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4 Quality system requirements

4 Quality system requirements

4.1 Management responsibility

4.1 Management responsibility

4.1.1 ***Quality policy***

The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels in the organization.

4.1.1 ***Quality policy***

Clause **4.1.1** of EN 29001 : 1987 applies.

4.1.2 ***Organization***

4.1.2 ***Organization***

4.1.2.1 *Responsibility and authority*

The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

a) initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system;

b) identify and record any problems relating to the product, process and quality system;

c) initiate, recommend or provide solutions through designated channels;

d) verify the implementation of solutions;

e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.1 *Responsibility and authority*

Clause **4.1.2.1** of EN 29001 : 1987 applies.

Particular requirement for all medical devices:

The **supplier** shall document the responsibility, authority and the interrelationship of all personnel who manage, perform and **verify** work affecting quality.

4.1.2.2 *Resources*

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see **4.18**), for management, performance of work and verification activities including internal quality audits.

4.1.2.2 *Verification resources and personnel*

Clause **4.1.2.2** of EN 29001 : 1987 applies.

4.1.2.3 *Management representative*

The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsiblities, shall have defined authority for

a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard; and

b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

NOTE 5. The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

4.1.2.3 *Management representative*

Clause **4.1.2.3** of EN 29001 : 1987 applies.

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4.1.3 ***Management review***

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see **4.1.1**). Record of such reviews shall be maintained (see **4.16**).

4.2 Quality system

4.2.1 ***General***

The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

NOTE 6. Guidance on quality manuals is given in ISO 10013.

4.2.2 ***Quality system procedures***

The supplier shall

a) prepare documented procedures consistent with the requirements of this International Standard and the supplier's stated quality policy; and

b) effectively implement the quality system and its documented procedures.

For the purposes of this International Standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.

NOTE 7. Documented procedures may make reference to work instructions that define how an activity is performed.

4.2.3 ***Quality planning***

The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, project or contracts:

a) the preparation of quality plans;

b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality;

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4.1.3 ***Management review***

Clause **4.1.3** of EN 29001 : 1987 applies.

4.2 Quality system

Clause **4.2** of EN 29001 : 1987 applies.

Particular requirements for all medical devices:

The **supplier** shall establish and document the specified requirements.

NOTE. If this European Standard is used for compliance with regulatory requirements, the relevant requirements of the regulations should be included in the specified requirements.

The **supplier** shall establish and maintain a file containing documents defining the product specifications, including complete manufacturing and quality assurance specifications for each type/model of **medical device**, or referring to the location of this information (see also **4.5.1** and **4.16**).

c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation;

d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;

e) the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed;

f) the identification of suitable verification at appropriate stages in the realization of product;

g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;

h) the identification and preparation of quality records (see **4.16**).

NOTE 8. The quality plans referred to (see **4.2.3a**)) may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.

4.3 Contract review

4.3.1 *General*

The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities.

4.3.2 *Review*

Before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order shall be reviewed by the supplier to ensure that:

a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance;

b) any differences between the contract or order requirements and those in the tender are resolved;

c) the supplier has the capability to meet the contract or order requirements.

4.3.3 *Amendment to a contract*

The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization.

4.3.4 *Records*

Records of contract reviews shall be maintained (see **4.16**).

NOTE 9. Channels for communication and interfaces with the customer's organization in these contract matters should be established.

4.3 Contract review

Clause **4.3** of EN 29001 : 1987 applies.

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4.4 Design control

4.4.1 *General*

The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

4.4.2 *Design and development planning*

The supplier shall prepare plans for each design and development activity. The plans shall describe or reference these activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as the design evolves.

4.4.3 *Organizational and technical interfaces*

Organizational and technical interfaces between different groups which input into the design process shall be defined and the necessary information documented, transmitted and regularly reviewed.

4.4.4 *Design input*

Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements.

Design input shall take into consideration the results of any contract review activities.

4.4.5 *Design output*

Design output shall be documented and expressed in terms that can be verified and validated against design input requirements.

Design output shall:

a) meet the design input requirements;

b) contain or make references to acceptance criteria;

c) identify those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g. operating, storage, handling, maintenance and disposal requirements).

Design output documents shall be reviewed before release.

4.4.6 *Design review*

At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted. Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required. Records of such reviews shall be maintained (see 4.16).

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4.4 Design control

4.4.1 *General*

Clause 4.4.1 of EN 29001 : 1987 applies.

