



Quality Manual

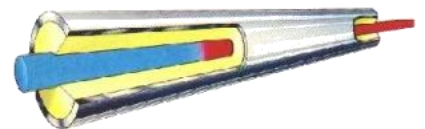
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SUMMARY

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Summary

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1. CORE BUSINESS, PURPOSE AND ORGANISATION OF THE MANUAL

The Quality Manual describes the activities of the company in design, development, manufacturing, trade and sales of sensors, heating elements, signal transmission cables and accessories.

The application field includes qualification tests, measurement and calibration of temperature sensors.

1.1 Targets

- Provide each person involved in product development with written references, insofar as the quality of this product depends on their action.
- Define the rules for setting up files related to design, procurement, manufacturing, control and, in general, any document containing information which may have an influence on quality.
- Demonstrate, when necessary, to an external organisation, our capability to achieve the required quality level.

1.2 Organisation

1.2.1 Issue

- **Periodicity:**
 - in response to significant development of the structure and quality management system at a minimum : every 3 years.
- **Responsibilities :**
 - Written** Quality Assurance Manager who make sure of the any other useful collaboration,
 - Controlled and approved** by the senior Management (see revision table)
 - any amendment of one page implies a change to the revision of the manual.
- **Specific case :**
 - Only for minor modifications between 2 issues, it is possible to manually modify the Quality Manager's master copy to identify remarks and suggestions. It is also applicable to the other Quality Manager's documents. Each hand written modification is dated and signed.
 - Also important relevant changes are transferred to the applicable parties between official revisions.

1.2.2 Distribution

1.2.2.1 Uncontrolled distribution

German, English, French and Chinese versions of the QA manual are available on the THERMOCOAX website (www.thermocoax.com) and the internal Document Management System (DMS).

In general, it is the reader's own responsibility to check with THERMOCOAX that he is in possession of the latest issue of the document.

1.2.2.2 Controlled distribution

- “Controlled Distribution” is to distribute systematically successive versions to the recipients listed as such in the "Ist of recipients".
- Updating of the **recipient list** (AD000D020) by the QA secretary.
- [Visa, date, exemplar number and recipients on the front page](#)
- [Internal Distribution](#) : a paper version is available at PQV-SGG and SRN + signature on the receipt list and destruction of the expired version
- [External Distribution](#): on request and if the recipient does not accept the electronic version available on our web site, we will send a CD-Rom with acknowledgement of receipt to be returned dated and countersigned

Applicable documents:

- [AD000D020 recipient list](#)

2. STANDARD REFERENCES

2.1 [Standard references](#)

Code 50-C/SG-Q de l'AIEA de 1996 (comprenant 50-C-Q)	ISO 9001
Code RCC-E / RCC-M A 5000	ISO 14001
10CFR50 Appendix B	OHSAS 18001
ASME section III Subsec NCA	EN 9100
KTA 1401 - AD 2000 – HP0/W0 and KTA 3201	QA-000725 – GRP-0087
NSQ 100	PART 21/G dernière édition en vigueur
EN ISO 3834-2	ECSS-Q-ST-20C
	AQAP 2110
ISO-17025	NF EN ISO/CEI 80079-34 (ATEX)
EIT90	ISO 19011
Remark : The applicable issue is available for consultation in document Management System or at QA report	

3. TERMINOLOGY

QA/AQ	Quality Assurance	LDA	List of applicable documents
AR	Acknowledgement of receipt	MA	Workshop instructions
ASME	American Society Mechanical Engineers	MQ	Quality Manual
CC	Confirmation of Order	POM/MOP	Production Organisation Manual
CdCF	Preliminary tender specifications	OF	Manufacturing Order
PL/CdP	Project leader	PDCA	Improvement process based on Plan - Do - Check - Act
NDT/CND	Non destructive Testing	QAP/PAQ	Quality Assurance Plan
COFRAC	French Accreditation Committee	PQD	Development Quality Plan
QC/CQ	Quality Control	MQP/PQR	Manufacturing Quality Plan
DA	Purchasing / Procurement request	PQA 90	Philips Quality Award
RF/DJD	Record file	PV	Test Report
PF/DP	Pricing file	PVRI	Individual Receipt Test Report
RF/DR	Reference file	QMOS	Qualification of Welding Operations
DS	Follow up document	QAPM	Quality Assurance Program Manual
EC	Heating element	RFF	Final Manufacturing Report
DSM/MTE	Control, measurement and testing equipment	HR/RH	Human Resources
DD (ED)	Design and Development	SAQ	Levels Quality Assurance
ERQ	Record related to quality	SQ	Quality requirements
FAI	First Article Inspection	SMQ	Quality Management System
FF	Manufacturing form	S	Special or specific
NCR/FNC	Non Conformity Report	TC	Thermocouple
FP	Data sheet	TGV	"Fast Track" Order
GMM	Group Management Manual	TCX/THX	THERMOCOAX
CAMS/GPAO	Computer Assisted Manufacturing System	TQM	Total Quality Management
ERP	Enterprise Resource Planning	SRN	Suresnes
DMS	Document Management System	PQV/PLQ	Planquivon Athis de l'Orne
HI	Rod Heater	SGG	Saint Georges des Groseilliers
ICPE	Classified Installations for Environment	8D	8 Do
PART21/G	Joint Aviation Requirements		
RCC-E/M	Design and manufacturing rules of electrical and mechanical material of nuclear plants		

(Italic = French version)

4. QUALITY MANAGEMENT SYSTEM

4.1 Process Generalities

The mapping of the processes and their interactions are described in the Group Management Manual (GMM)

Process Externalisation

Not applicable for THERMOCOAX

4.2 Quality Management System Documentation

4.2.1 Overview

The Quality Management System documentation is described in the GMM

4.2.2 Quality Manual

The subject, the content and the management of the manual are describe in chapter 1.

4.2.3 Document control

- **Procedure** - AD000D143 : Documents control
- **Responsability** - QA department
- **Means** - Document Management system (GED)
- **Concern** - procedures, instructions and guidelines
 - drawings
 - customer and supplier documents
 - applicable normes et reglementation
- **Approved document list** : AD000D053 which refer to GED

4.2.4 Record control

Every document established to provide evidence of conforming to requirements and operation is controlled, monitored, retained in a satisfactory condition and protected to minimize deterioration or change and to avoid losses

- **Procedure** - AD000D143 : Document management
- **Responsability** - QA department
- **Means** - Document Management system (GED)
- **Concern** - identification, storage, protection, retrieval by level of confidentiality, means, retention period and disposition of records

Applicable document:

AD000D143 Documents control

AD000D053 Applicable document lists

5. MANAGEMENT RESPONSIBILITIES

5.1 Management involvement

This paragraph is recorded in the Management Manual ([GMM](#))

5.2 Customer Feed-Back

To ensure the appropriate understanding of the customers' needs and expectations and those of other interested parties, the THX Management implemented a system to collect permanently information based on:

- The market study, customers' panel, competition and THX positioning within this competition,
- The analysis of the customers' needs:
 - Passive listening:
 - Documentation survey
 - Analysis of claims and returns
 - Active listening:
 - Commercial contacts / visits, exhibitions, telephone contacts, technical support,
 - Participation to conferences, exhibitions...
 - Tender review, contract review
 - Visits and audits of THX affiliates.
 - [Customer satisfaction survey](#)
- The manufacturing process performance evaluation
 - Product conformity: either 100% product control or sample inspection
 - Meet the requested delivery time represented in graphical form such as the [OTD](#), Productivity measurement.
 - Should the targeted results not be achieved, the process managers have to choose and put into operation the appropriate actions.

5.3 Quality policy

The policies and targets are :

- Re-examined annually at the time of the Management Review,
- Based on the analysis of the balance of the past year,
- Included in the continuous improvement process,
- Tools allowing the management to develop their leadership involving the staff,
- Disseminated to each members of staff through the general or individualised targets.

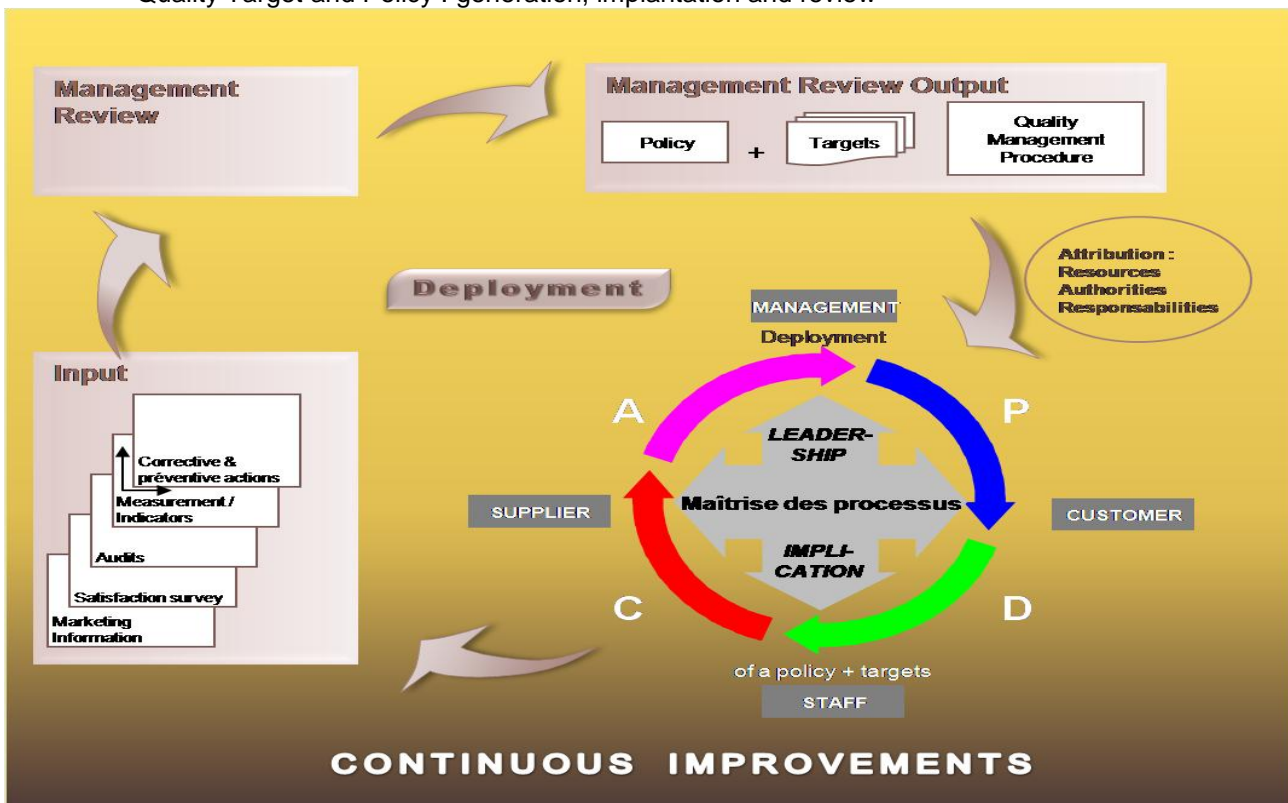
Decisions concerning strategy, policy, and targets are recorded in the following reports :

