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ČSN EN ISO 9001: 2015
ČSN EN ISO 13485: 2016
ČSN EN ISO 14001: 2015

93/42/EU (MDD)
2014/68/EU (PED)

Obsah / Contents

1 Kontext organizace / Context of the organization

The Quality Manual specifies the quality system means, through which the qualification of the producer to design and deliver a conforming product is achieved, and methods of demonstration of conformity with requests for the product quality. The specified methods are aimed especially at reaching of customer's satisfaction by preventing nonconformity in all phases from design up to service.

The management of our organization considers the introduction and maintenance of the quality management system to be a strategic resolution. We adjust the quality management system implementation to the context of the organization in consideration of possible risks, needs and expectations of clients and other engaged parties.
The organization set the internal and external aspects that are relevant for its purposes and strategic directions and the affect its ability to reach intended results within the quality management system.
The organization specified the engaged parties being of relevance for its QMS and their justified requirements.
The organization set the limits and applicability of its QMS so as to specify its extent. There were taken into consideration:

- external and internal aspects;
- requirements of relevant engaged parties;
- manufactured and supplied products.

The quality management system relates to the whole organization and all of its work sites and processes in full extent. It includes all the functions and departments displayed in the organization structure.

1.1 Rozsah a působnost příručky / Extent and force of the manual

The Quality Manual is outlined as an obligatory document.

In compliance with stipulations of individual articles of standards the manual relates to all the field of the company activities.

In the production assortment it means the appropriate level of demonstrability of real status conformity with requirements of standards and statutory regulations in all the processes being performed within the company.

The document is binding for all the persons employed in BMT Medical Technology s.r.o. Each employee of the company is personally responsible to his/her superior for observing the stipulations of the Manual. Assigned responsibilities cannot be delegated.

The Quality Manual takes into account the principles of quality arrangement for design, development, manufacture, putting into market and operation and service of medical devices and pressure equipment.

Requirements of standard articles related to sterile medical devices (7.5.5; 7.5.7) and implantable medical means (7.5.9.2) are not applied in consideration of the production character.

1.2 Řízení a správa příručky kvality / Management and administration of the Quality manual

- The management and administration of the Quality Manual is regulated by general rules specified in QSM 05-01.
- The QM section is responsible for storing, updating, distribution, change proceedings and filing.
- The current version of the Quality Manual is available in the program ISO PACK, database "Controlled Documentation ".
- Definitions, references and expert terminology, used in this manual, represent the application of expressions specified in ISO 9000.

2 Normativní odkazy / Normative references

The below stated documents are necessary for use of this document.

ČSN EN ISO 9001 (next ISO 9001)

ČSN EN ISO 13485 (next ISO 13485)

ČSN EN ISO 14001 (next ISO 14001)

In case of date-specified references, only the date-specified version applies. In case of references without date specification, the last version of referred document applies.

The contents of the Quality Manual was further extended in legislative requirements of the Directive MDD 93/42/EEC related to medical devices and the Directive PED 2014/68/EC related to pressure devices and Act No. 123/2000 Coll.

3 Termíny a definice / Terms and definitions

BMT	BMT Medical Technology s.r.o.
ČR	Czech Republic
ČSN	Czech national standard
EMS	Environmental management
EŘ	Economic management
EU	European Union
HE	Main standard
HN	Tool management
HV	Finished product
IP	Internal inspection
KS	Designing department
ME	Marketing export
MJ	Quantity unit
MŘ	Marketing director
NA	Purchase
OM	Rough gauge
OV	Production organization
PE	Firm standard
PM	Working gauge
LZ	Human resources
PVJ (ZPJ)	Management representative for quality (Representative for quality)
QAM	Quality Manual
QSM	Quality system directive
QPP	Operation procedure
QZJ	Quality record
RS	Repair and service
ŘJ	Quality management
ŘV	Production management
SM	Specified gauge
SJ	Quality system
THP	Engineering-economic worker
TK	Engineering inspection
TM	Inland marketing
TP	Technological procedure
TR	Technological development
TS	Service
TZ	Pressure device
VV	Production management
VKS	Technical manager of the designing department
VTK	Input engineering inspection

ZP Labour Code

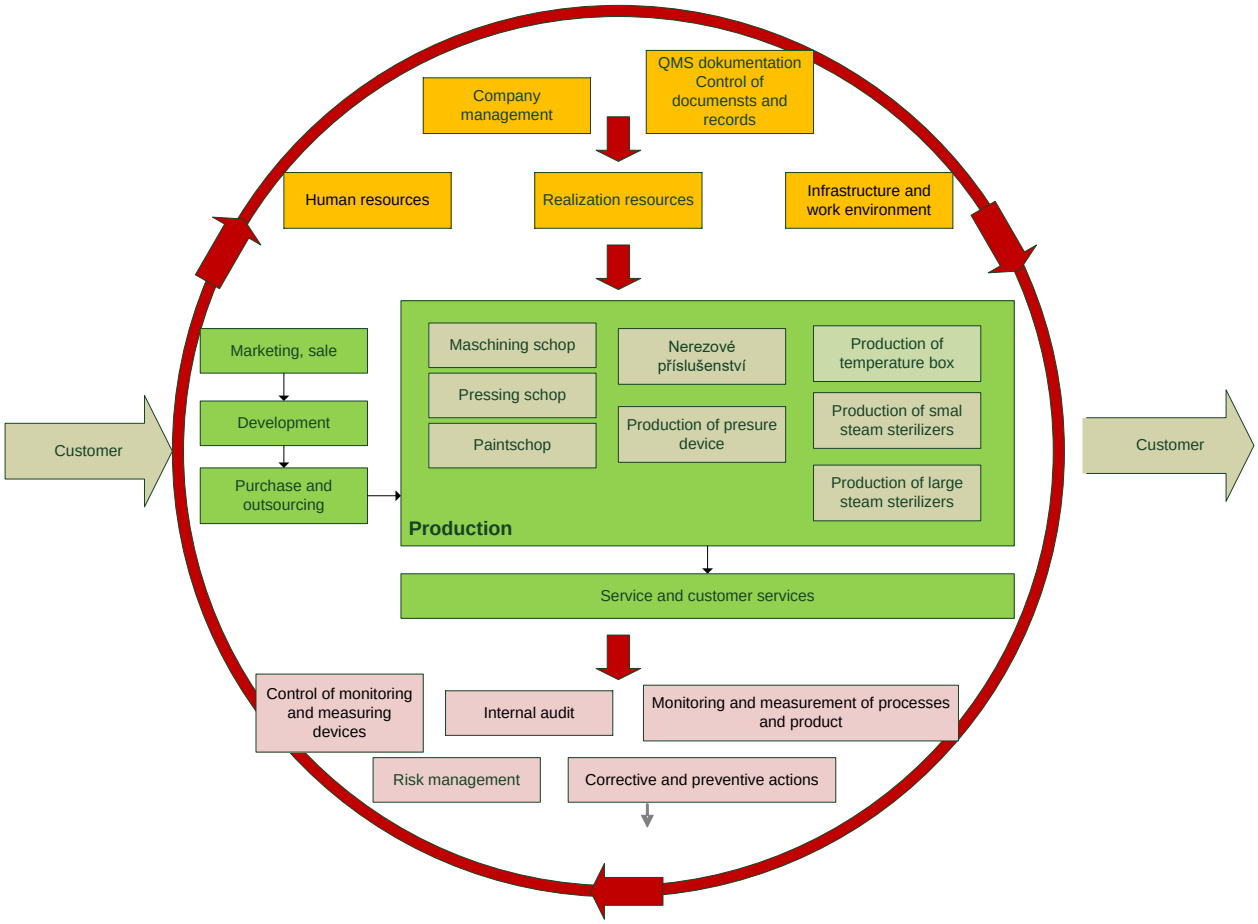
ŽP Environment

Environmental aspect: element of activities, products or services of an organization that may affect the environment (e.g. wastes)

Environmental aim: general environmental intention based on environmental policy, as set by the organization

Environmental profile: measurable results of the environmental management system related to environmental aspects management by the organization, based on environmental policy, aims and target values

3.1 Definice procesů a vazeb / Definition of processes and relations



4 Systém managementu kvality a EMS / EMS and quality management system

4.1 Všeobecné požadavky / General requirements

4.1.1

During the application of the Quality System there were respected requirements of the ISO 9001 and ISO 13 485 standards and the ISO 14001 standard setting the requirements of the environmental management system. There are also taken into consideration the requirements of regulations MDDC, PED, RoHS and other related regulations. Lists of regulations are kept in the company Intranet.

The individual chapters of the Quality Manual describe the way in which the organization:

- determines processes necessary for the quality management system and environmental management system and for their application within the whole organization
- determines the sequence and reciprocal effects of the processes,
- determines criteria and methods necessary for the guarantee of effective functioning and management of the processes,
- provides the accessibility of resources and information necessary for the support of functioning of the processes and for monitoring them,
- monitors and, where possible, measures and analyses processes,
- exercises measures necessary for achieving of planned results and a continual improvement of these processes, *keeps efficiency of the processes in consideration of ISO 13485.*

ecology The management in the area of the environment protection is based on obligations within the EMS policy and it is based on handling the significant environmental aspects and impacts in relation to legal and other requirements within the scope of operation management, readiness for emergency situations, setting the aims and target values and realization of environmental programs. The above stated fields are monitored or measured.

4.1.2

Within the bounds of the EMS and quality system there are defined the processes – see chap. 3.1.1. Within the scope of their definitions there is specified the following:

- process inputs and outputs
- process owner
- process suppliers and customers
- connection to basic documentation and records
- brief process description
- connections to other processes
- influence on risk management.

4.1.3

For each process there has been arranged:

- availability of sources and information;
- criteria and methods for arrangement of efficient functioning;
- measures to reach planned results;

- monitoring and measuring where appropriate;
- keeping records proving compliance with standards and regulations.

4.1.4

Process changes are evaluated from the point of view of:

- their impact on quality management system;
- their impact on medical means manufactures using the quality management system;
- proceedings in compliance with requirements of standards and regulations.

