ISO13485:2003
- An Overview -

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This presentation is based on

- **ISO13485:2003,** ***Medical devices - Quality management systems - Requirements for regulatory purposes***
- **ISO/TR 14969,** ***Medical devices - Quality management systems - Guidance on the application of ISO13485:2003***

This presentation focuses on the key sections of ISO13485:2003:

Section 4.0 - Quality Management System Requirements

Section 5.0 - Management Responsibility

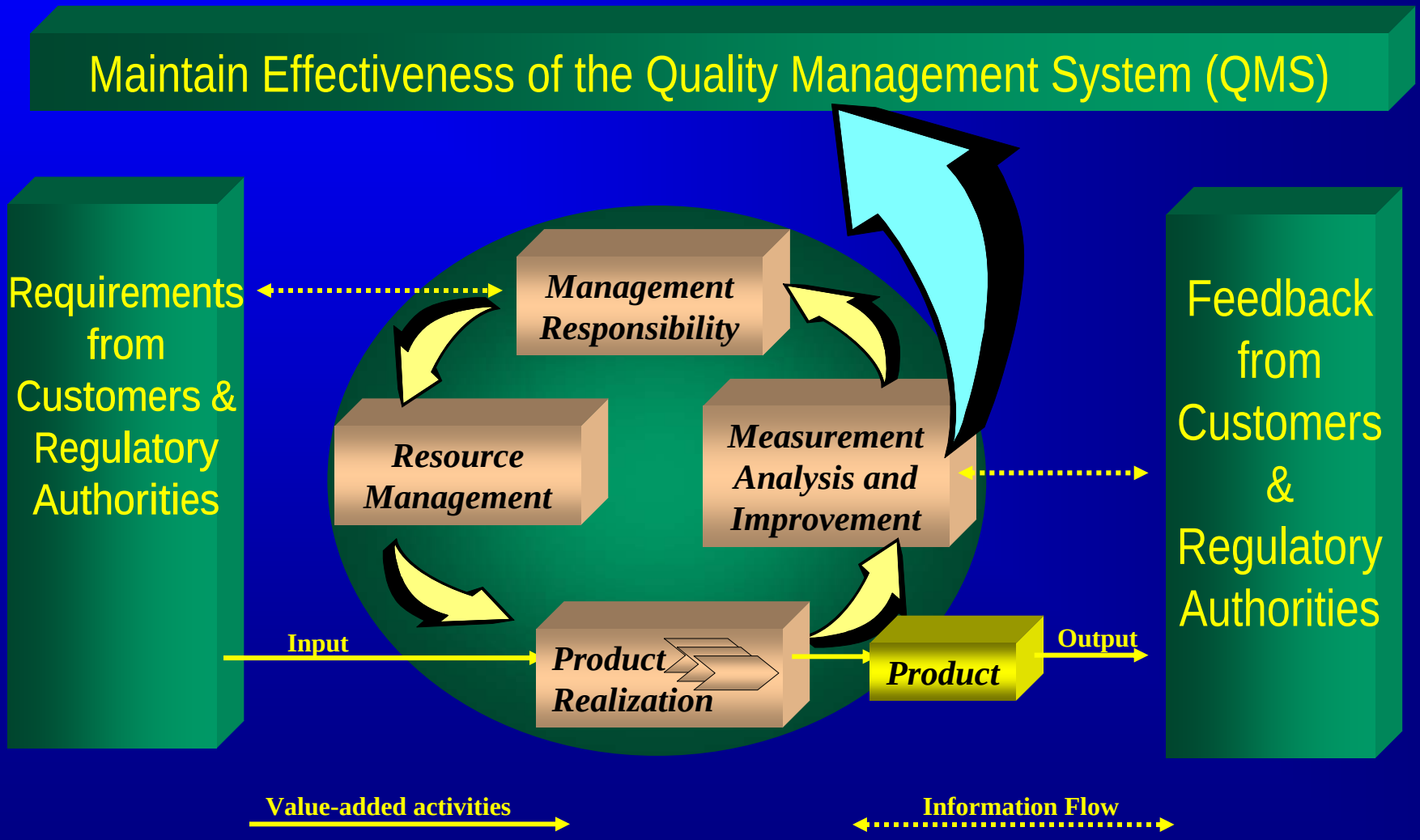
Section 6.0 - Resource Management

Section 7.0 - Product Realization

Section 8.0 - Measurement, Analysis, and Improvement

Process-oriented structure

ISO 13485:2003 promotes a process approach when developing, implementing, and improving a QMS