- Management Review, Budget Review
- Fortnightly Management meetings, Production meetings

- Sales Action Plan (SAP), Sales Meetings
- Customers Meeting Reports, Customers Visits Reports, Exhibitions,
- Leaflet "Individual Objectives"

5.4 Quality Management System Planning generation, implementation and review

Quality Target and Policy : generation, implantation and review



5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

- The responsibilities and authorities are described in the document PE100D004.
- The jobs descriptions are filled in personnel appraisal data files at Human Resources Department

Organisation chart

The nominal organisation chart is posted up in PLANQUIVON and in SURESNES. The language used is English. It is revised regularly according to staff changes and to the structure evolution.

5.5.2 Management representative

The Director designates Quality Manager as its representative.

This main missions are :

- Implement and maintain the quality processes

- Report to Director the performance of the Management Systems and their enhancement needs
- Raise awareness for the staff of interested parties requirements and nuclear safety.

5.5.3 Internal communication

The aim of this process is to communicate to the staff and other interested parties our strategy, QSE Policy, Company objectives and results, and also all useful information on THERMOCOAX, its commitments, products and services.

- **Procedure** - AD000D168 : gestion de la communication (Communication Management)
- **Responsability** - Defined in AD000D168
- **Moyen**
 - Orally
 - in Writing
 - Electronically
- **Input data** - Defined in AD000D168
- **Output data** - Defined in AD000D168

5.6 Description of management review process

- **Procedure** - AD000D186
- **Responsability** - Top Management team
- **Report** - classified in AD000P...
- **Methodes**
 - Part 1: Review of previous year
 - Part 2: Forecast for the coming year
- **Frequency** - full review once year, followed by monthly progress
- **Input data** - see AD000D186
- **Output data** - see AD000D186

Applicable documents :

PE100D004 Responsibility and authority
 AD000D168 Communication management
 AD000D186 Process and management review

6. RESOURCE MANAGEMENT:

6.1 Description of methods for resource management

The QMS can only function with the support off all the staff. Each contributes to the implementation and maintenance of the QMS. Infrastructure and Environment are involved in this implementation

QMS improvement involves:

- The document process "Human resources"
- Maintenance of infrastructure and equipment
- The decisions from management review on investisment

6.2 Human Resources

6.2.1 Recruitment

The procedure PE100D002 describes our position with regard to recruitment

6.2.2 Competence training and awareness

Competence Management

- **Requirement identification** : made by the Direct Manager and the Quality Expert, Environment, Security, Technical or computer
- **How** Job description in the staff assessment files
If necessary, a description of workstation tasks according to PP000D071 may be written
- **Evaluation of skill level** : by the Direct Manager
- **Registration : according to skill matrix** :
 - Manufacturing of product : PP000R155,
 - Design / Development : PP000R079,
 - Environment / Security : EV000R001
- **Monitoring / maintenance of the skill level** : by the Direct Manager by means of a quality record. The annual revision of the skill matrix is made during the annual interview with managers / collaborators / (cf : PE100D005)
- **Evaluation of training efficiency and revision of skill matrix:**
 - During the annual interview of the operator staff
 - For other categories : as required and/or during the annual interview.

Training / awareness

Training

The procedure PE100D003 describes our position concerning training and awareness.

The procedure PE100D005 describes our position concerning the annual interview, manager / collaborators.

Five types of training are practised within THERMOCOAX :

- ▶ Main competences training
- ▶ Technical training,
- ▶ Quality and Environmental training.
- ▶ Health & Safety training
- ▶ Software tools training

Awareness

- Initial commitment: according to the PE100D002 procedure
 - The QSE policy is jointly communicated by the Quality / Environment / Safety department
 - An introductory booklet or Power Point presentation given to new employees

- During introductory visit, the quality Department presents the Quality Management system and improvement actions in progress. A QSE booklet is given to every new employee.
- Hierarchical Manager will provide information on responsibilities and mission of the job
- Continuously: the aim is to make employees aware of :
 - Importance to conform to policy, procedures and all the requirements of QMS
 - Responsibilities and function of everybody, associated with emergency situations and their capacity to react
 - Potential consequences of any deviation to instructions and procedures

It is implemented by :

- Billposting of QSE policy
- Billposting and publication of articles in our internal newspaper, written or oral promotion of all "positive" actions
- Management engagement in actions in Normandy or others sites.
- From meetings (for example Enlarged management meeting) where management teams explain the general notions listed above.
- Internal communications intended to inform on integrated management system (QSE)

Recording

Training records are filed under reference AD100P... , at [Human Resources Department](#), and under reference AD900P for [subsidiaries](#) at quality correspondent office ..

6.3 Infrastructure

Including :

- a) building, work space and associated materials,
- b) equipment (software and materials) associated with the processes
- c) support services (eg. logistics, and communication).

Management Stages are :

Requirements identification

- **Responsibility** Director
- **Basis**
 - Management review
 - Production manager demands
 - Future order expectations
 - Resource inadequacy identification
 - Products in development
 - Metrology demand

Elaboration of the investment / purchase plan / actions definition

- **Responsibility** General management + Production + QA + Methods + Maintenance
- **Basis** Quotation or spending estimate, statement of laboratory and production requirements
- **Decision** Dependent on urgency and available annual investment budget

Implementation

- **Responsibility** Engineering Manager + Methods + Maintenance + Laboratory manager who will inform the Director
Investment budgets controlled by Administration and Finance Manager and Director

6.4 Working environment

It concern the working conditions (physical, environmental and others factors like noise, humidity, lighting or climatic ones)

The Management stages are :

Requirements identification

- **Responsibility**
 - Director
 - Production Manager
 - Environment/Safety Manager
 - CHSCT
 - CRAM
 - Works Physician
 - Works Inspection
 - Services Manager
- **Basis**
 - Building visit
 - Personnel request
 - National Regulations, hygiene, Safety, Working conditions + "French labor code"
 - Environmental rules
 - French Environmental Regulations (ICPE)

Elaboration of the investment / purchase plan / action definition

The same as Nr° 6.3

Implementation

- Made by :**
- CHSCT
 - Unit Production Manager, Safety, Environment or Direction
 - Users
 - Internal or external customers

- **Possibly concerns** - measurement / action monitoring and their suitability to meet their
 - identified requirements
 - evaluation of the reduction of the identified risk
 - evaluation of User satisfaction

Health & Safety

- **Manual / Procedure** - EV000D001
- **Responsibility** - QSE Director
- **Concern** - Health & Safety Management System
- **Standard** - OHSAS 18001
- **Input data** - French "Labour code"
 - Regulation
- **Output data** - Supervision plan
 - Health & Safety register
 - Equipment conformity
 - Health & Safety skill matrix
 - Impact evaluation
 - Risks analysis
 - Control report
- **Indicators** - Health & Safety management control data
- **Interested parties** - THERMOCOAX personnel
 - Customers
 - Shareholders
 - THERMOCOAX Health & Safety committee
 - Industrial physician / Factory inspectorate
 - Neighbours
- **Codification** - SE...

Maintenance

- **Procedure** - PP000D037 (THX SAS only)
- **Responsibility** - Maintenance department
- **Means** - SPLIT3 software
- **Methods** - Implementation of a preventives maintenance program
- **Frequency** - Defines according each equipment
- **Input data** - Machine builder recommendations, anteriority
- **Output data** - annual maintenance program
- **Indicators** - Number of preventive maintenance actions proponed per week

Documents applicables :

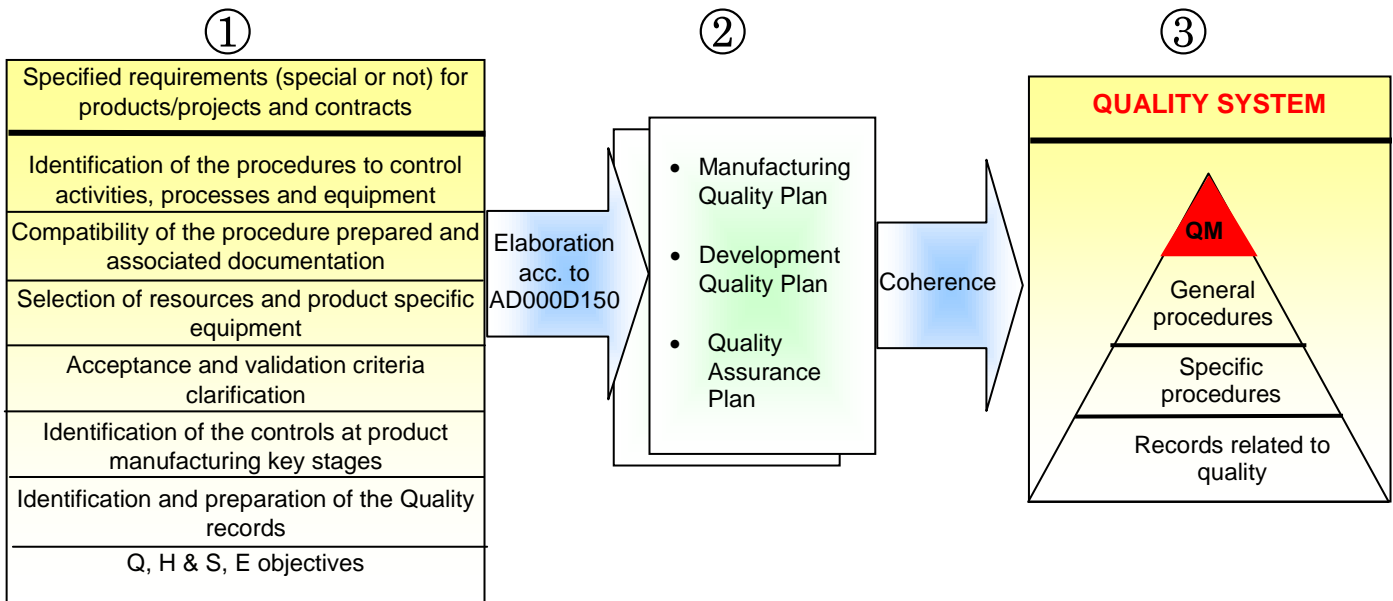
EV000D001	H & S-E management manual
EV000R001	Skill matrix for H & S-E activities
PE100D002	Recruitment
PE100D003	Staff training
PE100D005	annual appraisal
PP000D037	Maintenance procedure
PP000D071	Self inspection
PP000R079	Design skills matrix
PP000R155	Production skills matrix

7. PRODUCT MANUFACTURE

7.1 Planning of product manufacturing

According to the complexity of the product, project or contract and requirements specified by the customer, quality plans, Manufacturing Order Level is defined according procedure **AD000D138**. This document describes also the way to transmit the order to concerned department.

