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Content/ Obsah:

Revision history / história verzií

Revision: Revízia:	Description: Popis:	Date of issue: Dátum vydania:
1	Prvé vydanie po zmene medzinárodných noriem/ First revision	24.10.2017
2	English version added Updated: 4.1 – Context of the organization, 10. Improvement – "process owner" added in last paragraph Anglická verzia vytvorená Zmenené odseky: 4.1 – Kontext organizácie pridaný 10. Zlepšovanie – „majiteľ procesu" pridaný v poslednom odseku	12.10.2018
3	5.3. – FMEA team defined, 7.1.5.1.1 – statistical studies added 5.3 – definovaná skupina tvorcov FMEA, 7.1.5.1.1 – doplnené štatistické metódy pre meracie zariadenia.	28.1.2019
4	Correction of EN9100:2016 to EN9100:2018 Correction of grammatical issues C2i ltd. changed to c2i s.r.o. 5.2. – The politics of quality – website link changed	14.12.2020
5	4.3. – Including Scope of the QMS	28.12.2020
5.1.	4.3.2 – Including Customer specific requirements for IATF 5.2. – The name "The politics of quality" changed to "Company policy"; adding additional information Adding 5.2.1. – Conclusions from the guidelines	15.10.2021

	4.3.2 – Including Customer specific requirements for IATF 8.2.3.1.2. – Including Customer designated special characteristics	
5.2	Adding definition of Organization context – section 4 Section 4.1, 4.2 – Adding definition and explanation for the sub-clause 4.3 – adding definition and explanation for point a) and b) and how to be purposed the C2i purpose and strategic direction definition 4.4.1, 4.4.2, 4.4.c, 4.4.1f, g, h – adding definition and interpretation of the requirements for the 4.4 Quality Management System 5.0 – description the meaning of Leadership	17.12.2021
5.2	5.1 – adding definition and interpretation of the Leadership and commitment 5.1.2 – adding definition and interpretation for Customer focus 5.2 – Adding definition for the Company policy 5.3 – adding definition and interpretation for Roles, responsibilities and powers within the organization 6.0 – adding definition for Planning 6.1 – Definition and interpretation of requirements for Risk and Opportunity Activities 6.2 – adding definition and interpretation of Quality Objectives and plans on their achievement 6.3 – adding definition and interpretation of the clause for Planning of changes MMS00021 substituted by MMS00046	17.12.2021
6	9.1 added point process owners KPI 9.2 added IATF requirements for internal audit frequency and evaluation	10.11.2022
7	In chapters Purpose and Normative references: Added standards ISO 14001, TISAX, EN 17460 and EN 15085-2 S 4.3 Added railway industry. Reviewed and signed by new CEO	7.2.2025

Purpose:

The Quality Management System Guide of c2i s.r.o., Dunajská Streda describes the company's quality management system according to the current requirements of ISO9001, IATF16949, EN9100, ISO 14001, TISAX and railway standards like EN 17460 and EN 15085-2 S, which are introduced and maintained by c2i s.r.o. Dunajská Streda. It is to be used for the presentation of the system to all interested parties.

2. Scope:

Document applies to the entire c2i organization.

Terms and definitions:

QMS Quality Management System

QP Quality Politics

ZS Interested parties

1 Quality Management System

The success of the quality management system depends on the commitment at all levels and functions in the organization under the leadership of senior management. By its implementation, the top management may efficiently address its risks and opportunities by integrating quality management into business processes, strategic direction and company decision-making, by aligning them with other business priorities and integrating quality management into the overall management system.

The QMS manual contains details about QMS, followed by mandatory documented procedures, describes basic relationships within the company as well as outside and the core structure of the system. It refers to processed documentation. It also serves as a basis for auditing needs. Provides a comprehensive description of the security of qualified and objective activity for continuous and repetitive implementation and improvement of the system.

In addition, a methodology known as the Plan - Do - Check - Act (PDCA) can be applied to all processes, which can be described as follows:

- **plan:** set the goals and processes necessary to deliver results in line with customer requirements and organization policies,
- **do:** implement the processes.
- **check**: monitor and measure processes and products, compare them with the customer's policies, goals, and requirements for the product,
- **act**: implement activities to continually improve process performance.

Image no.1

The QMS guide is a basic document of the QMS system and contains the concept and principles of improving the management system of c2i s.r.o.

The chapters of this manual are developed in accordance with ISO 9001, IATF16949 and EN9100, which are an integral part of the entire management system of the company and are comprised of regulated organizational directives, to which further documentation is created consisting of a set of managed and unmanaged documentation in the form of internal regulations, standards, operating rules, records, instructions to ensure planning, organization, control of major and subsidiary support processes. The cross-linking of these documents and organizational guidelines addresses the QMS manual along with the EMS manual and the company's organizational chart.

The quality management system is part of the overall corporate governance system and defines and describes the following provisions, which are also the ISO 14001 standards.

2 Normative references

- EN ISO9001
- IATF 16949
- EN 9100
- ISO 14001
- TISAX
- Railway standards for Bonding EN 17460 and Welding EN 15085-2 S

3 Terms and definitions

The terms and definitions are described in the current revisions of above-mentioned international standards.

4 Organization context

These clauses require to determine the issues and requirements that can have an impact on planning of the quality management system. Interested parties cannot go beyond the scope of ISO 9001. There is no requirement to go beyond interested parties that are relevant to the quality management system. It must be considered the impact on the organization`s ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements or the organization`s aim to enhance customer satisfaction.

4.1 Understanding the organization and its context

The organization`s context involves the company “operating environment”. The context must be determined both within the c2i s.r.o. and external to the c2i s.r.o. It is important to understand the unique context of the c2i s.r.o. before starting strategic planning. To establish the context means to define the external and internal factors that c2i s.r.o. must consider when managing risks.
C2i s.r.o.`s **external context** includes its outside stakeholders, its local operating environment, as well as any external factors that influence the selection of its objectives (goals and targets) or its ability to meet its goals.

C2i s.r.o.`s internal context includes its interested parties, its approach to governance, its contractual relationship with its customers, and its capabilities and culture. C2i s.r.o.`s internal context is the internal environment within which c2i s.r.o. seeks to achieve its sustainability goals. The internal context may include:

- Product and service offerings.
- Governance, organizational structure, roles, and accountability.
- Regulatory requirements.
- Policies and goals, and the strategies that are in place to achieve them.
- Assets (e.g. facility, property, equipment and technology)
- Capabilities understood in terms of resources and knowledge (e.g., capital, time, people, processes, systems, and technologies).
- Information systems, information flows, and decision-making processes (both formal and informal).
- Relationship between the staff/members and the perceptions and values of their internal stakeholders including suppliers and partners.
- Organization`s culture.
- Standards, guidelines, and models adopted by the organization and Form and extent of the company`s contractual relationships.

Internal context can also be defined as anything within the organization that may influence the way in which the c2i s.r.o. manages its internal risks. Once the internal context is understood, one can conduct the macro-environmental external analysis using PEST (Political, Economic, Social, and Technological) analysis. This analysis determines which factors can influence how c2i operates. These factors cannot be controlled by c2i, but we must seek to adapt to them. The PEST factors can be classified as opportunities and threats in a SWOT (Strength, weaknesses, opportunities and threats) analysis.

