QUALITY ASSURANCE AND PRODUCT QUALITY

Daniel LACROIX - Pascal de BASTIANI
COGEMA LOGISTICS (AREVA Group), France

Abstract

The basic quality assurance requirements have to be completed by means that are oriented towards the quality of products; in COGEMA LOGISTICS our approach is based on four principles:

1) an integrated management system : Quality, health and safety, environment

2) an organization based on the responsibility of all actors , trust and transparency

3) a methodical approach to continuously improve the methods that are employed to achieve quality :
-process management
-corrective and preventive actions
-self assessments and various surveys

4) but at the same time strong procedures for control and monitoring of all activities :
-technical and quality audits (external and internal)
-at source inspections
-engineering activities inspections

This performance-based approach is necessary to guaranty the effectiveness of the traditional formal QA means

An integrated management system

In a global and coherent approach an integrated management system aims to take into account the requirements concerning different fields such as quality, safety, health and environment, but also more significantly all the company's activities, such as finance and human resources.
This global approach is based on a desire to achieve customers and stakeholders satisfaction, on regulatory and legal compliance, and on the integration of new sustainable development stakes.

The main integration factor of our system is our process approach (see figure n° 1), based on activities control and improvement in the reduction of the incidents and the prevention of any pollution, so that to increase our processes effectiveness.

In this global vision, each manager must continually research the effectiveness, the achievement of his objectives and reduce the frequency of incidents

Our approach isn't limited to taking into account our internal processes, it also aims to involve our suppliers in this integrated management vision.

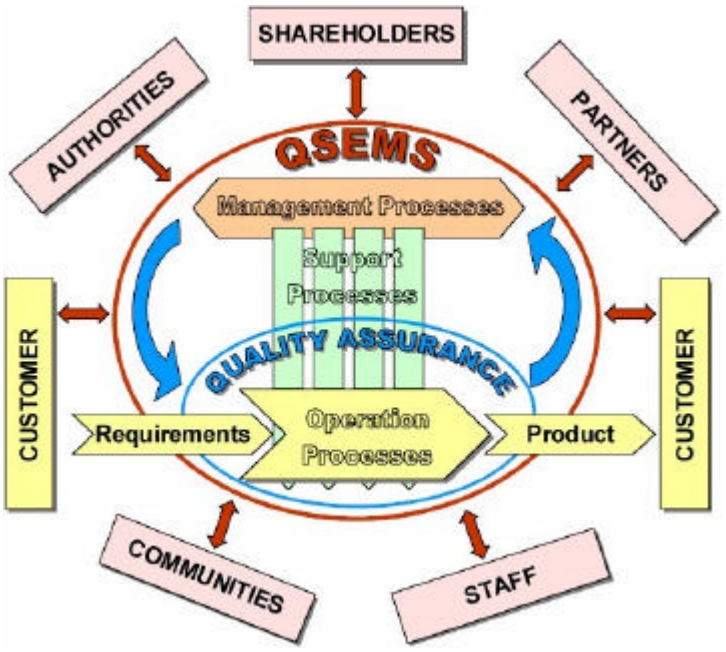
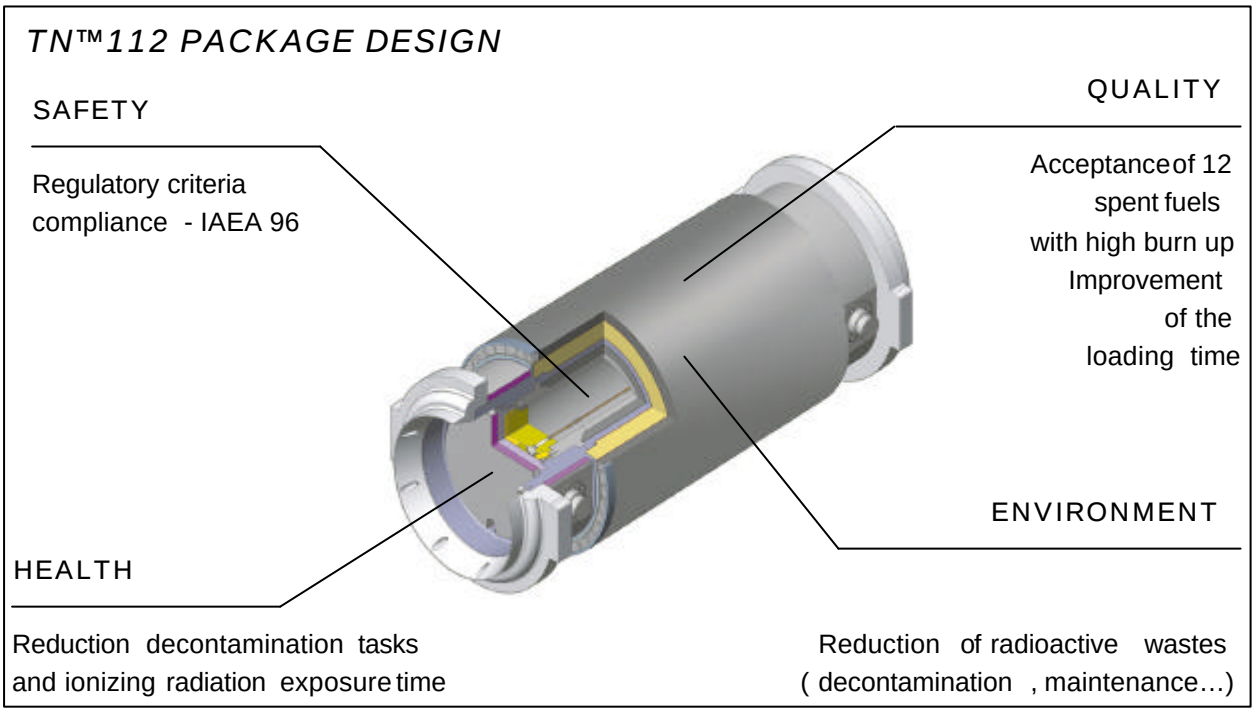