4. Quality Management System

4.1 - General requirements

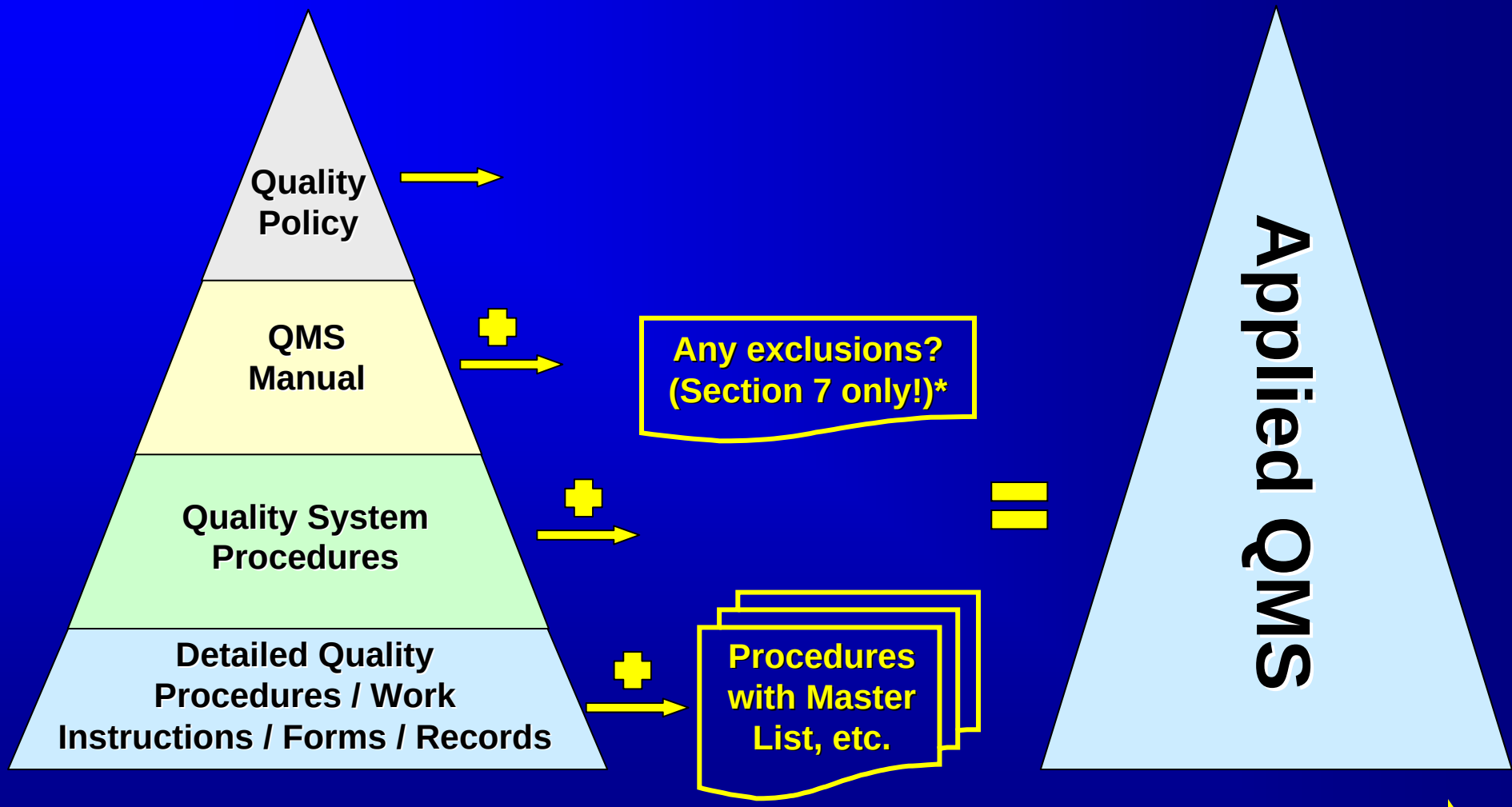
- Implementation and maintenance of an effective QMS to provide medical devices meeting customer and regulatory requirements.
- Ensure control of outsourced processes

Guidance Document SG3N17 currently being developed on what is considered adequate "control".

4.2 - Documentation requirements

- what is to be done and by whom, when, where, and how it is to be done, what materials, equipment and documents are to be used,
- how an activity is to be monitored and measured,
- Design History File, Technical File, Complaint File, device records, etc.

Quality System Definition



*see next slides

Product Realization - Exclusions

Exclusions of design and development (7.3) from the QMS is allowed only if allowed by regulation.
See NOTE 2 of 7.1: The organization ***MAY*** also apply the requirements given in 7.3 to the development of product realization processes.

Organizations whose quality management systems exclude design and development control (7.3 of ISO 13485), are still ***required to comply with the product verification and validation requirements as specified in 7.1 of ISO 13485 dealing with product realization*****.** In such organizations, the ***controls included in 7.3 should be considered for all changes made to the product***. Such changes will require objective evidence (e.g., product verifications and validations, inspection and test specifications, revised procedures, etc.) of the results of the activities described in 7.3 of ISO 13485.

Product Realization - Non-applicability

“Non-inclusion” of product realization requirements is allowed if those functions are not required by the nature of the medical device being provided by the organization.

For example, an organization providing single-use, sterile medical devices may not need to include within its quality management system elements related to installation and servicing.

5. Management Responsibility

5.1 Management commitment

- Is demonstrated by actions ensuring processes operate as an effective network of interrelated processes

5.2 Customer focus

- ensure customer requirements are understood

5.3 Quality policy

- Establishes commitment to: quality; continuing effectiveness of the quality management system; meeting customer and regulatory requirements
- Should be reviewed periodically for continued applicability

Case Study: Quality Policy

- The policy of Superior Devices, Inc., is to strive to sell products that satisfy our customers, comply with applicable standards and regulations, and reward employees who contribute substantially to our financial success with a share of our profits.
- Is this a good quality policy? Why or why not?

5. Management Responsibility

5.4 Planning

Includes:

- setting quality objectives & associated targets for the ***quality management system*** AND for ***medical devices & related services*** (see 7.1 a)
- defining timeframes for achieving targets

An organization's QMS is influenced by ***varying needs***, ***particular objectives***, the ***products provided***, the ***processes*** employed, the ***size & structure*** of the organization, etc.