4.1.5

If external sources must be used for any procedure that influences the compliance of the product with the requirements, such sources management must be ensured. The requirements for external sources arrangement and management are described in QSM 06-01. BMT uses external sources in the field of production cooperation.

4.1.6

The computer SW used in the quality management system has been validated. Records on validation are done and kept.

4.2 Požadavky na dokumentaci / Requests for documentation

4.2.1 Všeobecně / General

Documentation of the quality management system includes:

- documented declarations of the quality policy and objectives,
- quality manual,
- documented procedures required by ISO 9001 and ISO 13485,
- other documented procedures necessary for arrangement of effective functioning of the organization,
- records required by ISO 9001 and ISO 13485.
- *other documents specified in national or regional regulations.*

The documentation is applied and kept according to instructions specified in QSM 05-01.

4.2.2 Příručka kvality / Quality manual

The Quality Manual is the 1st level document and it is created and kept on the basis of requirements of the standard ISO 9001, ISO 13485, ISO 14001 in the electronic form.

- The extent of the quality management system is shown in the organizational scheme of organisation.
- QAM contains references to documented procedures.
- Description of the sequence and mutual relations.
- The Quality Manual is regulated by the guideline QSM 05-01 – Documents Control.

4.2.3 Dokumentace zdravotnického protředku / Medical device file

For each type of medical devices the organization available a technical documentation, identifying the documents that set the quality management system requirements.

In particular, the file contains:

- general description, intended use, marking, instructions,

- product specifications,
- specifications or procedures of production, packaging, storage, handling and distribution,
- monitoring and measurement procedures,
- installation and service requirements.

P2 QSM 05-01 specifies the procedures for development and administration of the technical documentation file.

4.2.4 Řízení dokumentů QMS a EMS / Control of documents

The documentation is, according to requirements of the standards ČSN EN ISO, divided into a scheme, the so called documentation pyramid.

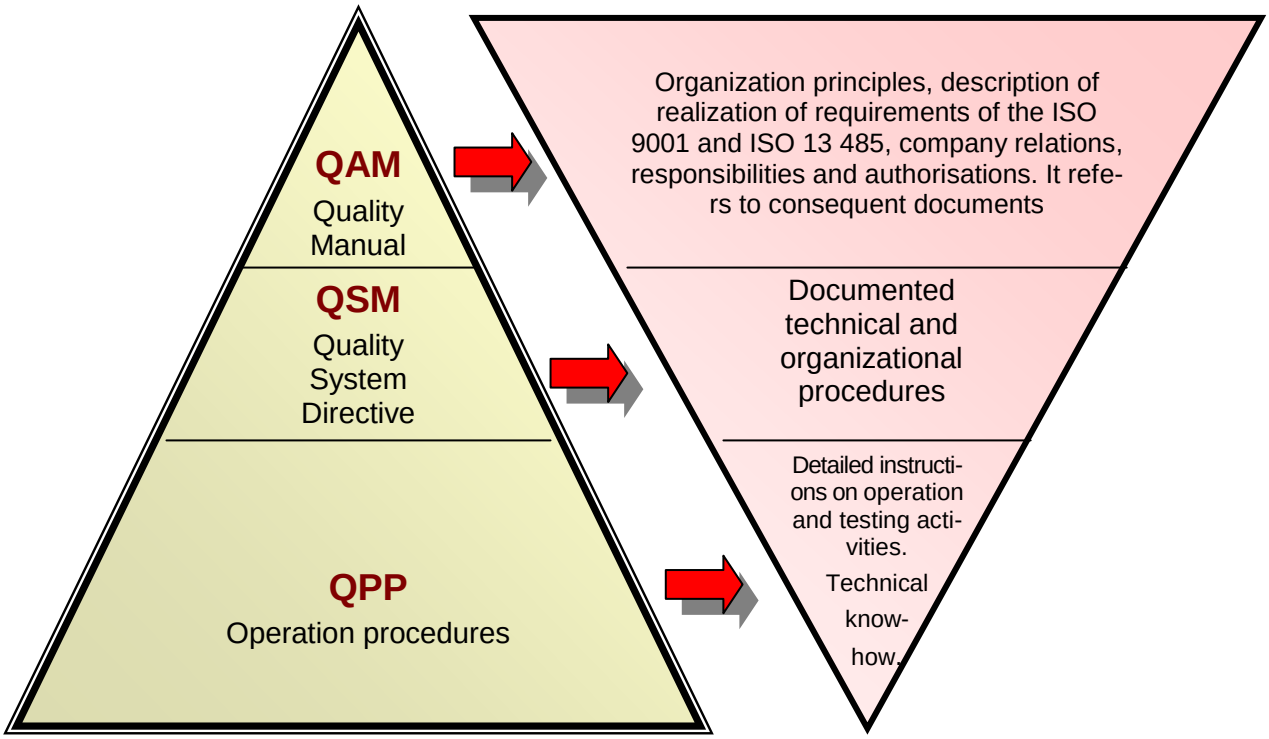


Figure 1 Documentation Pyramid

Quality manual (QAM), Quality system guideline (QSM), working procedures (QPP) and quality records (QZJ) are regulated only in the electronic form in the database "Controlled documentation" - ISO PACK. The management of QAM, QSM, QZJ is described in the guideline QSM 05-01, management of QPP is described in QPP 05-01.

Documented procedures are based on following principles:

a) The management representative for quality (PVJ) is responsible for the check-up and review of documents before their issuing from the viewpoint of their adequacy,

b) review and actualization of documents is described in QSM 05-01,

c) the electronic system enables only clear and unchangeable identification of documents,

d) distribution of documents proceeds in the electronic way. In special cases documents can be distributed in the written form, as managed documents, according to distribution sheet. The documentation department (responsible quality management employee) is responsible for actualization and distribution of these documents. The way of the document distribution shall guarantee that the valid version of the documents is accessible in all necessary departments,

e) the copy possessor is responsible for keeping the copy legible and at an easy accessible place,

a) for keeping and managing of the documents following persons are responsible:

- other than ČSN standards – control unit
- acts and regulations – company lawyer

The management of documentation of external origin is described in QSM 05-01. These documents are distributed in a similar way as internal documents in written form.

Outdated documents are withdrawn from circulation by the documentation department and replaced by valid ones.

The system ISO PACK secures, by means of appropriate access rights and database configurations, that the documentation changes are reviewed and approved by a responsible person.

One copy of the outdated documents is archived for the whole service life of products. After the expiration of this term the documents are discarded. Documents can also be archived on electronic carriers, this way of archiving is described in QSM 05-04.

As a managed documentation with procedures described in QSM 05-01 shall be considered also operating, service and installation instructions – the instructions are managed in a similar way as QSM in ISO PACK.

4.2.5 Řízení záznamů o kvality a EMS / Control of records

Management of records is described in the guideline QSM 05-01.

All the records must always be kept in such condition, that they are legible and can be looked up easily.

4.2.5.1 Definice / Definitions

EMS and quality records – are EMS and quality system documents. They contain results of procedures and activities, which are important for proving of its effectiveness, conformity of products with their documentation and for demonstration of the required quality of final products. They can be made in a written form or on electronic or other carriers.

4.2.5.2 Identifikace QZJ / Identification of quality records (QZJ)

Creator of each guideline, eventually of other documents, is obliged to verify the documentation being formed, whether it has not the character of the Ems or quality record. The creator of the appropriate documented procedure, in which there occur documents having the character of quality records, submits a draft of a specimen of a new document - type quality record (PVJ), and proceeds further according to QSM 05-01. In case the verified document has the character of the quality record, the responsible creator of the documented procedure includes the new document in the ISO PACK and the quality document (PVJ) in the list of quality records (QZJ).

4.2.5.3 Evidence záznamů / Record files

Specimens of valid records are available in ISO PACK. Quality records documents can exist in more copies. The places of filing the originals and terms of their archiving are given in QSM 05-01.

BMT Medical Technology s.r.o. prefers the archiving of records in an electronic form in EasyArchiv and SAP.

The way of handling and securing the documents saved in this way is described in QSM 05-05.

5 Povinnost managementu / Management responsibility

5.1 Odpovědnost managementu / Management commitment

The top management supply an evidence of their personal obligation and activities to develop and apply the quality management system and to maintain its efficiency by:

- informing the organization, how important it is to meet the customers' requirements and also the requirements of regulations and legal requirements, the top management carry it out in form of management orders, regular meetings and seminars,
- establishing the quality policy and quality objectives,
- carrying out the management review, see chapter 5.6,
- securing the accessibility of necessary resources, see chapter 6.

ecology Within the scope of the EMS, the management:

- is responsible for general protection of environment within the organization,
- is entitled to delegate relevant responsibilities and partial rights in the field of environment protection within the organization,
- appoints the management representative for the environmental management system,
- approves the control documentation of the environmental management system,
- arranges sufficient resources for fulfilment of aims in the field of environmental management system.

5.1.1 Požadavky právních předpisů a jiné požadavky / Requirements of legal regulations and other requirements

ecology The basic requirement of EMS is the compliance of all the activities with legal and other requirements that is our organization subject to. That is why we set the procedure for arrangements, availability and keeping all and any legal and other requirements directly related to environmental aspects of our processes, activities, products and services. These are for example:

- Directives, acts, government orders, regulations
- Regulations of local authorities
- Attitudes, licences and resolutions of state administration authorities
- Contracts, approvals, resolutions, authorisations of our company issued by state administration authorities
- Standards

The legal protection of the environment consists of so called constituent regulations:

- Environment – in general
- Water management
- Waste management
- Air protection
- Nature protection
- Protection of land resources and forest management

- Geology and mining
- Area planning and construction rules
- Assessment of impacts on the environment
- Chemical substances handling
- Prevention of serious accidents
- Genetically modified organisms
- Integrated prevention of pollution
- Power industry
- Noise
- Climate protection

For the purpose of monitoring the current legal regulations there has been created the **„Register of Legal and Other Requirements"** on company intranet, consisting of acts, regulations, instructions and other legislative regulations. The PVJ is responsible for updating, having access to current legislative regulations through the Internet, performing their continuous – or at least once per quarter – check and possible inclusion of changes. He updates the Register of legal and other requirements, applicable to the activities of our organization.