Political Factors	**Economic Factors**
Ecological/Environmental Issues/Global warm.	National economies and trends
Current legislation	General taxation issues
Anticipated future legislation	Taxation to activities, products, services
International legislation (global influences)	Seasonality or other weather issues
Regulatory bodies and processes	Market and trade cycles
Government policies, terms and change	Specific sector factors
Funding, grants and initiatives	Customer/end-user drivers
Market lobbying groups	Interest and exchange rates
Wars and conflicts	International trade and monetary issues
Social Factors	**Technology Factors**
Lifestyle trends	Competing technology development
Demographics	Associated/Dependent technologies
Consumer attitudes and opinions	Replacement technology/Solutions
Media views	Maturity of Technology
Law changes affecting social behaviors	Information and communications
Image of the organization	Consumer buying mechanisms
Consumer buying patterns	Technology legislation
Fashion and role models	Innovation potential
Major events and influences	Technology access, licensing, patents
Buying access and trends	Intellectual property issues
Ethnic/Religious factors	Global communication
Advertising and publicity	Maturity of the organization`s products/services

Although c2i sro cannot control the macro-environment factors, they need to be managed for their advantage. They also need to protect ourselves from PEST factors that may increase operational costs or affect our reputation. The external context`s micro-environment consists of c2i`s immediate operations and how they affect its performance and decision-making. These factors have a direct impact on the success of c2i sro. It is important to have a full analysis of the micro-environment before moving to strategy development. Some of the micro-environmental factors are like:

- **CUSTOMERS**
  C2i must attract and retain customers by offering products and services that meet their needs along with providing excellent customer service.
- **EMPLOYEES**
  There must be the availability of people with the motivation to remain as contributing members of the organization and develop the skills necessary to provide a competitive edge.
- **SUPPLIERS**
  Suppliers provide c2i s.r.o. with the resources they need to carry out our activities. If a supplier provides bad service, this affects the way c2i s.r.o. operates. Close supplier relationships are an effective way to remain competitive and secure the resources needed.
- **MEDIA**
  Positive media attention can bring success to c2i s.r.o. by maintaining its reputational strength. Managing the media (including the presence in social media) is a challenge.
- **COMPETITORS**
  Members of c2i s.r.o. need to have a sense of belonging. Can the organization offer benefits that are better than those offered by the competitors? Is there a strong value proposition? Competitor analysis and monitoring are crucial if c2i is to maintain or improve its position in the competitive landscape of the community. C2i s.r.o. must always be aware of its competitor`s activities. The landscape can change quickly.

As in the case of the macro-environmental context, c2i cannot always control its micro-environmental factors. But they must be carefully managed together and with internal context understanding. Both internal and external contexts can have influence over c2i s.r.o.
Customer pressures and complaints can force c2i s.r.o. to change various policies such as product returns and customer and technical support. Technological changes can provide new and more effective ways to manage communications, operations, shipping, and logistics. Cultural and religious differences may hinder product or service entry into certain countries. The government’s regulatory and trade policies can play a significant role in determining how businesses operate, especially regarding international trade, taxation, and regulations. The media, including social media, can have a significant impact on the company`s image and public relations. An unwelcome news video or news report can go viral fast, and if the company does not provide an acceptable response, the negative publicity and effects can last a long time. Sociological forces often drive what, where and how consumers buy products and services. There is an increasing trend in the number of consumers purchasing products online and reading reviews before making a purchase. Contextual issues can have a positive impact, as they may present opportunities such as new, improved, or increased availability of previously scarce resources, opening of or access to new markets, availability of innovative technologies leading to reduced costs, improved product quality, services, and operational efficiency.

Examples of internal issues **could include, but are not limited to:**

- **STRUCTURE OF THE ORGANIZATION**
- **ROLES WITHIN THE ORGANIZATION**
- **AVAILABILITY OF RELIABLE QUALIFIED AND COMPETENT WORKFORCE**
- **STABILITY OF WORKFORCE**
- **STAFF RETENTION**
- **IMPACT OF UNIONIZATION**
- **STAFF COMPETENCY LEVELS**
- **CONTRACTUAL ARRANGEMENTS WITH CUSTOMER**
- **PAYMENT TERMS FROM CUSTOMERS**
- **SOLVENCY OF CUSTOMERS**
- **EXPANSION OF CUSTOMER BASE**
- **THE OVERALL STRENGTH OF THE BUSNESS TO SUPPORT FUNDING NEEDS**
- **SERVICE LEVEL AGREEMENTS WITH CUSTOMERS**
- **THE CULTURE WITHIN THE ORGANIZATION**

Examples of external issues could include, but are not limited to:

- **Political, economic, social, technological, legal and regulatory –** Laws changing, affecting product conformity, minimum wage changing, evolutions in more efficient machinery affecting the price.
- **OPERATING PERMITS BECOMING TIGHTER ON EMISSION LEVELS –** technology demands.
- **OVERALL ECONOMIC PERFORMANCE IN THE COUNTRY –** above EU norm.
- **COMPETITIVE ENVIRONMENT –** overall low-cost of entry into the market.
- **ECONOMIC PLANS FOR THE FUTURE.**
- **THE NATURE AND IMPACT OF THE ECONOMY ON THE MARKET.**
- **CUSTOMER DEMOGRAPHICS.**
- **GENERAL LEVEL OF CUSTOMER CONFIDENCE.**
- **CUSTOMER EXPECTATION.**
- **STANDARDIZATION AND CERTIFICATION WITHIN THE INDUSTRY.**
- **REGULATION WITHIN THE INDUSTRY GENERALLY.**
- **TRADE ASSOCIATIONS AND LOBYYING POWERS.**
- **IMPACT ON NEIGHBOURS.**

The context of the company is documented in MMS00028 - Context and Risks in QMS.

4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

The company needs to determine external and internal issues that are relevant to its purpose, meaning what are the relevant issues, both inside and outside, that have an impact on what the company does, that would affect its ability to achieve the intended outcome of its management system. “Issue” covers not only problems, which would have been the subject of the prevention action previously, but also important topics for the management system to address, such as any market assurance and governance goals that the company might set for its management system. The company must determine relevant interested parties and relevant requirements of relevant interested parties.

An interested party is a person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity that is within the scope of the management system. Those will be externally interested parties that impose specific legal, regulatory, or contractual requirements in the company.

Interested parties would include:

- Shareholders.
- Owners.
- Management.
- Employees.
- Trade unions.
- Suppliers.
- Partners.
- Customers.
- Government agencies.
- Media.
- Society.
- Any other person or organization interested in the company.

Determining what is relevant or not relevant depends on whether it has an impact on the company`s ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements or the company`s aim to enhance customer satisfaction. The company can decide to determine additional needs and expectations that will assist it to meet its quality objectives.

c2i s.r.o. identified and documented stakeholders and their requirements that are relevant to the quality management system. c2i s.r.o. monitors and regularly reviews information about stakeholders and relevant requirements.

Interested parties and their requests are documented in **MMS00020 QMS stakeholders' register.**

4.3 SCOPE AND LIMITATION OF APPLICATION OF THE QUALITY MANAGEMENT SYSTEM

The seat of the company is Kračanská cesta č.51, 929 01 Dunajská Streda. The company c2i s.r.o. manufactures products from composite materials for the aerospace, automotive and railway industry. The company does not perform activities related to product design and development, and services, as no request from customer side. By any requirements from customer side, c2i s.r.o. will integrate in the QMS those requirements and processes, quality manual update will be done based on those customer-related requirements.

Top management has established responsibilities and powers to ensure that the quality management system meets the requirements of the standards mentioned above.

