

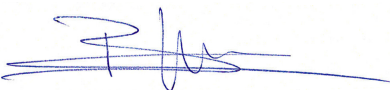
# Quality Manual

Revision G.1      29-01-2026

**Purpose:**

This Quality Manual is intended to clarify and document the quality policy of ICsense and to describe how the organization organizes its activities and processes, prepares and executes them, in order to comply at all stages of the process with the requirements of the ISO 9001:2015 and ISO 13485:2016 standards.

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<p style="text-align: center;"><b>Approved by</b></p>  <p style="text-align: center;">29.01.2026</p> <hr style="width: 80%; margin: 0 auto;"/> <p style="text-align: center;">Bram De Muer, CEO</p> <p style="text-align: right; margin-top: 10px;">Date</p>	<p style="text-align: center;"><b>ICsense PROPRIETARY</b></p> <p>The information contained herein, including all related documents, drawings, software, etc., is confidential, is the property of ICsense, and must be held in strict confidence and properly safeguarded by the recipient at all times.</p> <p>It may not be copied or reproduced, or disclosed to any other party, except with prior written authorization of ICsense. Authorized copies or reproductions of this confidential information, in whole or in part, must include this legend.</p>
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## 1 ICsense – A Brief Introduction

ICsense was founded in February 2004 by 4 PhDs in micro-electronics, as spin-off of the department ESAT-MICAS from the Katholieke Universiteit Leuven (KUL) in Belgium.

ICsense is Europe's premier IC design company offering design services and ASIC design and supply solutions for the automotive, medical, industrial and consumer market. ICsense core business is analog, mixed-signal and high-voltage IC design. ICsense core expertise is in:

- Sensor, actuator and MEMS interfacing with ADC-DAC
- Power and battery management
- High-voltage ICs
- High performance and low-power
- Communication

The offering consists of two parts:

- Customer-specific ASIC design and supply solutions, from idea to final product. ICsense manages the complete design of production-ready ICs, production test and assembly coordination and supply chain management through a network of partners.
- IC design services from consultancy and building block design up to complete mixed-signal ASICs or SoCs, including prototyping and prototype testing and volume production test support.

ICsense has 350m<sup>2</sup> of test facilities including Automated Test Equipment (ATE), handlers for final test, wafer probing (8"/12") and an ISO-7 certified cleanroom to perform the production test program development in-house for higher efficiency and product quality.

Today, ICsense has built up an impressive international customer portfolio and has become a well-known and respected supplier in the industry. ICsense's designs can be found in a wide range of applications such as smartphones, cars, implantable medical devices, battery chargers, cellular basestations, industrial plants, safety critical applications, satellites, ...

ICsense has customers all over the world: all major European countries, the United States, Japan, Australia, and South-Africa.

Since March 2017, ICsense is an independent subsidiary of the TDK group and centre of excellence for analog, mixed-signal and high-voltage IC design in TDK. The transaction is a win-win opportunity for both ICsense and TDK. ICsense can further boost its ASIC development and supply offering with a stable and strong partner in i.a. back-end and supply. TDK can further boost its sensor and actuator business.

ICsense does not work for TDK exclusively. ICsense continues developing innovative ASICs and providing IC design services for new and existing customers outside the TDK group.

ICsense uses state-of-the-art and industry standard EDA tools to develop its circuits and ASICs (Cadence, Synopsys, Siemens, Matlab/Simulink, Perforce). It has developed a proprietary structured analog-mixed-signal design environment that increases design efficiency, quality and traceability. The ICsense design team consists of more than 100 mixed-signal IC design experts.

ICsense is ISO 9001:2015 certified for design, development and production of microelectronic components and systems.

ICsense is ISO 13485:2016 certified for design, development and production of microelectronic components and systems.

ICsense is organized to developed ASICs compliant to automotive and industrial functional safety standards, i.e. ISO 26262:2018 up to ASIL B and IEC 61508 up to SIL 3.

ICsense is a member of Global Semiconductor Association, Flanders Semiconductor, Europractice, IEEE, Agoria and Flemish Chamber of Commerce.

## OUR COMPANY VALUES

**Innovation** Innovation runs in our veins. Thanks to our highly skilled engineers, large number of PhDs and strong research tradition as a spin-off of the University of Leuven. We design out-of-the-box – proud to offer you the optimal system.

**Excellence** We want to be the best at what we do. We want to achieve optimal performance at the lowest power and cost. First silicon success is our priority.

**Trust** Open and honest communication and close cooperation with our customers are essential for project success. Therefore, we operate as a part of your design or R&D team. We are ready to support you in all stages of your IC development.