Methodology : the same for all the different types of Order



This scheme is only applicable for Order "ASQ", "SQ" and "SAQ" in its entirety. For the others, we made part 1 coherent with the entire quality system (Part 3) with only instruction or drawing.

- Procedure : **AD000D150**
- Content : method of preparation and use of a Manufacturing Quality Plan, Development Quality Plan or Quality Assurance Plan

7.1.1 Project management

Concerning large company's projects and upon the Top Management's decision, the project main operating principles within THX are:

- Well defined responsibilities
- A program
- A multi-disciplinary team
- Well identified milestones
- Reviews to pass these milestones and/or follow-up the project

7.1.2 Risk management

- Type :
- Products risks,
 - Environmental risks,
 - Staff health and safety personnel
 - Risks appropriate to the company working.

Method Concerning the company in general, the risk management is based on processes.
Responsibility Process pilot
Procedure AD000D178 Risk Management Procedure

Unacceptable risk the pilot implements and manages a special action
 During the risk analysis, **special requirements** may be defined. They will be added to those already identified by the customers. **Decisive factors** and **key characteristics** (special process, Statement of Configuration) may follow.

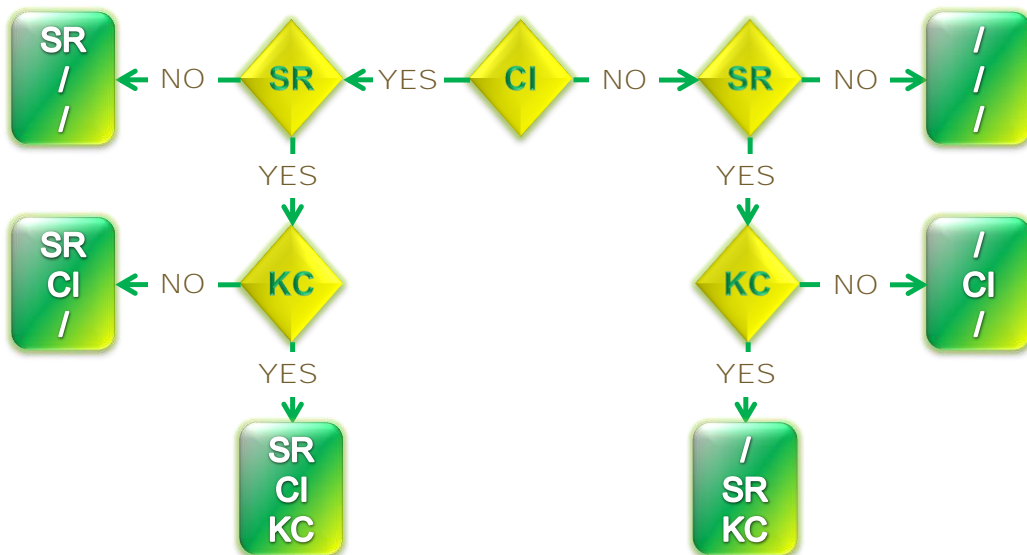
7.1.2.1 Definitions :

Risks: An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

Special requirements: Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry’s capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

Critical items: those items (e.g., functions, parts,, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items.

Key characteristics: An attribute or feature whose variation has a significant effect on product form, fit, function, performance service like or producibility that requires specific actions for the purpose of controlling variation.



Special Requirements (SR)
 Critical Items (CI)
 Key Characteristics (KC)

7.1.3 Configuration management

Procedure : AD000D175 statement of configuration

In addition to the procedure, this process is described in this manual at 3 places :

Ch 4.2	Quality Management System Documentation
Ch 7.1	Manufactured Product Planning
Ch 7.3	Design and development

7.1.4 Control of work transfers

Concern : Concern the transfers within the same facility or from one facility to another, from the organization to a supplier, from one supplier to another supplier.

Procédure : TR100D001 Activity transfer

Method : Based on a TR100D001, a multidisciplinary team fulfills a transfer file which includes milestones and meetings for organization during the preparation phase

Filling : the transfer documents are filed in TR100R...

Conformity control: par FAI et/ou contrôle du premier lot ou article si nécessaire

Preliminary external information: carried out specific to each case and based on contract and/or market.

7.2 Customer specific processes

7.2.1 Definition of product requirements

The contract review contains the requests for quotation written by the customer (DP file), our proposal after examination of the customer's needs International or National reglementation, the verification and the registration of the orders as well as their follow up.

- **Procedure :** AD000D149

7.2.2 Product requirement review

Tender review

➔ **Examination of the customer's requirements and the ability of the product to satisfy these requirements and risks identification (ex : new technology, short delivery time,...).**

- **Procedure** AD000D134 "Taking over the request for quotation"
The customer's requirements are compiled in a file (DP)
- **Responsibility** Sales and / or marketing and / or engineering Technical-Commercial department, depending on the complexity of the problem

Contract and order review

→ Examination of the conformity of the order to the offer.

- **Procedure :** AD000D138 : "customer orders processing"
The examination is made :
 - on receipt of the order. There could be a negotiation with the customer by either Logistics or Sales, Marketing and Engineering Department, depending on the subject.

→ Order revision .

- **When :** The case considered for an order which as already been received, checked and registered. That is to say when a comparison with the offer has already been completed.
- **Procedure :** AD000D149

7.2.3 Customer communication

- **Responsibility** - Sales Department assisted by other relevant departments,.
- **Concern**
 - Information on the product / THERMOCOAX support and its performance
 - Customers request / order processing
 - Complains and actions on non-conforming products
- **Identification of non-expressed requirements of the customer**
 - - based on our experience in heating solutions and temperature measurement
 - since 1957
 - - specific to market (legal constraints, regulation and standards) and in the environment where the product will be incorporated
 - - describe in AD000D167. This procedure lists the points required to clarify the product specification and its use.

7.3 Design and development

The design of a product can utilise new or developed procedures as judged against the experience and knowledge previously gained.

The design is completed according to methods controlled by general or specific procedures.

The aim is to assure that the declared needs are taken into consideration and examined in order to define a satisfactory product, which corresponds to the customer's expectations, and which is feasible and can be produced economically.

Part of Quality assurance

- ▶ To control application of the quality specifications, to check their relevance and promote their development,
- ▶ To use working methods based on written documents with hold-points to judge compatibility,
- ▶ To assist all the involved parties utilising experience that has been previously acquired (materials, techniques, standards, etc...),
- ▶ To ensure that internal and external information sources are known and are used exhaustively,

- ▶ To ensure that all documents issued during design are properly applied according to the "Document control" section of this Manual.,

Design vocabulary: **AD000D152**

7.3.1 Design and development planning

The development of a project is made according to successive stages resulting eventually in a **quality development plan** that defines the responsibilities and schedules the tasks to be completed. These stages are described in the following sentences :

- ▶ Evaluation of customer requirements
 - ▶ Feasibility study
 - ▶ Pre-development
 - ▶ Development
- Procedure : **AD000D153**

Designation development planning are established with software tools

7.3.2 Input data for design and development

As soon as they arrive, the input data are identified and their validity checked. When incomplete or ambiguous, steps are taken to correct this.

For development contracts involving new products or applications, the items in the contract review are integrated into the design input data.

An internal list of documentation can be made (see PP000D042) and joined to quality development plan (PQD).

7.3.3 Output data for design and development

- **Composition :**
 - the product qualification reports or the process definitions, qualitative as well as quantitative data
 - the results of the characterisation tests performed by THERMOCOAX (internal qualification) and by the customer in operational conditions (external qualification)
 - . example : tests, control sheet, analysis, drawings...
 - . documentation : quality development plan, product quality plan, order (OF), FF (see AD000D161),
 - . reports : design reports, tests reports, qualification reports

These data refer to the requirements given in the input data with acceptance criteria (specification norms....). All of these data help us to identify and assemble verification data.

These data also give information for purchasing, production and service preparation. They define essential characterisation for correct use.

7.3.4 Design and development review

- **THX synonymous:** Project Review
- **Procedure :** AD000D159
- **Subject :**
 - to evaluate the programme by measuring discrepancies, if any, between the proposed solution and the specification,
 - to control the design process at the different stages of development ,

- to decide when each stage of design is complete.

Responsibilities

- organisation by the project leader,
- participation in the review of all relevant functions at each stage.

7.3.5 Design and development verification

- Objective :** verify that the input and output data are compatible
- Frequency :** continuously by the project leader,
also during the design reviews,
- Recording :** all the output data documents are controlled and approved according to the rules defined in 4.4.2.3 'Document control'.
- Responsibilities :** design engineering activities verified by skilled individuals other than those who carried them out

7.3.6 Design and development validation

- Objective :** to attest the conformity of the design to the specification requirements.
to confirm the qualification of the product by THERMOCOAX (internal) and as defined by the customer in the working conditions (see PP000D045)
- Frequency :** - at the end of the development phase,
- when internal qualification is defined or if feed-back from end-users may not be transmitted by the customer as in specific applications (nuclear, aeronautic, aerospace, defence).