The CEO of the company entrusted the Quality Team Manager as the QMS manager, who is responsible person for the effectiveness of the quality management system; the Quality Team Manager is a representative of the quality management and is superior to all managers,

executives and other employees of the organization. To fulfill these tasks, the representative has the full support of the top management and all employees of the organization.

C2i s.r.o. has the specified limits and usability of the quality management system to create its subject. When considering this subject, c2i s.r.o. took it into consideration:

a) external and internal issues stated in 4.1, that are relevant to the purpose of the organizations, the strategic direction, and the ability to achieve intended results.
b) obligatory requirements of relevant interested parties stated in 4.2
c) departments and functions in MMS00006 company organigram
d) its activities, products and services
e) its powers and the ability to exercise management and influence.

All activities, products and services of c2i s.r.o. within the QMS subject are included in the Quality Management system; the subject is maintained as documented information and is made available to interested parties.

1) C2i`s PURPOSE AND STRATEGIC DIRECTION

PURPOSE
our reason for 'being' is a combination of our vision, mission and values.

WHAT IS OUR VISION?

WHAT IS OUR MISSION?

WHAT ARE OUR VALUES?

STRATEGIC DIRECTION:

2) c2i`s INTENDED RESULT OF ITS QMS

A. FROM THE SCOPE OF THE STANDARD
a) to demonstrate its ability to consistently provide products and services that meet customers and applicable regulatory requirements.
b) to enhance customer satisfaction through the:

- effective application of the QMS.
- process for continual improvement of the QMS.
- Assurance of conformity to customers and applicable statutory and regulatory requirements.

B. SPECIFIC TO c2i s.r.o.

- Reduction in waste, during manufacturing, through reduced rejects, effective corrective action and improvements in process understanding and compliance.
- To assist in the creation of an effective knowledge database for the consistent provision of product and service, and for business continuity purposes

3. EXTERNAL ISSUES:

- Contractual arrangements
- Competitive environment
- Legislation
- Regulation within industry generally.
- The overall economic climate in the country.

- Countries' environmental requirements affecting products and service.
- Technology advances.
- Standardization and certification within the industry.
- Relationship with external interested parties
- Perceptions/values of external parties interested.
- Key drivers and trends.
- Workforce culture within the sector and country.
- Construction delays.
- External inspections/audits.
- Competitors cease trading.
- Availability of raw materials.
- Power cuts in countries.
- Availability of external providers – machinery maintenance etc

4. INTERNAL ISSUES

- Structure of the organization.
- Roles within the organization.
- Availability of reliable, qualified and competent workforce.
- Stability of the workforce.
- Staff retention.
- Staff training levels.
- External providers competence and availability.
- Availability and quality of candidates to fulfil our vacancies.
- The culture within the company
- Working hours
- Staff morale
- Internal politics
- Governance, Policies, Objectives
- Strategies
- Capabilities
- Resources
- Knowledge
- General competence
- Technologies
- Information systems
- Decision-making processes
- Relationship with interested parties
- Perceptions/values of interested parties.
- Standards, guidelines, and models adopted.
- Contractual relationships
- Potential conflicts
- Processes for resolving conflicts.
- Social customs
- Management abilities.
- Priorities
- Database skills
- Root cause analysis abilities
- Improvement tools and abilities to apply.
- Ability to motivate the workforce.
- Project management expertise

- Understanding and experience in implementing ISO9001, IATF16949, EN9100, ISO14001 and railway standards
- Cooperation of workforce

5. PRODUCTS AND SERVICES OF THE ORGANIZATION

6. DETERMINED SCOPE

7. MANUFACTURING SITE/OFFICE:

8. APPLICABILITY:

All clause requirements are applicable to the above scope, except for 8.3 (Design and development of products and services). This is because the company does not design its products and services but produces products according to established/ defined standards and industry guidance. Clause 8.3 is therefore not applicable to our Quality Management System.

4.3.2. Customer specific requirements

Customer specific requirements should be evaluated and included in the scope of the organization`s quality management system. CSR are communicated through customer visits, audits, quality handbooks, customer portals or guidelines.

Customer specific requirements of automotive customers can be found and downloaded and implemented from the following link: Customer Specific Requirements – International Automotive Task Force (iatfglobaloversight.org)

4.4 Quality management system

To achieve the intended output, including improving performance, c2i s.r.o. has developed, implemented, maintained, and continuously improved the quality management system, including the necessary processes and their interoperability as required by the standard.

4.4.1 Clause requirements is to manage and control all company`s QMS processes including processes for operations. Company QMS includes processes for management (Leadership) activities, Planning which includes risk assessment, support processes (such as provision of resources etc), Operation, performance evaluation and improvement as part of QMS. Clause 4.4.1 requires the 'Process Approach' to be used in defining our QMS. Documentation of QMS processes and the need for and detail of specific process documentation is determined by ISO9001, IATF16949, EN9100, ISO14001, TISAX, railway standards, customer, regulatory and our organizational requirements, the complexity of products and processes, effect on quality, the risk of customer dissatisfaction, economic risk, effectiveness and efficiency, the competence of personnel.

4.4.2 Clause requires documents needed to ensure effective planning, operation and control for QMS processes. Documents must include a description of the interaction between QMS processes.

Process flowcharts can show how policies, objectives, influential factors, job functions, activities, material, equipment, resources, information, people and decision making interact and/or interrelate in a logical order.

Procedures are the way to document processes. They describe inputs and outputs, appropriate responsibilities, controls, and resources needed to satisfy customer requirements.

Clause 4.4 c requires to determine criteria for effective process operation and control. Criteria must be determined to control the input, outputs and resources used. (e.g. Raw materials as an

input to production must have acceptance criteria that they must meet before they can be used.)

These controls (criteria) must be established for each QMS process. Such controls may also come from the customer, regulatory or industry bodies. Equally important are the specific methods required for effective operation and control of each process. These may include:

- Job travelers
- Work instructions
- In-process inspection sheets/documents
- Specifications and drawings
- Set up checklist.
- Machine manuals etc.

This clause also requires to monitor and measure the QMS processes. Clause 9.1 provides requirements to plan and implement these controls for monitoring and measuring conformity to process performance criteria determined above.

Ways to monitor and measure QMS processes may include:

- Tracking against process parameters
- Goals and objectives
- Process check-sheets.
- Product acceptance criteria
- Production records
- Maintenance records
- Labor records
- Set KPIs for processes.

Under **4.4.1 d**, resources for QMS processes may include facility, material, equipment, labor, supplies, utilities etc. Every QMS process will require a different combination of resources. Resource details may be identified in specifications, production schedules, BOMs, production travelers or routers, work instructions etc.

Under **4.4.1 e** the company shall have to ensure that adequate responsibilities and authorities are assigned as per the requirements given in clause 5.3.

This promotes the use of risk-based thinking. Risk is defined as the “effect of uncertainty”.

Clause 4.4.1 f requires that when planning its QMS, the top management must implement and promote a culture of risk-based thinking throughout the company to determine and address the risks and opportunities associated with providing assurance that the QMS can achieve its intended result(s); provide conforming products and services, enhance customer satisfaction; promote desirable effects and improvement; and prevent, or mitigate, undesired effects.

Clause 4.4.1 g requires to evaluate of QMS processes as per requirement is given in clause 9.1.3 and evaluation may be done through a review of measurement and monitoring records and performance indicators for each process. These reviews must identify opportunities to improve QMS processes, use of resources and product quality.