Figure n° 1

Because of our approach to quality, health

and safety and environment we are able to integrate the necessary requirements at all stages in the life cycle of our products-from design and manufacturing to use and disposal (see figure n° 2).

Figure n° 2



An organisation based on the responsibility of all actors

ISO 9001 requires that "Top management shall ensure that responsibilities and authorities are defined and communicated within the organisation".

This is really a single statement for a major concern

We consider four levels of risks concerning this topic "organisation":

-Interfaces between different companies involved in the operations have to be identified and documented.

When the contractual link between the organization and the consignor is not accurate enough to explain each transport step, it is necessary to issue a document called "Expedition Protocol". This document describes the technical or regulatory actions, responsibility and who is in charge of each action between the organization and the consignor (truck/cask conformity, cask labeling, phone emergency...). The expedition protocol document can also indicate the communication links and the operation schedule if needed.

-Within each company responsibilities have to be clearly defined - Processes are very often complex.

Sequences of activities shall be determined and documented. The role of each actor shall be explained. Interrelation of processes shall be documented (see figure n° 3).

Diagrams and computer-aided systems are a good way to keep such means under control.

In COGEMA LOGISTICS we have built such a system, which is available at any time on each computer of the company.

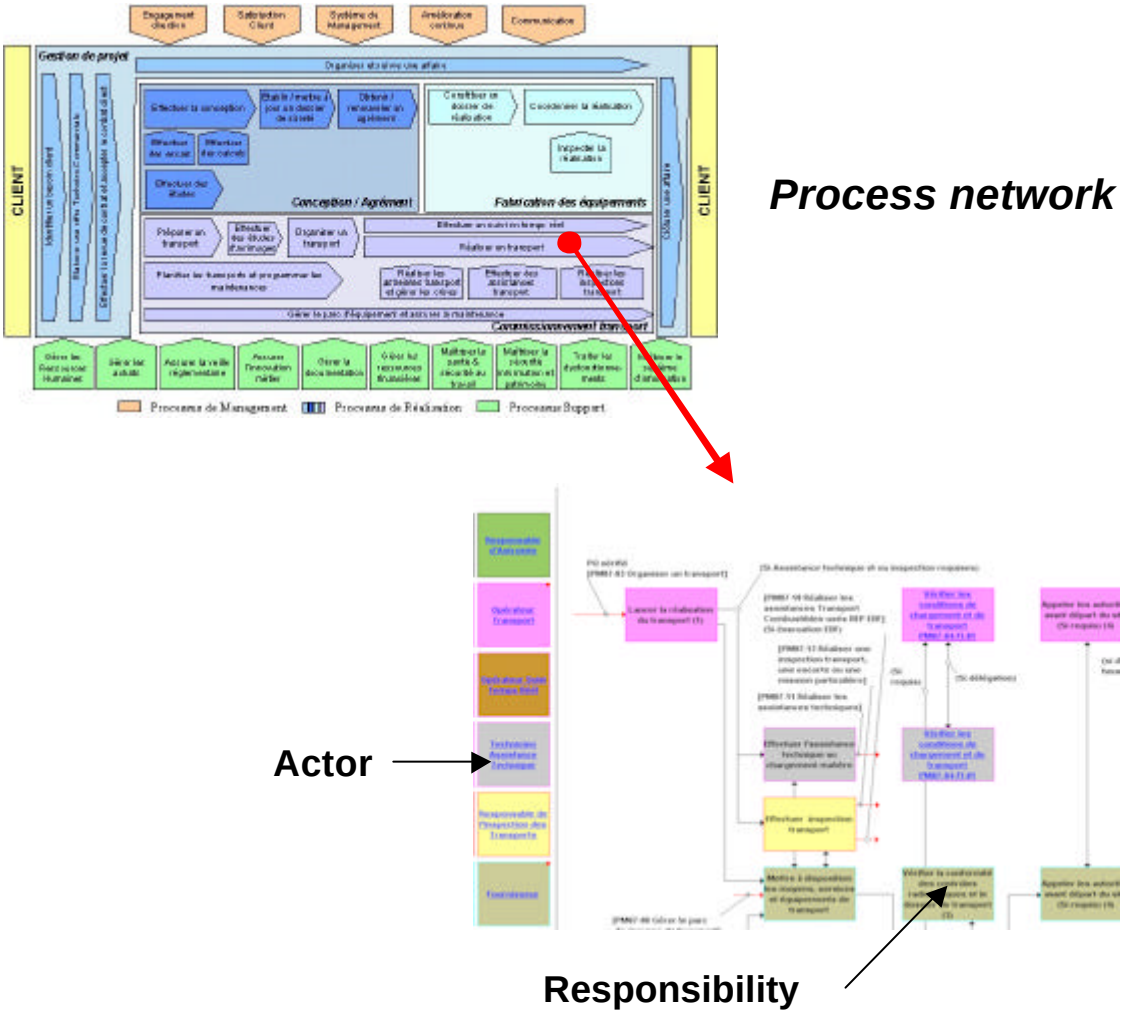


Figure n° 3

- For one simple task, there could be different people involved; there is a risk of dilution of responsibilities. Responsibilities of those who perform the work, inspectors, and representative of the customer and /or authorities should be clearly reminded ; one should avoid for example inspection records with a lot of signatures, with no definition of the role of each member.

- In any case, whatever the quality system, the human factor still remains a key point: factors which influence the working environment and fitness of personnel for duty should be addressed: especially for all operational activities (e.g. transportation activities) a methodical approach has to be implemented:

  - Identification of any dysfunction (even minor ones, see below " precursory events")
  - Analysis of these dysfunction towards human factors (with an appropriate check list)
  - Corrective and preventive actions
  - And especially appropriate internal policy, to develop transparency, and to keep every body well informed on the consequence of a failure in their field of work concerning safety (see 50 CSGQ basic requirement 3: " management fosters a "no-blame" culture to encourage employees to identify non conforming items, services and processes ")

A methodical approach to continuously improve the methods that are employed to achieve quality

- Process management

Process managers are appointed for each basic process. They are chosen from COGEMA LOGISTICS' cross-departmental functions:

- Engineering Division for processes having to do with Trade activities,
- Marketing and Sales Division and/or Paris Program Division and/or South-East Division for processes having to do with project management,
- Corporate Departments for support processes.