## FOR OUR CUSTOMER, THIS RESULTS IN

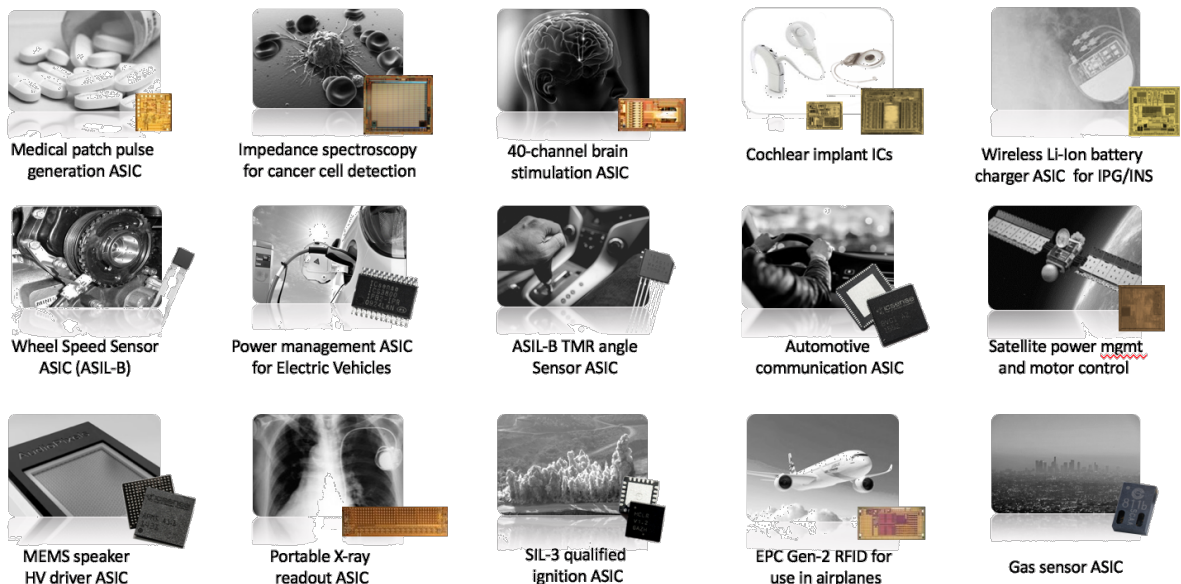
**Reduced technical risk** Our expert engineering team is trained to design high-performance innovative ICs on circuit and system/architectural level. They deliver high-quality and state-of-the-art results.

**Reduced time-to-market** First silicon success is our priority. Our success is based on a proprietary structured design methodology, broad IP library and ISO 9001:2015 certified quality procedures.

**Always there with our customer** Our customers are long-term partners. The better we know you and your way of working, the better our joint results will be. The proof? More than 90% of our customers return to work with us within three years after a first project.

## APPLICATION EXAMPLES

Several application examples can be found on <http://www.icsense.com>. Some examples include:



All ASIC developments are in a myriad of technologies and foundries in (Bi)CMOS/BCD/SOI 28nm to 0.8 $\mu$ m for voltages from 0.8 to >150V and temperatures from -50C to 200 degC.

## 2 ICsense's Management Team

- Dr. Bram De Muer**, Chief Executive Officer and co-founder.
- Dr. Wim Claes**, Chief Business Development Officer and co-founder.
- Dr. Yves Geerts**, Chief Operating Officer and co-founder.
- Ir. Pieter De Muyter**, VP Engineering.

## 3 ICsense external directors

- Mr. Takao Tsutsui (president)**, CEO of the Sensor Systems Business Company (SSBC) of TDK.
- Mr. Sam Maddalena**, director Absolute Sensing BV and CEO of TDK-Micronas GmbH.
- Mr. Francois Quoirin**, Finance, Accounting, Internal Audit Director at TDK Europe S.A.

## 4 Scope and Purpose

The Quality Management System (QMS) described in this manual covers all activities of ICsense, including design & development activities and production of ASICs. Production activities include low volume ATE testing and supply chain management for design and supply projects. The manufacturing and high volume testing activities are outsourced.

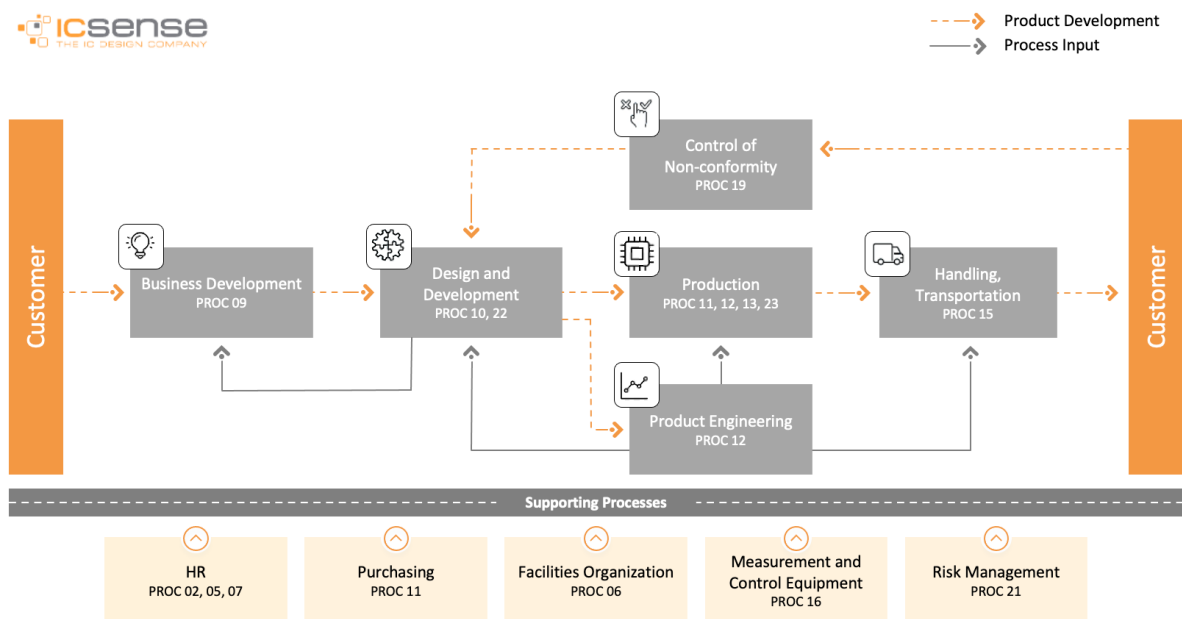


Figure 1: ICsense processes and interactions.

