INTERNATIONAL STANDARD

ISO 16426

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Fasteners — Quality assurance system

Éléments de fixation — Système d'assurance qualité

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 16426 was prepared by Technical Committee ISO/TC 2, *Fasteners*.

Annex A of this International Standard is for information only.

Introduction

This International Standard is the second in a series of two standards for mechanical fastener quality using a detection system and a prevention system respectively.

— ISO 3269 deals with acceptance inspection based on statistical sampling of fasteners at a given AQL level at the time of receiving and constitutes a detection system intended primarily for use by the customer.

— ISO 16426 deals with fully traceable mechanical fasteners which have been produced under a verifiable quality assurance system and constitutes a prevention system intended primarily for use by the fastener manufacturer.

Fasteners — Quality assurance system

1 Scope

This International Standard specifies requirements for a fastener quality assurance system to be met by the fastener manufacturers and distributors. These requirements are intended to reduce or prevent the production of non-conforming fasteners with the objective of approaching zero defects for the characteristics specified.

This International Standard outlines the requirements from receipt of raw material through the manufacturing process to delivery at the distributor or the user, who is the installer.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3269:2000, *Fasteners — Acceptance inspection*

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

ISO 15330:1999, *Fasteners — Preloading test for the detection of hydrogen embrittlement — Parallel bearing surface method*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1

advanced quality planning

process that facilitates an interpretation of design objectives into design requirements that are an integral part of the fastener quality plan, including process failure mode and effects analysis and control plans

3.2

alter

to perform any step after original manufacture which changes the geometry, mechanical properties or the performance characteristics of a mechanical fastener

3.3

C_{pk} value

measure of the capability of the process in relation to the process average based on the distance in units of standard deviation between the process average and the closest specification limit for characteristics that have a normal distribution pattern

3.4
customer
organization or person that receives a product

NOTE The customer may be the user or a distributor.

[ISO 9000]

3.5
commingling
mixing of identical fasteners from different manufacturing lots in the same container or bin

3.6
control plan
outline of the fastener manufacturing process which identifies control points that provide procedures for controlling and minimizing process and product variation

3.7
defect
non-fulfilment of a requirement related to an intended or specified use

NOTE In the presence of a defect, the fastener will not function in its expected or intended use.

[ISO 9000]

3.8
distributor (stockist)
organization or person that purchases finished fasteners for resale to others and of which there are three types:

3.8.1
alteration distributor
distributor who alters fasteners prior to delivery

3.8.2
pass-through distributor
distributor who resells original manufacturer's containers of fasteners without repackaging or alteration of the fasteners

3.8.3
repackaging distributor
distributor who only repackages fasteners prior to delivery

3.9
fastener characteristic
dimensional, mechanical or performance feature of the fastener

3.10
fastener quality assurance system
fastener manufacturing system that generally incorporates such elements as a written control plan, which includes provisions for prototype development, initial production and full production, including **advanced quality planning** (3.1), continual improvement, defect prevention, and in-process controls of dimensional, mechanical and performance characteristics of the fastener

3.11
lot contamination
introduction of dissimilar fasteners or foreign substances or products into a manufacturing lot of fasteners

3.12
manufacturer
organization which purchases raw material and converts the material into a finished mechanical fastener

3.13
manufacturing lot
quantity of fasteners of a single designation including product grade, property class and size, manufactured from bar, wire, rod or flat product from a single cast, processed through the same or similar steps at the same time or over a continuous time period through the same heat treatment and/or coating process, if any

NOTE 1 Same heat treatment or coating process means:

— for a continuous process, the same treatment cycle without any setting modification;

— for a discontinuous process, the same treatment cycle for identical consecutive loads (batches).

NOTE 2 The manufacturing lot may be split into a number of manufacturing batches for processing purposes and then reassembled into the same manufacturing lot.

[ISO 15330]

3.14
manufacturing lot number
unique number assigned by the manufacturer and which allows full traceability from the finished product back through all previous manufacturing operations to a given heat or cast number of the raw material of manufacture

3.15
non-conformity
non-fulfilment of a requirement

[ISO 9000]

3.16
non-conforming fastener
fastener with one or more non-conformities

3.17
non-conforming parts per million (ppm)
number of non-conforming parts in a finished manufacturing lot of fasteners related to 1 million pieces

3.18
product continual improvement
orderly process intended to reduce variation, waste and testing frequencies while improving productivity, quality and customer satisfaction

3.19
selected product characteristic
characteristic which is critical for assembling and/or for the function of the fastener and is designated by the customer

3.20
supplier
organization or person that provides a product

NOTE The supplier may be the manufacturer or a distributor.