4.4.2 *Design and development planning*

Clause 4.4.2 of EN 29001 : 1987 applies.

4.4.2.1 *Activity assignment*

Clause 4.4.2.1 of EN 29001 : 1987 applies.

4.4.2.2 *Organizational and technical interfaces*

Clause 4.4.2.2 of EN 29001 : 1987 applies.

4.4.3 *Design input*

Clause 4.4.3 of EN 29001 : 1987 applies.

Particular requirement for all medical devices:

The **supplier** shall identify requirements that are related to the safety of the **medical device** and shall include such requirements as design input data.

4.4.4 *Design output*

Clause 4.4.4 of EN 29001 : 1987 applies.

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4.4.7 *Design verification*

At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (see **4.16**).

NOTE 10. In addition to conducting design reviews (see **4.4.6**), design verification may include activities such as

- performing alternative calculations;
- comparing the new design with a similar proven design, if available;
- undertaking tests and demonstrations; and
- reviewing the design stage documents before release.

4.4.8 *Design validation*

Design validation shall be performed to ensure that product conforms to defined user needs and/or requirements.

NOTE 11. Design validation follows successful design verification (see **4.4.7**).

NOTE 12. Validation is normally performed under defined operating conditions.

NOTE 13. Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.

NOTE 14. Multiple validations may be performed if there are different intended uses.

4.4.9 *Design changes*

All design changes and modifications shall be identified, documented, reviewed and approved by authorized personnel before their implementation.

4.5 Document and data control

4.5.1 *General*

The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings.

NOTE 15. Documents and data can be in the form of any type of media, such as hard copy or electronic media.

4.5.2 *Document and data approval and issue*

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;

b) invalid and/or obsolete documents are promptly removed from all points of issue or use,

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4.4.5 *Design verification*

Clause **4.4.5** of EN 29001 : 1987 applies.

Particular requirement for all medical devices:

The **supplier** shall document and maintain records (see **4.16**) of all design **verification** activities including those where clinical investigation was involved.

4.4.6 *Design changes*

Clause **4.4.6** of EN 29001 : 1987 applies.

4.5 Document control

4.5.1 *Document approval and issue*

Clause **4.5.1** of EN 29001 : 1987 applies.

Particular requirement for all medical devices:

The **supplier** shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that specifications to which **medical devices** have been manufactured are available for at least the lifetime of the **medical device** as defined by the **supplier** (see **4.16**).

c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

4.5.3 Document and data changes

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

4.5.2 *Document changes/modifications*

Clause **4.5.2** of EN 29001 : 1987 applies.

4.6 Purchasing

4.6.1 *General*

The supplier shall establish and maintain documented procedures to ensure that purchased product (see **3.1**) conforms to specified requirements.

4.6.1 *General*

Clause **4.6.1** of EN 29001 : 1987 applies.

4.6.2 *Evaluation of subcontractors*

The supplier shall:

a) evaluate and select subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements;

b) define the type and extent of control exercised by the supplier over subcontractors. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors;

c) establish and maintain quality records of acceptable subcontractors (see **4.16**).

4.6.2 *Assessment of sub-contractors*

Clause **4.6.2** of EN 29001 : 1987 applies.

4.6.3 *Purchasing data*

Purchasing documents shall contain data clearly describing the product ordered, including, where applicable:

a) the type, class, grade or other precise identification;

b) the title or other positive identification and applicable issue of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;

c) the title, number and issue of the quality system standard to be applied.

The supplier shall review and approve purchasing documents for adequacy of specified requirements prior to release.

4.6.3 *Purchasing data*

Clause **4.6.3** of EN 29001 : 1987 applies.

Particular requirement for all medical devices:

To the extent required by the particular requirements for traceability in **4.8**, the **supplier** shall retain copies (see **4.16**) of relevant purchasing documents.