The scope of this document covers the ISO 9001:2015 and ISO 13485:2016 quality standards. This manual, together with procedures and other documented information, provides guidance in maintaining full conformity with the requirements of these International Standards.

For medical ISO 13485:2016 projects, the role of ICsense is restricted to design and supply of ASICs to the customer, who is the legal manufacturer. ICsense is not a legal manufacturer of medical devices, and no distributor of medical products. The ASIC is a medical device component: it is part of further assembly and not a medical device on its own. ICsense does not assume any product liability. Due to the activities undertaken by ICsense, following clauses are explicitly not applicable for the organization:

- Paragraph 6.4.2: There are no contaminated/ potentially contaminated products or sterile medical devices at ICsense.
- Paragraph 7.5.2: ICsense does not perform cleaning activities, sterilization activities or manufacturing activities.
- Paragraph 7.5.3: ICsense does not perform medical device installation activities.
- Paragraph 7.5.5: There are no sterilization processes at ICsense.
- Paragraph 7.5.7: There are no sterilization processes at ICsense.

Since ICsense remains responsible for technical support during the life cycle of the ASIC embedded in the medical device, ICsense is a critical supplier to its medical customers / the legal manufacturer.

Following items of the ISO 13485:2016 standard are only limitedly applicable to ICsense:

- Paragraph 4.2.3 medical device file: ICsense will store all relevant technical records such as specifications, verification data, test data, technical reports to enable technical support during the lifetime of the ASIC integrated in the medical device.
- Paragraph 6.4.1 Work environment: The work environment at ICsense is limited to offices and the design analysis area. ICsense maintains the cleanliness of these areas and the capability for ASIC prototype testing.
- Paragraph 8.2.3 Reporting to regulatory authorities: ICsense supports its medical customers to enable reporting to the regulatory authorities on demand in the format agreed with the customer.

Within this context ICsense will not perform post-market surveillance of the end customer as ICsense is not the legal manufacturer and has no direct relationship with the end-user (patient) of the product. In case of an incident, the vigilance process applies to the legal manufacturer who performs the root cause analysis. The project manager is the first contact point during development. The product engineer is the first contact point during production. They will take the necessary actions such as notification of the Quality Manager. In case of a complaint, PROC 17-00 will be followed. In case of non-conformities, PROC 19-00 will be followed. Customer feedback from the legal manufacturer is monitored through the customer satisfaction survey (PROC 17-00) or is received directly from the customer.

In addition, functional safety standards as IEC 61508 and ISO 26262:2018 set additional requirements to the quality management system as documented in ISO 26262-2 (Management of functional safety) and ISO 26262-8 (Supporting processes). The quality management system has been made compliant with these requirements. In functional safety projects, the quality management system is regularly assessed and audited by customer or external reviewers. Internal confirmation reviews are held to assure compliance with ISO 26262:2018.

## 5 Quality Management System

### 5.1 General Requirements

ICsense has established, implemented, maintains, and continually improves a Quality Management System (QMS) in accordance with the requirements of the International Standards ISO 9001:2015 and ISO 13485:2016, with the aim of maintaining its quality efficiency.

The processes needed for this Quality Management System, and their interactions, are depicted in Figure 1. In addition to the core processes (to realize the product from an initial idea), a number of processes have been identified to support, measure, monitor and analyze these processes, and to implement actions necessary to achieve planned results and continual improvement. They are discussed in more depth in the following sections of this Quality Manual.

Additional ISO 26262:2018 requirements have been implemented and elaborated where applicable.

### 5.2 Documentation requirements

The documentation of the Quality Management System includes a number of documented procedures, i.e. procedures that are established, documented, implemented and maintained under the surveillance of the Quality Manager. Documentation requirements relate to configuration management as required for ISO 26262-8.

These procedures cover the items expressly mentioned in the International Standards, as well as those procedures the organization deems necessary to ensure the effective operation and control of its processes (as depicted in Figure 1).

#### 5.2.1 Quality manual

This Quality Manual is part of the overall documentation of the organization, and constitutes the primary document for all employees, to inform and guide them through the company's QMS.

#### 5.2.2 Control of documents

Documents that are part of this QMS, or are relevant to the implementation and maintenance of the company's QMS, are controlled and managed according to PROC 03-00: Document Control. This procedure takes care of:

- The approval, review and re-approval of documents
- The identification of revision status
- The distribution of documents
- The prevention of unintended use of obsolete documents
- The continuous availability of documents

#### 5.2.3 Control of quality records

Records required for the QMS are controlled according to procedure PROC 04-00: Record Registration.

These records are thus maintained to provide evidence of conformance to requirements and of effective operation of the QMS.

Special instructions are maintained for retaining actual and obsolete controlled documents pertaining to medical projects and/or products.

## 6 Management responsibility

### 6.1 Management commitment

Management is committed to the development and improvement of the Quality Management System and to the maintenance of its quality efficiency. This Quality Manual as well as all operational and supporting procedures are communicated to every employee of the company.

