considerations are required on the following aspects:

- matching our products to the required needs;
- product conformity;
- service accuracy;
- communication quality.

To evaluate customer satisfaction and identify the necessary interventions, it should be noted that:

- Customer satisfaction is a process in continuous evolution;
- it is necessary to establish with the Client a communication process that serves as a strong element of loyalty and training of its personnel.

The methods are described in **P-SGQ-21** procedure.

9.1.3. Analysis and evaluation

Analysis of the satisfaction level is performed periodically and is based on:

- Total Complaints (Including Non Product)
- % (Rate) of Customer complaints Closed <15 days
- Supplier Quality
- VOC – DR 196
- COPQ
- Rework
- Scrap
- Warranty
- Goodwill Costs.

QA is responsible for monthly data collection on the "Quality Dashboard" and the related analysis which provides for it and submits it to management during the Review. The reference procedure is **P-SGQ-01.**

9.2 Internal audit

The Company carries out internal audits scheduled to monitor the SGQ, to verify that it is implemented in compliance with the reference standards and company policy and is effectively implemented and kept up-to-date to achieve the objectives set by the Management.
A program of Inspections is planned that takes into account the status and importance of the activities towards Quality, as well as the results of previous Inspections.
Regarding Quality, QA function plans internal audits based on the criticality of the company areas, the anomalies detected in the area and any complaints received from customers. All company functions are however subject to verification at least once a year. For the conduct of the audit, QA can use "Lists of

Feedback" that allow not to omit any verification point and record the objective evidences found. The completed "Feedback List", or the final report, are signed by the participants in the inspection (evaluators and assessed) for acceptance of the results.
The criteria, the extent, the frequency and the manners of the Inspections are being established. Results of the audits are documented by means of special records that are communicated to the verified functions. In the face of the deficiencies found, adequate corrective actions are promptly implemented according to **P-SGQ-12** Audit procedure.
The implementation and effectiveness of the actions undertaken is ascertained in the subsequent audits and appropriately recorded. The selection of the Evaluators and the conduct of the Audits ensure the objectivity and impartiality of the inspection process. The Evaluators do not carry out audits on their work.

9.3 Management review

The Management periodically reviews the SGQ to ensure its suitability, adequacy and effectiveness.

9.3.1. General

The object of the review is also the assessment of the need for changes in the organization's system, including policy and objectives. The review of the SGQ usually takes place annually (at the end of the fiscal year). The periodicity is lower in case of significant changes to the SGQ or in case of system inefficiency.

9.3.2. Management review input

During the re-examination the following elements are examined:

- the results of internal audits and assessments on compliance with legal requirements and any provisions signed by the Company;
- performance monitoring and objectives and targets achievement degree;
- checking the conformity of the supplied products and the services provided;
- non-conformities;
- the status of preventive and corrective actions;
- the actions subsequent to the previous reviews by the Management;
- recommendations for improvement;
- the circumstances arising from changes, including changes to the legal requirements and any provisions signed by the Company;
- changes on internal and external factors, needs and expectations of the interested parties, the related environmental aspects and risks and opportunities;
- the status of activities relating to the management of resources;
- the adequacy of the resources;
- communications for interested parts;
- performance indicators and risk analysis.

The Review includes the verification of the overall effectiveness of the SGQ for equipment intended to be used in explosive atmospheres.

9.3.3. Management review output

- Outputs include decisions related to:
- Suitability, adequacy and effectiveness of the integrated management system;
- Opportunities for continuous improvement;
- Changes to the integrated management system;

- Resources needed;
- Necessary actions;
- Opportunity to integrate the business management system with other business processes;
- Implication for the strategic directions of the organization.

Review object is formalized in a specific **RDIR** document, whose contents summarize the participants, the input data considered, the topics dealt with and the improvement actions decided that this document formalizes.

The Review document and the improvement objectives are presented in a meeting between the Management and the departments involved in order to expose the contents. During this meeting, changes to the objectives can be made if they are approved by the Management.

RDIR document is part of the documented evidence and records of the system.

10. IMPROVEMENT

Continuous improvement process is guaranteed by the Management Review, which takes place at least annually. The reference procedure is **P-SGQ-01.**

10.1 General

The process of continuous improvement is based on the improvement objectives assigned to the Company Departments by the Management during the review of the SGQ.
On a quarterly basis, regarding quality aspects, meetings are formalized for the analysis of company performance, whose updating is reported in the QUARTERLY QUALITY MEETING Report, shared with all the managers, where performance indicators planned audit results and improvement plans are registered.

The guiding principles of the objectives are as follows:

- full satisfaction of Customers' expectations, by complying with the mandatory regulations and the specifications defined and / or provided;
- the improvement of the Organization in order to raise the levels of environmental efficiency and health and safety, using at best the resources intended to business management;
- improving the sensitivity, the collaborative spirit and the attention of all staff towards the aspects defined as significant for the Organization;
- full compliance with applicable mandatory legislation (e.g. contractual regulations, national labor contracts, mandatory environmental legislation, health and safety in the workplace legislation, IECEx, ATEX, PED, etc.).

10.2 Nonconformity and corrective actions

In the event that situations that do not comply with the SGQ are detected at any stage of the production process, are implemented provisions of the and **P-SGQ-36**.

The company functions involved in the detected non-compliance are responsible to:

- define how to resolve the non-compliance;
- verify the resolution implementation;
- analyze the anomalies data in order to identify the causes of the non-conformity;
- propose any corrective and preventive actions with a more general impact.