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4.6.4 *Verification of purchased product*	4.6.4 *Verification of purchased product*
4.6.4.1 *Supplier verification at subcontractor's premises*	Clause **4.6.4** of EN 29001 : 1987 applies.
Where ~~the~~ supplier proposes to verify purchased product at the subcontractor's premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents.	
4.6.4.2 *Customer verification of subcontracted product*	
Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor.	
Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.	
4.7 Control of customer-supplied product	**4.7 Purchaser supplied product**
The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see **4.16**).	Clause **4.7** of EN 29001 : 1987 applies.
Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.	
4.8 Product identification and traceability	**4.8 Product identification and traceability**
Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation.	Clause **4.8** of EN 29001 : 1987 applies.
Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see **4.16**).	a) *Identification* *Particular requirement for all medical devices:* The **supplier** shall establish and maintain procedures to ensure that **medical devices** received for **refurbishing** are identified and distinguished at all times from normal production. b) *Traceability* *Particular requirement for all medical devices:* The **supplier** shall establish, document and maintain procedures for traceability. The procedures shall define the extent of traceability and facilitate corrective action (see **4.14**). *Additional requirements for active implantable medical devices and implantable medical devices:* The extent of traceability shall include all components and materials used, and records of the environmental conditions (see **4.9.1** B)d), when

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4.9 Process control

The supplier shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

a) documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality;

b) use of suitable production, installation and servicing equipment, and a suitable working environment;

c) compliance with reference standards/codes, quality plans and/or documented procedures;

d) monitoring and control of suitable process parameters and product characteristics;

e) the approval of processes and equipment, as appropriate;

f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g. written standards, representative samples or illustrations);

g) suitable maintenance of equipment to ensure continuing process capability.

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified.

NOTE 16. Such processes requiring pre-qualification of their process capability are frequently referred to as special processes.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate (see **4.16**).

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4.9 Process control

4.9.1 ***General***

Clause **4.9.1** of EN 29001 : 1987 applies.

A) *Personnel*

The **supplier** shall establish, document and maintain requirements for health, cleanliness and clothing of personnel if contact between such personnel and **product** or environment could adversely affect the quality of **product**.

B) *Environmental control in manufacture*

For **medical devices**:

a) that are supplied sterile; or

b) that are supplied non-sterile and intended for sterilization before use; or

c) where the microbiological and/or particulate cleanliness or other environmental conditions are of significance in their use; or

d) where the environmental conditions are of significance in their manufacture;

the **supplier** shall establish and document requirements for the environment to which **product** is exposed.

If appropriate, the environmental conditions shall be controlled and/or monitored.

C) *Cleanliness of product*

The **supplier** shall establish, document and maintain requirements for cleanliness of **product** if:

a) **product** is cleaned by the **supplier** prior to sterilization and/or its use; or

b) **product** is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use; or

c) **product** is supplied to be used non-sterile and its cleanliness is of significance in use; or

d) process agents are to be removed from **product** during manufacture.

If appropriate, **product** cleaned in accordance with a) or b) above need not be subject to the preceding particular requirements, i.e. A) Personnel and B) Environmental control in manufacture, prior to the cleaning procedure.

D) *Maintenance*

The **supplier** shall establish and document requirements for maintenance activities when such activities may affect **product** quality.

Records of such maintenance shall be kept (see **4.16**).

E) *Installation*

If appropriate, the **supplier** shall establish and document both instructions and acceptance criteria for installing and checking the **medical device**.

Records of installation and checking performed by the supplier or his authorized representative shall be retained (see **4.16**).

If the contract (see **4.3**) allows installation other than by the **supplier** or his authorized representative, the **supplier** shall provide the purchaser with written instructions for installation and checking.

4.9.2 ***Special processes***

Clause **4.9.2** of EN 29001 : 1987 applies.

Particular requirements for all medical devices:

The **supplier** shall ensure that the quality records (see **4.16**) identify:

a) the work instruction used;

b) the date the special process was performed;

c) the identity of the operator of the special process.

Additional requirement for sterile medical devices:

The **supplier** shall subject the **medical devices** to a validated sterilization process and record (see **4.16**) all the control parameters of the sterilization process.

4.10 Inspection and testing

4.10.1 ***Receiving inspection and testing***

Clause **4.10.1** of EN 29001 : 1987 applies.

4.10 Inspection and testing

4.10.1 *General*

The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

4.10.2 ***Receiving inspection and testing***

4.10.2.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in **4.10.2.3**) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan and/or documented procedures.