The quality policy that is formulated hereafter thus becomes known to and binding for the whole organization.

Management Reviews are organized on a regular basis, according to procedure PROC 01-00.

### 6.2 Customer focus

As already expressed by our company values (chapter 1), we want to ensure that customer needs and expectations are determined (PROC 09-00: Sales and Contract management), converted into requirements (PROC 10-00: Design and Development) and fulfilled with the aim of achieving customer satisfaction (further operational procedures).

### 6.3 Quality policy



The main goal of ICsense is to deliver the highest possible quality in our design services and turnkey ASIC services. This quality level is defined and specified by, or at least together with, our customers.

ICsense is a flexible and multidisciplinary team of engineers with long years of experience in microelectronic design & development activities, and ASIC turnkey solutions, from idea to product.

To serve the needs of our clients in the best possible way, we handle every project as per requirement of the client, depending on what kind of support or delivery is required. In doing this, we know and respect laws and regulations which may bear on our products or our organization.

The selection of equipment and subcontractors used in the project will only be based on specifications and requirements of the client and not on a product scope of the company.

Every project will be handled by a dedicated project team of specialists and project manager. This setup provides the best results and efficiency. ICsense believes that in every successful project the keyword is “communication”.

Clear external communication towards customers and equally important the internal communication in the project team is essential for a successful project.

Being part of the TDK group, ICsense is also striving to advance to zero defects. Quality cannot be assured by final inspection in the final production process, but quality assurance is needed for all processes. By making the highest quality product, we can provide customer satisfaction and consolidate customer confidence.

The quality management system described further in this handbook is a prime tool to organize and manage what we described in this quality policy and a token of our commitment towards our customers, external parties and employees, and towards maintaining the effectiveness of the quality management system and its continual improvement.

It will guarantee, through its implementation, the accomplishment of our quality policy and compliance with the international ISO 9001:2015 and ISO 13485:2016 Standards.

In addition, the QMS guarantees compliance of automotive and industrial functional safety critical ASIC developments with IEC 61508 and ISO 26262:2018 standards.

This Policy is reviewed on a regular basis during Management Reviews, according to procedure PROC 01-00.

## 6.4 Planning

Overall objectives for the company are expressed in a business plan, which is from time to time updated by Management, approved by the board, and communicated to the different stakeholders of the company. Revision of the business plan is discussed and approved at the occasion of Management Review meetings.

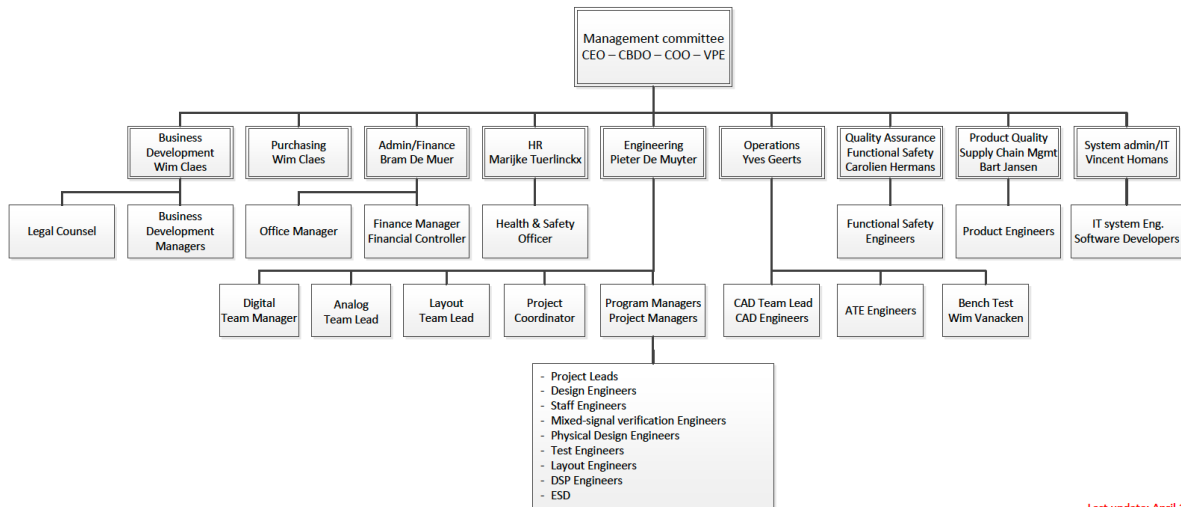
Quality objectives needed to meet the requirements for a given product, will be captured at the time of Requirements Specification (PROC 10-00) and may lead to Specific Quality Plans (PROC 08-00).

Quality objectives for the core processes (human resources – business development – design and development – product engineering – purchasing/suppliers – corporate) are defined in the KPI (key performance indicators) sheet. This sheet is completed quarterly and the data is evaluated during the biannual management review meeting according to procedure PROC 01-00.

At all relevant functions and levels within the organization, quality objectives are established in the Individual Performance Plans (PROC 07-00). They are measurable and consistent with the Quality Policy, and include the commitment to continual improvement.

## 6.5 Responsibility, authority and communication

### 6.5.1 Responsibility and authority



Last update: April 1<sup>st</sup> 2025

Figure 2: ICsense Functional organogram

Functions and their interrelations within the organization, including responsibilities and authorities, are defined and communicated according to procedure PROC 02-00: Job Descriptions. Their interrelation is illustrated in the organization chart depicted in Figure 2.