5.2 Zaměření na zákazníka / Customer focus

The top management arranges for the customer's needs and expectations and relevant requirements of regulations to be specified, turned into requirements and fulfilled.

5.3 Politika kvality a EMS/ EMS and quality policy

The top managements sets the EMS and quality policy. The EMS and quality policy is regularly reviewed and updated so as to efficiently react to momentary internal and external needs. It is the basis for the determination of the quality objectives. The top management takes care for the quality policy to be communicated and understood on all the levels of the organization.

Quality policy:

- it is based on business aims of the organization,
- it emphasizes personal engagement and activities to fulfil requirements and keep efficiency of quality management system,
- it provides the frame for setting and checking the quality aims,
- it is communicated and understood within the company
- it is regularly – once a year – reviewed from the point of view of suitability continuity.

The EMS policy sets general intentions of the organization in the field of environment protection. In the environment policy, the company management undertakes to permanently improve the field of care for the environment and fulfilment of legal and other requirements related to the organization activities.

The environmental policy is a declaration of intentions and rules related to general environmental profile of the company, providing it with a frame for its activities and for setting the aims and target values of the EMS.

The policy is independently documented; it is published in the company premises in a suitable way. The currency and suitability of the policy is checked within the scope of checks by the EMS management (1x per year). The proof of the activity is the management check record, processed by the PVJJ. In case of the policy to be found non-current, a new and updated one is approved for the forthcoming year, meeting the organization intentions in a better way.

5.4 Plánování / Planning

5.4.1 Cíle kvality / Quality objectives

The top management arranges setting of quality aims for all the sections and levels in the organization.

Their aims and characters are as follows:

- specific,
- measurable,
- ambitious,
- feasible,
- time-limited.

The quality objectives are subject to regular evaluation when reviewing the system by the management.

The basic quality objectives, based on the company's quality policy, are a part of process maps and also a part of the database Objectives in ISO PACK. Each manager is responsible for setting, realization and assessment of adequate aims related to processes performed by his/her section.

ecology In compliance with the environmental policy, the management annually sets the aims in the field of the environment with the purpose of increasing the level of care for the environment. The aims of environmental protection are further processed into concrete tasks with terms of fulfilment, responsibilities and necessary resources.

The aims and target values are based on identified significant aspects and they set contents and time fulfilment of the policy rules in the field of environment protection. More, there are also assessed the technological and financial possibilities, operation conditions and clients´ requirements.

The aims and target values are being approved by the company management, responsible for arrangement of resources needed to reach them. The aims and target values comply with the business intention for the given year. The procedures and means for reaching the defined aims and target values are processed in EMS programs.

The EMS programs include:

- formulations of environmental aims
- descriptions of measures, ways of realization
- schedule and terms of program fulfilment
- responsibilities and rights
- resources setting
- target value

For each EMS program, there must be stipulated the initial value or initial conditions description, used for the target value measuring. There is continuously assessed the fulfilment of defined aims and target values. The EMS programs are approved by the management, responsible for arrangement of resources needed for their contents and time fulfilment.

The management regularly checks and controls the fulfilment of tasks and aims and possibly adjusts aims and tasks in such a way so as they react to changes and incentives that may appear in the course of the year.

5.4.2 Plánování systému managementu QMS, EMS / QMS, EMS management system planning

Resources necessary for reaching the quality objectives are identified and planned.

The result of the planning is documented in the Quality manual, Quality system guidelines and other quality system documentation.

Quality plans in any form are only in form of the controlled documentation.

The environmental protection planning respectively environmental management system planning is used for its permanent improvement, fulfilment of environmental policy and improvement of environmental profile of our organization. For the improvement to be target-oriented and purposeful, it is necessary to set significant environmental aspects and to set target values for them (measurable or assessable). The target values must comply with the environmental policy of the organization and its aims.

5.5 Odpovědnost, pravomoc a komunikace / Responsibility, authority and communication

5.5.1 Odpovědnost a pravomoc / Responsibility and authority

Mutual relations of all the employees controlling, performing and proving the quality-affecting works, including arrangement of their independence and authorities, can be seen in the organization scheme of the company and from job descriptions of individual employees.

Responsibility within EMS

Managers

- They co-create the EMS policy in relation to the company strategy.
- They participate in setting the EMS aims, they transform the whole company aims into partial aims of their sections in compliance with the environment protection policy.
- They are responsible for transfer of information and additional instructions in the field of environment protection into their sub-contractors and their employees.
- They arrange training of subordinate employees.
- They participate in re-checking of EMS including proposals of its further improvement.

Employees and other persons working based on authorisation and/or in favour of the organization

- They are responsible for fulfilment of individual EMS requirements.
- They contribute within the scope of their work obligations, possibilities and skills to improvement of the environment protection.
- They are responsible within the scope of their work obligations for fulfilment of legal and other regulations as well as instructions of the competent manager (not only) in the field of the environment protection.
- They are responsible for fulfilment of specified work procedures.
- They are responsible for their assigned work protection aids and means.
- They are obliged to participate in training in the field of environment protection as well as safety and health at work arranged by the employer.
- They are entitled to make proposals for environment protection improvement at their work sites.

Internal auditors EMS

- They are responsible for full and appropriate performance of internal audit of the EMS pursuant to approved annual program of audits and specified procedure for performance of EMS audits in the organization.

Within the scope of internal EMS audit they identify the potential for further EMS improvement.

5.5.2 Představitel managementu / Management representative

The top management appointed, in their declaration No. 2/2008 of 15.4.2008, the management representative for quality with authorities that include:

- guarantee, that the processes of the quality management systems will be adopted and kept;
- submission of reports to the top management about the efficiency of the quality management system, inclusive demands for improvement;
- securing and support of awareness of the customer's requirements and regulations in the whole organization.

ecology **Within the scope of EMS, the management representative**

- is responsible for creation, implementation, application and improvement of the environmental management system in compliance with requirements of the standard ISO 14001.
- provides the top management with reports on EMS as a base for annual EMS check by the management.
- provides the top management with proposals for the EMS improvement.
- is responsible for operative solution of developed and potential problems in the environment protection field.
- participates in controls and meetings with state administration authorities in the field of environment protection.
- is co-responsible for announcement and liquidation of an accident.
- proposes and controls the status of all the accepted measures for arrangement of environment protection.
- checks permanent and thorough fulfilment of binding legal regulations and instructions in the field of environment protection, immediate elimination of detected faults.
- monitors development and current status in the field of requirements of legal and other regulations, arranges their fulfilment in practice.
- checks and updates the control documentation of EMS including this EMS Manual.

5.5.3 Interní komunikace / Internal communication

The company management and the heads of individual departments, on their regular meetings, inform each other about the condition and the effectiveness of the quality system. The heads of departments submit the information to their subordinates on regular working meetings.

The information about the Quality system is occasionally published in the journal **Paprsek** and in the internal **Intranet**.

ecology The aim of communication in the field of EMS is to reach controlled exchange of relevant information on environment protection inside and outside the company. Communication within the scope of EMS serves for direct dialogue with employees as well as with the public, competent authorities and engaged parties.

The following groups are of importance for environmental communication of the company:

- employees of the organization
- contractual partners (suppliers, clients, environmental organizations, banks, insurance companies)
- press and e-media
- engaged public
- state administration authorities
- company owners

Communication with employees or possibly contractual partners on the EMS field is performed on horizontal as well as vertical level via meetings (management, workshops, etc.), training, via the Intranet.

Provision of information to the public, state administration authorities and Czech Statistic Office follows applicable laws of the CR. In case of the obligation of data provision not to be expressly set by law, the executive manager decides on information provision on the basis of a concrete request.

If it is necessary to communicate on external basis on significant environmental aspects, the executive manager respective proxy is responsible for the communication.

5.6 Přezkoumání managementu / Management review

5.6.1 Všeobecně / General

The top management, in planned one-year-periods, carries out a review of quality management system.

ecology In regular intervals – once per year as a minimum – the company management performs the EMS review. The management representative for the EMS is responsible for preparation and processing of the check program. The aim of the EMS review is to arrange its appropriateness for the needs of the organization, its continuity and efficiency. The EMS review is recorded; the PVJ is responsible for processing.

5.6.2 Vstupy pro přezkoumání / Review inputs

Review inputs consist of:

Requirements of ISO 9001 and ISO 13485

a) Feedback
b) Claims settlement
c) Reporting to authorities
d) Results of external and internal checks (audits)
e) Monitoring and measuring of processes
    - External claims, feedback from clients
    - Assessment of contractors
    - Assessment of aims and quality policy
f) Monitoring and measuring of products
    - Internal claims (development of costs on non-complying products and repairs)
g) Preventive and corrective measures
h) Evaluation of measures of previous reviews by the management
i) Changes affecting the quality management system
j) Recommendations for improvements
k) Application of new or reviewed regulations
l) Risk management results

Requirements of 93/42/EEC, 2014/68/EU,

- Guidelines requirements fulfilment – CE mark
- Documentation condition,
- List of devices with CE mark,
- List of devices being prepared for CE mark,

The basic documents for the EMS review by the company management are mainly:

- Results of internal EMS audits and assessment of compliance with legal and other requirements
- Communication with external engaged parties
- Environmental profile of the organization, its assessment and interannual comparison
- Extent of fulfilment of environmental aims, target values and programs
- Status of conditions for remedy and preventive measures
- Consequent activities from recent review performed by the management
- Changed circumstances, including development of legal and other requirements
- Recommendations for improvement

5.6.3 Výstupy z přezkoumání / Review outputs

The review output is represented by "Report of the quality system (SJ) review by management" - QZJ 01-01.

The report contains minimally:

- measures accepted for the improvement of the quality system and its processes
- measures accepted for the improvement of the product with respect to the customer's requirements,
- measures accepted for the improvement of the product with respect to statutory regulations,
- measures accepted for the demands of resources,
- quality objectives specification.