5. Management Responsibility

5.4 Planning

Important

ISO13485 does **NOT** imply uniformity in the structure of quality management systems or uniformity of documentation!

5. Management Responsibility

5.5 Responsibility, authority and communication

Examples demonstrating Responsibility & Authority:

- documented position descriptions, including responsibilities and authorities
- organization charts
- can be included in documented procedures or flowcharts.
- Independence must be demonstrated for certain activities (e.g. internal audits, one design review participant; management representative)


Above documents must be controlled (see 4.2.3).


5. Management Responsibility

5.5 Responsibility, authority and communication

One management representative - designated by top management!

Functions can be entirely related to quality management system activities or in conjunction with other functions and responsibilities within the organization.

If responsibility for other functions, ensure no conflict of interest between the responsibilities!

5. Management Responsibility

5.5 Responsibility, authority and communication

Within an effective quality management system communications must be:

- encouraged
- clear and understandable
- bi-directional
- at all levels of the organization
- open and active

Examples: Internal audits, external assessments, management reviews, bulletin boards, all employee meetings, suggestion boxes, etc.

5. Management Responsibility

5.6 Management Review

Periodic assessment of the QMS for continued suitability, adequacy and effectiveness. **Inputs include:**

a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system,
g) recommendations for improvement, and
h) new or revised regulatory requirements.

5. Management Responsibility

5.6 Management Review

Outputs include:

a) agenda
b) attendance record
c) presentation materials
d) improvements needed to maintain the effectiveness of the quality management system and its processes
b) improvement of product related to customer requirements
c) resource needs
d) statement of conclusion the effectiveness of the quality management system

Case Study: Management Reviews Part 1

- Perfect Devices, Inc., (PD) established their quality system 5 years ago, and things have been running smoothly. They have been producing the same devices for the past 5 years. The FDA inspection 6 months ago was NAI. PD performs management reviews annually.
- Is an annual management review sufficient?

Case Study: Management Reviews Part 2

- Superior Medical, Inc., (SM) established their quality system 5 years ago. This year's production was double that of 5 years ago. Six months ago SM installed an ethylene oxide sterilization chamber and started distributing sterile devices. Several sterilization lots have failed. SM performs management reviews annually.
- Is an annual management review sufficient?

6. Resource Management

6.1 Provision of resources

Resources can be:

- people
- infrastructure
- work environment
- information
- suppliers and partners
- natural resources
- financial resources

Adequate resources are prerequisite to an effective QMS

6. Resource Management

6.2 Human Resources

Personnel performing work affecting product quality and device safety and effectiveness must be competent ….

- Qualifications include:
  - Education
  - Experience
  - Skills
  - EFFECTIVE Training (initial and refresher)
  - Formal certification (e.g. welding, soldering)

- Organization must be able to demonstrate this!

6. Resource Management

6.3 Infrastructure

Includes:

- Buildings
- Work space
- Utilities (water, electricity, waste management, etc.)
- Process equipment (software and hardware)
- Equipment maintenance activities & frequency
- Supporting services (cleaning, etc.)

If not considered and appropriately defined, the above examples can potentially affect conformance with product requirements!

Case Study: Facilities

- Oops! An existing piece of equipment was moved to make room for some new equipment. When scheduled maintenance was due on the first piece of equipment, the maintenance man was unable to perform these tasks, as the equipment was too close to the wall. He got creative and suggested installing doors in the wall to allow access to that side of the equipment. This is an outside wall!
- Is this an acceptable solution? Why or why not?

6. Resource Management

6.4 Work Environment

The most significant factors within the work environment that can affect product quality are:

- process equipment,
- established work environment (controlled environments, clean rooms, etc.)
- personnel – internal and ***external***! (health, cleanliness, protective equipment/gear, i.e. static dissipating wrist bands, hoods & gowning, etc.)

"Established" means defined, documented, implemented and maintained!

Case Study: Clean Rooms

- An electrical outlet in the clean room is not working, and an electrician has been called to replace it. SOPs (procedures) require employees who work in the clean room to wear a hair cover, face mask, shoe covers, lab coat and gloves.
- Should the electrician follow the same gowning procedures? Why or why not?

7. Product Realization

7.1 Planning of product realization

"Product realization" describes the processes starting with

- planning
- determination of customer requirements
- customer communication
- design and development (7.3),
- purchasing (7.4),
- production and servicing (7.5),
- control of monitoring and measuring devices (7.6)
- delivery of the medical device
- record keeping requirements

7. Product Realization

7.1 Planning of product realization

The organization shall determine :

- product quality objectives & requirements
- definition of medical device lifetime (record retention!)
- establishing processes & documents
- resource needs
- design and development (7.3),
- verification & validation
- monitoring and inspection
- test activities and product acceptance criteria
- **RISK MANAGEMENT**
- RECORDS

SG3/N15R8/2005 " Implementation of Risk Management Principles and Activities Within a Quality Management System" published in 2005

GHTF SG3 N15 Integrate Risk Management throughout product realization

- ISO 13485 requires the organization to establish documented requirements for risk management throughout product realization and suggests that ISO 14971 be consulted for guidance.

- SG3 developed SG3/N15R8/2005 to provide guidance on how to integrate risk management activities (for example those described in ISO 14971) into an ISO 13485:2003 based QMS.