4.10.2.2 In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided.

4.10.2.3 Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see **4.16**) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

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4.10.3 ***In-process inspection and testing*** The supplier shall: a) inspect and test the product as required by the quality plan and/or documented procedures; b) hold product until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see **4.10.2.3**). Release under positive-recall procedures shall not preclude the activities outlined in **4.10.3**a).	**4.10.2** ***In-process inspection and testing*** Clause **4.10.2** of EN 29001 : 1987 applies.
4.10.4 ***Final inspection and testing*** The supplier shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements. The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements. No product shall be despatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.	**4.10.3** ***Final inspection and testing*** Clause **4.10.3** of EN 29001 : 1987 applies.
4.10.5 ***Inspection and test records*** The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see **4.13**). Records shall identify the inspection authority responsible for the release of product (see **4.16**).	**4.10.4** ***Inspection and test records*** Clause **4.10.4** of EN 29001 : 1987 applies. *Particular requirement for active implantable medical devices and implantable medical devices:* The **supplier** shall record (see **4.16**) the identity of personnel performing any inspection or testing.
4.11 Control of inspection, measuring and test equipment **4.11.1** ***General*** The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which	**4.11 Inspection, measuring and test equipment** Clause **4.11** of EN 29001 : 1987 applies.

ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptablility of product, prior to release for use during production, installation or servicing, and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see **4.16**).

Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate.

NOTE 17. For the purposes of this International Standard, the term 'measuring equipment' includes measurement devices.

4.11.2 *Control procedure*

The supplier shall:

a) determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision;

b) identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;

c) define the process employed for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;

d) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;

e) maintain calibration records for inspection, measuring and test equipment (see **4.16**);

f) assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration;

g) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

h) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained;

i) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

NOTE 18. The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance.

4.12 Inspection and test status

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspection and tests (or released under an authorized concession (see **4.13.2**)) is dispatched, used or installed.

4.12 Inspection and test status

Clause **4.12** of EN 29001 : 1987 applies.

4.13 Control of nonconforming product

4.13.1 ***General***

The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.

4.13 Control of nonconforming product

Clause **4.13** of EN 29001 : 1987 applies.

4.13.2 ***Review and disposition of nonconforming product***

The responsibility for review and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be reviewed in accordance with documented procedures. It may be

a) reworked to meet the specified requirements;

b) accepted with or without repair by concession;

c) regraded for alternative applications; or

d) rejected or scrapped.

When required by the contract, the proposed use or repair of product (see **4.13.2**b)) which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see **4.16**).

Repaired and/or reworked product shall be re-inspected in accordance with the quality plan and/or documented procedures.

4.13.1 ***Nonconformity review and disposition***

Clause **4.13.1** of EN 29001 : 1987 applies.

Particular requirements for all medical devices:

The **supplier** shall ensure that nonconforming **product** is accepted by concession only if regulatory requirements are met. The identity of the person authorizing the concession shall be recorded (see **4.16**).

If **product** needs to be reworked, the **supplier** shall document the rework in a work instruction that has undergone the same authorization and approval procedure as the original work instruction.

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4.14 Corrective and preventive action

4.14.1 ***General***

The supplier shall establish and maintain documented procedures for implementing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

4.14.2 ***Corrective action***

The procedures for corrective action shall include:

a) the effective handling of customer complaints and reports of product nonconformities;

b) investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation (see **4.16**);

c) determination of the corrective action needed to eliminate the cause of nonconformities;

d) application of controls to ensure that corrective action is taken and that it is effective.

4.14.3 ***Preventive action***

The procedures for preventive action shall include:

a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyse and eliminate potential causes of nonconformities;

b) determination of the steps needed to deal with any problems requiring preventive action;

c) initiation of preventive action and application of controls to ensure that it is effective;

d) ensuring that relevant information on actions taken is submitted for management review (see **4.1.3**).

4.15 Handling, storage, packaging, preservation and delivery

4.15.1 ***General***

The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.

4.15.2 ***Handling***

The supplier shall provide methods of handling product that prevent damage or deterioration.

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4.14 Corrective action

Clause **4.14** of EN 29001 : 1987 shall apply.

Particular requirements for all medical devices:

The **supplier** shall establish and maintain a documented feedback system to provide early warning of quality problems and for input into the corrective action system.

If this European Standard is used for compliance with regulatory requirements which require post marketing surveillance, this surveillance shall form part of the feedback system.

All feedback information, including reported **customer complaints** and returned **product**, shall be documented, investigated, interpreted, collated and communicated in accordance with defined procedures by a designated person (see **4.1.2.1** and **4.1.2.2**).

If any **customer complaint** is not followed by corrective action, the reason shall be recorded.