Outputs from EMS review by the management must include all the resolutions or activities related to possible needs in the following fields:

- changes of environmental policy
- recommendations for setting new aims, target values and programs
- changes of any elements of the environmental management system in compliance with the obligation of permanent improvement

6 Management zdrojů / Resources management

6.1 Poskytování zdrojů / Resources provision

The organization guarantees resources that are necessary:

- for application and improvement of quality management system processes and maintaining its efficiency
- for guarantee of the customer's satisfaction and meeting the requirements of valid regulations.

Necessary resources are defined, planned and applied during the preparation and realization of the processes.

ecology Necessary resources for application, keeping and permanent improvement of functional EMS are identified, planned and controlled by the organization management. Responsibility for arrangements of necessary resources belongs to the director of the organization. Resources are represented by means assigned to systematic improvement of EMS in compliance with policy and aims of the EMS, leading to improvement of environment protection level in the company.

The resources include

- human resources
- specialized skills
- infrastructure
- technologies
- financial resources

The organization has processed and documented the extent of authorisations, responsibilities and work obligations for all the categories of functions affecting the environment protection. Job descriptions, including qualification criteria, are kept by the Human Resources department. Concrete names for positions are specified in job contracts. During regular training courses, the employees of the organization are informed about the EMS operation, with updating of relevant documents, regulations or procedures. In the course of the training courses, the employees are informed about the range of their assigned authorizations and responsibilities.

6.2 Lidské zdroje / Human resources

6.2.1 Všeobecně / General

The chapter Human resources is dealt with in the guideline QSM 18-01.

6.2.2 Odborná způsobilost, vědomí závažnosti a výcvik / Professional qualifications, awareness of importance and training

The organization:

- sets necessary competences for the employees. The employees with responsibilities within the quality management system meet the requirements of professional competence as emerging from their work contents. The responsibilities make a part of job descriptions.
- arranges training and other measures for reaching or maintaining competences, it plans training courses for individual employees.
- the efficiency of training courses is assessed, e.g. based on interviews with employees.

- motivates the employees so as to be aware of relevance and importance of their activities, e.g. in the form of consultations, interviews, etc.
- keeps records of education, training courses and skills in personal files of employees.

The organization arranges professional competence of its employees as well as persons working in its favour in such a way so as the activities connected with significant environmental aspects are performed by competent persons only.

All the employees whose work activities may affect the environment must be aware of environmental aspects and impacts of the works performed. That is why it is necessary for their work activities to be preceded by professional preparation aimed at the field. Fulfilment of the requirement is arranged in such a way that each employee must be trained appropriately so as to be able to minimize or avoid possible negative environmental impacts as emerging from his activity. Simultaneously, he/she is advised of impacts of his/her activities.

All the employees and persons working for our organization must be advised of:

- seriousness and importance of their activities and role in reaching the environmental aims
- system of environmental management established within the organization
- significant environmental aspects of the organization and its impacts to the environment
- their roles and responsibilities in the EMS
- positional consequences of non-fulfilment of specified operation procedures
- behaviour in case of an accident

A record is made on the instructions for the employees.

6.3 Infrastruktura / Infrastructure

The company identifies, provides and keeps equipment for reaching the conformity of the product:

a) it keeps buildings, working environment and corresponding technical equipment on the appropriate level,

b) it carries out regular maintenance of machines and devices and renovation of machine stock in accordance with the customer's demands and with the company investment plan, see QSM 09-03, with regular maintenance and renovation of hardware and software, see QSM 05-04, makes records of the performed maintenance

c) it arranges auxiliary services for a fluent run of the production, for example manipulation with products and material between centres, see QSM 15-01.

6.4 Pracovní prostředí / Work environment

The company is obliged to guarantee work safety and health protection and to create conditions for personal injury prevention at all workplaces without reservation. This regulation is valid also for external workplaces, where such conditions must be agreed.

Rights, duties and responsibility of employees on all levels are specified in the Law Code and extended in the Work Order. There is a Collective agreement concluded in the firm that specifies work-law, social and other conditions for employees and the employer. The objective is to prevent conflict situations and to guarantee suitable working atmosphere for the employees when meeting the company business aim. Every employee is obliged to cooperate actively in the sphere of the health protection and to be aware of his responsibility for his own and his colleagues' health. Special attention is paid to the duty to inform all employees about fire protection and providing of first aid.

There are specified inspections, checks and revisions carried out on the technical devices, the section of Administration and Maintenance being responsible for technical matters.

The Human Resources section is responsible for the field of work protection and safety, the Administration and Maintenance section is responsible for fire protection.

Every employee of the company, when concluding the contract of work, is trained by a person authorized for Work protection and safety (OBP) and Fire protection (PO). Than he is trained in Work protection and safety (OBP) and Fire protection (PO) directly in concrete conditions of his workplace. This training is recorded in personal cards at the Human Resources section (LZ).The training is repeated in statutory periods. All employees undergo input, ordinary, periodical and, in case of high-risk workplaces, also output health examinations in statutory periods. These records are filed at Human Resources section (LZ), being responsible for the realization.

There is an authorized person in the company, according to the Law Code, engaged in Work protection and safety (OBP) and also a prevention worker for Fire protection (PO). A person competent for Fire protection (PO) is contractually guaranteed. The firm, in accordance with legal regulations, creates categories for all works in the firm since 1.1.2002. These works are systematically monitored and précised. An employee is informed about the appropriate work category, according to the Law Code. The firm searches for high-risk works systematically and allocates personal protective working aids. The Human Resources section (LZ) is charged with issue of these personal protection work aids (OOPP), the head of the section orders them according to valid legal regulations.

The firm offers products that are harmless for health, safe and ecologically clean. Before putting into operation all safety parameters are verified according to appropriate standards. The objective of the company is to meet adequate requirements of the legal order of the Czech Republic and EU recommendations concerning health, safety, fire protection, working hygiene and working environment, to guarantee meeting the requests for quality and ecology on certified level, from the viewpoint of savings.

The character of the production does not place an increased stress on health, cleanness and clothes of employees. Within the framework of the company there are no plants with special conditions of working environment.

6.5 Řízení kontaminace / Contamination control

The organization has available a documented procedure for control of potentially contaminated products QPP 19-03 Used product handling. The handling procedure defines the activities that should prevent from contamination of the environment, employees or other products.

7 Realizace produktu / Product realization

7.1 Plánování realizace produktu / Planning of product realization

During the product realization there are collected and kept the documents that contain product definitions, production specifications, quality arrangement specifications and requirements concerning safety of medical devices and pressure devices. These documents are available at the Document Management System.

While planning the product realization, the following procedure is applied:

a) specification of requests for the product and of the product quality objectives,

b) analysis of resources demand for guarantee of necessary processes, guarantee of documented procedures,

c) specification of activities of verification, validation, checks and testing, of acceptability criteria of the product,

d) definition of records necessary for evidence of meeting the claims posed on the realization processes and the final product.

The company documents the risk management requirements in the course of the product realization. The company keeps records of the performed risk management in a special file for each product – "Risk management". The risk management is processed in accordance with the requirements of the standard ISO 14971.

The procedures of the Risk management are described in QSM 04-01, 04-03.

The Risk management process covers the entire product lifetime. The information that is relevant from the viewpoint of safety or reliability is collected in the FMEA.

The process of planning and realization of OEM products is performed in compliance with quality system principles and it is defined in detail in QSM 21-08.

7.1.1 Externě zajišťované procesy / External processes

Within the bounds of the production processes planning some processes are planed externally – in cooperation, due to lack of capacities or suitable technology.

The way of the processes control is described in QSM 06-01.

The processes arranged in this way are subject to reviews regarding:

- influence on product reliability or safety,
- requirements towards validation.

The operation performed based on co-operation are performed on the basis of contractual relations by and between BMT Medical Technology s.r.o. and the co-operator. These contracts include even the agreement on performed works quality, ways of take over and sanctions. As a part of process validation there is also performed an audit at the contractor (co-operator).

The contractors are regularly assessed in compliance with procedures, specified in chap. 7.4.1.1.

7.2 Procesy týkajících se zákazníka / Customer related processes

7.2.1 Identifikace požadavků týkající se produktu / Determination of requirements related to product

The customer's requests for the product are identified in "Accompanying documents" in the database Lotus Notes:

a) for non-standard products

b) for standard products

minimally in the range of:

a) identification of requests for availability, delivery and support,

a) requirements not specified by the customer but necessary for the intended use - requirements specified by the producer,

b) requirements resulting from regulations and legal requirements.

7.2.1.1 Identifikace požadavků pro export – Zastupitelská smlouva / Identification of export requirements – Agency Agreement

With the assistance of the commercial representative the ME officer ascertains the national requirements for introduction of the instruments made by BMT Medical Technology s.r.o. on the local market. (see the section of a standard Agency Agreement: "A commercial representative undertakes to cooperate actively in certification of instruments and continuously obey the valid technical standards and the requirements for operation of products stipulated in this contract and to inform the represented subject about the national requirements and their alterations"). The ascertained information are handed over to the respective expert departments to solve and for example, in the forms of specification in the Accompanying sheets, in the form of e-mails, in the form of consultative meetings for the purpose of determination of procedures for placing of merchandise on the market territory in question etc.

The requirements for elaboration of language versions of the accompanying documentation are described in QSM 05-01.

7.2.2 Přezkoumání požadavků týkajících se produktu / Review of requirements related to product

The requirement review procedure is described in QSM 03-01.

This procedure guarantees that:

a) requests for the product are defined and documented,

b) customer's requirements are confirmed before accepting them,

c) before accepting the order there are differentiating requirements of tender or demand resolved,

d) the organization is able to meet requirements in the given range.

Review results are recorded in the Accompanying document.

7.2.2.1 Postup přezkoumání / Review procedure

Chronologically this procedure includes matters of following fields of activities:

- in BMT Medical Technology s.r.o. the demands are, after their acceptation, forwarded to the appropriate department, to whom the demand belongs. The appropriate officer, after identification of eventual information, defines roughly the suitable goods and after revision of the demand (after the agreement with the customer) makes an offer. The process of demand review itself deals with variants, if it is a standard or non-standard product, if it is or is not on stock.