Clause 4.4.1 h calls for improvement in the process as per the requirement is given in Clause 10. When process non-conformities occur, then corrective action is required to bring the QMS process under control. Corrective action process is not just for product related non-conformities, process must be continually improved through the setting of incrementally, realistic, measurable objectives. Planning for continual improvement requires a review of processed data, resources and controls to bring about the desired change.

Clause 4.4.1 a – 4.4.1 h must be applied to all QMS processes.

Procedures, responsibilities, authorities, risks, opportunities, evaluation and calls for improvement are documented in document MMS00046 Business Process Landscape c2i s.r.o.. and its related process procedures.

5 Leadership

Leadership is mostly about behavior. Leadership relies most strongly on less tangible and less measurable things like trust, inspiration, attitude, decision-making, and personal character.

5.1 Leadership and commitment

It is the responsibility of top management to provide leadership and direction for quality management within the company. They must establish strategic quality management policies, directives, and objectives consistent with the purpose and capabilities of the company. The quality policies and quality objectives are to be established for the quality management system that is compatible with the strategic direction of the company. The company should have clarity in its mission and vision, and policies are to be developed in line with the mission. The objectives are to be in line with the vision of the company. The strategies are to be developed and modified from time to time depending on the situation by keeping the target of achieving the vision. This work is to be done by the top management. Top management must establish the organizational structure and internal environment that motivates personnel to achieve the organization`s quality management goals and objectives.

Ensuring the integration of the quality management system requirements into the company`s business process is the prime responsibility of the top management. If the top management is not committed and taking ad hoc decisions, shortcuts, and unethical means of achieving their interest, the system cannot be implemented effectively.

Ensuring that the quality management system achieves its intended outcomes/outputs requires the clear identification of key result areas for achieving the objectives, preparing the action plan, working as per that plan, reviewing the action and results, and taking suitable corrective and preventive actions. The top management is the driving force to educate, guide, coach, remove the obstacles, encourage, review, recognize the performers, modify the goals, and to be a role model in implementing the system. If the top management is not committed and does not work as per the system, it cannot expect the same to be implemented by others. Hence, engaging, directing, and supporting people to contribute to the effectiveness of the quality management system become its prime responsibility.

Promoting improvement is the need for a competitive environment, where the customers are dictating the terms, and their expectations are changing very fast. It is the responsibility of the top management to push the company to innovative approaches not only for reducing waste, improving efficiency, reducing the cost of operations, identifying the unwanted process and eliminating them but also for improving the aesthetic values of our products and improving our services to the customer. Improving the quality of staff is also very important if the company has to improve.

Top management must provide adequate resources to develop, implement, maintain and improve the QMS. The QMS performance must periodically reviewed to determine its suitability, adequacy, and effectiveness. The processes within our company that perform these activities must be identified. These processes include – business planning, quality planning, management review, internal communication, organization structure etc. Top management will be the process owner of all these processes. They must communicate regularly to the company on the importance of meeting customers and regulatory requirements. The communication process must define what needs to be communicated, to whom, the methods used, the frequency, and the means for determining communication effectiveness. Top management can communicate in different ways including meetings, documented policies, memos, directives, email, etc.

5.1.2 Customer focus

Our company depends on our customers. So, it is important that customer relationships be effectively managed. We must understand the current and future needs of customers; we must meet their requirements and strive to exceed their expectations.

There are risks in achieving customer satisfaction. The top management needs to facilitate people in identifying those risks in advance and help them to devise alternative solutions to meet customer expectations. To ensure this we must understand our customer`s specific needs and requirements in terms of products, price, delivery communication, service, and support. There must be an effective process for communication and review of the above requirements to relevant personnel or departments within the organization. It is the top management role to provide the leadership and commitment of time and resources to ensure this happens.

Clause 8.2.1 will get in the details of Customer communication and Clause 8.2.2 gets further into the details of understanding and processing customer requirements.

Clause 9.1.2 sets requirements for monitoring and measuring customer satisfaction.

Clause 5.1.2 provides the top management overall responsibility for customer relationship management, while clause 8.2.1 and 8.2.2 provides the front end and clause 9.1.2 provides the back end, of the underlying and detailed activities of customer relationship management. The requirements of Clause 5.1.2 – customer focus can be included in the following processes: business planning, communications, sales and marketing, customer satisfaction feedback, etc. It`s required to be identified what specific documents will be needed for effective planning, operation, and control of these processes.

It is the responsibility of the top management to ensure that customer requirements are understood clearly by all in the company who are involved in providing the products and services to the customer.

To create, implement and maintain QMS, a system manager has been appointed to plan, execute, monitor and review QMS with the aim of constantly improving it, as a representative of top management in collaboration with responsible employees. Relevance to international QMS standards and customer requirements is regularly reviewed by internal audits and certification audits, by a third independent party. QMS is implemented in all the requirements of international standards of QMS and customer requirements. In the context of continuous improvement, any worker can propose changes and modifications to QMS in any way. The QMS will provide updates, including communications with top management about new changes and necessary resources.

EN9100 Requirement: Product and service compliance is monitored as well as on-time delivery, corrective actions are addressed if targets are not met.

IATF16949 Requirement: The organization has defined and implemented a corporate responsibility policy that includes anticorruption policy, a code of conduct for employees and an ethical escalation policy.

Related documents and records:

Management Commitment - leadership

5.2 The Company Policy

Developing the QMS must be a strategic business decision and therefore top management must provide the necessary direction and leadership, starting with establishing the quality policy and objectives. The company quality policy provides a top management vision on quality management for the company. It provides the company with focused direction, i.e. high-level goals and objectives for quality management. The quality policy must be consistent with the scope of the QMS and other business, management, and organizational strategies within the organization.

Clause 5.2.2a requires documentation to the quality policy and Clause 5.1.1c requires to be specified the commitment to satisfy applicable requirements and clause 5.2.1 d continually improves the effectiveness of the QMS.

Clause 4.3 specifies requirements for the scope of our QMS.

What is stated in the quality policy must lead to establishing quality objectives. Must be checked out the process performance indicators. Stating that the QMS will continually improve the effectiveness in the quality policy, which can lead to a number of objectives, as the QMS is composed of many processes, meaning that this could have one or more objectives for each process. Not all quality objectives need to be stated in the quality policy, but top management must clearly be involved in providing direction, establishing and reviewing these objectives. Leadership needs to establish, review and maintain a policy, but also needs to ensure that it is applied within the organization. The internal communication process must cover how the quality policy is communicated throughout the company. Personnel must understand the importance and impact of the quality policy on the work they do. The quality policy must be reviewed periodically by top management, for significant changes in the organization. Such changes may result in changes to the quality policy. The establishment of the quality policy must be parts of the business planning or QMS planning processes . A review of the quality policy for continuing suitability should be part of the company management review process. As a quality document, the quality policy is controlled by clause 7.5.3 control of documented information.

Top management has defined a company's policy (CP) and has ensured that, within the defined scope of its quality management system, CP is proportionate to the nature scope of its activities, products and services and includes a commitment to continual improvement of QMS. CP is documented, implemented and maintained; communicates with all interested parties of the organization and is accessible to the public at www.c2i.com/press/press-releases/certifications/

Company policy will be reviewed by corporate governance once a year in the management review; the update is if it goes out-of-date (eg a major change in company). Changing the QMS policy is done by issuing a new policy with a new signature and date.

Company policy is maintained as documented information, communicates with it within the organization and is available to interested parties.

The Company Policy document is part of the Quality Management Manual but is also an independent single document. It is bilingual and a new status does not affect the revision status of the management manual.