7.3.7 Design and development changes

- **Procedure :** AD000D158
- **Origin :** external or internal request
- **Recording :** modified documents are checked and approved in the same way as for the initial documents. If necessary the statement of conformity will be updated

7.3.8 Organisational and technical interfaces

These could be internal or external and are listed in the table allocating the design activities for each phase of the development work. They are also referred to in the development quality plan written by the project leader assigned to a given project.

The project leader

- **Nomination :** [we have 2 options](#)
 1. [Project requires close, daily relationship with the customer including the monitoring of commitment \(cost, schedule, milestone...\); in this case the project manager belongs to commercial team](#)

2. Project can be carried out independently by technical engineer

The choice between each option is made by one or more members of management team. Tasks to run as a project manager remains identical.

- **Design Abilities** PP000R079
- **Responsibility:**
 - define objectives and product design phase,
 - control task definition and the allocation to the qualified personnel,
 - plan production tasks with logistics,
 - participate in budget definition ,
 - organise design or project reviews,
 - control the internal and external dispatch results to interested parties,
 - promote communication and cooperation between all implicated personnel involved with exchanges, these can be :
 - oral or internal work meetings
 - written when other departments are involved (i.e development plan, working and internal notes, meetings...)
 - when skills from outside the company are required (testing laboratory, analysis, etc....) the purchasing procedure AD000D136 applies
 - contact the customer if necessary

7.4 Purchasing

7.4.1 Purchasing process

- **Responsibility :** Purchasing department
- **Mission :** Search the international market for suppliers capable of tendering to a procurement specification possibly associated with the application of a Quality Assurance programme approved by THERMOCOAX.
- **Procedure** AD000D136

Relationship with the supplier :

The reciprocal relationship linking THERMOCOAX and the supplier are :

- **THERMOCOAX**
 - to analyse our needs and look for one or more suppliers,
 - to provide the supplier with a technical specification which gives an accurate description of the inspections and the required documents,
 - to justify the reasons for these constraints (quality, price, lead times) detail may possibly be given about the conditions of use of the product..
- **The supplier**
 - to be approved by THERMOCOAX (see PP000A009),
 - to state clearly any objections encountered at certain points of the specification,
 - to tender.

Definition : the term "sub-contractors" defines the THERMOCOAX suppliers.

Preliminary survey for a possible order

- **Subject** : - to ensure the supplier's organisational efficiency with regard to Quality Assurance and technical expertise
- **Procedure** : - to send a typical preliminary survey questionnaire (**AD000P900**), Or/and possibly to visit the supplier
- **Criteria** : - defined in the approval procedure PP000A009,
- adapted to the product concerned or required service,
- Account is taken that the supplier has already been subject to a survey for a similar matter and his reputation for such a product or service is unquestionable (for example : SANDVIK, LCIE, LNE, CEA, CEP, etc....).

Approval of a supplier

- **Procedure** : PP000A009
- **Concern** : Q1 and Q2 rated supplies

To conclude the survey, THERMOCOAX recognises the supplier as able to supply regularly, products which are in accordance with the procurement specification.

The supplier inquires about general requirements applicable to supplied goods and sub-contractors : "Quality Assurance, Environment, Health & Safety requirements for suppliers" ref. PP000A042.

THERMOCOAX establishes an agreement form itemising the products concerned. This information is processed in a computerised data base.

7.4.2 Purchasing data

Definition : data contained in orders referring to pre-established technical specifications, drawings or suppliers product catalogue.

From these data, the suppliers are classified according to 3 quality levels : Q1, Q2 and Q3.

Purchasing processing :

- **Procedure** : AD000D136
- **Q1 level**: - purchasing requests concerning either a customer order or an internal order for stock in advance. They are generated by the Logistics or the users' departments, completed by the Purchasing department and countersigned by Technical Management, Finances and Administration and Quality.
 - purchasing orders are approved by Quality before being sent to the supplier. This approval is accepted when signed and dated by the approved person.
- **Q2 and Q3 levels**: - requests are issued by Logistics or the users' departments and completed by the Purchasing department, which then generates and dispatches the orders accordingly.

Should an order be modified, an amendment is generated by the Purchasing department. This amendment would follow the same rules as the original order with regard to control, approval and dispatch.

Trading :

- **Procedure :** AD000D166
- **Level :** Q2
- **Concern :** Product sales by THERMOCOAX without significant added value.

7.4.3 Product inspection**Control of supplied products**

The control is carried out for every component, piece or material that may have an affect on quality. A control or test plan resulting from the procurement specifications is applied or, when necessary, a specific procedure is established for the material to be controlled. This will become the reference for the control of conformity of the supplied product.

- **Procedure :** N° 8.2.4 of this manual "Supervision and measurement of the product"
- **Aim :** to prepare data to be used by the Purchasing department for the follow-up of the supplier's evaluation (see PP000A039).

Inspection U h ` h \ Y ` g i d d `] Y f Ð g ` d f Y a] g Y g

Depending on the THERMOCOAX requirements, an inspection can be carried out at the supplier's premises.

A control and test plan (Quality Plan) with a schedule is issued by the supplier prior to the visit by the THERMOCOAX inspector. The inspector reserves the right to have any tests already performed, carried out again and to assist with all or part of the remaining tests.

Where the result is accepted, it will be approve by the QA inspector. The Quality plan, or Statement of Conformity and/or the material is dully signed as accepted. This stands as authorisation for delivery. When this signature is missing from the documents, an authorisation for dispatch will be written by THERMOCOAX.

The inspector will have made arrangements to ensure a proper identification of the goods subject to acceptance.

Unless there is a justified exception, the goods can be dispatched only when all items and certificates listed in the procurement specification have been received and controlled by THERMOCOAX QA.

These goods are subject to a simplified receiving inspection procedure.

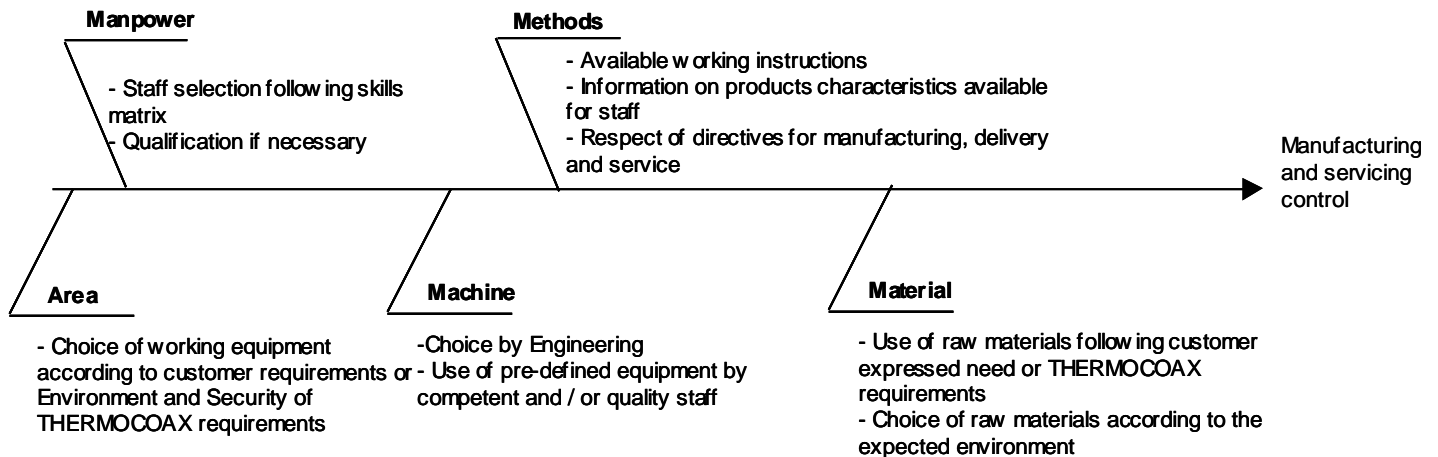
Inspection by the customer at the suppliers premises

Depending on the requirements of their order, the customer or an appointed organisation (DPSMQ, TÜV, OSAC) can, possibly, carry out a control of the product in the supplier's premises in conjunction with THERMOCOAX. In this case, the Quality plan issued by the supplier will itemise the inspection points which are passed on to the customer by THERMOCOAX.

7.5 Manufacturing and services

7.5.1 Manufacturing and services control

This control is made as follows :



7.5.1.1 Production process verification

When requested for the first production run of a new part or when changes occur, a First Article Inspection also called FAI is carried out according to JA000D002.

7.5.1.2 Control of production process changes

Each change affecting production process, tools, and software programs is controlled and validated at first by the personnel who validated it originally after assessment that the product conformity is maintained.

7.5.1.3 Control of production equipment, tools and software programs

These means are validated before use. They are preserved and stored according to the good practices of the company.

7.5.1.4 Post delivery support

We respond to the customers' demands case-by-case be it for an off-site work undertaken at the customer's facility or for problems detected after delivery. The established documentation follows the rules defined in chapter 4.2 of this manual.

7.5.2 Manufacturing process and services validation

The general manufacturing process is in the document **PP000D056**.

- **Definition :** Basic techniques used by THERMOCOAX for product manufacture.

- **Responsibility :** Engineering.
- **Validation :** Each confirmation order is validated :
 - . cable : by the cable workshop manager,
 - . other products : the main parameters are checked 100% in final control.
- **Qualification :** Manufacturing qualification process of new products is made according to PP000D045.
- **Special processes :** Some manufacturing operations which can not be checked by a control or a further test. The formal customer approval or of official organisations can be a preliminary for the process used and the qualification of operators.
- **Qualification :** [Special process \(welding, soldering, crimping, heat treatment, surface treatment, non destructive testing\) for which the control is important for the product quality appeal to specific qualification as described in AD000D184 "special process control"](#)

7.5.3 Identification and traceability

Traceability

- **Scope :** all items or components received by THERMOCOAX and any manufactured products (separated or batched) have precise identification marks

Their identification is maintained during storage, machining and assembly in such a way that all items may be traced without any doubt. The recording of these identifications ensures the required traceability with regard to the statement of configuration if available.