QSM 03-01 includes also reviewing of demand concerning contract where products delivered by the customer are included.

- offer – for the exactness of processing the offer the appropriate sales officer is responsible. The printed offer is sent to the customer and one copy is enclosed to the demand.
- order – the obtained order is forwarded to the appropriate officer. If there was an offer before order, there comes a check of conformity between the order and the offer. Eventual ambiguities of the order will be agreed by the appropriate sales officer with the customer.

On the basis of the received and checked order the sales officer reconfirms the offer into the contract of purchase or creates the contract of purchase directly in the SAP ERP.

Contract of purchase – is filed in the SAP ERP. The process of contract review is finished by the confirmed contract of purchase.

If the contract of purchase is confirmed to another than the final user – then the consumer is obliged to file the purchase of this products to the final consumer.

7.2.2.2 Změna smlouvy / Change of contract

If the contract is not confirmed because of irrelevant changes made by the customer, the sales officer of Inland marketing (TM), Marketing export (ME), Service (TS) settles the controversial issues with the customer. He makes a record of this negotiation and encloses it to the already printed contract of purchase.

If the contract is not confirmed because of relevant changes made by the customer, the sales officer proceeds, according to the extent of the changes.

In case the contractor sets up a request for the change of the delivery date in the already closed contract of purchase, there is proceeded according to QSM 09-01.

In case the customer sets up a request for the change of the delivery date in the already closed contract of purchase, this contract is realized according to the procedure valid for the customer order – without previous offer.

Inland marketing (TM) – informs appropriate departments about the duty to interrupt works on the order being realized till the consumer's requirements are settled and a new contract of purchase is made.

7.2.3 Komunikace / Communication

The organization communicates with customers by:

a) communication of information on product through the propagation department and in cooperation with the marketing,

b) settlement of demands, orders, contracts and their changes,

c) feedback from the customer, inclusive complaints, especially during the phases of the pre-purchase and post-purchase customer care.

d) *information messages in the framework of solution of preventive and corrective measures, eventually solutions of measures arisen in connection with an undesirable event.*

In case that there comes to alterations, modifications or to other impacts causing a necessity of issuance of additional informative warnings regarding to medical devices already introduced on the market and namely in the spheres of:

- *utilization of medical devices,*
- *alterations of modification of medical devices,*
- *return of the medical devices,*
- *destroying, liquidation of medical devices,*

It is realized by means of business partners, service centres or directly by sending –a notice for the final user of the medical devices. Actual approach is determined on the basis of assessment of the notice character in cooperation of the design department, quality control, marketing and service.

7.3 Návrh a vývoj / Design and development

7.3.1 Obecně / General

The field of design and development is described in QSM 04-01.

7.3.2 Plánování návrhu a vývoje / Design and development planning

The requirement or a theme for a new product is reviewed by the marketing department at first.

The following items are used as tools for request acceptation assessment:

- *risk analysis results ,*
- *established requirements of clients,*
- *possibilities for market launching,*

- *competitors' situation,*
- *value analysis results,*
- *QFD,*
- *and other suitable methods.*

In case of an approval the topic is submitted to the designing department (according to the guideline QSM 04-01).

Requirements on new products shall also include definition of parameters according to chapter 7.2.1, inclusive further additional requirements determined by the company.

The technical manager of the designing department (VKS) creates a plan of technical development, inclusive cost breakdown for the solution. The technical development plan is, after discussion, approved by the Marketing director (MŘ). The projects can be inserted in the plan during the year. The Marketing director (MŘ) decides about the priorities of the solved projects after discussion with the technical manager of the designing department (VKS).

The technical manager of the designing department (VKS) appoints one of the designing department employees as the responsible solver and further collaborators. The activities, that, during the designing, affect the product quality, are planned in the departments and assigned to employees, whose qualification, knowledge, experience and personal features guarantee meeting the objectives of the project.

Development and adopting of technical development (TR) tasks is divided into phases.

One part of the description of individual phases (QSM 04-01) is the definition of documents necessary for the transition from one phase to another one, inclusive requirements on review, verification and validation.

On the basis of the discussion of technical development plan with the Production management (ŘV) individual adopting phases can be so ranged, that they overlap each other for purposes of using the capacity of all departments, who take part in solution, and so the project solution can be accelerated in this way.

The output of the planning is documented.

7.3.3 Vstupy pro návrh / Design and development inputs

New products are the aim of the development. Assumed products, care for standard products in the production, implementation of new technology etc. do not belong there.

A development topic can be initiated and enforced at the department of Inland marketing (TM) by anybody. Here the topic will be considered and its turning into development demand will be decided.

The topic, turned into "Development demand" will be considered on the common meeting by representatives of:

- Marketing,
- Design department,
- Quality management,
- Service,
- Production management,
- Economic management.

During the discussion the topic will be considered, apart from other things, from the viewpoint of the firm strategy, actuality of the development at the time of its finishing, approval and certification, productive capacities and possibilities, necessary professional knowledge of the designing department employees, payoff of invested financial means, alternative solutions etc.

Inputs for draft and development include:

a) requests for functionality and workmanship and security according to the intended use,

b) applicable legal requirements and requirements of regulations,

c) information drawn from previous similar drafts

d) other fundamental requirements

e) risk management outputs

These inputs are reviewed and approved from the viewpoint of adequacy.

7.3.4 Výstupy z návrhu / Design and development outputs

Design and development outputs relate to individual development phases.

Phase 0 Marketing setting, project, opposition procedure

Phase 1 Function sample

Phase 2 Design and manufacture of a prototype

Phase 3 Type test

Phase 4 Development completion, opposition procedure

Outputs of the draft and development:

a) meet the input requests for the design and development,

b) provide suitable information for purchase, production and for service providers,

c) contain acceptance criteria for the product

d) specify those product characteristics that are fundamental for its safe and proper use.

Records of design and development outputs are kept and archived.

7.3.5 Přezkoumání vývoje / Design and development review

The technical manager of the designing department (VKS) and representatives of other departments, dealing with the solution, carry out inspections of fulfilling the development tasks systematically, minimally per quarter. If there is some deviation from the technical development (TR) plan during the project solution, the technical manager of the designing department (VKS) suggests a measure and after its approval the Marketing director (MŘ) makes the change of the technical development (TR) plan.

Changes of the technical development (TR) plan are described in QSM 04-01.

The review results and records of necessary measures are kept in the form of quality records.

Within the bounds of review the capability of the design and development results to meet the required parameters is verified, all problems are identified and necessary measures determined

7.3.6 Ověřování vývoje / Design and development verification

The development verification proceeds in the phase E2a, during the prototype design, by evaluating requirements of standards and other regulations, as the first part of the risk analysis.

Further part of the development verification proceeds in the phase E2c, during functional tests of the prototype and software debugging, under leadership of the responsible solver.

The final phase of the development verification, verification of the whole solution, in the phase E3 during the type tests and creating of appropriate protocols and test reports.

7.3.7 Validace vývoje / Design and development validation

The development validation is a part of the phase E4. It is realized at selected clinics and / or type testing rooms, to which the devices are delivered for routine use, together with documents for evaluation.

After filling-in the documents, the evaluation of the draft is carried out at a meeting, held in the firm, where expert departments are present, under leadership of the Marketing director (MŘ).

The product validation shall be finished before delivering it to the customer.

7.3.8 Přesun návrhu a vývoje / Design and development transfer

The procedures for transfer of design and development into production, i.e. arrangement and assumption of production technology are described in QSM 03-01 and consist of the following phases:

ETAPY OSVOJENÍ VÝROBY / PRODUCTION ADOPTION PHASES

Phase 5 Technology schedule

Phase 6 Technological procedures and technical and economic standards

Phase 8 Tools design and manufacture of tools and measuring gauges

Phase 10 Manufacture of proving batch, opposition procedure

Phase 11 Product test

Phase 12 Adjustment of technical documentation and tools, opposition procedure

7.3.9 Řízení změn vývoje / Control of design and development changes

The development changes can be a result of development review according to 7.3.4, minimally once per quarter.

The development changes are also suggested and discussed in opponent talks in individual phases E0 to E2.

In case of necessary development changes outside these specified terms, there is an extra meeting called and documented with the appropriate record, according to which the changes of the technical development (TR) plan are carried out.

7.3.10Dokumentace návrhu a vývoje / Design and development files

The organization maintains design and development documentation for each type of medical device. This documentation includes records generated to demonstrate conformity with design and development requirements and records for design and development changes. See QSM 03-01.

7.4 Nakupování / Purchasing

7.4.1 Proces nakupování / Purchasing process

The department of Purchase (MZ) is obliged, on the basis of technically clear requirements of the departments who have the authority to require the purchase of material and services, to guarantee these inputs so that they are in accordance with the received requirements of technical standards, contracts of purchase and quality parameters.

If, for relevant reasons, the purchase is not carried out by the supply officer directly, the purchase documents must be submitted to the officer additionally. In this way it is guaranteed, that all purchase officers have the necessary information.

Purchase activities are described in QSM 06-01 in detail.

The archiving of documents (bills of delivery, contracts, invoices, material specification) follows the file and discard order – QSM 05-02.

7.4.1.1 Hodnocení dodavatelů / Evaluation cofcontractors

The procedure of contractors evaluation is described in QSM 06-04.

The basis for the selection of qualified contractors is competence and ability of the contractors to provide deliveries in accordance with given requirements, specified in the order. The selection is carried out before closing the order event. contract of purchase. In case of newly purchased materials, before sending the binding order, an inquiry with the exact specification of the required material is send to potential contractors. On the basis of the received offers, lists of possible contractors are created according to following categories:

A - ***exclusive contractor***

B - ***alternative contractor***

C - ***potential contractor (possible for the future)***

D - ***forbidden contractor***

Methods of contractor's competence recognition

- appreciation and evaluation of the contractor's competence and his quality system directly at his place – input contractor audit
- evaluation of product patterns
- experiences with similar supplies in the past
- results of tests of similar supplies
- published experiences of other contractors

Evaluation and records of contractors are a part of ISO PACK.

