T&CPI Guideline requirements to the quality assurance system for the manufacturing (including reconditioning, repair, remanufacturing and routine maintenance) **of packagings, Intermediate Bulk Containers and Large Packagings for the transport of dangerous goods.**

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11

Contents

1 General

1.1 Area of application

This guideline has been compiled on the basis of the regulations that apply to:
transport by sea, described in the
- IMO (International Maritime Organisation)
  International Maritime Dangerous Goods (IMDG) Code
transport by air, described in the
- ICAO (International Civil Aviation Organisation)
  Annex 18 with the "Technical instructions for safe transport of dangerous goods by air",
transport by land, described in the
- ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road),
and transport by rail, described in the
- RID (Regulation concerning the International Carriage of Dangerous Goods by Rail)

These international regulations (based on the UN recommendations on the transport of Dangerous Goods – Model Regulations) are included in the national regulations in The Netherlands.
This guideline lays down the directives contained in the above regulations with regard to the quality assurance for the manufacturing (including reconditioning, repair, routine maintenance and remanufacturing) of packagings, in order to guarantee that every packaging is manufactured and tested in accordance with a quality assurance system approved by the competent authority. In this guideline packagings also include Intermediate Bulk Containers and Large Packagings. The guideline serves as interpretation of the regulations concerned for The Netherlands and for the UN-marks issued in The Netherlands. UN-marks in this Guideline also cover RID/ADR-marks and registration marks for reconditioning and repair.

1.2 Implementation of the quality assurance system

The quality assurance systems to be applied must fully meet the requirements set in this guideline within one year following the start of the manufacturing of packagings for the transport of dangerous goods.

1.3 Definitions

See point 4

1.4 Authorised organisations

The authorised organisation for assessing the quality assurance system formulated by the manufacturer of the packaging is:

In the Netherlands,
T&C Packaging International
Verlengde Poolseweg 16
NL-4818 CL Breda

1.5 Responsibilities

Responsibility of the manufacturer,
The manufacturer is responsible for the formulation and application of a quality assurance system for the manufacturing process. The relevant demands of this guideline must be included in the manufacturer's quality assurance system.
The manufacturer takes the responsibility for the conformity with the approved design type.

Responsibility of the holder
The relevant demands of this guideline must be included, where relevant, in the quality assurance system of the holder of the UN-mark. The holder is responsible for the applied mark to the packaging that meets the requirements set for the corresponding UN mark. This includes the obligation to inform the manufacturer(s) of the packaging about the requirements which apply to the manufacturing of approved packaging.
The holder of the UN-mark and the manufacturer must enter into an agreement allowing the authorised organisation to assess the complete quality system.

Responsibility of the authorised organisations
The authorised organisation as mentioned in 1.4 is responsible for the supervision of the quality assurance system in accordance with this guideline.

2 Quality Assurance System

2.1 General

Formulating the system of quality assurance
The manufacturing of packagings is to be subject to a quality assurance system which, on the basis of this guideline, is to be formulated in such a way as to ensure a sufficient degree of certainty that the packagings produced meet the quality requirements set. This quality system should be based on the standard EN-ISO 9001 or a comparable standard.
The system is to be formulated and adapted to the nature of the company in question, subject to the provisions laid down in this guideline.

Certification of the quality assurance system
Certification of the quality assurance system on the basis of the standard EN-ISO 9001 or a comparable standard is not mandatory.

Identification of manufacturing location
The required quality assurance system is applicable for every manufacturing location of the manufacturer. The manufacturer must assure that every manufactured packaging can be identified unambiguously concerning the manufacturer and manufacturing location. A separate identification is necessary when this is not evident from the applied UN-marking. The way of identification can be selected by the manufacturer, but he has to record it.

2.2 Requirements to be met by the quality assurance system

General requirements
The quality assurance system must contain general stipulations in terms of organisation and more specific stipulations for the manufacturing process (quality plans). It would be advisable to lay down the stipulations governing the quality system in a quality handbook.