7. Product Realization

7.2 Customer-related processes

Focus is on product and services to be supplied. This includes requirements related to the product:

- design input/output for new product development,
- customer delivery expectations vs. delivery schedules
- customer feedback & communications relative to orders placed or product delivered
- regulatory or legal requirements
- design related factors included in customer orders
- unspecified customer expectations.

7. Product Realization

7.2 Customer-related processes

Review of product requirements prior to committing to supply:

- product requirements defined & documented
- resolution of contract/order discrepancies
- ensure ability to meet defined requirements

Review of post-marketing product performance

- additional product information (e.g. service, additional applications, maintenance, upgrades)
- customer complaints
- advisory notices

Again, records are key!

7. Product Realization

7.3 Design and development

Established procedures describing design processes and ALL design activities

- goals and objectives of the design and development program (i.e. what is to be developed, timeline, etc.)
- the markets intended
- identification of organizational responsibilities with respect to assuring quality during the design and development phase, to include interface with any suppliers
- identification of the major tasks by phases of the design
- expected outputs (deliverables and records) from each phase

7. Product Realization

7.3 Design and development

Established procedures describing design processes and ALL design activities (cont.)

- identification of appropriate existing and anticipated measurement & monitoring devices for development of product specifications, verification, validation and production related activities
- the selection of reviewers & composition of review teams
- planning transfer to production
- risk management activities
- supplier selection

7. Product Realization

7.3 Design and development

Design inputs include:

- intended use of the device,
- Indications and contra-indications for use of the device,
- performance claims and performance requirements (including normal use, storage, handling and maintenance),
- user and patient requirements,
- physical characteristics,
- human factors/usability requirements,
- safety and reliability requirements,
- toxicity and biocompatibility requirements,

7. Product Realization

7.3 Design and development

Design inputs (cont.):

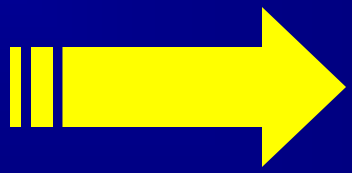
- electromagnetic compatibility requirements,
- limits/tolerances,
- measurement and monitoring instruments,
- risk management or risk reduction methods
- reportable adverse events, complaints, failures for previous products,
- other historical data,
- documentation for previous designs,
- compatibility requirements with respect to accessories and auxiliary devices,

7. Product Realization

7.3 Design and development

Design inputs (cont.):

- compatibility requirements with respect to the environment of intended use,
- packaging and labeling (including considerations to deter foreseeable misuse),
- customer/user training requirements,
- regulatory and statutory requirements of intended markets,
- relevant voluntary standards (including industry standards, national, regional or international standards, “harmonized” and other consensus standards),



7. Product Realization

7.3 Design and development

Design inputs (cont.):

- manufacturing processes,
- sterility requirements,
- economic and cost aspects,
- lifetime of the medical device requirements, and
- need for servicing.

Case Study: Hospital vs. Home Use

- For several years Advanced Devices has been selling a patient monitor for use in the hospitals. Recently one of their salespeople suggested marketing the patient monitor for home use since patients are spending less and less time in the hospital.
- Will home use change the design input? Why or why not?

Case Study: Hospital vs. Home Use

Considerations:

- User less skilled, no medical training
- Users impaired? Poor vision, poor manual dexterity?
- User environment different; electromagnetic interference from TV, cell phones, etc.
- Multiple users, etc.

7. Product Realization

7.3 Design and development

Design outputs may include:

- specifications for raw materials, component parts and sub-assemblies,
- drawings and parts list,
- customer training materials,
- process and materials specifications,
- finished medical devices,
- product and process software,
- quality assurance procedures (including acceptance criteria),
- manufacturing and inspection procedures,

7. Product Realization

7.3 Design and development

Design outputs (cont):

- work environment requirements needed for the device,
- packaging and labeling specifications,
- identification and traceability requirements (including procedures, if necessary),
- installation and servicing procedures and materials,
- documentation for submission to the regulatory authorities where the medical devices will be marketed, if appropriate, and
- a record/file to demonstrate that each design was developed and verified in accordance with the design and development planning

7. Product Realization

7.3 Design and development

Design reviews may address the following questions:

- Do designs satisfy specified requirements for the product?
- Is the input adequate to perform the design and development tasks?
- Are product design and processing capabilities compatible?
- Have safety considerations been addressed?
- What is the potential impact of the product on the environment?
- Do designs meet functional and operational requirements, for example, performance and dependability objectives?

7. Product Realization

7.3 Design and development

Design reviews (cont.):

- Have appropriate materials been selected?
- Have appropriate facilities been selected?
- Is there adequate compatibility of materials, components and/or service elements?
- Is the design satisfactory for all anticipated environmental and load conditions?
- Are components or service elements standardized and do they provide for reliability, availability and maintainability?
- Is there a provision in tolerances, and/or configuration, for interchangeability and replacement?

7. Product Realization

7.3 Design and development

Design reviews (cont.):

- Are plans for implementing the design technically feasible (e.g. purchasing, production, installation, inspection and testing)?
- If computer software has been used in design computations, modeling or analyses, has the software been validated, authorized, verified and placed under configuration control?
- Have the inputs to such software, and the outputs, been appropriately verified and documented?
- Are the assumptions made during the design processes valid?

Case Study: Design Review

- Can a formal design review be conducted without holding a meeting?
- Would circulating design review issues and approving outcomes by e-mail or on paper be an acceptable alternative to holding a meeting?

