Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

25 June 2021

Sub-Committee of Experts on the Transport of Dangerous Goods

Fifty-eighth session
Geneva, 28 June-2 July 2021
Item 6 (d) of the provisional agenda
Miscellaneous proposals for amendments to the Model Regulations on the Transport of Dangerous Goods: other miscellaneous proposals

Supplementary comments to ST/SG/AC.10/C.3/2021/30 "Proposal for the Establishment of an Informal Working Group on Quality"

Submitted by the International Dangerous Goods and Containers Association (IDGCA)

1. For the easier understanding of the essence of our proposal in ST/SG/AC.10/C.3/2021/30, IDGCA would like to provide a few supplementary comments and point out some issues with the requirements for quality system in the new Chapter 6.9 as an example.

2. The "quality system" wording used in Chapter 6.9 is rather misleading and has not been used at all in the normative or scientific literature for a long time. Here are three main terms that can be used in this regard (taken from ISO 9000: 2015 "Quality management systems - Fundamentals and vocabulary"):

(a) Quality management system – part of a management system with regard to quality.

(b) Quality control system – part of quality management system focused on fulfilling quality requirements.

(c) Quality assurance system – part of quality management system focused on providing confidence that quality requirements will be fulfilled.

Example: An organization undertakes to supply a 2 mm thick steel sheet (one of the quality parameters). The organization has a *quality control system* that consists of verified thickness gauges, trained controllers, and agreed control procedures. This system will allow the output to meet the requirements for steel thickness. The organization has a *quality assurance system* that includes processes of designing, manufacturing, product control, personnel training, equipment management, infrastructure maintenance, etc. This system provides predictability that, in the output, thickness (quality) requirements will be met. Fulfilment of requirements is ensured in advance, and not at the last stage – control. The *quality management system* ensures the interconnection and interaction of these processes and is also aimed at its continuous improvement.

3. Inaccurate use of terms may lead to further misinterpretations after translation into different languages. For example, "quality system" was translated as "quality assurance system" in Russian version of Chapter 6.9.

4. It may not be necessary to put forward requirements for a quality management system within the scope of standard ISO 9001 into the Model Regulations, but if any requirements are to be the normative basis, then they should be clearly formulated. Phrases like "It [the quality system] shall be documented in a systematic and orderly manner in the form of written

policies, procedures, and instructions.” (from 6.9.2.2.2.1) are not specific and invite various interpretations of "systematic" and "orderly".

5. According to 6.9.2.2.2.5 Maintenance of the quality system:

> “The manufacturer shall maintain the quality system as approved in order that it remains adequate and efficient.”

6. Efficiency is defined as the relationship between the results achieved and the resources spent on it. But resources are an internal matter of the organization, and cannot be the subject of requirements for it.

7. The status of the competent authority is not clear in the context of the quality management system`s audit. Why is it competent and who authorizes it to carry out audits? There is a concern that if the audit and certification of the quality management system becomes a mandatory procedure controlled by the competent authority, then the audit and certification may be delegated by the competent authority to other organizations and companies, which will create large non-production costs for the enterprises. The ISO 9001 standard is intended and should remain for voluntary use.