Identification of raw material and components

Batch number :

- **When :** after the receiving inspection
- **By whom :** by the purchasing department or subsidiaries quality representative
- **Where :**
 - on the label attached to the product. With the designation, the supplier name and date received
 - repeated on the product itself if necessary
 - transmitted to the supplier when signing a contract so that they mark the product themselves, if applicable

Symbol (clover, cross...):

- **Applicable on:** raw materials or Q1 level components allotted to receive a batch number
- **Where :**
 - onto the product together with the QA marking
 - repeated on each piece of the batch
- **Attribution :** the list of symbols is kept up to date by Quality Control in a register

Miscellaneous products having no batch number have to be identified rigorously (Purchasing order number for example).

Identification of complex mechanical, electrical, electronic circuits and other equipment

Identification number

- **Applicable on :** complex mechanicals
special devices (jigs) constructed by THERMOCOAX
- **When :** after the receiving inspection
- **Where :** on the equipment
- **Allocation:** there is a register of these special complex assemblies and special devices with these identification numbers. The identification numbers are given by the Maintenance or Metrology departments of supervision and measures devices (DSM). The supplier's name, type and date of receipt are also logged in the register

Tools and jigs which may have an affect on quality, are identified by their drawing number, their tool numbers or, if not, by the code of the applicable instruction.

Identification of products and test samples

- **Procedure :** AD000D112
- **Serial or batch number :**
These numbers correspond to generation:
 - at different dates,
 - with a lot change of a major starting material,
 - with a major modification of a drawing or of a manufacturing procedure.

The follow up of the identification is made by using various manufacturing documents (routing cards, welding procedures, metallurgical tests, control sheets).

Particular actions to be undertaken to display non-conformance or rejected items

- **Procedure :** AD000D146
- **Marking on product :** - red = discarded + Orange label "QA hold"
- white with information on deviation or use specific orange label = deviation observed, or assumed, on the product

Inspection and test records

- **Test report :** The results of each final inspection operation are written down in a test report providing the following information:
 - manufacturing order number,
 - customer's name or the Quality Assurance code of the job,
 - number and/or the designation of the control step,
 - inspector's name and signature,
 - date of the operation,
 - quality assurance code of the inspection procedure with the revision index,
 - complete identification of the inspected material,
 - results and their units,
 - observations and possible abnormalities
 - reference of the annex documents,
 - inventory number of the equipment used.

- **Summary report:** a document specially drawn up within the scope of a project and grouping a certain number of operations to be performed on equipment supplied in alphanumeric order.
The original copy is given to Quality Assurance in order to set-up the file and the inspection follow-up document.
- **Simplified document:** for particular, specific techniques (metallurgic or welding), it only carries the complete reference and the photocopies of corresponding pages of laboratory or workshop booklets, regularly kept up-to-date.

These test reports are established in such a way that they can be inserted, the method most often used into the form of photocopies, into the final file. Synoptic tables and summary sheets (one sheet per piece) will enable clarification and comparison if necessary.

Inspection and test status

All the inspections and tests are the subject of test reports, inspection identifications; validations etc and allow us to ensure that the products conform to the specified requirements. If a quality plan is used, the state of advancement of inspection and testing is noted on it, by the workshop supervisors / operators or quality control supervisors.

NB: it is not possible to identify inspection and test status directly on the product.

In the case of deviation, the product is treated according to the procedure (AD000D146) sorted according to a deviation permit prior to delivery to the customer. This authorised deviation permit is then included in the product release document (RFF or Certificates of Compliance).

7.5.4 Customer property

Applicable on :

Customer property is :

- ↳ Intellectual ownership (For example, confidential information that could require an agreement between Customer and THERMOCOAX)
- ↳ [Products and components](#)
- ↳ Products – components - documentation – software – equipments etc... placed at THERMOCOAX disposal and owned by the customer.

Verification

- **Procedure :** **PP000D022**
- **Application :** - products, components or sub-assemblies supplied by the customer
- **Record :-** - customer are requested to supply all documents proving that the product conforms to specification.
- a receiving test report is issued and a THERMOCOAX identification number is given in case the product is stored before used.

Storage

After identification and verification, the product supplied by the customer can be used immediately or later.

In the first case it is delivered to the concerned workshop to manufacture to the order.

In the second case it is kept in a special area devoted to that purpose, in the stores.

In the case that none of the customer's products are used for the completion of the order, they are kept in the special area or returned to the customer, as required.

Preservation / handling

Handling and preservation of the products supplied by the customer is the same as for THERMOCOAX products.

Anomaly

When customer property is lost, damaged or unusable, THERMOCOAX inform the customer writing and keeps this records.

7.5.5 Product preservation

Aim

To insure the product protection : to avoid contamination, identification loss, etc., during intermediate stages. Applicable from design up to the final phase of shipment and to include, if necessary, written instructions.

Handling

Insofar as one operation does not immediately follow another, the integrity of a cleaning process is preserved by the use of protecting barriers (polyethylene films, special packaging, etc.) and special equipment for the operators.

Wherever a particularly high level of cleanliness is required, the use of clean lint free clothes, gloves, etc is required.

Storage

▪ **Intermediate storage**

During manufacture, components and products are placed in suitable zones, which guarantee adequate protection and cleanliness.

▪ **Final protective storage**

This stage follows technical acceptance.

The pre-packed goods, with desiccators if necessary, are subject to the same rigorous conditions as during intermediate storage.

▪ **Storage of products limited shelf-life**

To avoid any risk of using a product which is out-of-date, it is required to control its period of validity

- Procedure : **PP000D030**

- When : starting at receiving inspection

▪ **Storage of rejected products**

- Procedure : PP000D031

- Where : stored separately with identification.

Packaging

▪ **Procedure :** **PP000D055**

▪ **Responsibility :** the workshop carrying out the last manufacturing and control operation.

The packaging of standard and specific products is adapted to the relevant dimensions and weight. The product identification is retained during the packaging operations.

Preservation

To preserve products, specific rules are respected during the various operations of storage and handling.

- **stainless steels:** PP000D032.
- **products limited shelf life** (resins, glue...) requiring particular storage temperatures are kept in air-conditioned cells.

Delivery

- **Procedure :** **PP000D055** : packing and shipment
- **Specific cases :**
 - for S, AS, ASQ, SQ and SAQ orders, Quality Assurance intervenes to control the following points on product to be shipped:
 - that tests specified in the contract and the technical acceptance have been carried out,
 - that the contractual documents file is complete and checked,
 - that the marking and identification labelling are included,
 - that protection and packing are in conformity with that described in the procedures and operational specifications,
 - that the product is ready for shipment and the quantity is in conformity with that specified on the order
 - that all required documents are provided.
 - for SAQ orders, the goods can only be shipped when the corresponding dispatch note bears the Quality Assurance stamp, the signature of its manager and the date
Quality Assurance may intervene up to the closing of the packing box and possibly affix stamped seals.

Shipment : - by carrier, selected and agreed by THERMOCOAX, or as designated by the customer on Logistics request.

7.6 Control of monitoring and measuring equipment

7.6.1 Introduction

- **Field of application :** equipment, instruments, standards and gauges used to carry out controls, measurements and tests
- **Origin :** supplied externally or developed and built in-house.
Receiving : physical, dimensional and electrical measurement equipment received is always routed through the ECME metrology lab in order to be controlled, identified and recorded. A technical direction for use and a constructor's Certificate of Compliance is supplied with the apparatus.
Regarding gauges, a calibration certificate will be requested either from the manufacturer or from the metrology laboratory organisation.
For software, their capacity to satisfy the forecasted usage is confirmed by internal qualification before first using if necessary.
- **Old terminology :** it is possible to find in THERMOCOAX documentation, the old terminology "Inspection, measuring (ECME) and test equipment" issued for the version 94 of standard ISO 9001.

Utilisation

When a product is being developed, R & D, Manufacturing and QA must arrive at an agreement in order to define the characteristics of the test material, to decide on the use of existing equipment or on its possible modification, or on the acquisition or manufacture of new equipment.

Inspection equipment used

In stock we have : Devices of mechanical and physical testing equipment, dimensionnal equipments, electrical and temperature measurement equipments, NDT testing benches, devices testing

The relevant inventory is updated by the Metrology Manager. The computerisation of the handling and monitoring of this inventory allows efficient control of the calibration schedule (see PP100D024).

7.6.2 Calibration

- **Purpose :** Action aimed at periodically checking the accuracy and precision of measuring and test equipment in order to maintain them at a constant level.
- **Frequency :** as recommended by the manufacturer and/or according to the recommendations accredited laboratories (LNE, LCIE....).
It may be modified according to use and metrological quality, further to Quality Assurance approval.
- **Responsibility :**
 - The R & D department is entrusted with this control and the calibration of the gauges by ISO 17025 accredited organisations
 - **Calibrations** are carried out by ECME Metrology which follows -up the inventory and the permanent planning of the measuring and test equipment and if necessary, calls for organisations or companies accredited by the COFRAC or equivalent.
 - Quality Assurance verifies that:
 - the method used guarantees accurate calibration and that the calibration programme is systematically carried out.
 - when a deviation is identified during the process of a calibration, the products subject to earlier control and test are acceptable. Otherwise, the procedure AD000D146 will apply.
 - the ECME monitoring equipment is described in the procedure PP100D024.
- **Procedure :** The control and calibration procedures are defined in the documents:
 - Electrical measurement equipment **PP000C024**
 - Physical and dimensional equipment **PP000C018**
 - Equipment from the temperature calibration laboratory **PP000C029**

Note : During manufacture, when there are possible deviations in dimensional test equipment, it is possible make checks, with gauging rings, a gauge block and working standards available in the Metrology department.

Calibration records

When calibration is carried out, the control results are recorded in the computerised laboratory file (see **PP100D024**).

Particular constraints referring to control equipment and standards

The equipment has to be used within its normal range and its operation must be quite rigorous in minimising errors :

- its precision range must be adequate.
- a detailed technical note referring to the equipment use must be available.
- the written procedure referring to the ongoing control is stuck on a notice board or filed close at hand in order to consult it easily (optional).
- the security for the staff and the material systems must operate correctly,
- The environment conditions are suitable for calibrations, measurements, inspections and tests.