Case Study: Design Review

- Nowhere in the standard or the guidance is it stated that a design review must be conducted by holding a meeting!
- If all design review requirements of the standard are met, the design review could take place by e-mail or review of paper summary.
- Design reviews conducted by e-mail or paper probably are best used for relatively simple reviews.

Case Study: Design Review

- Please keep in mind that additional requirements may exist for electronic records, as well as electronic signatures.

- If design reviews are conducted via e-mail or paper copy circulation, results of the review will still need to be documented. Documentation typically includes identifying attendees, which is best done by signatures next to printed name. Print a signature page from the e-mail, sign and scan it and retain in the Design History File.

Case Study: Design Review

- Persons making authorized entries on records or verifying such entries should do so in clear legible writing, and should confirm the entry by adding their initials, signature or equivalent, and the date (14969 guidance).

7. Product Realization

7.3 Design and development

Design verification is necessary to ensure that the design outputs conform to specified requirements (design inputs).

- tests (bench tests, lab tests, chemical analysis, etc.)
- alternative calculations,
- comparison with proven design,
- inspections, and
- document reviews (e.g. specifications, drawings, plans, reports).

7. Product Realization

7.3 - Design and development

Design validation goes beyond the technical issues of verifying output met input. It is intended to ensure that the medical device meets user requirements and the intended use.

- actual or simulated conditions
- consider capability and knowledge of user
- operating instructions
- compatibility with other systems
- the environment in which it will be used
- any restriction on the use of the product
- performed on production or production equivalent unit(s)

If production equivalent – need to document why it is equivalent!

7. Product Realization

7.3 Design and development
Control of design and development changes

- Product design may require change or modification for many reasons.
- Change can happen during or after the design phase
- Changes may result from:
  - design review
  - design verification or validation
  - omissions or errors during the design phase which have been identified afterwards

7. Product Realization

7.3 Design and development

- Changes may result from:
  - difficulties in manufacturing, installation and/or servicing
  - risk management activities,
  - requests from the customer or supplier,
  - changes required for corrective or preventive action
  - changes needed to address safety, regulatory, or other requirements
  - improvements to function or performance

7. Product Realization

7.3 Design and development

- When changes are necessary, evaluate effects on:
  - product requirements and specifications
  - intended use
  - current risk assessment
  - different components of the product or system
  - manufacture, installation or use
  - Verification and validation
  - the regulatory status of the product

7. Product Realization

7.4 Purchasing

Guidance Document SG3N17
currently being developed on what is adequate "control".

Supplier selection and control consists of:

- establishing criteria (product, parts, quality system, process controls, metrology, etc.)
- evaluating against those predetermined criteria
- selecting
- ongoing monitoring

The extent depends on the nature and risk associated with the product or service, and includes outsourced processes.

Purchasing should only occur from list of approved suppliers!

Case Study: Purchasing Controls

- Perfect Devices, Inc. is evaluating potential suppliers of a plastic resin for injection molded parts. Perfect contacted several potential suppliers to schedule audits to evaluate them, but two large firms have declined to be audited.
- What should Perfect Devices, Inc. do?

1. Buy only from firms allowing audits?
2. Find another way to evaluate large firms?
3. Other alternatives?

7. Product Realization

7.4 Purchasing

Purchasing information describes the product to be purchased in sufficient detail, such as:

- technical information and specifications,
- test and acceptance requirements,
- quality requirements for products, services, and outsourced processes,
- environmental requirements (in manufacturing, storage, transportation, etc.)
- regulatory requirements,
- certification requirements

Case Study: Incoming Acceptance - 1

- Perfect Devices, Inc. recently selected three new suppliers based on the following information:
  1. Aim To Please, Inc.: Supplier audit documented an excellent quality system.
  2. A-1 Plastics: Refused audit, highly recommended by other device manufacturers.
  3. OK Parts, Inc.: Sole source of component! Supplier audit: No quality system!
- Which approach to acceptance of incoming components would you recommend for each supplier?

Case Study: Incoming Acceptance - 2

Aim to Please, Inc. - A-1 Plastics - OK Parts, Inc.

From ANSI.ASQ Z1.4:

1. “Tightened Inspection followed by normal inspection when 5 consecutive lots are acceptable
2. “Normal Inspection” followed by reduced inspection and 10 consecutive lots are accepted and additional criteria in 8.3.3.b are met.

7. Product Realization

7.4 Purchasing

Purchasing information (cont.):

May also include:

- requirements for product approval and subsequent changes
- procedures, processes & equipment
- qualification of personnel
- QMS requirements
- method of communication
- responsibilities (special instructions, traceability & test records, record retention & retrievability, etc.)
- conditions for review & changes to purchasing agreement

SUPPLIER RECORDS and the **ORGANIZATION'S RECORDS**

7. Product Realization

7.4 Purchasing

Verification of purchased product to ensure specified requirements are met:

- receiving Inspection (shipments are complete, properly identified, undamaged)
- product incoming inspection (100%, sampling, skip lot, etc.)
- certification of suppliers
- certificates of conformance or acceptance test reports from supplier

Must be procedurally defined within the organization's QMS, ***including actions when requirements are not met***!

Applies to *ALL product received from outside the organization's QMS*!