The Process manager is in charge of steering processes consisting especially of improving its performances. For that, he must:

- Be aware of and know requirement changes affecting the processes: input data, output data, environment, regulation requirements, etc.
- Identify et monitor environmental impacts related to the process implementation (for trade processes),
- Make sure dysfunction are handled properly, and initiate corrective and preventive actions for the processes,
- Measure process effectiveness and search the factors contributing to the operations effectiveness,
- Identify and implement process improvements.

The assignments of the process manager are listed in the Process Manager Charter (see figure n° 4):

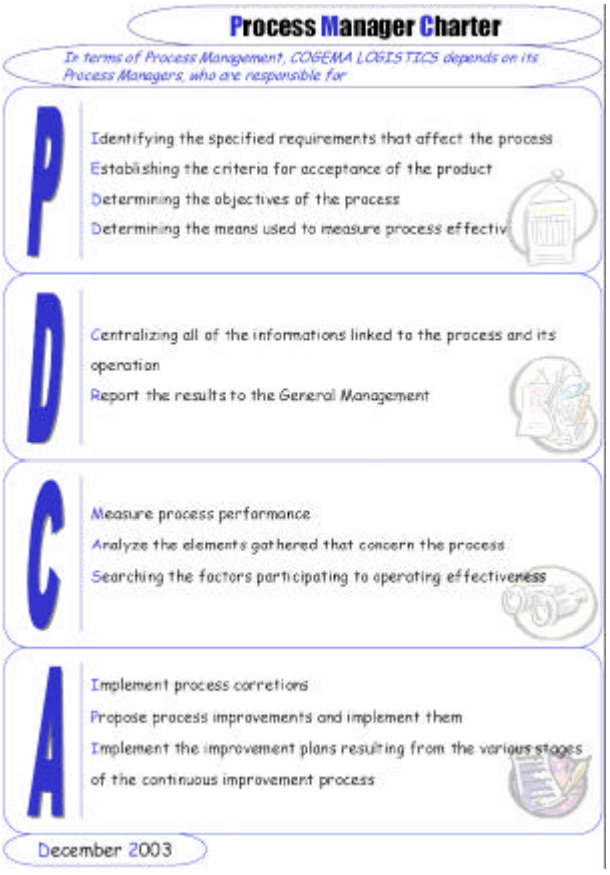


Figure n° 4

- Corrective and preventive action

Corrective actions should be used as a dynamic tool for improvement; it is necessary to go further than the concept developed by ISO 9001 and to take care of precursory events.
In COGEMA LOGISTICS we have implemented a system called "PDG" which allows, with a method based on risk analysis, to identify such events:
All dysfunctions are treated with this tool, and classified into four classes:

-not significant problems
-precursory events, to be analysed before decision to open or not to open a corrective action
-events for which a corrective action is systematically required
-major events

- Self assessment and various survey

Self-assessment is a basic tool, necessary to complete all common QA Tools. It is a good way to take into account some data and indicators which could be significant concerning performance and safety (e.g.: human factors) (see figure n° 5).

Figure n° 5

Self assessment AREVA WAY

10 business principle, 32 performance improvement goals, 100 performance criteria.

The 10 principles :

- Governance
- Financial performance
- Customer satisfaction
- Commitment to employees
- Risk Assessment and prevention
- Respect for the environment
- Innovation
- Community involvement
- Dialogue and consensus building
- Continuous improvement

Strong means for control and monitoring of all activities

Relationships are based on confidence and the sense of responsibility of each actor. But confidence must be based on facts. For that reason we have implemented a systematic second level control, for each activity.

Engineering activities inspections

Quality products managers are appointed. They are responsible to guarantee the strict compliance of all activities with the applicable documents.

For each step of a project, starting from the tender, up to the issuance of the compliance certificate, they have to perform verifications based on a "Product Quality plan".
This document identifies
- the action to be checked,
- the extent of verification to be done,
- the records which are required.

The objective is to apply to these activities the same rules as for operational activities even if the nature of the task (tender review, issuance of an order, design review…) leads to some difficulties to define accurately the scope of the inspection.