7.6.3 Identification

The equipment is systematically identified:

- with a THERMOCOAX label indicating the identification number.
- with a green label indicating the inventory number, the period of validity. A white label gives information on the precision of the equipment and the ranges not available, or not calibrated, for multi-range or multi-functional equipment. These two labels are stamped for validation by the technician who carried out the calibration.
- small instruments (micrometers, callipers, ...):
 - the **inventory number** is **engraved** on the instrument
 - the **green and the white labels** are on the conditioning box of the instrument.
- instruments used as tools and not usable for controls:
 - the **red label** "calibration not required" and "do not used calibration expired" is affixed to the instrument.

7.6.4 Downgrade, overhauled or broken equipment

Downgraded equipment

Should this equipment be used as a tool, it will be marked clearly with a red label "calibration not required" and "do not used calibration expired".

Overhauled or broken equipment

The overhauled or broken equipment will be marked with a label utilising the letter "R". Smaller instruments are kept by the Metrology department in a locked cupboard. Larger equipment is kept in the zone of the rejected products. A copy of the follow-up sheet is given to the accounting department.

Applicable documents:

AD000D112	THX products
AD000D134	Customer's request for quotation
AD000D136	Purchasing procedure
AD000D138	Processing customer order
AD000D146	Control of non conformance
AD000D149	Contract review
AD000D150	Manufacturing and development quality plan – Follow up document
AD000D152	Vocabulary used in design
AD000D153	Design

AD000D159	Project review / design / development
AD000D161	Document preparation (only french version)
AD000D166	Negoce activities (only french version)
AD000D167	Identification des besoins latents (only french version)
AD000D175	Configuration management
AD000D178	Gestion des risques (only french version)
AD000D184	Maitrise des procédés spéciaux (only french version)
AD000P900	Supplier request
JA000D002	First article report
PP000A009	Procurement subcontracting
PP000A039	Suppliers procurement evaluation
PP000A056	Approved supplier list ASL
PP000C018	Dimensionnal & electrical test equipment
PP000C024	Electrical equipment
PP000C029	Temperature calibration test equipment
PP000D022	Receiving inspection
PP000D030	Storage monitoring for product with expiry date
PP000D031	Processing rejected product
PP000D032	Recommendation for manipulation and storage of stainless steel
PP000D042	Plan de documentation interne (only french version)
PP000D045	Qualification de produits et procédés de fabrication (only french version)
PP000D055	Packaging of THX products
PP000D056	Réalisation du produit
PP000R079	Skill matrix design
PP100D024	Gestion informatique des appareils de mesure
TR100D001	Trame pour transfert d'activité

8. MEASUREMENT, ANALYSIS & IMPROVEMENT :

8.1 General

Thermocoax plans and implements measures for monitoring, measurements, analysis and improvements in order on the one hand to demonstrate the conformity of products to internal and external requirements, on the other hand, to ensure the compliance of the QMS and continuously improve the effectiveness of integrated management systems

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

- **Procedure :** We use a lot of information from sources related to customers' perception on their requirements satisfaction level
- **Types of information :**
 - customer's comments and complaints
 - customers requirements, interested parties,
 - evolution of market needs, technical survey
 - information related to competition
- **Methodology :**
 - customers' loyalty assessment
 - complaints / returns management
 - direct communication through commercial contacts, technical contacts, visits, exhibitions....
 - on-time delivery performance
 - set action plan to handle the identified deviations and achieved results assessment

8.2.2 Audit

Introduction

Purpose : to analyse and evaluate the elements of the Quality system in order to maintain its efficiency and to identify possible improvements.

These audits are prepared and performed by the Quality Department and trained and qualified auditors.

Types of audit:

- **Internal audits:**
 - performed by THERMOCOAX auditors
 - **performed by external organisations** : on the request of Management's or Quality Assurance, an external expert may head a quality investigation using the same methods and with the same aim as for an internal audit.
- **Suppliers/subcontractors audits: carried out by THERMOCOAX at supplier's sites**

Periodically, the Purchasing department, assisted by Quality Department, reviewed the suppliers to audited taking their performance evaluation account and also in case of deviation observed on the quality of their products and/or their services, and upon renewal of the supplier's agreement

In addition, qualifications given to the supplier by other organisations or key customers are taken into consideration : eg Quality system certified ASME NQA1, EN9100, ISO 9001, 14001, COFRAC accreditation PART21/G...
- **Customer quality Audits at THERMOCOAX** : with a view to insure the correct application of the Quality Assurance programme and on the request of the Director, QA representatives of THERMOCOAX's customers can have free access to the THERMOCOAX sites.

Note : The audit reports and appended documents are filed under AD000P501, P502,...

Schedule

- **Method** : annual programme
- **Responsibilities**: Management approval
- **Reference** : AD200P...
- **When** : made during the management review (AD000P...)
- **Contents** :
 - internal and external audits anticipated for the coming year.
 - after a period of 3 years, it will be verified that audits have covered all quality assurance areas during the period considered.
- **ISO 17025** :
 - one internal audit will be carried out annually. This audit will relate all paragraphs of the ISO 17025 and to the last modification of COFRAC documents..

THERMOCOAX auditors

- **Procedure** : AD100D001 'auditors training and qualification'

Auditors methodology used

- **Procedure** : AD000D162

In particular, auditors control the satisfactory distribution of documents and their issue. They will also check their application.

- **Application field :** Audits can be limited to a product inquiry on processes and procedures in correspondence with manufacturing in order to guarantee that applicable requirements are respected.
- **Questionnaire :** Each auditor makes a questionnaire adapted to the audited programme chapter.

For suppliers audits, the questionnaire preparation is made by the auditor and adapted to the audited company. The questionnaire takes into account the THERMOCOAX requirements in Quality Assurance (cf. type of questionnaire AD000P900/P901/P902).
- **Audit plan :** in due time the auditor communicates an audit plan to the concerned department providing information about :
 - The date and the place of audit
 - The duration
 - The program
- **Corrective actions: the auditor enters each corrective action on a Corrective Action sheet.** Follow-up is made with the department involved and QA according to the plan stated on the Corrective Action sheet.
- **Audit report :** An audit report is written by the auditor in agreement with the audited department and distributed to involved parties as well as to the Quality Manager and the Director. This report includes any recommendations and/or remarks that the audited department has to take into account. These follow from observations made during the audit.

Audited management verify that all correctives actions are implemented immediately according to actions plan in the aims remove detected anomalies and their root causes. The follow up include the effective verification of the implemented corrective action and the reporting of the results.

For the supplier audits, following the closure meeting an audit report is written by the auditor and distributed to the involved parties and purchasing dept. The supplier purpose an action plan.

8.2.3 Process monitoring and measurement

Chapter 6.4 of our Management Manual [GMM](#) informs how we describe, interrelate and monitor the processes.

Each process manager or pilot supervises and measures periodically the process' performances. He summarizes them in a QA form for the Management Review.

For each sub-process, there is not necessarily a specific indicator.

Indicators are chosen by a manager as a function of supervision or identified improvement requirements.

Case by case, engineering, design and development departments, technical and production management, workshop managers in collaboration with quality department can decide to supervise a process or a product for a determined time. In this operation we can use the individual's measurement reports, by sampling or statistical tools (AMDEC, FMEA, periodical statistics on defects...)

8.2.4 Product monitoring and measurement

Receiving inspection

- **Means :** documented procedures, procurement specifications, drawings ...
- **Responsibility :** Quality Control

- **Concern :** purchased products, along with product supplied by the customers for the fulfilment of their order.
- **Procedure :** **PP000D022**
 Inspection and testing are covered by the following points :
 - dimensions,
 - aspects,
 - technical characteristics,
 - identification of materials,
 - documents, etc...
 Possibility for a chemical analysis or complementary tests to be chosen.

In-process inspection

For SAQ orders

- **Means :** A SAQ Manufacturing Quality Plan, including manufacturing and control operations, is systematically established (cf. AD000D150).
- **Responsibilities :** the workshop managers, QA and QC .
- **Constitution of the quality plan :** - Relevant reference documents
Requirements of different control organisations (THERMOCOAX QA, Customer's QA...) represented by the following symbols :
 - . **A** = Hold point,
 - . **C** = Notification to call for an inspector,
 - . **N** = Issue of a workshop report (internal),
 - . **R** = Issue of a control sheet or a certificate given by the customer (constructor file).**Hold point** : when a hold point is listed opposite a manufacturing or control operation it can not be undertaken without the presence or the written agreement of the concerned testing organisation.
 The THERMOCOAX Quality Assurance agreement to continue manufacture (removal of THERMOCOAX hold point) is recorded by a Quality Assurance mark on the original copy of the Quality Plan.
- **Use of the quality plan** : After each control of a manufacturing step, the corresponding operations on the quality plan are **dated** and **signed** by the personnel responsible for the update of this document and by the inspector.
- **Modification :** **partial delivery** : arrangements are made regarding the Quality Plan and test reports for a given operation to avoid any ambiguity between a signature accepting full manufacture and a signature accepting part of it :
 - . additional indication on test report if necessary
 - . on the Quality Plan, explicit information on each step affecting each partial delivery etc.**modification of with procedure** : during manufacture (possibly after discussion, control and agreement the customer). In this case there can be a discrepancy between the revision indexes noted on the Quality Plan and the latest version of the procedure at the workstation.
 Quality Control advises Quality Assurance which will then decide to:
 - a) maintain the former index and use the procedure before amendment.
 - b) give authorisation to amend the index on the Quality Plan.
 Quality Control will then affix its stamp on the amended index along with the date of amendment.

- c) Log the 2 indices in the Quality Plan with the date and the identification of the manufactured pieces to which the modification applies. This relates to the manufacturing batch on partial delivery.

For SQ et S orders

- **Means :** a manufacturing sheet, an internal note or a note made directly on the manufacturing order.

Quality Assurance can impose the establishment of a Quality Plan according to the complexity of the order files under SQ.

For special tests

- **Definition :** these are operations carried out on components during manufacture, or on pilot samples, in order to investigate the influence of parameters having aspects that could not be detected during the development phase.
- **When :**
 - when detailed improvements to manufacture are envisaged following various observations.
 - as a follow-up of a non-conformity sheet which identifies a deviation from the specification.
- **Procedure :**
 - executed according to a pre-established plan with reference to written procedures detailing execution.
 - to take into account identification imperatives required at each stage.
- **Records :** for each result, tests reports are established.