[ISO 9000]

3.21
trace number
alphanumeric code assigned by a distributor, which identifies the original manufacturer and manufacturing lot number

3.22
traceability of fasteners
ability to determine or verify the history of a finished fastener through records of its identification, to establish its shipment, manufacturing process and the specific heat number of raw material from which it was manufactured

3.23
user
organization or person that purchases or otherwise acquires fasteners and installs them for purposes of assembly or overhaul and maintenance

3.24
zero defect conception
conception that establishes an objective that no fasteners with defects are present, within a given mechanical fastener lot, which impair their expected or intended use

4 Information to be provided by the customer

The customer shall specify this International Standard at the time of the order.

The order shall designate the selected product characteristics, if any, considering the intended application, or a reasonably foreseeable application and its consequence.

5 Requirements

5.1 General

The selected product characteristics as designated by the customer shall be included in the written control plan. This control plan is part of the quality assurance system to be used by the manufacturer.

The manufacturer and the customer shall agree on appropriate ppm and/or C_{pk} values and a method for evaluation for each respective selected characteristic.

For all other characteristics, the manufacturer may use the quality plan of his choice and the customer shall rely on ISO 3269 to evaluate the level of conformance of the purchased fasteners.

Fasteners manufactured under the conditions of this International Standard shall be delivered in manufacturing lots.

Fasteners shall correspond to the description and/or designation on the shipping document. The shipping document shall include at least the designation of the fasteners and the manufacturing lot number or trace number.

The label on the package shall include the manufacturer's or distributor's name or identification (including country of origin) and the manufacturing lot number or trace number, as well as the necessary information concerning the description and/or designation of the fasteners.

The manufacturer shall be able to provide documentation for any manufacturing lot, to prove the compliance of the fasteners to the specifications, and this shall include at least:

— heat analysis (chemical composition);

— heat treatment if applicable;

— mechanical properties;

— performance characteristics if applicable;

— dimensions;

— finish if applicable.

Documentation shall be provided to the purchaser only upon request. The manufacturer shall be able to provide full manufacturing lot documentation for a ten-year period from the date of the sale to the customer, provided the customer gives the manufacturing lot number to the manufacturer. The distributor shall be able to provide full manufacturing lot documentation for a ten year period from the date of the sale to the customer, provided the customer gives the manufacturing lot number or the trace number to the distributor.

5.2 Traceability

Fasteners shall be traceable. The documentation for traceability shall be preserved by the manufacturer for at least ten years from the date of sale to the customer. The party responsible for alteration and/or repackaging of the fasteners shall also maintain full traceability for at least ten years from the date of sale to the customer.

In case of dispute, the supplier shall be able to provide all necessary information relating to the manufacturing lot number. The customer, upon opening the original packaging, assumes full responsibility for all subsequent traceability.

5.3 Lot integrity

To maintain lot integrity, fastener manufacturing lots shall not be commingled.

5.4 Delivery

All fasteners shall be delivered to the user in the manufacturer's or distributor's original, unopened, sealed package unless otherwise agreed with the user. Fasteners manufactured to specific ppm and/or C_{pk} values shall not be repacked.

5.5 Product continual improvement

For those selected characteristics for which a reduction in ppm levels through product continual improvement is to be achieved, it is desirable that the user return to the manufacturer all non-conforming parts from a given lot discovered during assembly. They shall be analysed by the manufacturer in order to gain knowledge on how to improve the process.

6 Summary of responsibilities

6.1 Responsibilities of the manufacturer

The manufacturer shall:

— provide and maintain full documentation in accordance with 5.1;

— maintain traceability in accordance with 5.2;

— maintain lot integrity in accordance with 5.3.

6.2 Responsibilities of the distributor

6.2.1 General

The distributor of fasteners shall maintain lot traceability for each lot of fasteners purchased from a manufacturer who complies with this International Standard.