7.4.2 Informace pro nakupování / Purchasing information

The material necessary for the production is ordered on the basis of specification, which is written in the material card. The designing department employee, who initiated the drawing of the material card, is responsible for entirety and exactness of the specification. Alternative materials can be used only if the specified features of the products are not worsen and if their use is in accordance with approved technical conditions. Use of alternative material is approved by the appointed Designing department employee on the basis of deviation proceedings, see QSM 09-04.

The Design department (KS) identifies products with special monitoring mode, and the range of their identification. These products are, during the whole production process, administered in this way and their identification is, after building-in in devices, transferred into output protocols.

7.4.3 Ověřování nakupovaného produktu / Verification of the purchased product

Documents necessary for demonstration of conformity with specified requirements:

- order,
- specification of products or materials,
- receiving document with the quality management record of the result of the input technical control (TK),
- bill of delivery,
- certificate of warranty, certificate etc.,
- stock card with the ordinal number of the delivery.

For the proper goods acceptance the goods receiving worker together with the appropriate store-keeper is responsible.

The goods receiving worker is obliged, before confirming the documents of the goods take-over from the carrier or contractor, to carry out (if possible) the check of quantity and dimensions according to the bill of delivery.

In case the weight, quantity in quantity units (MJ) or dimension do not agree with the data in the bill of delivery, he is obliged to mark this fact in the bill of delivery demonstratively or to interrupt the goods acceptance and to inform the Engineering inspection (TK), event. the appropriate supply officer, about this fact.

The way of material reception through the input engineering inspection (TK) is described in QSM 10-01. The marking of the inspection type is included in the stock bill SAP ERP.

Unsatisfactory material is marked with the sign MATERIAL IN CLAIM and with the number of the claim protocol and stored in the specified room till the claim is settled; see QSM 10-01 and QSM 13-01.

7.5 Výroba a poskytování služeb / Production and service provision

7.5.1 Řízení výroby a poskytování služeb / Control of production and service provision

The level of production management is an inseparable part of production quality guarantee in BMT Medical Technology s.r.o. The main aim of the management activity is to coordinate all inputs, that affect the production from the viewpoint of requests for quality and effectiveness, to create conditions for keeping these principles during the production process itself and improve systematically both the management activity and the production realization.

7.5.1.1 Všeobecné požadavky / General requirements

Production in the BMT is planned and performed in controlled system.

Controlled conditions include:

- accessibility of information, describing the product characteristics,
- accessibility of documented procedures, operation instructions, etc.,
- using suitable equipment,
- monitoring and measuring equipment,
- application of monitoring and measuring,
- application of activities for release and supplies,
- procedures for marking and packaging.

Each product is identified and a record is made so as to arrange traceability – output protocol of a product.

Requirements relevant for the production management process are in:

QSM 06-03	Material storage - inputs
QSM 08-01	Identification and traceability
QSM 09-01	Production process management
QSM 09-02	Tools management
QSM 09-03	Provision of resources – infrastructure, work environment, investments planning
QSM 09-05	Technological and design documentation management
QSM 10-01	Checks and tests
QSM 11-01	Control measuring and testing equipment management
QSM 13-01	Non-compliant product management
QSM 15-01	Handling, storage, packaging, protection and supplies

Within the scope of the operative plan processing, the OV sets partial terms for arrangement of individual phases of production preparation that he continuously monitors, mainly:

- Processing or updating the design and technological documentation.
- Release of production and service documentation.
- Status of material arrangement in individual groups of materials.
- *Status of monitoring and measuring equipment, performance of monitoring and measuring.*
- There are continuously assessed the checks results and realisation of corrective measures is arranged.

The Production organization (OV) coordinates activities during the production preparation on the basis of terms specified as a part of the operative production plan. This department controls the issuing of production documents directly.

From the beginning of the production order realization the Production management (ŘV) controls, in form of meetings, the activities of workshop dispatchers and intervenes in the production course operatively from the viewpoint of fluency and

demands of the finishing operations. They monitor the term and volume fulfilment of the operative plan. They check piece completeness of individual orders manufacture.

The individual foremen and dispatchers are responsible for appropriate reporting of works performed and for depreciation of materials used in orders with consequent conclusion of production orders within the ERP system.

The Production organization (OV) is responsible for uniform mode of production assignment both administratively (allocation of order numbers) and really (production inclusion into the operative plan).

7.5.2 Čistota produktu a řízení kontaminace / Cleanliness of product

The character of the product does not place an increased stress on product cleanness in accordance with the requirements of ISO 13485.

7.5.3 Činnosti při instalaci /Installation activities

The installation of the product is performed on the basis of Installation plans of the devices, eventually according to the instructions in the Operating instructions.

With the large steam sterilizers the customer is offered the execution of the installation qualification (IQ) according to the requirements of EN 285. Its execution depends on the mutual contractual relation between BMT Medical Technology s.r.o. and the customer.

If the installation is performed by BMT Medical Technology s.r.o. engineering records are made about it – service department.

The company can authorize their representative to perform the installation, and then he is obliged to keep records of the performed activities and archive them for the lifetime of the device, eventually to submit them to BMT Medical Technology s.r.o. for archiving – service department.

7.5.4 Činnosti při servisu / Servicing activities

User instructions, on the basis of which the users are obliged to perform regular servicing (maintenance), are a part of the Operating instructions. Service engineers are also provided with Service instructions, these instructions are a part of the managed documentation of the company.

Records of the performed activities are made in the service book of the device. Record of service activities performed by the company is also a part of the job ticket, see QSM 19-01.

7.5.5 Zvláštní požadavky na sterilní zdravotnické prostředky / Particular requirements for sterile medical devices

Not applied.

7.5.5.1 Řízení provozu z hlediska EMS / Operation management from the EMS point of view

ecology The organization identified processes and activities that have or may have significant environmental aspects and controls them in compliance with its environmental policy. The PVJ of the organization processed and now it keeps a register of environmental aspects and impacts, being a base for operation management in such a way so as to minimize negative environmental impacts.

Just at the moment of concluding contracts with clients, the responsible employee reviews whether the client´s requirement can be fulfilled from the environmental point of view, whether it will not cause problems to the company regarding fulfilment of legal and other requirements in the field of environment protection.

The basic fields of operation management related to significant environmental aspects are as follows:

- Nature and landscape protection
- Operating the air polluting sources (air protection)
- Waste management

- Water management mode
- Soil protection
- Dangerous chemical substances and mixtures
- Power management

7.5.5.2 Havarijní připravenost a reakce / Emergency readiness and reaction

The emergency readiness and reaction to accidents provides reduction of undesirable environmental impacts. In connection with realization of orders of our company it is possible to say that there is a minimal possibility of an emergency situation development. There are considered exceptional accidents or emergency situations:

- by leakage of water-harmful substances
- by soil contamination
- by leakage of air-harmful substances
- by fire

Being aware of the risks, our organization tries to minimize the impacts:

- by devices in which the rarely used chemical substances are used, trapped, stored or transported – they are placed in such a way so as to avoid undesirable leakage of dangerous substances,
- there are used such devices that are suitable from the point of view of environment protection and that correspond with acts and implementation regulations,
- there are performed regular checks of contractors.

The identification of emergency situations is included in the registry of environmental aspects, where are identified and specified even possible impacts of activities during emergency conditions of operation – potential accident development.

7.5.6 Validace procesů / Validation of processes

In case of processes, where the result procedure cannot be verified by consecutive monitoring or measuring, the validation of processes is carried out.

Within the bounds of the production process there are three spheres of validation necessity evaluation and appropriate responsibilities defined:

- *production processes performed in BMT Medical Technology s.r.o. – manager of the production department responsible*
- *production processes performed outside the firm, secured through cooperation – cooperation worker responsible*
- *software controlled processes – manager of information technology department responsible – QSM 05-04.*

Each newly developed process shall be reviewed whether it meets the validation criteria. The review of processes and the way of validation is approved by the management representative for quality (PVJ)

For these processes are specified and recorded:

a) criteria for review and approval of processes,
b) requests for equipment and qualification of employees,
c) use of specific methods and procedures,
d) requests for records.

Software creates a special category.

The software installed in the devices is validated before the first use. There are made records of the validation.

7.5.7 Zvláštní požadavky na validaci procesů pro sterilizaci / Particular requirements for validation of processes for sterilization

Not applied.

7.5.8 Identifikace / Identification

Specification of identified elements and the way of their identification are described in QSM 08-01.

Procedures of identification and handling of products returned as claims or repairs are described in, QPP 19-03 and QSM 19-03.

Identification of components, where the traceability is required, is a part of output device protocols.

The way of identification of product condition is described in QSM 10-01. Record of performed checks is a part of the output device protocol.

The running supervision of quality is introduced in form of self control in the company, the performed activity is recorded in the forwarding bill (with signature) by the responsible employee.

7.5.9 Sledovatelnost / Traceability

Procedures in QSM 08-01, traceability of key components is arranged by their specification in protocols from output tests of devices. The devices are identified by their serial numbers, the course of the order is registered in SAP.

7.5.10 Majetek zákazníka / Customer's property

Customer's property includes devices shipped for repair, see QSM 19-03 and Intercompany MMM / BMT. Materials supplied by the parent company MMM for processing in the subsidiary company BMT (usually welding works of material of MMM) are identified by a delivery note. After delivery of material / parts from MMM these parts are taken on receipt of goods from the carrier and delivery notes are marked by the product receiving department - see QSM 06-01. The marked delivery note identifies a whole set of parts to be processed in BMT.

7.5.11 Ochrana produktu / Preservation of product

The system of manipulation, storing, packing, protection and delivery of material with the objective not to worsen the quality of the material and finished products is described in the guideline QSM 15-01 – Manipulation, storing, packing, protection and delivery.

There are solved the matters of NA warehouses and dispatching.

The storage of purchased materials in the NA stock describes especially the way of storing the material with respect to protection against:

- damaging by climatic influences
- impairment of material by deformation as a consequence of improper storage.

There is separately mentioned the safety aspect of storing and marking of dangerous materials.

QSM 15-01 does not solve: storage of tools and production aids, manipulation and storage of materials in the production process.