Self-inspection

- **Definition :** inspection of the work by the operators themselves, according to specified rules.
- **Aim :** self-inspection is performed by the operators in order to provide evidence from the beginning, of any deviation regarding the specification mentioned on the follow-up document which accompanies the product (cable workshop)
 - pre-established tests reports
- **Procedure :** PP000D071

Independent control

When specified in the customers' orders meant for the Nuclear, ADS and other special markets, the checking, validation, supervision, special controls and tests related to the product activities are carried out by individuals not involved in carrying out the activity.

Before product release

- **Definition :**
 - with reference to the Quality Plan, procedures, instructions and applicable drawings, the final inspection is carried out based on successive validations (stamp control AD000P016 mentioned in the tests report) during the whole manufacturing process of the product.
 - the product is declared to conform or non-conform
- **Record :**
 - created according to specified requirements:
 - . individual test reports (PVRI)

- . final manufacturing report (RFF)
- . statement of Compliance

Work acceptance

- **When :** at the end of the product manufacturing cycle
- **Procedure :**
 - all inspections and tests which are based on a procedure, may be carried out with the customer's agreement.
 - carried out in the customer's presence, if requested
- **Records :** the results of control are written on control report. They used to permit the dispatch of the product.

Certification

- **Procedure :** Quality Assurance draws up a Statement of Conformity / Certificate of Compliance or a final manufacturing report (RFF) with all necessary elements allowing the customer to judge the conformity of the product to its requirements.
- **When :** according to the order and/or the customer's requirement

8.3 Non-conformity control product

8.3.1 Claims and Returns

We have issued procedures reforming to customer's complaints as well as possible product returns

- **Responsibility :** [QA Department](#) with the help of any concerned departments

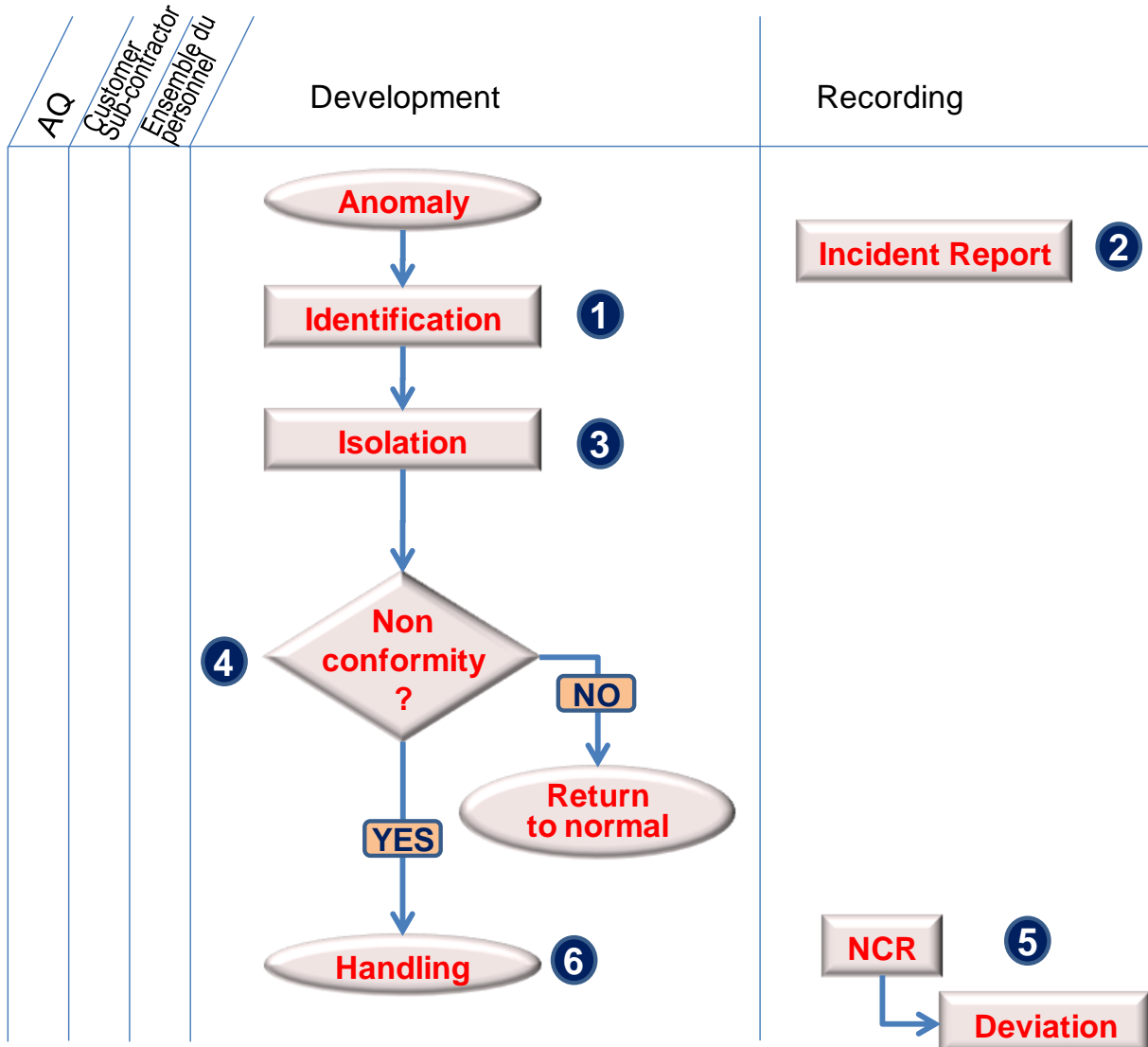
Handling of customer claims

- **Procedure :** **AD000D160**
- **Subject :** to provide answers as quickly as possible to any complaints. This is made by a strict follow-up of the proposed solutions and of the actions taken.
- **Means :** performance indicators (response time, subject of the complaint)
[Weekly](#) meetings

8.3.2 Treatment of returned products

- **When :** following a customer's complaint. When the return of the product seems to be justified whether within or outside the guarantee period.
- **Procedure :** **PP000D017** : technical and commercial comment.
- **Preventive actions:** the condition of any returned product is examined at same time as the complaint. This examination helps clarify any anomalies that occur when the product is used. It also helps to correct these anomalies.

8.3.3 Non-conforming products



R = Responsible for the action -

P = Participate in the action

Quality Assurance insure the initiation, the follow-up, the filing and the archiving of all documents relating to anomaly treatment, non-conformity and resulting actions.

Definition

- **Anomaly :** any non-fulfilment of the intended usage. This can apply to damage, lost or unusable product.
- **Curative actions :** These are used to reduce the consequences of any dysfunction
- **Identification :** by means of a white adhesive tape (non stainless steel polluting) giving information on the deviation or of special orange label
- **Documentation :** incident report written by the person who discovered the deviation or their superior
This report may be :
 - - a test report on receiving inspection,
 - - a workshop test report
 - - a welding report

- - a customer's complaint
- - any related communication
- - ...

- ③ **Isolation :** when possible, they are stored in areas provided
- * **Notification to all concerned departments :** the incident report is immediately passed on to Quality Assurance.
- ④ **Evaluation of the deviation:** Quality Assurance and any involved departments determine whether the deviation is a non-conformity or not, as described above. In cases of non-conformity, the product is identified with a reference, a mark, i.e a in red adhesive tape + Orange label "QA HOLD"
- ⑤ **Documentation :** Quality Assurance issues a non-conformity sheet (FNC) to include the following information : description of the non-conformity (its nature, its extent), curative, corrective and preventive actions to be made and with possibly a request for a deviation.
- ⑥ **Examination and handling of a non-conforming product:** This is described in the procedure AD000D146. It can be :
- return
 - acceptance and deviation with or without repair
 - downgrading
 - rejection

The product is subject to a control following any return or repair.

* Notification to involved departments : Quality Assurance dispatches the corresponding documents to involved departments and possibly also to sub-contractors and customers.

Processing nuclear safety concerns and reporting of the defects non-conformances concerning substantial safety hazards in the manufacturing of the parts to be used in a nuclear power plant (10CFR21) are described in the procedure AD010D002. [For countries outside the USA, use the document SE500D001](#)

Non conformity product

A product is considered to be non-conforming when it no longer complies with the specified internal or external requirements during the development cycle at THERMOCOAX or during the guarantee period.

The various types of non-conformities are :

- non-conformity relating to procurement
- non-conformity to the specified requirements of THERMOCOAX products
- failure or incident leading to a breakdown or an abnormal operation where conformity to the contractual documents is normally well established.
- failure of the product in operation which led to a complaint (AD000D160) or a customer's return (PP000D017). It is to be defined by Quality Assurance whether the return is handled as non-conformity or not

8.4 Analysis of supplied materials and documentation

***To improve we have to measure.
Following this principle, we have divided the data
analysis into 3 parts :***

8.4.1 Customer satisfaction

See chapter 8.2.1 and 5.2

8.4.2 Process efficiency

In this manual, we have explained how we have identified our processes and sub-processes / *Activities* and what is defined with respect to supervision and measurement.

This is also applicable to supervision and measurement on products, as defined in instructions, drawings, manufacturing quality plans or development information.

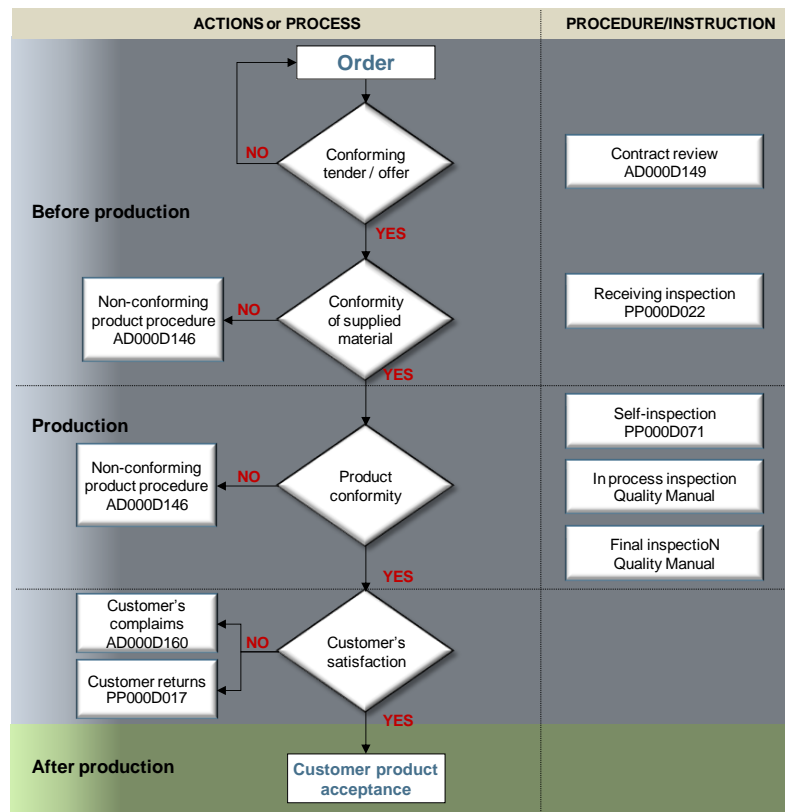
Each time we have defined the recording support to be used, those responsible and at what frequency.