The prevention of problems
The quality assurance system should emphasise the prevention of problems. Its goal should be to ensure that every packaging produced meets the requirements laid down in the regulations. Packaging manufacturers must formulate a documented system and update it on a regular basis.

Special arrangements
Special arrangements can be obtained in agreement with the authorised organisation in case there is a need to deviate from this guideline under the condition an equivalent quality level is assured.

2.3 Quality assurance

With regard to the stipulations of the quality assurance elements of the standard EN-ISO 9001 or a comparable standard, the following points have to be included in the quality handbook:

Quality assurance programmes
Quality assurance programmes for the manufacturing process have to be documented in the form of a quality plan.

Quality Plan
The quality plan must include all critical points in the process as well as the process control measures taken at those points and the required documentation at the workplace.

The quality plan must therefore comprise:
- A simplified process diagram arranged in stages;
- The critical points in the process;
- A description of the inspection method, the inspection frequency and the standard applied (target value and tolerance);
- References to instructions, specifications, procedures and registration records.

Minimum requirements
For the minimum requirements that must always be met in the formulation of any quality plan, refer to the annex to this guideline, which deal with the requirements that apply to each packaging design type. The frequencies as given in the quality plans must be considered as minimum frequencies.
Internal control
The quality assurance system must be assessed systematically and regularly by or on behalf of the manufacturer (internal audit), in order to demonstrate its continuing efficiency and to allow the implementation of any necessary corrective measures (see 2.4).
These assessments and the possible actions as a consequence of the audit have to be performed according to procedures put in writing.

The results and findings of the assessments have to be laid down in a report, together with details of the corrective measures taken.
Internal assessments have to be carried out by an expert appointed by the manufacturer. This expert should not directly be involved in the activity that is audited.

Modifications
Modifications of the quality assurance system
The quality system must comprise a procedure for the approval of modifications to the quality assurance system.

Modifications to the approved design type
The quality system must include a procedure for the assessment of modifications to the permitted design type.

Personnel
Personnel must be competent in relation to the tasks to be performed. An organisation scheme must be available indicating which persons with what functions are involved in the manufacturing. Function descriptions with required level of education must be available.

Facilities
The manufacturing company must possess the proper facilities and equipment, including the possibilities to perform the required controls and tests in a correct way. External facilities may be used after agreement of the authorised organisation.

Procedure for complaints
A procedure for complaints (internal/external) must be present in order to record and to treat them.

2.4 Corrective measures

The cause of the shortcomings
The cause of the shortcomings must be traced and measures must be taken to prevent repetition. Packagings with shortcomings must to be judged and treated according to section 2.5.

Analysing possible causes and to exclude recurrences
In order to trace possible causes and to exclude recurrence in the future all relevant processes, the performed work and quality controls must be analysed.

Corrective measures
The implementation of the corrective measures must be laid down in procedures.

2.5 Control of packagings with shortcomings

Packagings with shortcomings must be:
- Reconstructed. After determination by means of an inspection that the packaging fulfils the quality demands and that the packaging completely corresponds with the design type, it is allowed to affix the UN mark on the packaging; or
- Classified for other purposes. The UN mark on those packagings that deviate from the specifications must be removed/rendered unrecognisable; or
- Rejected and destroyed.

2.6 Quality documentation

There must be a well-organised documentation system to allow the operation of the quality system to be monitored efficiently.
This documentation system (quality handbook) should at least contain:
- A quality assurance system
- Quality plans
- Implementation procedures
- Testing procedures
- Work instructions
- Specifications
- A quality registration system

Changes in documents must be implemented in a prompt and adequate way. A register of documents or a similar system must be set up in order to prevent the use of invalid documents.

2.7 Quality registration records

Quality registration records must be kept at least 5 years and in any case longer than the probable lifetime of the packaging.