### 6.5.2 Quality Manager and management representative

It is the responsibility of the quality manager, together with the management representative, that the Quality Management System is established, implemented and maintained. Tasks of the quality manager are:

- Schedule audits (internal/external) and manage the audit team
- Schedule and prepare management reviews and write reports
- Update and distribute QMS related documentation (including statutory and regulatory requirements)
- Maintain quality record databases
- Communicate to the organization:
  - The importance of meeting requirements of customers and other interested parties
  - The importance of meeting statutory and regulatory requirements
- CPA initiation, follow-up, registration and closure (use of JIRA)
- Communication with certification organization whenever organizational or process-related changes occur in the QMS, which can influence the compatibility with existing quality standards
- Report to Management the key quality parameters and key quality issues on company and project level

The role of management representative is fulfilled by the CEO. In case of absence, he can be replaced by the CBDO, COO or VPE. Tasks of the management representative are:

- Prepares management reviews and report to the management committee on the performance of the quality system and any need for improvement
- Has QMS related documentation (including statutory and regulatory requirements) maintained and updated by the Quality Manager
- Communicates to the organization:

1. Importance of meeting customer requirements
  2. Importance of meeting statutory and regulatory requirements
  3. Importance of meeting QMS requirements
- Supervises the Quality Manager's tasks and responsibilities

#### 6.5.3 Internal communication

Communication between the various levels of the organization, regarding the processes of this QMS and their effectiveness is achieved by the implementation of the Internal Audit procedure (PROC 18-00) as well as by the Performance Management system of the organization (PROC 07-00).

Once a month (preferably the 9th, as "9" sounds like "Q" in Japanese), a "Q-day" is organised to improve quality awareness within the company. An e-mail is sent with tips and tricks, howto's, information, etc. on increasing quality in daily work routines.

Quarterly meetings are held with all employees, where the Quality Manager or CEO highlights parts of the QMS and discusses recent changes. This meeting is also used to propagate the safety culture in ICsense in line with ISO 26262:2018.

#### 6.5.4 External communication

The Quality Manager maintains communication with the certification organization. Whenever he judges necessary, he informs that organization of evolutions and/or modifications which have an impact on the Quality Management System. Verification whether such evolutions have occurred, is also part of the agenda of the Management Reviews.

### 6.6 Management review

Management reviews the QMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness and according to procedure PROC 01-00: Management Review.

This review evaluates the need for changes to the QMS, including changes to the quality policy and the quality objectives.

### 6.7 Changes

In case changes to the QMS are planned, all employees are made aware of any changes that affect the process in which they are involved. Subsequent monitoring is undertaken to ensure that QMS changes are effectively implemented. Following items are considered:

- the purpose of the changes and their potential consequences (risk and opportunities);
- the integrity of the management system (how does the change effect current process?);
- the availability of resources;
- the allocation or reallocation of responsibilities and authorities.

## 7 Resource management

### 7.1 Provision of resources

A number of procedures aim at providing, in a timely manner, the resources needed to implement, maintain and improve the processes of the QMS and to address customer satisfaction, by meeting regulatory and customer requirements. They address human resources as well as facilities and the work environment.

### 7.2 Human resources

To guarantee the necessary competencies (based on applicable education, training, skills and experience) of employees who are assigned responsibilities defined in the QMS:

- These competencies are documented in the job descriptions for every function in the organization, according to PROC 02-00: Job Description.
- Competency and training needs are identified and the necessary training provided and evaluated where needed, according to PROC 05-00: Training and Competency Management. This procedure also takes care of the maintenance of appropriate records of education, experience, training and qualifications of employees.

### 7.3 Infrastructure

Facilities needed to achieve conformity of products, are provided by the organization, according to procedure PROC 06-00: Facilities Organization. Even though ICsense also addresses the medical market, no special work environment conditions are required.

### 7.4 Maintenance

Maintenance of Facilities is governed by the same procedure PROC 06-00 and records are maintained accordingly.

### 7.5 Work environment

The same procedure (PROC 06-00) caters for the management of the physical factors of the work environment, whereas procedure PROC 07-00: Performance Management determines the rules and processes to manage the human factors, needed to achieve conformity of products.

Instructions for working in the cleanroom and cleanroom validation is part of PROC 23-00: Production Testing.

## 8 Product realization

### 8.1 Planning

The product-specific quality plan is fixed and documented as in procedure PROC 08-00: Quality Plan.

This plan refers to the different procedures that describe:

- How quality objectives for the product, project or contract are determined
- How resources and facilities specific to the product are provided
- Which verification and validation activities are needed, as well as criteria for acceptability
- Which records are necessary to provide confidence of conformity of the processes and the resulting product?

## 8.2 Customer-related processes

### 8.2.1 Development Interface Agreements

As required by ISO 26262:2018, a DIA (development interface agreement) is setup and signed that clearly defines the responsibilities of each party according to the RECI principle. (PROC 22-00)

### 8.2.2 Identification of customer requirements

Identification of customer requirements including requirements for availability, delivery and support, product requirements not specified by the customer but necessary for the intended or specified use, and obligations related to the product, including regulatory and legal requirements, have to be determined prior to signing a contract.

The rules of conduct for these matters are managed according to procedure PROC 09-00: Sales and Contract Management.

### 8.2.3 Review of product requirements

The identified customer requirements, together with additional requirements determined by the organization, have to be reviewed prior to the commitment to supply a product to the customer.