Packing of finished products – is specified by technological procedures, the packing proceeds as the last technological operation at appropriate workplaces

Requests for special packing (overseas packing, event. some other specific packing) are solved separately.

The goods dispatching workers accept only identifiable goods for storing.

Storing of finished products – (because of dispatching planning, the finished production is handed over to the stock at the end of the working week). The handing over to the stock is possible only, besides handing over the product itself, together with filing the product in the stock of finished products (HV), namely on the basis of the delivery bill.

After an eventual long-term storage the appropriate goods, on request of the marketing department, get back to the production department, where it is inspected and marked "inspected".

Commercial articles – is filed separately in the SAP ERP.

Goods delivery – is carried out on the basis of bills of delivery drawn by the goods dispatch department. The condition of drawing the bill of delivery is proforma invoice and agreement of serial numbers.

The loading itself is connected with the check of the consignment completion, intactness of packing and confirmation of the 1.copy of the bill of delivery by the appointed goods dispatching worker. On the basis of this 1.copy the invoice will be drawn. In case of dispatching goods abroad there follows the process of cooperation with the department of customs declarations. Drawing of customs documents require, besides the customs invoices, to specify the gross and net weight and number of loaded pieces. The dispatching documents are filed. This guideline has a close connection to activities connected with the guideline QSM 03-01.

The way of handling and protection of goods and material in the production process is described in QSM 15-01.

7.6 Řízení měřicích a monitorovacích zařízení / Control of monitoring and measuring equipment

Determination of responsibility, rights and duties when using and keeping the measuring devices and keeping them in the appropriate condition, suitable and right selection of measuring devices and measuring methods, lists of measuring devices, periodical verification event. Calibration of all measuring devices in specified terms and records of these inspections etc. create the *Company Metrology System.*

The complete firm metrology, on the basis of present legal regulations, is limited to the protection of public interest and more detailed execution is up to independent decisions of firms according to their demands in the field of measurement.

In the firm BMT Medical Technology s.r.o. the system of the firm metrology is specified by the guideline QSM 11-01.

This QSM guarantees the realization of the point 7.6 of the standard ISO 9001 and it is the **Metrology order** of the firm at the same time.

Measuring gauges serve for defining the value of the measured quantity.

According to the Metrology Act No. 505/1990 Coll., measuring gauges are classified as follows:

- standards (main standard HE, firm standard PE)
- specified working gauges (further specified gauges, SM)
- non-specified working gauges (further working gauges, SM)
- reference materials, provided they are destined for the function of a standard or of a working gauge.

To guarantee the company's demands in the field of measurement with a low required accuracy the measuring devices are included in the category of working gauges of rough character (further rough gauge, OM). They are used only for a rough orientation, where they cannot affect the production quality and work safety.

The basic condition of uniformity and correctness of the measurement is a consistent connection with state standards, i.e. periodical verification of main standards (HE), specified gauges (SM) and calibration of working standards (PE) and working gauges (PM) and primary calibration of rough gauges (OM) and keeping these gauges in required condition.

Keeping gauges in required condition means:

- proper use and right storing of the gauges,
- organized and regular inspections of the gauges,
- maintenance, repairs and withdrawal of substandard gauges,
- perspective and systematic management of gauge purchase.

7.6.1 Měřidla podléhající ověření / Verification subordinated gauges

The gauges subordinate to verification (main standard HE, specified gauges SM) must be submitted to official verification at the appropriate metrology laboratory always, if:

- there is a new gauge handed over for use and the producer or the contractor of the gauge did not hand over the valid verification bill of the gauge,
- the validity of the gauge verification expired or if there cast doubt about the correctness of the measured values.

The request for the gauge verification shall be, according to location, submitted at the appropriate metrology laboratory of the Czech Metrology Institute (ČMI), who guarantees the required metrology operation or submits the request to another appropriate metrology body or directly to the State Metrology Centre (SMS).

7.6.2 Měřidla podléhající kalibraci / Calibration subordinated equipment

The equipment subordinate to regular calibration (working gauges PM) must be submitted to the appropriate metrology laboratory of the company at least once during the determined calibration period and then always, if

- there is a new gauge handed over for use and the producer or the contractor of the gauge did not hand over the valid calibration bill of the gauge
- the validity of the gauge calibration expired,
- there cast doubt about the correctness of the measured values or before an especially exact or complicated measurement

If the company does not possess, in one of the measurement branches, any standard or any inspection device, and because of a low quantity of working gauges (PM) it is not economical to buy them, the company metrologist (MeS) agrees the inspection of these gauges with another subject, who can guarantee the inspection professionally.

7.6.3 Evidence měřidel společnosti / Documentation of the company equipment

The company metrologist (MeS) guarantees independent technical documentation of all standards (E), specified gauges (SM) and working gauges (PM) used in the company.

The central documentation (file sheets of the gauges) is kept in form of a record in the computer database of the company metrologist (MeS), which contains following data:

- identification number of the gauge,
- gauge (name, identification number of the gauge group in the gauge list, type and dimension, measured quantity, gauge standard, integration, accuracy class, serial number, producer, production year, year of putting into operation, actual price)
- gauge location (place, sign),
- user (personal number, name, centre),
- calibration, event. official verification, date of calibration, event. verification and date of the next calibration event. verification, standard and way of calibration, notes (service, repairs of the gauge etc.).

Note.:

List of equipment kinds used in the company divided according to measurement quantities and categories of measuring gauges together with given terms of verifications or calibrations, way of marking and way of calibration or verification marking (marks, sheets, cards etc.), see Appendix 2 QSM 11-01.

Each measuring gauge of the company (except rough equipments OM) must have, besides specified marking, its identification number. The *equipment identification number* is represented, in case of equipments marked with their serial number by the producer, by this serial number, in case of equipments without serial number, by the file number. Equipments (except rough equipments, OM) without identification number must not be used in the company.

7.6.4 Lhůty kontrol / Inspection periods

The inspection period is a period specifying interval between two regular verifications (calibrations) of the equipment.

The time of validity of the specified equipment (SM) verification is specified by the Institute for Technical Standardization, Metrology and State Testing (ÚNMZ) in the Bulletin of the Institute for Technical Standardization, Metrology and State Testing, in norm of precept.

The time of validity of the main standard (HE) verification is specified by the verification body with respect to the proposal of the standard possessor.

The calibration period of the appropriate working equipment (PM) is specified by the company metrologist (MeS) on the basis of standards, technical documentation and recommendations of the measuring devices producers, assortment, operating conditions, frequency of use and actual experiences of administrators and users of the equipment.

Note:

List of inspection periods for the gauges used in the company, see Appendix 2 QSM 11-01.

8 Měření, analýza a zlepšování / Measurement, analysis and improvement

8.1 Všeobecně / General

In the company there are planned and applied processes of monitoring, measuring and analysis necessary for:

a) demonstration of the product conformity,

b) guarantee of QMS conformity

c) the process of continual improvement and keeping of QMS effectiveness.

These activities are described in following QAM chapters and in individual QSM.

8.2 Měření a monitorování / Measurement and monitoring

8.2.1 Spokojenost zákazníka / Feedback

During the phases of the pre-purchase and post-purchase customer care the company monitors information concerning the customer's attitude, whether the company met all his requirements,.

Procedures of collecting, analysis, processing and further treatment of the obtained data are described in QSM 03-01, QSM 19-01.

8.2.2 Vyřizování stížností / Complain handling

QSM 14-02 Client's claims document contains the procedure for complain handling. The procedure contains description of activities for information receipt, assessment whether it is a claim or not, claim investigation, resolution on acceptance or non-acceptance of remedy measures, resolution on whether a responsible authority is to be informed or not. Records are kept on claims settlement.

Customers' claims and remarks are filed in the service department, the responsible employee records the claims in the ISO PACK database –"Improvement" – Customer's impulses or SAP.

In this database all information and documents are collected that serve for the claim settlement.

8.2.3 Hlášení oprávněným orgánům / Reporting to regulatory authorities

The procedures of undesirable events reporting are described in QSM 21-03.

8.2.4 Interní audit QMS a EMS/ Internal audit

The topic of internal audits is solved in QSM 17-01

The audit plan considers all elements of the quality management system. The basic document is "***Annual audit plan***" – ISO PACK – database "Internal audits". It is submitted for approval by the audit program leader to the company management.

This plan contains:

- list of audited sections (eventually quality system elements),
- terms of execution of individual audits,

The audit plan is created especially on the basis of:

- the results of previous audits;
- requirements of responsible employees;
- frequency of problems;
- customers' reactions etc.;
- requirements of regulations and standards.

8.2.4.1 Průběh prověrky / Audit course

The course of the internal audit is documented in the database "Internal audits" of the ISO PACK system.

The auditing team leader is responsible for well-timed (i.e. in the given term) and answerable execution of the given internal audit according to the in advance created and approved answer sheet. At the beginning and at the end of the internal audit there proceeds a talk of the auditing team with the head of the audited section.

After the execution of the internal quality audit the auditing team leader creates "Audit report" on the basis of evaluation of the audit answer sheet.

8.2.4.2 Písemné zprávy z prověrek a opatření k nápravě / Written audit reports and corrective measures

The written report of internal and external quality audits is represented by the audit protocol. The protocol makes a part of the ISO PACK program. For every non-conformity written in the record a corrective measure is specified.

8.2.4.3 Interní audit EMS / Internal audit EMS

ecology On the basis of results of previous audits, identified non-conformities and their correction, changing legislative requirements, aims and programs EMS for relevant calendar year, the management representative plans the internal audits.

The internal audits of the environmental management system are periodically repeated in compliance with annual program of internal audits, so as it is possible to check whether the activities related to EMS and results reached are in compliance with specified requirements and so as to set the efficiency of EMS.

Internal audits are performed in the way of auditing the individual work sites, by using the method of an interview with a specified employee, by comparison of presented documentation and relevant records with reality, whether the requirements of the ISO 14001 standard are fulfilled. The internal audits are based on requirements of ISO 14001 and they are performed in compliance with requirements contained in this manual in such a way, so as all the applied elements of the standard and all the work sites are used in the course of the calendar year. Simultaneously, related environmental aspects and risks in the field of environment protection are taken into consideration.

