INTERNATIONAL STANDARD

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Fasteners — Quality assurance system

Éléments de fixation — Système d'assurance qualité

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Foreword

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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.

6.2.2 Responsibilities of the alteration distributor

Any alteration carried out by the distributor transfers the responsibilities from the manufacturer to the alteration distributor.

6.2.3 Responsibilities of the repackaging distributor

The repackaging distributor shall have in place verifiable procedures to prevent lot contamination, and to maintain all the original fastener characteristics as supplied by the manufacturer. Any repackaging carried out by the distributor transfers the responsibilities from the manufacturer to the distributor for those characteristics which may be affected by the repackaging operation.

6.3 Responsibilities of the user

The user shall supply all the information required in clause 4.

Additionally, the user shall take all prudent measures to assure the integrity of the fasteners purchased in accordance with this International Standard.

7 Disposition of nonconforming lots

7.1 General

Records of disposition shall be maintained by the fastener supplier.

7.2 Manufacturer's options

The manufacturer may choose one of the following options for the disposal of fastener lots that have been found to contain fasteners with non-conformities on his manufacturing plant.

— They may be scrapped.

— They may be 100 % inspected and any detected non-conforming parts removed.

— They may be reworked or reprocessed to correct the non-conforming characteristic(s).

— The user may be informed of the non-conformity or non-conformities and his advice requested on their disposal. If the user considers that the degree to which the characteristic(s) deviate(s) from specified requirements will have no significant effect on the assembly or performance of the fasteners in their service application, the user may authorize a written release of the fasteners for completion of production or for shipment, as applicable.

7.3 User's options

Taking into consideration economical consequences, the user may agree with the supplier on one of the following options for the disposal of those fastener lots that have been rejected after delivery.

— If the user considers that the degree to which the characteristic(s) deviate(s) from specified requirements will have no significant effect on their performance in the intended service application, the user may authorize release of the parts or fastener lots for that use and advise the manufacturer in writing.

— They may be scrapped.

— They may be 100 % inspected and any detected non-conforming parts removed.

— They may be reworked or reprocessed to correct the non-conforming characteristic(s).

— They all may be returned.

If the supplier is a distributor, then the rework, inspection or reprocessing should be agreed with the fastener manufacturer.

7.4 Distributor's options

Taking into consideration economical consequences, the distributor may agree with the manufacturer on one of the following options for the disposal of those fastener lots that have been rejected after delivery.

— They may be scrapped.

— They may be 100 % inspected and any detected non-conforming parts removed.

— They may be reworked or reprocessed to correct the non-conforming characteristic(s).

— They all may be returned.

7.5 Re-inspection

All fastener lots that have been reworked and/or reprocessed shall be re-inspected for the characteristic(s) found to be non-conforming and all other characteristics that would be affected by the reworking or reprocessing operation(s). If no parts inspected are found to be non-conforming, the fastener lots may be approved for delivery or use as applicable.

Annex A
(informative)

Considerations to achieve ppm values

A.1 State of the art in the production of fasteners

A.1.1 Aspects of mass production

With the requirements put upon the delivery quality of fasteners, by the customers, the special features of mass production are taken into account. The machines used today in the production of fasteners (e.g. presses, rollers) allow a flow rate of 60 parts per minute to 800 parts per minute depending on the type, size and operating cycle of the machine in use. The number of parts produced by a manufacturer can amount to up to several million per day, which requires special measures for maintaining the process capability. In addition, the parts are transferred into other vessels many times during the production process, the number of transfer operations depending on the length of the production chain (e.g., for cold heading, thread rolling, washing, quenching and tempering, surface treatment, applying corrosion protection, etc.) more than 20 times is not unusual. Special measures are taken to prevent mechanical damage (especially at points of impact) and to avoid contamination.

The quality objective, zero defects, cannot be realized with today's state-of-the-art methods. To achieve this aim, intermediate objectives are set by specifying criteria for evaluating the delivered quality of fasteners. In this International Standard, such criteria are based on non-conforming parts per million (ppm) and/or process capability (C_{pk}) for specified characteristics.

A.1.2 Influences of the production process

The requirements on measurements and tolerances for certain characteristics are based on the production process applied (cold-forming processes, metal cutting treatment, heat treatment, etc.). Some examples are given below to illustrate this.

In the manufacture of fasteners, a number of production processes are reached by means of cold forming. The adherence to the tolerances depends not only on the material used but also on a number of other influencing factors; e.g., contours produced by means of free forming in open dies do not usually strictly adhere to tolerances as do those contours made by means of flowing material into closed dies. Sharp edges cannot always be avoided with certain cold forming processes. In such cases, it is often not possible to give clearly-defined tolerances or limit values.