The Company policy elements:

- Company policy
- Company vision

5.2.1. Conclusions of the guidelines:

1. Concentration on managerial tasks
   - We will lead visibly as role models and make leadership performance measurable.
   - We will focus on the employee and promote communication, delegation and qualification
2. Securing all processes and procedures
   - We will evaluate the reliability of the processes and improve them if necessary.
   - Preventive process assurance is an integral part of the planning phase

3. Increase in productivity
   - The continuous increase in productivity is a declared goal of the company
   - Profitability and competitiveness are prerequisites for maintaining jobs
4. Constant further development of quality
   - We will further develop our preventive measures and involve the partners
   - Continuous improvement activities are an integral part of our system

5.3 Roles, responsibilities and powers within the organization

Top management must establish the organization necessary to deploy the QMS. It must define the structure, hierarchy, and line of reporting. It must ensure that the duties, responsibilities, and authority of all personnel are defined and communicated. All personnel must be clear on their duties, responsibilities, and authority in meeting customer and regulatory requirements. Organization charts, job descriptions, standard operating procedures, work instructions, etc., are the ways that top management may use to define and document this. These must be communicated and deployed throughout the organization. Orientation training, appointment posting, training on procedures and work instructions, etc., are the ways in accomplishing this. The organization structure and lines of reporting; responsibility and authority of managerial functions and departments can be established by top management and the responsibilities and authorities for the rest of the organization may be established by HR working with various process owners.

Some of the roles (responsibilities and authorities included) which Top management needs to identify but not limited to are:

- Understanding the company mission, vision, policies, and objectives carefully, and communicating the same in simple language down the line. The role should ensure that people have understood the same and will be able to demonstrate it in their routine activities.
- Helping Head of Departments in deriving the departmental objectives, policies and goals, considering the company objectives and policy. The Head of Department concerned is responsible for writing the policy and goals for his/her department and sections.
- Liaison with standard bodies and getting the latest applicable national and international standards required for implementing and maintaining all series of standards;
- Explaining the concept of standards throughout the organization. This can be achieved by giving training;
- Communicating the importance of meeting customer as well as regulatory requirements during the training program or on any other occasion found suitable for this purpose. Liaison with marketing, quality and production people in understanding the real concerns and requirements of customers and ensure that they are communicated down;
- Proactively discussing with the people and ensuring that all have understood the real essence of the quality policy, quality objectives and goals, their role in achieving the goals and in complying with the statutory, legal and regulatory requirements;
- Identifying the processes required for implementing quality management systems that can help to achieve company goals is a very important step in the implementation of the quality management system;
- There should be a role for helping the Head of Departments in identifying the controls in processes identified and documented. This should be done by considering the company objectives, goals, requirements of quality management systems, and legal and regulatory requirements;
- Getting the documents, work procedures, work instructions, job descriptions, process parameters, and specifications etc. prepared by the personnel concerned and bringing them under control;

- Over a period, we see a number of formats are developed in the organization, and some of them may be a duplication of work. Scrutinizing all the formats used in the organization and standardizing them is a very important activity. There must be a role to collect all the forms, list them, index them, discuss them with the more effective and user-friendly;
- Maintaining the master list of all documents, records, and forms, and the distribution charts is one of prime responsibilities of the Management Representative;
- Interpreting customer requirements and communicating down the line are important activities;
- As technology advances and the company adopts new technology and systems, there is a need to amend the procedures and the documents. Making arrangements for adequate audits in the event of any changes in the system, process or people;
- Preparing the procedures, instructions and manuals and documenting them are not the end of implementation. Everyone needs to read, understand and implement them in their routine work. Training people to adapt to the system;
- We need a team of internal quality auditors to periodically audit the systems throughout the organization. Identifying the potential internal quality auditors and arranging their training programs;
- Developing procedures for internal quality audits and training the users for the implementation;
- Internal audits need to be planned in advance and communicated to the users for the effective implementation of the systems. Planning internal quality audits and making arrangements for the audits;
- Liaison with the certifying body and top management and getting audits done;
- Following up with the certifying bodies in getting the certificate;
- Maintaining records for internal quality audits, management review, external audits, follow-up for the actions decided in the management review and the correspondences relating to the implementation of quality management systems;
- Reporting the progress in the implementation of the quality management systems to the top management from time to time;
- Getting information proactively on the changes coming in the quality management systems and alarming the people in the organization in time;
- Ensuring the integrity of the management system is maintained when changes are planned and implemented;

Some of the above tasks may be delegated, but it is the management`s responsibility to ensure they are planned, implemented, and achieved. The implementation and adherence to systems is the responsibility of the top management.

Top management has ensured the establishment and communication of responsibilities and competencies for relevant roles within c2i s.r.o. and to established responsibilities and competencies in line with international QMS standards.

Top management has established responsibilities and authority to ensure that the quality assurance system complies with the requirements of the international standards of QMS; it also determines top management performance information on the quality management system performance, including QMS performance, which will be submitted by QMS through management review.

The top management is maximally supported by all employees at all levels of the organization in its efforts to improve performance; therefore, the responsibilities and powers of the responsible personnel in the processes and activities are defined. Each employee has a responsibility, hence what he has to do, what he is obliged to respect when carrying out his

activity; at the same time, he is given the power - what he can, what he is entitled to, what authority he has in his activity. Submitting system performance information is being negotiated at regular ECR meetings.

Requirements IATF16949: Company c2i, s.r.o. appointed a customer's voice to ensure that customer requirements are met.

Top management defined responsibilities of customer voice in relevant job descriptions. Responsible people are informed, and they have to sign the job description.

One of the key purposes of a quality management system is to act as a preventive tool. Thus, when implementing processes, we must consider the risks which might appear in the process or on the interface of two consecutive processes. Such risks must be analyzed by the management on more levels.
One of the core tools for risk assessment is FMEA, which has a defined core team. This team consists of the multidisciplinary team, which means, that must contain at least one member of each department related to PFMEA, for e.g. production, technical team, quality, purchasing, logistic…If somebody is not able to join regular FMEA meeting, must nominate a deputy.

The owner of the FMEA process is the leader of the Technical department. In case of need he/she can involve further experts and professionals above the core FMEA team.

The final version of the FMEA shall be approved by the Quality manager and the Technical department leader. For FMEA we are using a registered FMEA form template and we have a regular meetings.