The process for conducting this review is also described in PROC 09-00: Sales and Contract Management.

### 8.2.4 Change management

Change management towards customers is handled in PROC 22-00 and in PROC 09-00 for ECOs.

### 8.2.5 Customer communication

Communication with customers relating to product information, enquiries and contracts (or changes to contracts), is also governed by PROC 09-00.

Communication with regards to customer feedback, including customer complaints, is governed by procedure PROC 17-00: Customer Satisfaction and Complaint Management.

## 8.3 Design and development

Design and development are guided by procedure PROC 10-00: Design and Development. This procedure describes how the overall process has to be managed, and which sub-processes describe in more detail the different needs and requirements of a design and development process that is consistent with our quality policy. The development process with phases, tasks, milestones, reviews is shown below. It also shows the ISO 26262:2018 specific items.

Most design and development orders can be considered as projects. PROC 22-00: Project Management, describes how such project is managed and documented to ensure quality and efficiency of ICsense's operations.

Both procedures hold several procedures like dedicated reviews, change management, escalation management, risk management, safety analysis, lessons learned and safety planning for compliance with ISO 26262:2018 requirements. Special attention is drawn to safety analysis; deductive quantitative analysis is used for (A)SIL qualification and failure rate calculation, i.e. a Failure Mode, Effect and Diagnostics Analysis. ICsense is not equipped to carry inductive analysis in-depth (Failure Tree Analysis).

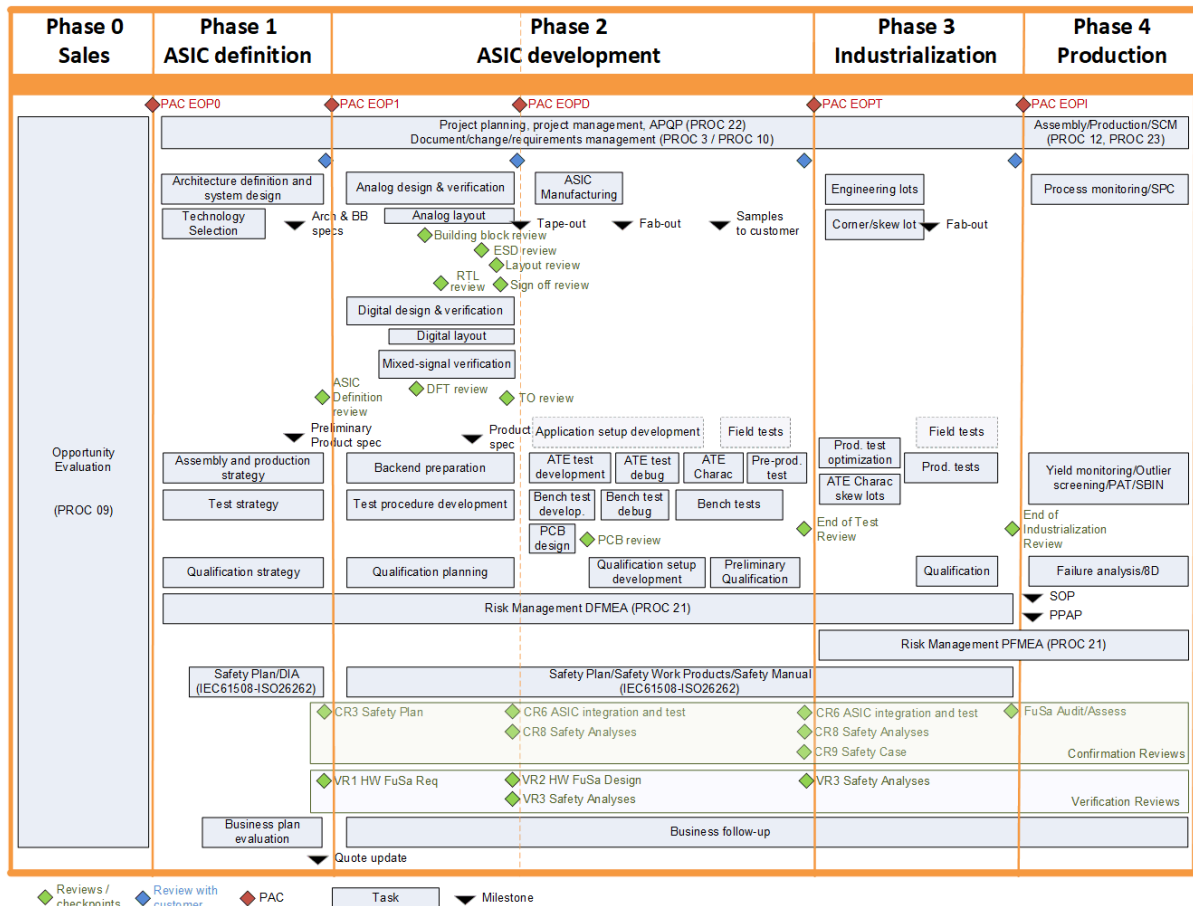


Figure 3: ICsense Development process.

## 8.4 Risk Management

Risks and opportunities of the QMS are identified and actions to address these risks are planned and implemented according to PROC 21-00: Risk Management. A Business Continuity Plan (BCP) is in place to ensure that organization's critical business processes can continue to operate during and after a disruptive event.