In the production of threaded fasteners, there are differences in the screw threads based on the method in which the threads are formed which affect geometry, tolerances, roughness, thread laps, etc.

For screws with large length:diameter ratio, there is an increasing probability of warping (especially if the last stage of production involves a quenching and tempering heat treatment). The corresponding tolerances are specified considering the individual part and production method.

When coating the parts for corrosion protection, differences in the local thickness of the coating cannot be avoided and will vary depending on the part size and the coating method, and may cause differences in the local salt spray corrosion resistance. In such cases, depending on the type and geometry of the fastener, corrosion resistance is based on significant surfaces of the fastener. Adherence to completion of salt spray testing prior to shipment is not always practical because of the testing time required which may exceed several hundred hours. For this reason, corrosion resistance is assured by means of suitable production management measures utilizing in-process control. A quality judgement of this characteristic by evaluation of ppm is not possible. The same applies for the application of lubricants on fasteners to meet specified limits of coefficients of friction. The adherence to such a specification (e.g., $\mu_{tot} = 0{,}08$ to 0,14) can only be ensured by means of suitable production management measures utilizing in-process control, and checked by means of random testing.

These examples illustrate the need for close collaboration between the manufacturer, distributor and user.

A.2 Repackaging considerations

Repackaging increases the risk of introduction of dissimilar fasteners or foreign parts and that of mechanical damage.

A.3 Sources of non-conforming items and means to achieve specified ppm values

There are three sources of non-conforming item namely:

— fasteners with non-conforming characteristics;

— foreign or mixed parts (dissimilar fasteners);

— contaminants (metallic or non-metallic) which are not fasteners.

It is common practice to include only fasteners with non-conforming characteristics and dissimilar fasteners in the establishment of ppm values unless otherwise agreed. This is schematically illustrated in Figure A.1.

Foreign or mixed parts can result either from the manufacturer's production chain or the production chain of another party or from other sources.

Parts with non-conformities in measurements, geometry and other properties result from unsystematic or systematic process characteristics.

Examples of unsystematic process characteristics are:

— cracks in raw material, occlusions;

— welding points in wire;

— sporadic chipping in an extrusion die;

— parts with missing characteristics such as parts without threads or without knurl;

— threads with pitch errors;

— internal drive with excessive coating material, etc.

Examples of systematic process characteristics are measurement and/or tolerance deviations.

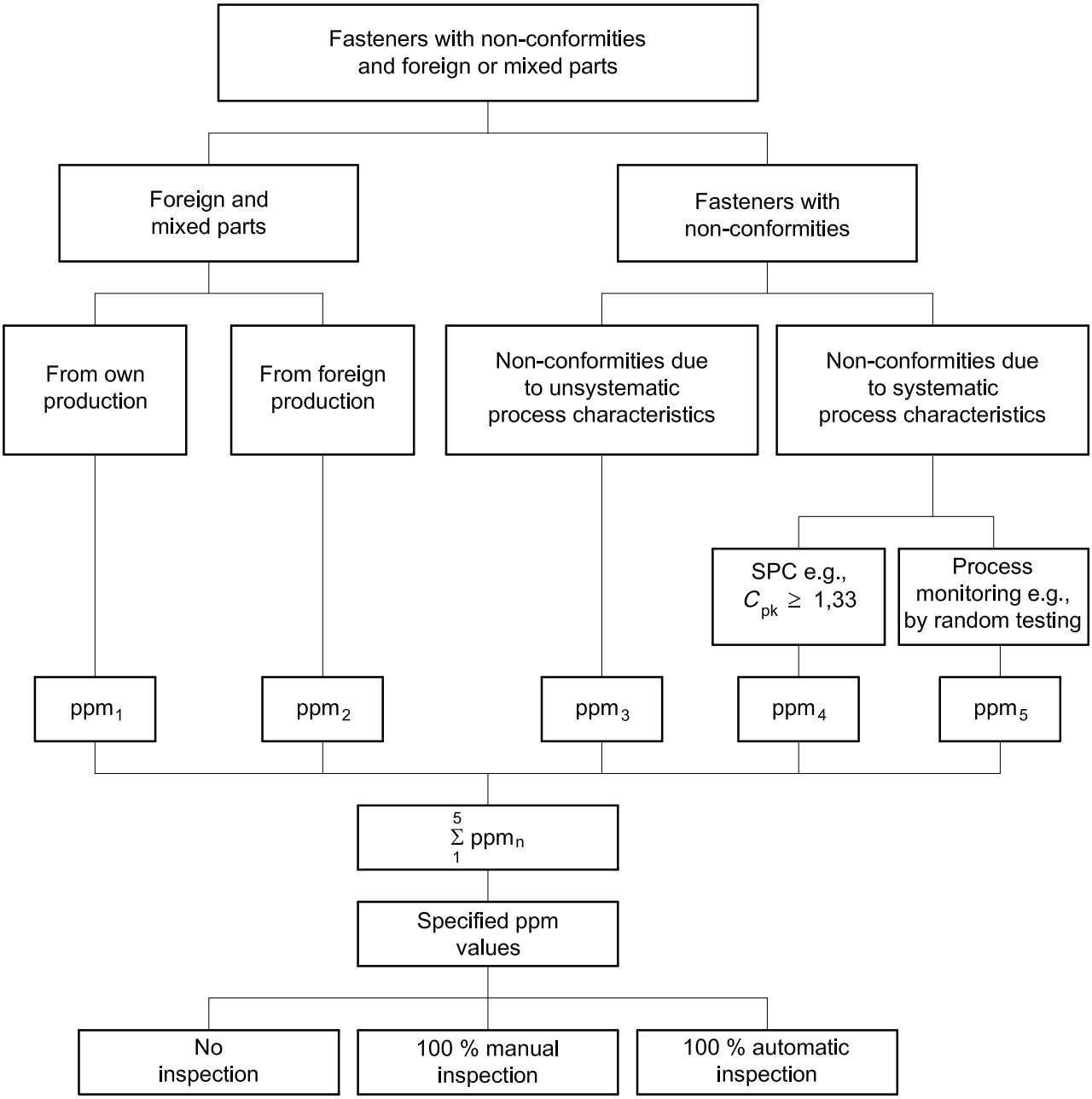
While unsystematic non-conformities cannot be recognized by statistical process control (SPC), systematic non-conformities can usually be limited by the application of SPC.