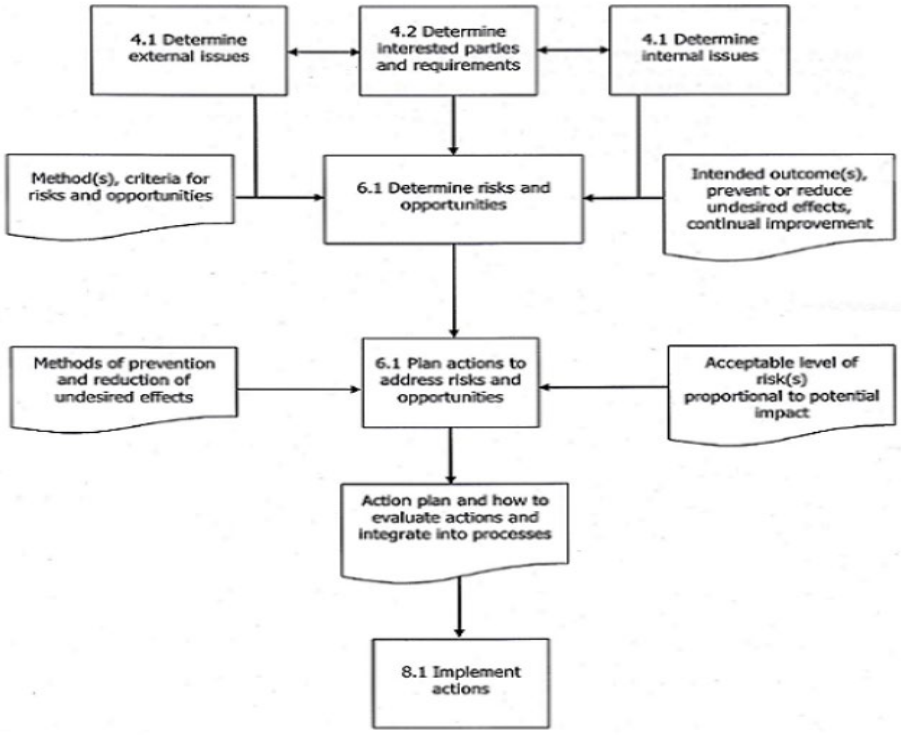
Related documents and reports

Job Descriptions

Organigram of the company – MMS00006

6 Planning

Once highlighted risks and opportunities in clause 4, it needs to stipulate how these will be addressed through planning. The planning phase looks at what, who, how and when these risks must be addressed. This proactive approach replaces preventive action and reduces the need for corrective actions later on. Focus must be also placed on the objectives of the management system. These should be measurable, monitored, communicated, aligned to the policy of the management system, and updated when needed.
The risks and opportunities identified will lead to policies and objectives.



Planning Process

6.1 Risk and Opportunity Activities

It is the responsibility of top management to provide direction, authorization and, resources, and review for QMS planning. When developing the QMS process controls for determining customers' requirements, design – if appropriate -, development, manufacture, delivery and customer support, must be always focused on meeting customer and regulatory requirements as well as the planned QMS objectives established in clause 6.2.
QMS planning requires to identify all the QMS processes and describe their sequence and interaction. When planning the company QMS, Top Management must implement and promote a culture of RISK-BASED THINKING throughout the company to determine and address the risks and opportunities associated with providing assurance that

- the QMS can achieve the intended result(s)
- provide conforming products and services, enhance customer satisfaction;
- promote desirable effects and improvement
- prevent, or mitigate, undesired effects.

The actions to address these risks and opportunities must be integrated into the QMS processes using the PDCA cycle.
Planning requires monitoring and measuring these actions and gathering, analyzing, and evaluating appropriate data and information to determine the effectiveness of the implemented actions. The planning must be periodically reviewed and updated as necessary.
By planning the QMS, the company must consider the risks and opportunities defined by external and internal issues as well as the needs and expectations of interested parties, relevant for purpose and strategic direction.
Risk management must be implemented at all levels of the company, from the strategic to the operational level. The result of risk assessment should be considered in documenting the plans for process operation and risk control.
At the business and QMS planning stage, the company should:

- Determine the categories of risk from – strategic, operational, environmental legal, social, and financial points of view that the organization may be exposed to – that could impact company ability to conducts its business operations without disruption and to provide customer satisfaction and achieve sustained success.
- Risk management methodology must be appropriate to the size and complexity of the organization. Must be established a list of risks under each of the categories described above, that might influence the achievement of process, product and service objectives
- The methodology must include the following steps to:
  - Identify each potential risk
  - Describe the potential outcome of the risk
  - Identify the potential cause(s) of risk outcome
  - Rate the consequence or severity of the outcome
  - Rate the likelihood of the cause occurring
  - Rate the probability of early detection of the outcome should it occur
  - Establish risk tolerance criteria
  - Categorize each risk into critical, high, medium or low based on using a combination of severity, occurrence, detection ratings, and other relevant factors to establish an overall risk score to all risks listed. Based on risk score must be established priority in addressing identified risks
  - Identify and determine the adequacy of any existing control to address the identified risk

- Determining appropriate controls to respond to each identified risk (process control plans).
- Determine compliance with predetermined tolerance criteria for acceptability of risk
- Provide and use risk management information for strategic decision-making and managing operations

Methods to identify risks

- Looking at the past history of performance, lessons learned, current operations and planned future activities to identify potential risks or undesirable outcomes;
- Looking at current activities and problems encountered, current and planned future activities
- Using various tools such as cross-functional teams, flow charts, checklists, risk analysis diagrams to brainstorm and facilitate risk identification, analysis, and evaluation

The purpose of risk management controls is manifold and could include:

- Avoiding the risk, where the only option is not to go forward with an activity or to withdraw from it;
- Taking the risk where risks have desirable potential consequences
- Altering risk, optimizing potential opportunities and minimize threats
- Transferring risk by measures including insurance, contractual arrangements, trade unions, partnerships, and joint ventures
- Retain risk, where no worthwhile controls actions are feasible, and the risk is within the organization`s risk tolerance
- Removing the source of the risk by alternate or new technology

c2i, s.r.o. has documented MMS00038 Risk management process.

In planning the quality management system c2i, s.r.o. considers:

- issues - external and internal;
- requirements – as interested parties

- the subject of its quality management system and the risks and opportunities related to its objectives, binding requirements, and other issues and other requirements that need to be addressed to provide assurance that the quality management system can achieve its intended outputs and achieve a steady improvement.

C2i s.r.o. considers and plans how it will take action to address the mandatory obligations and the risks and opportunities to be taken into account; how it plans to take action in different ways using its quality management system processes or other processes and to determine the effectiveness of the measures taken.

IATF16949 Requirement: To risk analysis, c2i, s.r.o. includes the findings of the meeting actions, product audits, field complaint analysis, correction analysis, claim analysis, non-business analysis, and additional work. Risk analysis must be documented and retained.

c2i, s.r.o. has to develop an emergency plan to ensure the delivery of parts and compliance with the requirements.

6.2 Quality objectives and plans of their achievement

The purpose of quality objectives is to determine conformity to customer, regulatory and relevant stakeholders` requirements, and effective deployment and improvement of the QMS.
Clause 6.2 sets specific requirements for the planning of quality objectives, which requires to be documented. It is as well required to monitor and measure and evaluate results to the planned objectives. Top management must provide leadership, organization, and resources to deploy and achieve planned quality objectives. The process and the personnel responsible needed to achieve the quality objectives must be determined. The quality policy provides the framework for establishing quality objectives in order to be consistent with it. The organization must ensure that specific quality objectives are established at relevant functions, levels, and processes needed for QMS.
The quality objectives should be relevant to meeting the requirements of the products and services and enhancing customer satisfaction. Quality objectives are used to measure the performance of products, service processes, customer satisfaction, suppliers, use of resources, and the overall performance and effectiveness of the QMS.
Quality objectives may be established for all QMS processes.
Quality objectives may be set as various functional levels of the company – top management, departments, processes, project teams, individuals.
A review of the quality objectives must be part of the management review process. After the review, the Quality objectives may be updated as appropriate. As documented information, the documented statement of objectives must be controlled by clause 7.5.3.
C2i s.r.o. must set the quality objectives for the relevant functions, levels and processes necessary for the quality management system. Quality objectives are in line with quality policy; are measurable; monitored; communicated; c2i s.r.o. maintains documented information on quality objectives.

When planning how to achieve its quality objectives, c2i must define:

- What to do;
- What resources will need;
- How will I be responsible;
- When the objective will be achieved;
- how the results will be evaluated, including indicators to monitor progress toward achieving their measurable quality objectives.