7. Product Realization

7.5 Production and service provision

Control of production and service requires ***controlled conditions*** and includes many aspects:

- infrastructure (see 6.3)
- documentation and records (procedures, specifications, work instructions, test results, etc.)
- defined by *impact on quality* & *regulatory requirements* as well as *output from risk management activities*
- suitable equipment (process, measurement, monitoring)
- activities for release, delivery, and post delivery, including traceability

Records are key!

Case Study: Installation Instructions

- Zap Em, Inc. manufactures linear accelerators for radiation therapy for cancer. Zap Em installs the equipment for a significant fee. Hospitals have requested installation instructions for self-installation. Zap Em says they would be glad to provide instructions and equipment if the hospital employees attend Zap Em's 2 day installer training for $9,500.
- Is Zap Em entitled to withholding instructions from 3rd party installers unless they attend a training course?

7. Product Realization

7.5 Production and service provision

Validation of processes for production & service is required where the resulting output cannot be verified!

Guidance document
SG3/N99-10 (Edition 2) " Quality Management Systems - Process Validation Guidance." published.

- defined criteria for review and approval of processes
- approval of equipment and ***personnel qualification*** 
- use of specific methods and procedures
- criteria for revalidation 
- software used in automated processes **MUST** be validated 

7. Product Realization

7.5 Production and service provision
Validation of processes for production & service (cont.)

Process validation activities can be described in phases:

- definition, review and approval of equipment specifications
- installation qualification (IQ)
- operational qualification (OQ)
- performance qualification (PQ)

Validation is a complex activity – SG 3 has developed specific guidance on this topic (GHTF/SG3/N99-10:2004).
A separate presentation “Process Validation Guidance” addresses this in greater detail.

7. Product Realization

7.5 Production and service provision

Identification is required throughout the product realization process. It includes:

- raw materials
- components
- finished medical devices

This facilitates fault diagnosis in the event of quality problems and is a pre-requisites for traceability!

Provisions for identifying & segregating returned medical devices from conforming product must also be established!

7. Product Realization

7.5 Production and service provision

Traceability means the ability to trace the history or location of a product or activity by recorded identification:

- forward to customers (also known as “device tracking”)
- backward to raw materials, components, processes used in manufacturing, calibration, etc.

Example: trace a nonconformity back to it’s source and determine location of the remainder of the affected batch/series.

Particular requirements are defined for implantable devices!

7. Product Realization

7.5 Production and service provision

Customer property within the context of the standard is defined as property or assets owned by the customer and under control of the organization.

Examples of such property are

- raw materials or components supplied for inclusion in product (including packaging materials),
- product supplied for repair, maintenance or upgrading,
- product supplied for further processing (e.g., packaging, sterilization or testing),
- customer intellectual property

These must be properly identified, safeguarded, maintained, etc.

7. Product Realization

7.5 Production and service provision

Preservation of product applies throughout the product realization processes and includes storage, handling, transportation and delivery (may include installation).

- gloves, static-dissipative measure, gowning,
- temperature, humidity, dust (particle count),
- packaging
- method of transportation (air, sea, ground, environmentally controlled, etc.)

To avoid damage, deterioration or contamination during handling, storage, distribution.

7. Product Realization

7.6 Control of monitoring and measuring devices

The standard explicitly refers to monitoring and measuring devices, **including software**. To ensure valid results, instruments shall be

- calibrated or verified at specified intervals (traceable to standard!)
- uniquely identified (traceability to products!)
- protected from damage/deterioration or inadvertent adjustment during storage and use

Software used in the monitoring or measurement process must be validated!

Exempt from calibration may be: instruments used for indication only (not quantitative!), volumetric measurement glassware, etc.

8. Measurement, analysis and improvement

8.1 General

Monitoring and measurement processes are required to:

- ensure product conformance
- ensure conformance of the QMS
- maintain effectiveness of the QMS

These processes include measurement and analysis of products AND processes.

8. Measurement, analysis and improvement

8.2 Monitoring and Measurement

Feedback as key performance indicators of the QMS include:

- customer related information, post-market surveillance, etc.)
- internal & external audit results
- monitoring and measurement of processes (not limited to production processes but also QMS processes!)
- monitoring and measurement of product (may extend to point of installation!)

8. Measurement, analysis and improvement

8.3 Control of nonconforming product

This includes nonconforming product occurring in the organization's own facilities as well as to nonconforming product **received** or **delivered** by the organization.

- determine product(s) affected
- identify the nonconforming product (at supplier, in house, in transit, at customer)
- document the existence and root cause of the nonconformity
- evaluate the nature of the nonconformity

8. Measurement, analysis and improvement

8.3 Control of nonconforming product (cont.)

- determine and record disposition to be made,
- control (e.g. by physical segregation) the subsequent processing of the nonconforming product consistent with the disposition decision
- notify others as appropriate (regulatory authorities, customer, supplier, alternate manufacturing facilities, etc.)
- define and implement **corrective** and **preventive** actions
- assess the effectiveness of corrective and preventive actions

8. Measurement, analysis and improvement

8.4 Analysis of data

This includes determination, collection, and analysis of appropriate data to demonstrate the

- suitability and effectiveness of the QMS and
- to evaluate if improvement of the QMS effectiveness can be made.

This encompasses supplier performance, product conformance, trends of processes & products, feedback, etc.

The results of these activities should feed into management reviews as well considered for risk management activities.

They also serve to identify opportunities for preventive actions.