The application of SPC cannot guarantee the delivery of fasteners with non-conformities, on a statistical basis. If, for instance, a C_{pk} value of 1,33 for a single characteristic is assumed, this means that 99,994 % of the fasteners are within the specification for this particular characteristic. If the process is exactly centered, statistically, 0 to 60 fasteners per one million fasteners may then be outside the tolerance limits.

A.4 Inspection

A.4.1 General

To achieve specified ppm values one of the following inspection options may be applied, where inspection means to check parts for selected characteristics and to remove detected parts with non-conformities.



A.4.2 Automatic inspection

With automatic inspection, individual or multiple characteristics can be inspected. Experience has shown that for one single specified characteristic, after automatic inspection there is still an average remaining level of non-conformities of about 10 ppm. With an automatic inspection process, usually four or five characteristics are checked simultaneously. So for these fasteners, on average, 50 ppm can be expected.

A.4.3 Manual inspection

After 100 % manual inspection, remaining ppm values may be about 10 times higher than for fasteners which have been automatically inspected.

A.4.4 Inspection limitations

There are characteristics where an evaluation of ppm values of a production or delivery lot by the manufacturer is not practical because these characteristics cannot be 100 % inspected. This applies, e.g., for characteristics that require destructive testing, such as testing for corrosion resistance, tensile testing, or testing for torque/tension relationship to check coefficients of friction. The requirements for such characteristics are assured by means of a suitable monitoring process, based on a written control plan.

If a characteristic is specified and is considered critical with respect to its intended use, all concerned parties are expected to take prudent measures to approach zero defects.

A.5 Examples of characteristics for the establishment of quality criteria

Table A.1 shows some characteristics that the manufacturer and customer may include in an agreement for specified ppm values and/or C_{pk} values.

Table A.1 — Examples of characteristics which may be specified

Dimensions	Functions and forms	Mechanical and physical properties
Length	Thread	Hardness
Thread length	Internal drive	Tensile strength
Thread diameter	External drive	Surface discontinuities
Flange diameter	Prevailing torque element	Proof load
Head diameter	Form and position tolerances	
Shank diameter	Pilot point	
Head height	Washers present	
Nut height		
Depth of internal driving feature		
Width across flats		
Width across corners		

A.6 Restriction for the establishment of C_{pk} values

In the case of foreign and mixed parts, the specification of C_{pk} values is not possible since they are not statistically distributed. Only ppm values may be established for foreign or mixed parts.

Bibliography

[1] ISO 9001:2000, Quality management systems — Requirements

ICS 21.060.01

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