Guideline for the application of the quality assurance programme for the manufacturing (including reconditioning, repair, routine maintenance and remanufacturing) of packagings, Intermediate Bulk Containers and Large Packagings for the transport of dangerous goods

This guideline is of application from: 01-11-2017

With a transition period of 6 months ending on : 01-05-2018

Number of pages : 12 + 1 annex

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 International Maritime Dangerous Goods (IMDG) Code", published by IMO (International Maritime Organisation)
- transport by air, described in
  "Annex 18" and the "Technical instructions for safe transport of dangerous goods by air", published by ICAO (International Civil Aviation Organization)
- transport by land, described in the
  ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road),
- transport by rail, described in the
  RID (Regulation concerning the International Carriage of Dangerous Goods by Rail)
- transport by inland waterways, described in the
  ADN (European Agreement concerning the International Carriage of Dangerous Goods by inland waterways)

These international regulations (based on the "UN recommendations on the transport of Dangerous Goods – Model Regulations") are included in the national regulations.
This guideline lays down the directives contained in the above regulations with regard to the quality assurance programme 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 management programme approved by the competent authority. In this guideline packagings also include Intermediate Bulk Containers and Large Packagings. The guideline serves as interpretation of the national regulations and for the related UN-marks issued by the concerned country. UN-marks in this Guideline also cover RID/ADR-marks and registration marks for reconditioning and repair.

1.2 Implementation of the quality management system

The quality management 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

Only the authorised organisations recognized by the competent authorities for the transport of dangerous goods are authorised to assess the quality management system formulated by the manufacturer of the packagings. The authorized organization to assess the quality management system formulated by the manufacturer of the packagings 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 management system for the manufacturing process. The relevant demands of this guideline must be included in the manufacturer's quality management system.
The manufacturer is responsible for the conformity of the produced packagings with the approved design type.

Responsibility of the holder
The relevant demands of this guideline must be included, in the quality management 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.
In case the holder is different from the manufacturer, 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 management system.

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

2 Quality Management System

2.1 General

Formulating the system of quality management
The manufacturing of packagings is to be subject to a quality management 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 must be formulated and adapted, in accordance with the provisions of this guideline, to the nature of the company in question.

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

Identification of manufacturing location
The required quality management system is applicable for every manufacturing location of the manufacturer. The manufacturer must assure that the manufacturing location of every packaging can be unambiguously identified. A separate identification is necessary when this is not evident from the applied UN-mark. The way of identification can be selected by the manufacturer and must be recorded after approval from the authorised organisation.

2.2 Requirements to be met by the quality management system

General requirements
The quality management system must contain general stipulations in terms of organisation and more specific stipulations for the manufacturing process (quality plans). The stipulations governing the quality system must be incorporated in a quality manual.

The prevention of problems
The quality management 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 manual

Based on the quality assurance elements of the standard EN-ISO 9001 or a comparable standard, as a minimum the following points must be included in the quality manual:

Quality management system
Quality management system for the manufacturing process has 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 include:
- A simplified process in stages;
- The critical points in the process;
- A description of the inspection method, the inspection frequency and the standards applied (reference values and tolerances);
- References to instructions, specifications, procedures and registration records.

Note: For the minimum requirements applying to each packaging design type : see the annex to this guideline.

Internal control
The quality management 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 management system
The quality system must include a procedure for the approval of modifications to the quality management system.

Modifications to the approved design type (if applicable)
If modifications to the approved design type are authorised to be applied by the relevant transport regulations, the quality system must include a procedure for the assessment of them.

Personnel
Personnel must be competent in relation to the tasks to be performed. An organisation scheme must be available indicating which functions/persons are involved in the manufacturing. Function descriptions with required level of education and competencies 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 to record and to treat complaints (internal/external) must be present.

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 be judged and treated according to section 2.5.

Analysing possible causes and exclude recurrences
In order to trace possible causes and to exclude recurrences in the future all relevant processes, the performed tasks and the 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 reconstruction it is only allowed to affix the UN mark on the packaging if by means of an inspection it has been determined that the packaging fulfils the quality demands and that the packaging completely corresponds with the design type; or
- Classified for other purposes.
  After the UN mark on packagings that deviate from the specifications has been removed/rendered unrecognisable, the packagings may be used for other purposes; or
- Destroyed.

2.6 Management of Quality Documentation

There must be a well-organised documentation system to allow the operation of the quality management system to be monitored efficiently.
The Quality Manual and the non-exhaustive list of related supporting documents (see below) are part of the documentation system:
- implementation procedures
- specifications
- work instructions
- testing procedures
- registered data

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.

3 External Control

3.1 Supervision

The authorised organisation must supervise the quality management 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 Belgium/the Netherlands, the quality management system may be supervised by the competent authority of the concerned country. 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 by the authorised organisation. 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 at least once a year. These audits are meant to check whether the required quality management system has been implemented and applied correctly.
The frequency of the audits can be reduced (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 as well 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 within a time period to be determined by the authorised organisation. The authorised organisation will assess the corrective actions 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 (temporarily) non-active. 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 include which points were evaluated and the results of the assessment.

3.5 Competence requirements for auditors

Auditors assessing quality management systems for packagings for dangerous goods must be able to prove that they have sufficient knowledge of:
- the standards for quality management systems and experience with their application;
- the manufacturing process in question;
- legislation governing the transportation of dangerous goods and specifically of packaging requirements;
- the requirements set for the quality management 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 whom the registered UN-mark is allocated. This entity is entitled to apply the UN mark to the packagings, according to a quality management system, assessed by the authorised organisation issuing the UN-mark.

Manufacturer:
The legal entity who is manufacturing (including reconditioning, repair, routine maintenance and remanufacturing), the packaging, according to a quality management system, assessed by the authorised organisation issuing the UN-mark.

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

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

Quality assurance programme[3]:
Means a systematic programme of controls and inspections applied by any organization or body which is aimed at providing adequate confidence that the standard of safety prescribed in these Regulations is achieved in practice.

Quality Management System[2] (=Quality Assurance System):
Management system to direct and control an organization with regard to quality.

Quality Manual[2]:
Document specifying the quality management system of an organization.

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

Specification[2]
Document stating requirements.

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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
3 Source : Recommendations on the transport of Dangerous Goods; Model Regulations

5 Repealing provisions

This Guideline replaces the following procedures:

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. (editie Augustus 16, 2016)**

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). **(editie Augustus 16, 2016)**

Annex 1 - Minimum requirements set for the quality plans of the quality assurance system for the production of packagings (including Intermediate Bulk Containers -IBC's and Large Packagings -LP's).

6 Annex

Annex 1 - Minimum requirements set for the quality plans of the quality assurance system for the production of packagings (including Intermediate Bulk Containers -IBC's and Large Packagings -LP's).