Case Study: Data Analysis

- Which items below would be appropriate data sources to analyze to identify non-conforming product and quality problems?

1. Incoming Acceptance Records
2. Complaints
3. Service Records
4. Sales Figures
5. Internal Audits
6. Records of Installation
7. Customer Lists
8. Reports of external audits
9. Personnel Records
10. Lawsuits
11. Finished device Acceptance Records
12. In process Acceptance Records

Case Study: Data Analysis

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5. **Internal Audits**
6. **Records of Installation**
7. Customer Lists
8. **Reports of external audits**
9. Personnel Records
10. **Lawsuits**
11. **Finished device Acceptance Records**
12. **In process Acceptance Records**

8. Measurement, analysis and improvement

8.5 Improvement

This again covers a broad scope:

- continued suitability and effectiveness of the QMS
- documented complaint investigations and resulting actions
- product advisory notices (field corrective actions, etc.) communicated to customers and (where applicable) to regulatory authorities

8. Measurement, analysis and improvement

8.5 Improvement

Corrective action is intended to eliminate nonconformities with the intent to prevent recurrence. Nonconformities may be identified

- in the QMS
- on the product
- in manufacturing processes
- in metrology
- with training
- environmental conditions
- control of equipment
- with suppliers, etc.

SG3 has identified the need to develop guidance documents on "significance of nonconformities" and "CAPA principles and practices"

8. Measurement, analysis and improvement

8.5 Improvement

Effective **corrective action** includes the following:

- clear and accurate identification of the nonconformity
- affected process(es) or procedure(s)
- identification of affected device(s) and recipient(s)
- identification of the root cause of the nonconformity,
- action required to prevent recurrence
- required approvals prior to taking action
- records that corrective action was taken as identified
- Effectiveness checks (likely to prevent recurrence, no new risks introduced by the corrective action, etc.)

8. Measurement, analysis and improvement

8.5 Improvement

Preventive action is initiated to address ***potential*** nonconformities. Sources to consider include information & data from:

- receiving and incoming inspection
- products requiring rework, reject or yield data
- customer feedback and warranty claims,
- process measurements,
- identification of results that are out-of-trend but not out-of-specification,
- suppliers performance
- service reports, and,
- concessions/deviations.

While the information covered during this session is based on ISO13485:2003 and ISO/TR14969,

it essentially describes

GOOD BUSINESS PRACTICES.

If successfully implemented, the organization's quality system will meet the requirements of the European Medical Device Directive (MDD 93/42/EEC).

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 1030 / 13485 / 1

Certification Médical-Santé

Le LNE certifie que le système qualité développé par
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3000 North Grandview Blvd.
WAUKESHA, WI 53188
USA

pour les activités / *for the activities*

Conception, fabrication, contrôle final de dispositifs ou systèmes de diagnostic tomodensitométre par émission de positron, dispositifs ou systèmes de diagnostic X-Ray, dispositifs ou systèmes de diagnostic tomodensitométres (scanners), gaines équipées (gaine + tube radiogène)
Design, manufacture, final test of medical diagnostic positron emission tomography devices or systems, medical diagnostic X-Ray devices or systems, diagnostic computed tomography devices or systems, X-ray tube assembly (housing + tube)

réalisées sur le site de / *performed on the location of*

GE Medical Systems, LLC
3000 North Grandview Blvd.
WAUKESHA, WI 53188, *USA*

GE Medical Systems, LLC
4855 Electric Avenue
MILWAUKEE 53219 - USA

est conforme aux exigences de la norme internationale
complies with the requirements of the international standard

ISO 13485 (2003)

Date de délivrance : 31 mars 2005
Date of issue : March 31, 2005

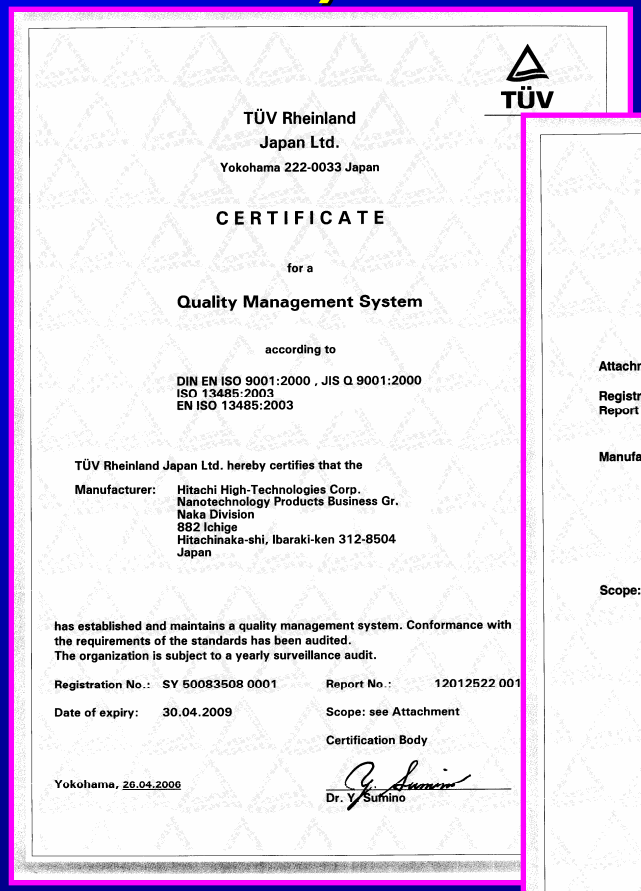
Date d'échéance de validité : 20 décembre 2005 (inclus)
Limit expiry date : December 20, 2005 (included)

