NOTE CONCERNING THE PREPARATION OF EVIDENCE TO BE ESTABLISHED IN ORDER TO COMPLY WITH THE INITIAL ASSESSMENT REQUIREMENTS OF Directive 2007/46/EC

According Annex X of this Directive, during initial assessment, the Approval Authority shall verify:

"The existence of satisfactory arrangements & procedures" to ensure control of conformity to the approved type;

In case the manufacturer is not certified ISO 9001:2008 or equivalent, those **satisfactory arrangements & procedures** shall include, at least, evidence of the following basic requirements:

Quality management system

Key items:

Identification of the scope of activities.

e.g. Manufacturing of motor vehicles of category M, N and their trailers category O according to the Regulatory Acts (2007/46/EC, Annex IV part I)

e.g. Conversion and construction of motor vehicles of category M according to the Regulatory Acts (2007/46/EC Annex IV part I)

Required documented procedures [*]

- Control of documents (* 4.2.3.)
  - How do you update and review documents?
    - Regulations, production documents, drawings, …
  - How do you identify changes and latest document status?
  - How do you ensure that your documents remain legible and readily identifiable?
  - How do you handle old documents (documents which should not be use any more)
- Control of records (* 4.2.4.)
  - How do you identify the records?
  - How do you store these records?
  - How can you retrieve them?
  - What is the storage time and how do you protect them during the full storage time?
- ***Internal audit (see * 8.2.2.)***
- Control of non-conforming product (* 8.3.)
  - How do I handle and identify (marking) products who do not conform to the specifications?
  - How do I prevent the use of these non-conforming products?
- Corrective action (* 8.5.2)
  - How do you eliminate the causes of non-conformities?
  - How do you prevent the recurrence of these non-conformities?
- Preventive action (* 8.5.3)
  - How do you eliminate the causes of potential non-conformities?
  - How do you prevent the occurrence of these non-conformities?

Description of the main processes.

- description of the interaction of the processes of the quality management system (= flowchart)

[*] ISO 9001:2008

Management responsibility
Key items:

Appropriate quality policy.

Measurable quality objectives.

Defined responsibilities & authorities (organization).
- organogram

Assignment of a management representative.
- Person(s) who act as contact person(s) for the approval authority for the conformity of production and who has (have) the power to take action in case of non-conformity and/or recall

Resource management
Key items:

Competent personnel to achieve conformity to product requirements.
Providing training or other actions to achieve the necessary competence.
- training plan (e.g. for new employees)
- availability of training records with evaluation to determine the qualification (skills)

Infrastructure and work environment provided to achieve conformity to product requirements.
- equipment used in the production process (e.g. welding and tooling equipment and the maintenance thereof,…)

Product realization
Key items: *(some of these may be excluded when found not applicable)*

Preparation for product realization.
- e.g. production file including drawings, assembly instructions, verification and results, final inspection sheet

Determination & review of product related requirements.
- Do you take the latest Regulatory Acts into account before accepting an order from a customer?

Design & development plan, specifications, review, verification & validation.

Purchasing requirements & verification.

- Do you ensure that the purchased product conform to the purchasing requirements?

Controlled conditions during production

- What are your “in process”-checks?

Ensuring identification & traceability of products and materials.
Control of monitoring & measurement equipment.

Do you have :

- a calibration / verification plan
- instructions for calibration / verification
- calibration results (certificates records)
- appropriate identification to show the calibration status
- measures for appropriate use

Measurement, analysis & improvement

Key items:

Measurement of meeting customer’s requirements. (Customer satisfaction)

- ***How do you handle customer complaints?***

Measurement of the quality system effectiveness. (Internal audit)

Measurement of the processes and monitoring according objectives.

Measurement of product characteristics according requirements.

- Do you do sampling checks to ensure that the product conforms to the specification and requirements of the Regulatory Acts?

Analysis of all collected data. (Measurements)
Conversion of analysis results into action in order to improve continually.

- ***Do you verify the measurements and do you use this information to improve your process and product?***

Implementation of corrective actions in order to prevent reoccurrence of nonconformities.

Implementation of preventive actions in order to prevent occurrence of nonconformities.

Remark:

ISO 9001 or ISO/TS 16949 are the best suitable guidelines for better understanding of above identified key points of evidence to be provided for initial assessment. However, full compliance to the ISO 9001:2008 standard is not mandatory. Examples of non-mandatory requirements are:

- Quality policy.
- Quality objectives.
- Management review
- Design & development plan, specifications, review, verification & validation.
- Measurement of the quality system effectiveness. (Internal audit)
- Measurement of the processes and monitoring according objectives.
- Continual improvement

Although these requirements could be audited when mentioned in the quality documentation, these will not be considered as non-conformity against the Initial Assessment.

Effective control of conformity of production procedures/arrangements

- In the initial assessment stage, the manufacturers have to demonstrate the existence of effective control of conformity procedures.

- For manufacturers applying the Belgian individual approval scheme, reports according to the applied Regulatory Acts suffice (correct version of the Regulatory Act is important).

- In case the Manufacturer applies series production (unlimited, small series, National, European, Worldwide), a control plan should exist for all approvals/ type approval documents/Regulatory Acts, whichever the case may be (according to the applied method).

Note: A control plan differs from a test report in the addition of a sampling ratio, whereas test reports (individual approvals) are tested 100%.

FURTHER INFORMATION CONCERNING THE PREPARATION OF EVIDENCE TO BE ESTABLISHED IN ORDER TO COMPLY WITH THE CONTINUED VERIFICATION ARRANGEMENTS REQUIREMENTS OF Directive 2007/46/EC

During a COP audit (renewal audit) the auditor will, in general, not reaudit the quality system as it was audited/evaluated in the initial assessment stage or via an ISO 9001:2008 certification (or equivalent).
However, important changes to the quality system will be reaudited.
The implementation of the quality system will, in any case, be evaluated through the audit as described below.

Important pillars for COP audit:

- People (training, understanding work instructions, evaluation in practice)
- Machines (maintenance, work environment/conditions, work instructions)
- Measurement- / test equipment (calibration/verification, use of measurement equipment – in practice)
- *Existance* and *implementation* of effective control of conformity of production procedures, taking in account:
  - Requirements according the Regulatory Acts
  - Build specifications
  - Marking requirements
  - Test methods and correct use thereof
- Non-conformity handling
- Recall-procedures / Recall-activities