The **supplier** shall maintain records (see **4.16**) of all complaint investigations. When the investigation determines that the activities at remote premises played a part in the complaint, a copy of the report shall be sent to those premises.

If this European Standard is used for compliance with regulatory requirements, the **supplier** shall establish, document and maintain procedures to notify the regulatory authority of those incidents which meet the reporting criteria.

The **supplier** shall establish, document and maintain procedures for the issue of **advisory notices** and the **recall** of **medical devices**. These procedures shall be capable of being implemented at any time.

4.15 Handling, storage, packaging and delivery

4.15.1 ***General***

Clause **4.15.1** of EN 29001 : 1987 applies.

Particular requirements for all medical devices:

The **supplier** shall establish and maintain documented procedures for the control of **product** with a limited shelf life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded.

If appropriate, special provisions shall be made for the handling of used **product** in order to prevent contamination of other **product**, the manufacturing environment or personnel.

4.15.2 ***Handling***

ISO 9001 : 1994	EN 46001 : 1993
4.15.3 ***Storage***	4.15.3 ***Storage***
The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated. In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.	Clause **4.15.3** of EN 29001 : 1987 applies.
4.15.4 ***Packaging***	4.15.4 ***Packaging***
The supplier shall control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.	Clause **4.15.4** of EN 29001 : 1987 applies. *Particular requirements for sterile medical devices:* The **supplier** shall establish and maintain procedures to ensure that: a) the **medical device** is presented in a container which maintains the sterility of the **medical device**, except for those **medical devices** for which only the inner surfaces of the **medical device** are sterile and the **medical device** is such that the sterility of the inner surfaces is maintained; b) the **medical device** is capable of being presented in an aseptic manner, if its use so requires; c) the package, or **medical device** if only the inner surface is sterile, clearly reveals that it has been opened. *Additional requirements for active implantable medical devices and implantable medical devices:* The **supplier** shall record the identity of persons who perform the final **labelling** operation (see **4.16**).
4.15.5 ***Preservation***	
The supplier shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.	
4.15.6 ***Delivery***	4.15.5 ***Delivery***
The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.	Clause **4.15.5** of EN 29001 : 1987 applies. *Particular requirements for active implantable medical devices and implantable medical devices:* The **supplier** shall ensure that the name and address of the shipping package consignee is included in the quality records (see **4.16**). The **supplier** shall require that any authorized representative maintains records of distribution of **medical devices** and that such records are available for inspection.

ISO 9001 : 1994

4.16 Control of quality records

The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

NOTE 19. Records may be in the form of any type of media, such as hard copy or electronic media.

4.17 Internal quality audits

The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits shall be recorded (see **4.16**) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on the deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see **4.16**).

NOTE 20. The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3).

NOTE 21. Guidance on quality system audits is given in ISO 10011.

EN 46001 : 1993

4.16 Quality records

Clause **4.16** of EN 29001 : 1987 applies.

Particular requirements for all medical devices:

The **supplier** shall retain the quality records for a period of time at least equivalent to the lifetime of the **medical device** defined by the **supplier**, but not less than 2 years, from the date of dispatch from the **supplier**.

The **supplier** shall establish and maintain a record for each batch of **medical devices** that provides traceability to the extent required by **4.8** and identifies the quantity manufactured and quantity released for distribution. The batch record shall be **verified** and authorized.

NOTE. A batch may be a single **medical device**.

4.17 Internal quality audits

Clause **4.17** of EN 29001 : 1987 applies.

ISO 9001 : 1994	EN 46001 : 1993
4.18 Training The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see **4.16**).	**4.18 Training** Clause **4.18** of EN 29001 : 1987 applies. *Particular requirement for all medical devices:* The **supplier** shall ensure that all personnel who are required to work under special environmental conditions or who perform special processes (see **4.9.2**) or functions are appropriately trained or supervised by a trained person.
4.19 Servicing Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements.	**4.19 Servicing** Clause **4.19** of EN 29001 : 1987 applies.
4.20 Statistical techniques **4.20.1** ***Identification of need*** The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics. **4.20.2** ***Procedures*** The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in **4.20.1**.	**4.20 Statistical techniques** Clause **4.20** of EN 29001 : 1987 applies. *Particular requirement for all medical devices:* The **supplier** shall establish and maintain procedures to ensure that sampling methods are regularly reviewed in the light of the occurrence of nonconforming **product**, quality audit reports, feedback information (see **4.14**) and other appropriate considerations.