Instruction PP000D072 explain how to initialise and administrate the indicators associated with the process or products to be supervised. For each indicator, we define a SMART objective which means :

- Specific or Simple
- Measurable
- Achievable
- Realistic
- Timing

The indicated manager analyses the data and informs any concerned persons (eventually by visual indicator).

8.4.3 Product conformity



Checking process of the conformity of products to specified requirements is as follows :

- **Measurement :** each anomaly is observed and controlled according to it's origin (claims, returns, non-conformity)
- **Analysis** applicable to :

 - Customer's claims
 - Customer returns
 - Non-conformity
 - Preventative actions
 - Corrective actions
- **Improvement :** after an analysis of defect recurrence, the staff implicated in relation with the quality department and/or Top Management will decide on the corrective actions and/or preventative actions needed.

8.5 Improvement

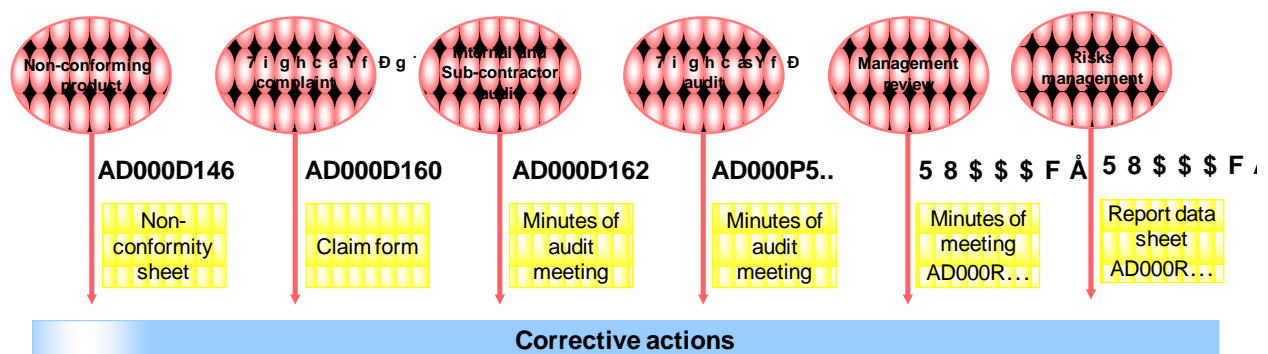
8.5.1 Continuous improvement

See chapter 5

8.5.2 Corrective actions

They act on **causes** of dysfunction and noted anomalies, in order to avoid re-occurrant problems.

They appear as follows :



The records are processed according to each case. Quality Assurance controls the follow-up.

8.5.3 Preventive actions

Act on the causes of the **potential** failures and deviations in order to avoid their occurrence.

They are identified when analysing :

- ▶ "Quality Management" indicators : customers' complaints, product returns, non-conformities- other indicators : lead time, stocks
- ▶ results of surveys and audits, of customer communications (suggestions, benchmarking, marketing etc...)
- ▶ recurrent deviations identified by customers
- ▶ data regarding suppliers : performance evaluations, deviation recurrences

- **Responsibilities** The tasks of personnel involved are to determine the preventive and corrective actions and implement them.

The Quality Assurance function is to ensure coherence and confirmation of the various actions.

- **Application** The preventive and corrective actions can be :
 - new or revised procedures,
 - modifications to the design (AD000D158),
 - training or information sessions for involved personnel (for a process change following a human error),
 - procurement specification evolution,
 - introduction of amendment sheets.
- **Procedure** AD000D163

Preventive and corrective actions : mutual activities

- **Tools for investigation and handling** The investigation and implementation of corrective and preventive actions can be facilitated with :
 - the creation of improvement teams,
 - the use of quality tools to solve problems,
 - the generation of an action plan,
 - the introduction of internal audits (products, processes, procedures),
 - the introduction of supplier audits.
- **Efficacy** efficacy can be measured by :
 - the reduction of the number of failures
 - the improvement according to the relevant indicator,
 - evaluation of customer survey
 - evaluation of audit results,
 - evaluation of supplier's performance (quality of the product, lead time, etc).

Efficacy can be assessed in several situations :

 - non-conforming product or supply : non-conformity forms are periodically passed to the involved persons for information and/or action.
 - internal audits : control by the auditor of actions undertaken following a previous audit allows the efficacy to be measured.
 - in general : corrective and preventive actions are regularly examined during Quality Management reviews.
- **Follow-up** QA department verifies that corrective and preventive actions are carried out in a short time and their efficiency. If not, information is given to the individual responsible for the action
- **Generalisation** : Prior to clear the corrective action, an analysis will determine if similar deviations exist on other non-conform products in order to generalize a joint action if applicable

Documents applicables :

AD000D149	Contract review
AD000D150	Manufacturing and development quality plan – Follow up document
AD000D158	Modification of the design and product
AD000D160	Customer's complaints monitoring
AD000D162	Quality, environment health and safety audit
AD000D163	Corrective and preventive actions
AD000P016	Authorized personnel
AD010D002	Manufacturing of parts to be used in USA NPP
AD100D001	Training and qualification of THX auditors
PP000D017	Customer's returns
PP000D022	Receiving inspection
PP000D071	Self inspection
PP000D072	Establishment of THX indicators
PP100D012	Computer control of NCR, CAS,/PAS and 8D reports

9. NUCLEAR SAFETY

9.1 Definition

9.1.1 Safety culture

"The safety culture is that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance"

Safety Series 75-INSAG-4 (IAEA)

9.1.2 Nuclear safety

Nuclear safety includes all measures taken at all stages of design, equipment manufacturing, construction, operation and decommissioning of an installation to ensure safe operation and prevent nuclear and radiation accidents and limit their consequences.

9.2 Applicables documents

- **INSAG** Report by the International Nuclear Safety Agency Group,
- **DOE P.450.4** Safety Management System Policy of U.S. Department of Energy
- **10 CFR Part 21** Reporting of Defects and Noncompliance
- **Ministerial order dated on aug 10th, 1984 whis will be abrogated on july 1st, 2013 with the order dated feb 7th, 2012**

9.3 Responsibilities

The various tasks in the safety culture of our company are:

Senior Management:

- Declaration and management involvement for Safety Policy: the satisfaction of safety requirements in our profession is explicitly displayed in the QSE policy signed by the senior management team and the management involvement (see § 5.1 of this manual).
- Clear definition of roles: the responsibilities of each are defined in the H&S - Environment manual and procedure PE100D004
- Organization of responsibilities in the nuclear sector: QSE Department translated texts regulatory in safety requirements, organizes survey about safety issues and regulations
- System Quality Management: Our system is designed to ensure the product conforms to its specifications and to the particular requirements of Safety. It relies on a structure and system of independent monitoring (Quality Management is independent, the monitoring system is composed of audits, surveillance and monitoring, formal design reviews, reviews...)

- Training staff to safety culture: during the welcome training and / or action of specific training
- Campaign for continuous improvement and self-evaluation:
 - Annual Management Review
 - Process Review by the designated responsible
 - Self-assessment according THERMOCOAX SAS standard
 - Communication to staff in the company meetings

Management

- Staff indoctrination of the importance and impact of their activities on Safety during the welcome training or presentation of the workstation by hierarchical manager
- Clear definition of responsibility of everybody in the work entrusted (eventually by any internal note...)
- Compliance with safety requirements in the work realized
- Quality System Management application is defined to provide attention needed by safety problems
- Human Resource Management in ensuring that the adequate resources are devoted to safety (match between skills and position held needs of the and by implementation of necessary training activities).

Staff

- Performing work in accordance with the requirements of safety and enforcing the Quality System Management
- Adopt a rigorous and prudent approach to implement questioning attitude and risk assessments for:
 - Understand the work procedure, the context of its activity and its impact on safety
 - Anticipate problems
 - Know where necessary to interrupt its activities
 - Avoid deadlocks
 - Alert in case of difficulties
- Suggest improvements in the way of carrying out the activities on the basis of their feedback through management, contacts with engineering or Industrialization Dept.

9.4 The questioning attitude

The questioning attitude is encouraged through indoctrination on nuclear safety, including the presentation of booklet on safety culture. The main issues that we suggest to staff at all levels:

- Do I understand the task?
- What are my responsibilities?
- How do they relate to security?

- Do I have necessary knowledge to proceed?

- What are the responsibilities of others?
- Are there any unusual circumstances?
- Do I need any assistance?
- What can go wrong?
- What could be the consequences of failure or error?
- What should be done to prevent failures?
- What do I do if a fault occurs?

Note: Each member of the company has the possibility to clarify its doubts on topics relating to products under manufacturing or already delivered, by calling on his manager or the person designated by the Executive Management (QSE Director), or the QSE department.

9.5 Reporting of defects and non conformities

Depending on the nationality of our client, we implement an appropriate procedure:

AD010D002 Declaration of defects and nonconformities according to 10CFR21 commands USA

SE500D001 Declaration of defects and nonconformities according INSAG-4 for orders outside the U.S.

Applicable Documents THERMOCOAX:

- AD010D002 Declaration of defects and nonconformities according to 10CFR21
- SE500D001 Declaration of defects and nonconformities according INSAG-4
- SE000R067 Booklet "Safety Culture"