Pour Le Directeur Général
For the General Director
Laurence DAGALLIER
Directeur Certification
Certification Director

cofrac

2004-12-15

LABORATOIRE NATIONAL D'ESSAIS • Établissement Public à Caractère Industriel et Commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier 75724 Paris Cedex 15 • Tél. 01 40 43 37 00 • 01 40 43 39 78 • Fax 01 40 43 37 37 • Internet : www.lne.fr



TÜV

TÜV Rheinland
Japan Ltd.
Yokohama 222-0033 Japan

CERTIFICATE

for a

Quality Management System

according to

DIN EN ISO 9001:2000 , JIS Q 9001:2000
ISO 13485:2003
EN ISO 13485:2003

TÜV Rheinland Japan Ltd. hereby certifies that the

Manufacturer: Hitachi High-Technologies Corp.
Nanotechnology Products Business Gr.
Naka Division
882 Ichige
Hitachinaka-shi, Ibaraki-ken 312-8504
Japan

has established and maintains a quality management system. Conformance with the requirements of the standards has been audited.
The organization is subject to a yearly surveillance audit.

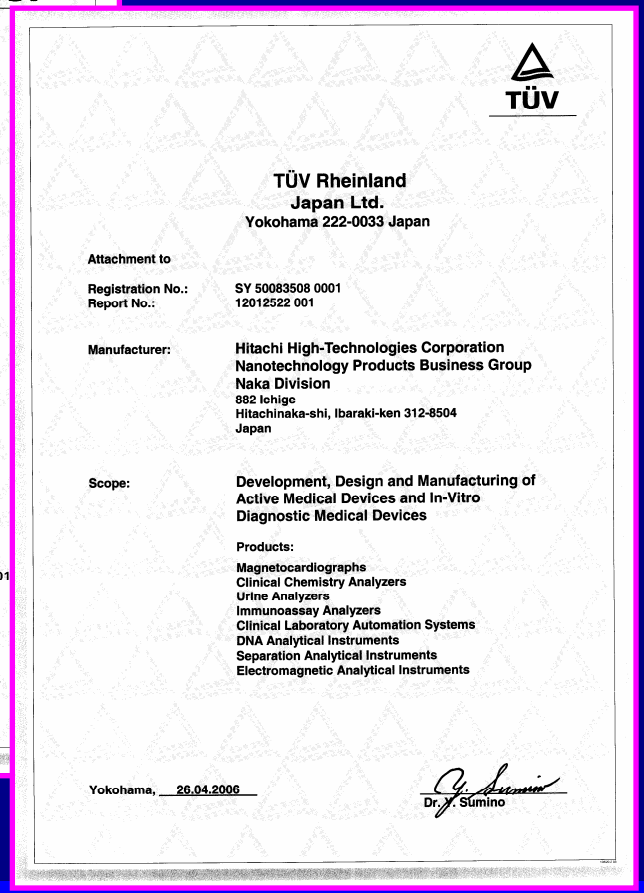
Registration No.: SY 50083508 0001 Report No.: 12012522 001

Date of expiry: 30.04.2009 Scope: see Attachment

Certification Body

Yokohama, 26.04.2006

Dr. Y. Sumino



TÜV

TÜV Rheinland
Japan Ltd.
Yokohama 222-0033 Japan

Attachment to

Registration No.: SY 50083508 0001
Report No.: 12012522 001

Manufacturer: Hitachi High-Technologies Corporation
Nanotechnology Products Business Group
Naka Division
882 Ichige
Hitachinaka-shi, Ibaraki-ken 312-8504
Japan

Scope: Development, Design and Manufacturing of Active Medical Devices and In-Vitro Diagnostic Medical Devices

Products:

Magnetocardiographs
Clinical Chemistry Analyzers
Urine Analyzers
Immunoassay Analyzers
Clinical Laboratory Automation Systems
DNA Analytical Instruments
Separation Analytical Instruments
Electromagnetic Analytical Instruments

Yokohama, 26.04.2006

Dr. Y. Sumino

For further guidance, please refer to

ISO/TR 14969

Thank you on behalf of Study Group 3 and the GHTF for your time and attention.

Questions?

APPENDIX

Examples of Key Records

- Management Review (5.6.1)
- Education, training, skills and experience (6.2.2.e)
- Product realization processes (7.1.d)
- Product requirements review and action (7.2.2)
- Product requirements inputs (7.3.2)
- Design reviews and actions (7.3.4)
- Design verification and actions (7.3.5)
- Design validation and actions (7.3.6)
- Design changes (7.3.7)
- Design change reviews (7.3.7)

Examples of Key Records (cont.)

- Supplier evaluation and actions (7.4.1)
- Process validation (7.5.2)
- Traceability (7.5.3)
- Customer notification regarding damage to customer property (7.5.4)
- Production or service delivery, as determined to be necessary for special processes (7.5.2)
- Review of previous measuring results when measuring equipment is found not to conform to requirements (7.6)
- Calibration or verification (7.6)

Examples of Key Records (cont.)

- Internal audits (8.2.2)
- Product release authorization (8.2.4)
- Nonconformities and actions taken (8.3)
- Corrective actions taken (8.5.2 e)
- Preventive actions taken (8.5.3 d)