C2i s.r.o.. considers how activities to achieve quality objectives can be integrated into the business processes of c2i. In setting and reviewing long-term goals, it takes into account legal requirements, business plan and focus, technological options, financial, operational, business and other requirements.

Targets are approved by the management of the organization. Approved targets become binding for every employee of the organization; they are all familiar with the targets. In the case of fundamental changes in the company, the objectives are re-viewed, and their recency is verified by the management of the company in the management consulting. In the case of outdated objectives, a new record of current targets is made and all heads of departments and responsible staff involved in developing and addressing new goals are brought to their attention.

Targets need to be updated if: Achievement of the target lost its justification, its significance increased, or there is a need to set a new target. Objectives are updated by senior management in cooperation with the relevant Head of Units. And these are subject to the management process approval by the management. The overall assessment of the

achievement of the targets is in management review report. If necessary, the continuous evaluation is at the company's management meetings**.**

6.3 Planning of changes

The continuity and effectiveness of the QMS must be substantially maintained in the event of significant changes in the QMS or company, e.g. management, ownership, relocation, technology, product, the shift in customer base, etc.
All these changes must be carefully planned so as not to disrupt the company`s ongoing capability and responsibility to effectively meet customer and regulatory requirements.
Change control requires:

- careful planning of nature and timeline for the changes
- determining the impact or outcome of changes
- ensuring adequate resources are available to implement the change
- top management authorization
- change deployment and follow-up.
- review of the QMS by top management after changes are affected.

Once processes are determined, the organization needs to identify the risks and opportunities associated with these processes. To achieve the benefits associated with the determination of risks and opportunities, changes may be needed.
These changes can be related to any element of the process:

- inputs
- resources
- people
- activities
- controls
- measurements
- outputs etc.

Consideration of newly introduced risks and opportunities needs to be taken into account with the changes. There can be changes in QMS due to customer feedback, customer complaint, product failure, employee feedback, innovation, determined risk, determined opportunity, internal audit results, management review results, identified non-conformity.
Changes may occur in e.g. processes, documented information, tooling, equipment, employee training, supplier selection, supplier management etc.
To achieve the benefits associated with changes, the organization should consider all types of changes that may need to occur. The successful management and control of these changes is a core requirement within the QMS – some changes need to be carefully managed, while others can be safely ignored. In order to sort through this, the organization should consider a method to prioritize. To determine the priority, the organization must consider a methodology that allows it to consider:

- consequences of the change
- likelihood of the consequence
- impact on customers
- impact on interested parties
- impact on quality objectives
- effectiveness of processes that are part of the QMS

When planning changes the following steps need to be implemented:

- Define the specifics of what is to be changed
- Have a plan (tasks, timeline, responsibilities, authorities, budget, resources, needed information etc)
- Engage other people as appropriate in the change process
- Develop a communication plan (people within the company, customers, suppliers, interested parties etc.)
- Using a cross-functional team review the plan to provide feedback related to the plan and associated risks
- Train people
- Measure the effectiveness

Prior to making any change, the organization should consider unintended consequences. After making the change the organization must monitor the change to determine its effectiveness and to identify any additional problems that might be created. Records of some important changes are need as part of the Quality Management System.
C2i s.r.o. has developed and implemented a procedure for Change Management (ORS00072) Changes to QMS are planned. The following aspects are considered when planning changes:

- the purpose of the changes and their possible consequences;
- integrity of the quality management system;
- availability of resources;
- allocation or redistribution of responsibilities and powers.

7 Support

7.1 Resources

C2i s.r.o. identifies and provides the resources needed to create, implement, maintain, and continually improve the quality management system. In determining the necessary resources, c2i takes into account the infrastructure, externally provided resources; information systems, competencies; technology, financial, human and other resources that are specific to its activities, products and services; resources should be provided in a timely and effective manner. When assigning resources, it considers the current and future needs of the organization.

Company c2i s.r.o. identified and provided the people needed to effectively implement the quality management system, and to operate and control its processes and ensure their education.

C2i secures and maintains the infrastructure necessary to carry out its processes and to ensure the consistency of products and services.

c2i s.r.o. when designing an infrastructure applies a multidisciplinary approach while trying to eliminate or at least minimize risks. When changing the process or introducing new products, c2i performs a feasibility study, taking into account capacity considerations.

Requirement EN9100: c2i s.r.o. secures and maintains the environment necessary to conduct its processes to ensure compliance with products and services, taking into account human and physical factors such as:

- Social factors;
- psychological factors;
- physical factors.

Requirement IATF16949: Company c2i s.r.o. ensures cleanness and order in operation and provides for the necessary maintenance and improvement activities, including infrastructure maintenance.

C2i s.r.o. identifies and provides the resources needed to ensure valid and reliable monitoring and measurement results to demonstrate compliance of products and services with the requirements set. The company will examine whether the resources are appropriate for the specific type of monitoring and measurement activities being carried out and ensure their continued suitability. The needs are regularly reviewed and communicated to the management of the company. Evidence of suitability of the source for monitoring and measurement is documented.

IATF16949 Requirement: The measuring and monitoring equipment is documented in the production control plan and their capability is reviewed by studies.

IATF 7.1.5.1.1

Statistical studies are conducted to analyze the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan.

The applicable analytical methods and acceptance criteria is defined always according to customer requirements (e.g. VDA 5, MSA).

These studies are carried out in regular intervals according to customer requirements or according to internal needs arising from introducing new measurement equipment or the change of existing ones.

The person responsible for such statistical studies is trained and nominated via relevant job description.

Measuring and monitoring equipment that is used to demonstrate the conformity of products or processes are regularly calibrated and maintained. Proof of calibration is retained.

The procedure for controlling the measuring instruments is described in the document:
ORS00039 Metrology Directive.

c2i s.r.o. constantly examines and determines the knowledge necessary to conduct its own processes and ensures the conformity of products and services.

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

In managing changing needs and developmental trends, c2i, takes into consideration its current knowledge and defines the way in which all the necessary additional knowledge and necessary updates can be obtained or made available.

7.2 Competences

The company continually examines and determines the suitability of persons performing activities under their supervision that affect the performance and efficiency of the quality management system; ensure that those persons are competent on the basis of adequate training, training or experience; if necessary, take measures to obtain the required capability and assess the effectiveness of the measures taken; it keeps the relevant documented information as proof of competence.

7.3 Awareness

c2i, s.r.o. ensures that people working under the management of the organization are aware of:

- Quality policy: quality objectives and related actual or potential impacts associated with their work;
- their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- the consequences of non-compliance with the requirements of the quality management system, including non-compliance with the organization's binding requirements.
- relevant documented information on the quality management system and its changes;

- their contribution to the compliance of products or services;
- their contribution to product safety;
- the importance of ethical behavior.

7.4 Communication

c2i s.r.o. has developed a documented procedure for managing external and internal communication as described in MMS00034 Manage Communication Process Definition.

7.5 Documented information

The management of documented information and the management of documents and records is documented in ORS00003 Procedure for Issue and Control of Procedures.

8 Operations

8.1 Planning and managing operations

c2i has created, implemented, managed and maintained processes necessary to meet the requirements for production and delivery of products as follows:

- Specifies product requirements,
- Specifies criteria for processes and for the acceptability of products and services,
- Identify the resources needed to achieve product compliance and timely delivery,
- Identifies the resources needed to comply with product and service requirements and on-time delivery of products and services;
- Controls processes in accordance with the criteria;
- Identifies, maintains documented information as necessary to verify that the processes have been carried out as planned; to demonstrate the conformity of products and services with their requirements,
- sets the management processes and measures needed to guide critical units, including management of the production process, if key features have been identified;

- appoints a representative of the relevant organizational functions for operational planning and control;
- defines processes and resources to support the use and maintenance of products and services;
- identifies products and services to be procured from external suppliers;
- sets up the necessary management measures to prevent the delivery of uncompliant products and services to the customer.