Before and during the different stages of Design and Development, design risks are managed according to procedure PROC 21-00: Risk Management using a DFMEA sheet. This methodology is mandatory for automotive ISO 26262 projects, industrial functional safety IEC 61508 projects, ISO 13485 projects and design and supply projects. To identify possible risks during ATE production testing, a process FMEA has been performed.

Project risk management is governed by PROC 22-00, section risk management. To prevent manipulation of quality data, a quality compliance risk assessment has been implemented according to PROC 21-00: Risk Management.

## 8.5 Purchasing

Purchasing activities are managed and controlled conform PROC 11-00: Purchasing, and cover following activities:

- Authorization to purchase
- Supplier selection
- Supplier evaluation on a regular basis
- Product verification, including verification activities at the supplier's premises.

## 8.6 Production and Service operations

### 8.6.1 Operations Control

Production and Service operations are controlled through:

- The availability of information that specifies the characteristics of the product
- Where necessary, the availability of work instructions, manuals and standards of good craftsmanship.
- The use and maintenance of suitable equipment for production and service operations
- The availability of measuring and monitoring devices
- The implementation of monitoring activities
- The implementation of defined processes for release, delivery and applicable post-delivery activities
- A product specific control plan for ATE production testing.

These activities are implemented, controlled and maintained according to procedures PROC 12-00: Product Engineering and Service Provision, PROC 15-00: Handling, Packaging and Transportation, PROC 16-00: Measurement and Controls and PROC 23-00: Production Testing.

### 8.6.2 Validation of processes

Deficiencies are monitored according to procedures PROC 10-00 and PROC 12-00. The monitoring and analysis of the data may and will lead to Corrective Actions directed towards improving these processes.

### 8.6.3 Identification and traceability

The identification, where appropriate, of the product throughout production and service operations, including status identification and traceability requirements are managed according to PROC 13-00: Identification and Traceability and PROC 23-00: Production Testing.

### 8.6.4 Customer property

Exercising care with customer (and supplier's) property, in order to verify, maintain and protect such property while it is under the organization's control or being used by the organization, is governed by procedure PROC 14-00: Customer property. This procedure also takes care of the preservation of intellectual customer property, through the use of Confidentiality Agreements.

### 8.6.5 Preservation of product

Preservation of conformity with customer requirements during internal processing and delivery is managed as described in procedure PROC 15-00: Handling, Packaging and Transportation and PROC 23-00: Production Testing.

## 8.7 Control of measuring and monitoring devices

Control of measuring devices is done through regular calibration by external companies and internal verification of measuring devices, as described in procedure PROC 16-00: Measurement and Controls.

## 9 Measurement, analysis and improvement

### 9.1 Planning

Measurement and monitoring activities are governed by a number of procedures:

- PROC 16-00: Measurement and Controls
- PROC 17-00: Customer Satisfaction and Complaint Management
- PROC 18-00: Internal Audit
- PROC 19-00: Control of Nonconformity
- PROC 20-00: Corrective and Preventive Actions
- PROC 21-00: Risk Management

### 9.2 Measurement and monitoring

#### 9.2.1 Customer Satisfaction

The methodologies used for obtaining and using customer information on his satisfaction and/or dissatisfaction are described, implemented and maintained according to procedure PROC 17-00: Customer Satisfaction and Complaint Management.

#### 9.2.2 Internal Audit

Periodic internal audits are conducted conform procedure PROC 18-00 to determine:

1. Whether the QMS conforms to the requirements of the International Standard
2. Whether the daily operations (workflow) conform to the QMS procedures
3. Whether the QMS has been effectively implemented and maintained

The procedure describes the responsibilities and requirements for conducting those audits, ensuring their independence, recording results and reporting to management.

#### 9.2.3 Measurement and monitoring of processes

Realization processes necessary to meet customer requirements are monitored during internal audits, performed according to procedure PROC 18-00.

Quality objectives for the core processes (human resources – business development – design and development – product engineering – purchasing/suppliers - corporate) are defined in the KPI (key performance indicators) sheet. This sheet is completed quarterly and the data is evaluated during the biannual management review meeting according to procedure PROC 01-00.

#### 9.2.4 Measurement and monitoring of product

Evidence of conformity with acceptance criteria is documented and products are subsequently released according to procedures PROC 10-00: Design and Development, PROC 11-00: Purchasing and subcontractors, PROC 12-00: Product Engineering and Service Provision and PROC 23-00: Production Testing.

### 9.3 Control of nonconforming products

Products which do not conform to the requirements are treated and controlled to prevent unintended use or delivery. When detection of the nonconformity occurs after delivery or use has started, appropriate actions have to be taken regarding the consequence of the nonconformity.

These actions are governed by procedure PROC 19-00: Control of nonconformity.

## 9.4 Analysis of data

Data to determine suitability and effectiveness of the QMS are collected and analyzed according to procedures:

- PROC 01-00: Management Review
- PROC 17-00: Customer Satisfaction and Complaint Management
- PROC 18-00: Internal audit

## 9.5 Improvement

Continual improvement is obtained through the implementation of a number of procedures:

- PROC 01-00: Management Review
- PROC 17-00: Customer Satisfaction and Complaint Management
- PROC 18-00: Internal audit
- PROC 19-00: Control of nonconformity

These procedures may all lead to Corrective and/or Preventive actions, according to PROC 20-00: Corrective and Preventive Actions.

## 10 Reference to the international standards

The following table lists all quality procedures that make this Quality Management System, with their reference to the appropriate paragraph or section of the ISO 9001:2015 and ISO 13485:2016 international standards.