2.8 Work instructions

Work instructions must provide a description of the manufacturing method and the means of manufacturing.

3 External Control

3.1 Supervision

The authorised organisation must supervise the quality assurance system as described in this document, in order to prove that the system meets the requirements laid down in the regulations. If manufacturing takes place outside Netherlands, the quality assurance system may be supervised by the competent authority of the country in question. In this case the national requirements established for the system must be comparable with the requirements established in this guideline and be recognised as such. It must also be shown that the supervision actually occurs.

3.2 Implementation

Periodic control
Each manufacturing site must be audited in the first 2 years of manufacturing basically at least once a year. These audits are meant to check whether the required quality assurance system has been implemented and applied correctly.
The frequency of the audits can be reduced to once every 2 years (to be judged by the authorised organisation) when the quality-/manufacturing system was found to be on a sufficiently correct level. The frequency can always be adapted when defects or process modifications are observed.

The authorised organisation will carry out checks of packagings bearing a UN mark. These checks consist of a comparison of the packaging (on a random basis) with the approved type and of testing of packagings. These checks may take place at the audited company or at the laboratory of the authorised organisation. Checks are done both at the premises of the manufacturers and the holders of UN-marks. The audits are performed by or on behalf of the authorised organisation by auditors, meeting the necessary competence requirements (see 3.5).
The audits can be performed unannounced.

3.3 Shortcomings

If assessment of the system reveals shortcomings in relation to the guideline, the manufacturer or holder must redress these shortcomings as quickly as possible within a time period to be determined by the authorised organisation. The authorised organisation will assess the actions as proposed and indicates what will be the follow-up (this can involve a new assessment). If shortcomings are found repeatedly and particularly if the packaging fails to comply with the specifications of the construction type, the authorisation time period for manufacturing will be adapted and/or UN-marks will be made dormant. In addition the concerned Ministry will be informed.

3.4 Reports

The results of the assessments and checks have to be laid down in writing. The report has to include at least data showing the audited company, the site, the date of the audit and the relevant packaging types (UN marks). The report must also indicate which points were evaluated and include the results of the assessment.

3.5 Competence requirements for auditors

Auditors assessing quality assurance systems for packaging for dangerous goods must be able to prove that they have sufficient:

- Knowledge of the standards for quality assurance and experience with their application;
- Knowledge of the manufacturing process in question;
- Knowledge of legislation governing the transportation of dangerous goods and specifically of packaging requirements;
- Knowledge of the requirements set for the quality assurance system for packaging marked with a UN mark.

3.6 Costs

All costs related to the external control are charged to the manufacturer and holder. The necessary packagings required for the control must be made available to the authorised organisation.

4 Definitions

Holder[1]:
The legal entity to which the UN mark is registered. This entity is entitled to use the UN mark.

Instruction:
A workplace-dependent description of the implementation, control or inspection method.

Manufacturer:
The legal entity who is manufacturing (including reconditioning, repair, routine maintenance and remanufacturing), the packaging, according to a quality assurance system, that has been approved by the competent authority of the UN-approval.

Procedure:
Specified way to carry out an activity or a process[2].

Quality Assurance:
Part of quality management focused on providing confidence that quality requirements will be fulfilled[2].

Quality Plan:
Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract[2].

Specification:
Document stating requirements[2].

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1 The holder referred to in the definitions is not necessarily the same legal entity as the manufacturer
2 Source of the definitions: EN-ISO 9000:2005

5 Annexes

Annex 1 - T&CPI Minimum requirements set for the quality plans of the quality assurance system for the production of packagings (including IBC's and Large Packagings)

Annex 2 – T&CPI Minimale eisen aan het kwaliteitsplan van het kwaliteitsborgingssysteem bij het bewerken (reconditionering, ombouw, routine onderhoud en reparatie) van verpakkingen (inclusief IBC's en Grote Verpakkingen)