When planning product implementation, the following factors are considered:

Customer´s product specifications and specifications of:

- logistics
- manufacturability
- project planning
- acceptance criteria.

c2i, s.r.o. ensures the safety maintenance of secret information at all levels.

c2i, s.r.o. has established processes for managing operational risks that are regularly overviewed, identified, monitored, and measures are identified to eliminate or minimize risks.

c2i has established processes for managing product configuration for the aerospace industry, which is documented in the ORS00015 - Configuration Management

c2i has established processes to ensure product safety over its whole lifetime. In planning, implementing and managing processes, it identifies and manages risks, manages critical items, analyzes potential events that are or may be associated with product safety, communicates these events, and provides training to the individuals concerned.

c2i has established processes to prevent the use of counterfeit products throughout the supply chain and in all processes of c2i s.r.o.

8.2 Requirements on product and service

c2i s.r.o. has established processes for communicating with the customer, which include:

- Providing product and service information,
- Solving requests, contracts or orders, including changes;
- Receiving feedback from customers about products and services, including customer complaints;
- Customer property management;
- Establish, if necessary, specific emergency response requirements

Product or service requirements are reviewed in the context of internal, customer, legal, and official requirements, with risks identified and managed.

c2i performs activities to review product manufacturability, examining all aspects and requirements of the customer and the product. Manufacturability review is a multidisciplinary process, and all the organizational units are involved working together.

IATF16949

8.2.3.1.2 Customer designated special characteristics
The organization shall conform to customer requirements for designation, approval documentation, and control of special characteristics.

8.3 Product and service development

c2i s.r.o. does not perform activities in the field of product and service development. Responsibility for product design is with the customer.

8.4 Managing external services and products

c2i has established processes to manage outsourced processes, products and services to ensure compliance.

The company has established the necessary processes for the selection, evaluation and management of suppliers. All internal and external requirements are communicated to suppliers and are regularly reviewed. Description of the activities and competencies is included in ORS00027 - Purchasing procedure.

8.5 Manufacturing and provision of services

c2i s.r.o. has established processes for production control. The needed documentation for the production of products is created, which contains all the features of the products, all the necessary steps for the production of the workpiece and the intended objectives. In production management, tools, equipment, measuring and monitoring equipment and software programs are also managed.

Special processes are identified and validated.

C2i performs activities to verify production processes to demonstrate the conformity of the manufacturing process and the manufactured products.

Material, process, and product tracking is implemented in all manufacturing processes.

Customer or third-party assets are managed and marked.

Changes in the manufacturing process or the product are controlled and documented.

8.6 Release of products and services

C2i has implemented processes to verify at appropriate stages whether the requirements for products and services have been met. The release of the products and services to the customer shall not be withdrawn until the planned measures are satisfactorily completed unless the competent authority and, where applicable, the customer otherwise allow.

Company c2i s.r.o. keeps documented release information for products and services that contain:

- proof of compliance with the acceptance criteria;
- Traceability for the ones who have allowed the release.

If a product qualification is required to present, c2i s.r.o. ensures that the documented information demonstrates that the products and services meet the specified requirements.

8.7 Managing non-conformities

Company c2i s.r.o. has established non-conforming event management processes that are described in the directive, ORS00035 Control of non-conforming products***.***

9 Product evaluation

9.1 Monitoring, measuring, analyzing and evaluation

C2i has monitored, measured, analyzed and evaluated its quality objectives and defines:

- what needs to be monitored and measured
- satisfaction of the customer,
- QMS performance and efficiency,
- whether planning was effectively implemented,
- the effectiveness of corrective actions
- supplier performance
- need to improve QMS
- each process owner shall have an opportunity to assess their own process (KPI)

9.2 Internal audit

C2i performs internal audits at scheduled intervals to provide information on whether the quality management system meets the organization's own requirements for its quality management system and the requirements of international QMS standards; whether it is effectively implemented and maintained.

Program of internal audit

C2i has established, implemented and maintained internal audit programs, including frequency, methods, responsibilities, planning requirements, and reporting on its internal audits. When creating an internal audit program, it must take account of changes affecting the organization and results of previous audits.

C2i audits all quality management system processes over each three-year audit cycle calendar period, according to an annual program, using the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, the organization sample customer-specific quality management system requirements for effective implementation. The complete audit cycle remains three years in length. The quality management system audit frequency for individual processes, audited within the three-year audit cycle, shall be based upon internal and external performance and risk. C2i maintains justification for the assigned audit frequency of their processes. All processes are required to be sampled throughout the three-year audit cycle and audited to all applicable requirements in the IATF 16949 standard, including ISO 9001 base requirements, and any customer-specific requirements. The audit plan must specify the approximate dates of the audition and the person responsible.

The process of internal audits is defined in ORS00040 – Internal audit procedure.

9.3 Management review

Top management must review the organization's quality management system at the beginning of the next year to ensure its consistent suitability, adequacy and efficiency.

Inputs and outputs are listed in the international standards of QMS.

C2i must keep the documented information as evidence of the results of the screening.
The process is fully described in the MMS00055.

10 Improvement

C2i has identified opportunities to improve and implement the necessary activities to achieve the intended outputs of its quality management system.

Non-compliance and corrective action

When non-compliance occurs, c2i must:

a. respond to non-compliance and if necessary, take action to manage and correct non-compliance and address the consequences, including mitigation of adverse impacts; and also, c2i must:
b. assess the need for action to eliminate the causes of the non-conformity so that such non-conformity would not occur again or elsewhere by means of:
- investigation of non-conformity ;
- identifying the causes of non-conformity;
- Determine whether there are similar non-conformities or if there is a probability that the non-conformity could potentially reoccur,

c. implement any necessary action;
d. examine the effectiveness of any corrective action taken;
e. make changes to the quality management system if it is necessary.

Corrective actions must be proportionate to the significance of the effects of non-occurrences that have occurred, whether external or internal impacts. C2i must keep documented information as evidence of:
- the nature of the non-conformity and any follow-up action taken;
- results of any corrective actions.

In the case of an identified non-conformity, the process owner determines the cause (s) so that corrective actions can focus on the relevant part of the QMS system. When developing a non- conformity plan, the organization will consider what action should be taken to address the problem, what changes are to be made to remedy the situation to restore normal operation (s) to be done in order to eliminate the cause (s) avoid repeating the problem or prevent it from happening elsewhere.

Organization is to keep documented information as evidence of the nature of the non-conformity and any subsequent follow-up activities and results of any corrective action.

Continuous improvement

C2i continuously improves the suitability, adequacy and efficiency of the quality management system to improve the performance of QMS. This process is described in ORS00159.

Links

M

MMS00006 Organigram of the company,
MMS00020 Register of interested parties of QMS
MMS00046 Business process landscape
MMS00034 Communication Management
MMS00055 Management review procedure

O

ORS00003 Procedure for issuing and managing documentation
ORS00159 Continuous improvement
ORS00040 Internal audits
ORS00015 Configuration Management
ORS00027 Organization procedure for Purchasing
ORS00035 Management of non-conforming products
ORS00039 Metrology Directive