The non-conformities detected are kept for statistical purposes to implement corrective and preventive actions aimed at the continuous improvement of the company's environmental performance. The corrective actions are taken to eliminate the causes of existing non-conformities, defects or other unwanted situations in order to prevent their recurrence.
The responsibilities and procedures for implementing corrective actions are described in detail in the **P-SGQ-36**.

These procedures include:

- non-conformities review;
- the search for the causes that determined the non-conformities on the SGQ,
- the definition of the corrective actions necessary to eliminate the causes of the non-conformities appropriate to the importance of the problems and commensurate with the relative risks;
- implementation of corrective actions;
- recording of the results and effectiveness of actions and any updating of company procedures for changes to the SGQ;
- the review of the results of the corrective actions and the information to the Management (input for the review of the SGQ).

The documentation concerning the corrective actions implemented is kept in accordance with the reference procedure.

10.3 Continual improvement

The continuous improvement of the Company is born at a strategic and daily level, through the tools highlighted in the table.

Improvement type	Service tools
Strategic	Quality Policy, objectives and process indicators
Daily	Corrective actions, closure of non-compliance, monitoring of process results, personal training, monitoring and measurement of satisfaction, staff and user suggestions, internal inspections
Project plans/changes	Management of improvement projects based on PDCA methodology (Plan, Do, Check, Act).

ATTACHMENT 1: Correspondence among the standards ISO 9001, and ISO/IEC 80079-34

ISO 9001:2015		ISO/IEC 80079-34:2018 (chapter 7)		SGQ Manual	
0	INTRODUCTION			0	PROCESSES APPROACH AND RISK ASSESSMENT (UNI EN ISO 9001:2015)
1	QUALITY MANAGEMENT SYSTEM PURPOSE AND APPLICABILITY	1	Quality management system purpose and applicability	1	SGQ PURPOSE and APPLICABILITY
2	QUALITY MANAGEMENT SYSTEM REFERENCE STANDARDS	2	Quality management system reference standards	2	REFERENCES STANDARDS
3	TERMS AND DEFINITIONS	3	Used terms and definitions	3	TERMS, DEFINITIONS
4	ORGANIZATION CONTEXT	4	Quality management system	4	ORGANIZATION CONTEXT
4.1	Uderstand the organization and its context			4.1	Internal and external relevant factors
4.2	Understand needs and expectations of stakeholders	4.1	Quality management system structure	4.2	Stakeholders needs and expectations
4.3	Determine the quality management system applicability			4.3	Applicability
4.4	Quality management system and related processes			4.4	Integrated Management System requirements and related processes
5	LEADERSHIP			5	LEADERSHIP
5.1	Leadership and commitment	5.2	Customer focus	5.1	Leadership and commitment
5.2	Policy	5.3	Quality policy	5.2	SGQ policy
5.3	Roles, liability and authorities in the organization	5	Management responsibility	5.3	Roles and liabilities
		5.1			
6	PLANNING	5.4	Planning	6	PLANNING (plan-do-check-act)
6.1	Actions to face risks and opportunities			6.1	Actions to face risks and opportunities
6.2	Quality goals and planning for their reaching	5.4.1	Quality goals	6.2	SGQ goals and planning for their reaching
6.3	Modifications planning	5.4.2	Quality management system planning	6.3	Modifications planning
7	SUPPORT			7	SUPPORT
7.1	Resoruces	6	Resources management	7.1	Resources
		6.1			
		6.2			
		6.3			
		6.4			

ISO 9001:2015		ISO/IEC 80079-34 (chapter 7)		SGQ Manual	
7.2	Competence	6.2.2	Competence, training and awareness	7.2	Competence
7.3	Awareness			7.3	Awareness
7.4	Communication	5.5.3	Internal communication	7.4	Communication
7.5	Documented information	4.2	Requirements related to documentation	7.5	Documented information
		4.2.1	List of the documents which constitute the Quality management system		
		4.2.2	Quality manual		
		4.2.3	Document control		
		4.2.4	Recordings control		
8	OPERATING ACTIVITIES	7	Product realization	8	OPERATING ACTIVITIES
8.1	Operational planning and control	7.1	Product planning and realization	8.1	Operational planning and control
8.2	Products and services requirements	7.2	Processes related to Customer	8.2	Products and services requirements
8.3	Design and development of products and services			8.3	Design and development of products and services
8.4	Processes control, products and services provided outside the company	7.4	Procurement process	8.4	Processes control, products and services provided outside the company
8.5	Services production and expenditure	7.5	Service production and expenditure Monitoring and measuring equipment control	8.5	Services production and expenditure
8.6	Products and services realease	7.6		8.6	Products and services realease
8.7	Non.compliant outputs control	8.3	Non-compliant product control	8.7	Non.compliant outputs control
9	PERFORMANCES EVALUATION	8	Measurement, analysis and improvement	9	PERFORMANCES EVALUATION
		8.1			
9.1	Monitoring, measuring, analysis and evaluation	8.2	Monitoring and measuring	9.1	Monitoring, measuring, analysis, evaluation
		8.4	Data analysis		
9.2	Internal Audit			9.2	Internal Audit
9.3	Management review	5.6	Organization review	9.3	Management review
10	IMPROVEMENT	8.5	Improvement	10	IMPROVEMENT
10.1	Generality			10.1	Generality
10.2	Non-compliances and corrective actions	8.5.2	Corrective actions	10.2	Non-compliances and corrective actions
		8.5.3	Preventive actions		
10.3	Continuous improvement	8.5.1	Continuous improvement	10.3	Continuous improvement