At source (suppliers' premises) inspections

An independent monitoring is performed for all activities:

- fabrication of cask
- transportation activities
- maintenance activities

Qualified and certified inspectors perform this monitoring, with methods and tools which are available on a specific computerised reference database.

Monitoring is planned through a general monitoring plan (see figure n° 6).

Figure n° 6: sample of Surveillance Program (Fabrication)

SURVEILLANCE PROGRAM (FABRICATION) - Sample

SY : Mandatory *SV : Mandatory at each inspection visit* *S : Random check* *3 = 3 times a year (case of continuous fabrication)*
(according to the nature of the operation - Can't be nil)

OPERATIONS	Surveillance Frequency		audit
	NORMAL	REDUCED	
Prerequisites			
Kick off meeting	SY(2)	SY	
Verification of QP at initial state	SY	SY	
List of sub-contractors	SY		X
List and documents status	SY		X
PROCUREMENT			
			X

SURVEILLANCE GUIDE - SAMPLE

COGEMA LOGISTICS		INSPECTION GUIDE X-RAYS FILMS			Page 1/2
DT/FE			Name	Signatures	Date
Ref. GI C5-E	Rev. 0	Writer			
		Verification			
		Approval			

CHECK POINTS	RECORDING OF THE PARAMETERS	C : conform NC : not conform NA : not applicable
• The procedure used has been approved by A-CL		
• Verification of the operators qualifications		
• Identification of the X-Ray film completed by an "R" in case of repair.		
• Presence position and number of penetrameters and presence of the letter "F" in case of penetrameters placed on film side.		
• The areas to be interpreted are correctly identified		

n° 7).

For each inspection an inspection report is issued
By this way each year 1000 inspection reports are done. They give data to evaluate the performance of subcontractors and are taken into account to give the "level of confidence" (see below).

Technical and quality audits

Independent assessments are conducted to measure the effectiveness of processes and of work performance.
They consist of audits, which cover all the activities including engineering activities and subcontracted activities.
The frequency of these audits is once a year. They are performed by qualified auditors, who are technical specialists in the field they audit.

The aim of these audits, which started with systemic audits, is to evaluate the efficiency of QA systems concerning quality of products and services. For instance, for fabrication activities auditors pay particular attention to:

- special processes (heat treatment, welding activities, resin pouring),
- non-destructive examinations (RT: Radiographic Test, UT: Ultrasonic Test, LP: Liquid Penetrant Test, MT: Magnetic Particles Test),
- Subcontracted products and services.

Conclusion

This performance based approach is necessary to guaranty the effectiveness of the traditional formal QA.
It shall be monitored through data in quantitative terms:

- satisfaction measurements,
- process measurements,
- non conformances trend analysis,
- results of self assessment,
- number of weaknesses identified at subcontractor plants.

Concerning subcontractors, the level of confidence is measured through an indicator, with 4 levels :

-0= supplier blacklisted
-1 = loss of confidence ; specific decisions to be implemented
-2 = normal level
-3= higher level of confidence ; specific means could be adopted for monitoring

Last but not least, the organisation has to demonstrate the effectiveness of its quality system through indicators.
One of the best performance indicators evaluates the capability of the organisation to prevent major dysfunction and to continuously improve its methods; this could be done through trend analysis for a number of product deficiencies and weaknesses in QA programs:

$$\text{Global performance indicator} = \frac{D}{D + E}$$

D = number of deficiencies and weaknesses which are identified and treated by the organisation.

E = number of deficiencies and weaknesses, which were not identified in the normal sequence of checks (i.e.: customer complains, departure from local regulations, incidents during transportation.

Quality assurance does not consist only of formal requirements.
It shall be developed in close relationship with a results oriented approach, based on the quality of products and services .
In many cases, unfortunately, quality assurance is reserved to some specialists and could be disconnected from the real basic quality of products.
To avoid such deviation we, at COGEMA LOGISTICS, try to keep quality assurance means close to operational processes

References:

INTERNATIONAL ATOMIC ENERGY AGENCY, Vienna, 1996 : safety series n° 50-C/SG-Q