This allows the reader of this manual to better position the different elements of the QMS in the overall context of these international standards.

Identification and Subject of document	Ref. to ISO 9001:2015	Ref. to ISO 13485:2016
PROC 01-00 Management Review (includes context analysis, Quality Policy review & communication, and updating of Organization Chart)	4.1./4.2./4.3./4.4. 5.1./5.2./7.4 6.2/6.3 9.3.	4.1.1./4.1.2/4.1.3/4.1.4 5.1./5.2./5.3./5.5.3 5.4. 5.6./8.4
PROC 02-00 Job Descriptions	5.3	5.5.1./5.5.2
PROC 03-00 Document Control (paper and/or electronic format, control & release, safeguarding against loss or deterioration)	7.5	4.2.
PROC 04-00 Record Registration	7.5	4.2.5.
PROC 05-00 Training and Competency Management	7.2./7.3.	6.2.
PROC 06-00 Facilities Organization	7.1	4.1.6 6.1./6.3./6.4
PROC 07-00 Performance Management	7.2	6.2.
PROC 08-00 Quality Plans	8.1.	7.1.
PROC 09-00 Sales and Contract Management	8.2.	7.2.
PROC 10-00 Design and Development	8.3.	7.3./4.2.3
PROC 11-00 Purchasing	8.4.	7.4./4.1.5
PROC 12-00 Product Engineering and Service Provision	8.5/8.6	7.5.1/7.5.4
PROC 13-00 Identification & Traceability	8.5.2	7.5.8/7.5.9
PROC 14-00 Customer Property	8.5.3.	7.5.10
PROC 15-00 Handling, Packaging, Transportation	8.5.4.	7.5.11
PROC 16-00 Measurement and Controls	7.1.5	7.6/8.2.6
PROC 17-00 Customer Satisfaction and Complaint Management	9.2.1.	8.2.1./8.2.2/8.2.3
PROC 18-00 Internal Audit	9.2	8.2.4./8.2.5./8.4
PROC 19-00 Control of nonconformity	8.7	8.3.
PROC 20-00 Corrective and Preventive Actions	6.1 10	8.5.
PROC 21-00 Risk Management	4.4 / 6.1	7.1./7.3.2.
PROC 22-00 Project Management	8.3.	7.3.
PROC 23-00 Production Testing	8.5/8.6	7.5.1/7.5.6/ 7.5.8/7.5.9/7.8.11

As documented in the different sections of this document, all procedures are in line with requirements of the IEC 61508 standard, the ISO 26262:2018 standard Parts 1-12 and SN 29500 and/or ISO 26262-11 for failure rate figures.

Date	Revision	Who	Approval	Description
17/06/2008	A.	Q. Officer	BDM	First version
24/09/2014	C.2.	Q. Officer	BDM	
23/09/2015	C.3.	Q. Officer	BDM	Update Organogram Update formatting Added history table
12/10/16	D	BDM	CBDO	Overall update: development process, organogram, ISO26262
03/04/17	D.1	BDM	CBDO	Update of introduction and Board after TDK acquisition
03/06/2017	E.1	Q. Officer	-	Update for ISO9001:2015 and ISO13485:2016. Never released
20/04/2018	E.2	CH	BDM	Major Update for ISO9001:2015 and ISO13485:2016.
11/07/2018	E.3	CH	BDM	Update to better describe the scope for ISO13485
05/02/2019	E.4	CH	BDM	New figure with processes and procedures Scope and Purpose: also include 6.4.2 as 'non-applicable' Add Quality Poster to quality policy
24/05/2019	E.5	CH	BDM	Scope and Purpose: also include 7.5.3 as 'non-applicable'
12/05/2020	E.6	CH	BDM	Update ISO 26262 according to second edition (ISO PAS 19451 and IEC/TR 62380 are part of ISO 26262-11:2018) Replace Quality Officer by Quality Manager Replace RECI by RASIC Update Figure 2: ICsense Functional organogram Update Figure 3: ICsense Development process.
09/07/2020	E.7	CH	BDM	Update Figure 1: ICsense processes and Update section 8.1 Planning
19/08/2021	E.8	CH	BDM	Update Figure 2: ICsense Functional organogram
04/03/2022	E.9	CH	BDM	Update Figure 3: ICsense Development process. Add ATE in ICsense – A Brief Introduction Small update ICsense's Management Team, ICsense external directors
25/04/2023	E.10	CH	BDM	Update Figure 2: ICsense Functional organogram Update ICsense external directors
28/08/2023	E.11	CH	BDM	DIA ISO 26262: replace RASIC by RECI
19/04/2024	F.1	CH	BDM	Update ICsense's Management Team, ICsense external directors Update Scope and Purpose, including new Figure 1: ICsense processes and interactions. Update Figure 2: ICsense Functional organogram Rename PROC 12-00 into Product Engineering and Service Provision
24/09/2024	F.2	CH	BDM	Update organogram and management team after the departure of Tim Piessens
01/04/2025	F.3	CH	BDM	Update organogram: finance
29/01/2026	G.1	CH	BDM	Add PROC 23 Production testing

## 11 Further Information

For further information on ICsense, please contact us :

[info@icsense.com](mailto:info@icsense.com)

ICsense NV

Gaston Geenslaan 14

B-3001 Leuven – Belgium

Tel : +32(0) 16 589 700

[www.icsense.com](http://www.icsense.com)