8.2.5 Měření a monitorování procesů / Measuring and monitoring of processes

In possible the organization monitors running processes, determines their effectiveness and further objectives of their improvement. The evaluation of the processes proceeds on the basis of qualitative parameters drawn from the production objectives. The evaluation results are a part of the Management review, they are also the basis for specification of eventual preventive or corrective measures.

The objectives of processes and their evaluation criteria are included in the ISO PACK database – "Company objectives".

8.2.6 Měření a monitorování produktu / Measuring and monitoring of product

8.2.6.1 Vstupní kontrola / Input inspection

The goods receiving employees carry out the material acceptance and file the material. The way of inspecting the material destined for the inspection is marked in the stock bill (in form of a computer record) in accordance with the checklist.

The material is inspected according to the checklist in one of following ways specified in QSM 10-01 in detail:

- *„A" - visual inspection* - by a goods receiving employee,
- *„B" - check of contractor's certificates* - by an employee of the input engineering inspection (TK),
- *„C" - measurement inspection* - by an employee of the input engineering inspection (TK), the result of such inspection is "Acceptance protocol".

8.2.6.2 Mezioperační kontrola / In process inspection

Every employee of BMT Medical Technology s.r.o., who realizes the production is obliged to proceed in accordance with the valid production and technological documentation. He carries out a systematical and final inspection of his work, which is confirmed by his signature on appropriate forwarding bills.

The in process inspection of operations, eventually parts that affect the product quality immediately or where the nonconformity is repeated, is carried out by that production employee, for whose operation the control was determined. Frequency, range, way and means of the inspection are determined by the Designing department in cooperation with a technologist. They are written in the forwarding bills or in the technological procedure (TP) of the product. The production employee, who carries out the inspection, confirms with his signature in the appropriate field of the forwarding bill or technological procedure, that by him manufactured, checked and handed over products are in accordance with requirements determined in the appropriate production documentation. In controversial cases the employee is obliged to call the quality system controller, who carries out the inspection and draws a decision.

The employee must not continue his work until all determined inspections are carried out properly. He also guarantees that he does not do consecutive operation in case he was delivered material with an apparent defect. In case he does not do it, the foreman assumes the responsibility.

8.2.6.3 Výstupní kontrola / Output inspection

It arranges the inspection of the manufactured (finished) product before final operations, i. e. marking and packing. It is regulated by inspection procedures and drawing documentation. The output inspection employees make test records and mark the products in the way described in QSM 10-01.

A part of the inspection protocol is presentation of identity of the employee who carries out the inspection.

8.2.7 Monitorování a měření v rámci EMS / Monitoring and measuring within EMS

The organization monitors key measuring features of the EMS system and the environment field that have or may have significant impact on the environment. The extent, methods of monitoring and responsibilities are controlled by the management representative for the EMS, who also checks the area and prepares outputs for a report to be checked by the EMS management. For this purpose, the organization developed, documented and it keeps procedures of regular monitoring and measuring of key features of processes and activities that may show significant impact on the environment and measuring the range of reaching specified environmental aims and target values.

General, the following items of the environment are monitored and measured:

- emissions from road vehicles (technical checks)
- water consumption (part of the contract of rent)
- electric power consumption (part of the contract of rent)
- production of waste (part of the contract on waste removal)
- fuels consumption (through CCS)

- consumption of dangerous chemical substances and mixtures (mainly VOC)

The proper measuring gauge is not used for measuring and monitoring in environmental protection. Calibration of external measuring gauges is performed by the owner (media supplier).

The monitoring and measuring results are recorded in ISO PACK – in the **Register of monitoring and measuring** and they serve as a base for assessment of environmental profile of the company within the scope of EMS review by the management and conformity assessment.

8.2.8 Hodnocení souladu / Conformity assessment

ecology The organization arranges periodical assessment of conformity with requirements of legal regulations and other requirements – so called conformity assessment. The assessment is performed continually as needed, but at least within the range of the EMS review by the management. The management representative for EMS is responsible for conformity assessment. The managers, whose activities are touched by the given legal regulation, are responsible for partial fulfilment of legal regulations and other requirements. The result of the assessment is the recording performed, which will make a part of the report for review by the management.

The conformity assessment is also performed through assessment of internal and external audits and controls for arrangement of conformity with requirements of external and internal regulations and standards, procedures and processes, technologies and products.

The conformity assessment recording is performed via the record **Assessment of conformity with legal and other regulations**.

8.3 Řízení neshodného produktu / Control of nonconforming product

8.3.1 Obecně / General

Designation of a non-conforming product is determined in QSM 10-01, namely with a warning adhesive tape, eventually with an identification adhesive tape.

8.3.2 Opatření v reakci na neshodný product zjištěný před dodáním / Measures in reaction to non-conforming product detected before delivery

8.3.2.1 Příjem zboží / Goods receipt

The inspection at the goods receiving department proceeds according to QSM 10-01.

In case of identification of nonconformity, the employee of the Input engineering inspection (VTK) makes appropriate designation and detaches the non-conforming products and writes the “Claim protocol”, see QSM 06-01. Then he submits the filled-in protocol to the department of Purchase (MZ). Purchase (MZ) guarantees the return of the goods or agrees on repair with the contractor or the goods can be destroyed in BMT Medical Technology s.r.o. The decision is written in a protocol and one copy is submitted to the Quality management (ŘJ).

In case there is a small defect, that can be repaired and has no direct influence on the product quality, the Purchase (MZ) can demand an exceptional releasing by the appropriate professional (design, technology) who decides about the repair in BMT Medical Technology s.r.o. and the decision is marked in the “Acceptance protocol”. One copy of this protocol receives the quality management department (ŘJ).

8.3.2.2 Ve výrobě / In production

Identification of non-conforming products during the production is the obligation of every employee. In case of a suspicion of non-conforming products or their identification, everybody, who has detected this fact, is obliged to inform his superior and detach the non-conforming piece from the production.

The head – foreman of the centre calls a quality management engineer. The engineering inspection employee marks visibly (see QSM 10-01) all non-conforming products and guarantees their isolation at the places that have been des-

tined for this isolation and marked in the appropriate way. In case of voluminous pieces with complicated manipulation it is possible to keep them at their place. Nevertheless it is necessary to mark them with a warning adhesive tape and red colour.

The engineering inspection (TK) employee writes a waster report for the non-conforming pieces, see QSM 13-01. About eventual recoverability of the non-conforming product decides the engineering inspection (TK) employee after a discussion with the foreman, eventually with the technologist and the designer.

8.3.2.3 U výstupních zkoušek / At works tests

If there occur - during the works tests - some variations from the requests for product quality, which cannot be removed before the product delivery, the Production management asks the Inland marketing (TM) for exceptional releasing of the product, one copy receives the Quality management.

The product must not be released if it is necessary to carry out repairs in the manufacturing firm.

Inland marketing (TM) in cooperation with Quality management (ŘJ) informs the appropriate foreman and service centre about the decision of the employee, who carries out the works tests, to release the product exceptionally.

If it is necessary to accept the non-conforming product based on an exception due to urgent operation reasons, it is necessary to state identity of the person approving the exception. The procedure for release with exception is described in QSM 10-01.

8.3.3 Opatření v reakci na neshodný produkt zjištěný po dodání / Measures in reaction to a non-conforming product established after delivery

QSM 19-02 Claims.

8.3.4 Přepracování / Rework

If it is necessary to rework the product, the contractor must document its reworking in an operation instruction that must be subject to the same authorization and approval procedure as the operation instruction. The records on reworking must be kept, the product after reworking must be checked.

8.4 Analýza údajů / Analysis of data

For the purpose of demonstration of suitability and effectiveness of QMS there are suitable data specified, collected and analyzed, see database “Company objectives”.

Further data consist of:

a) feedback, chapter 8.2.1,
b) conformity with requests for product, chapter 7.2.1,
c) features and process and product trends, estimation of potential nonconformity resources and specification of preventive measures,
d) information about the evaluation of contractors,
e) audits,
f) service reports

Records of the results of analyzes are part of the review of the management.

8.5 Zlepšování / Improvement

8.5.1 Obecně / General

On the basis of conclusions and results obtained of:

a) quality policy,
b) quality objectives,
c) internal and external audits,

d) data analysis,

e) corrective measures,

f) preventive measures,

g) QMS review by management,

The company identifies and performs changes that are necessary for securing and keeping the QMS efficiency.

8.5.2 Opatření k nápravě / Corrective action

In order to prevent repeated occurrence of nonconformity, the organization takes measures to remove their causes. There is a documented procedure QSM 14-01 determined, by means of which the requests for:

a) nonconformity review, inclusive customer's claims,

b) determination of nonconformity causes,

c) evaluation of necessity of the measure,

d) specification and applied measure,

e) records of results of applied measures,

f) applied measure review.

The system of corrective measures is regulated and documented in ISO PACK, database "Improvement ".

8.5.3 Preventivní opatření / Preventive action

In order to prevent possible occurrence of nonconformity, the organization takes measures to remove their causes. There is a documented procedure QSM 14-01 determined, by means of which the requests for:

a) determination of possible resource of nonconformity

b) evaluation of necessity of the measures,

c) specification and applied measures,

d) records of results of applied measures,

a) applied measures review.

The system of preventive measures is regulated and documented in ISO PACK, database "Improvement ".

The Risk management results are the predominant input for performing the corrective measures.

8.5.4 Neshoda, opatření k nápravě a preventivní opatření v rámci EMS / Non-conformity, corrective measures and preventive measures within the scope of EMS

The organization has created documented and well-kept procedures for definition of responsibilities and authorities for solutions and checking non-conformities in the field of EMS. The aim is to minimize negative impacts and efficiently limit any environment damage.

Non-conformities in the field of environmental protection may occur e.g. in the field of:

- waste water and air pollution
- non-fulfilment of operation conditions (poor technical conditions, excessive power consumption, etc.)
- non-conformities related to the process and EMS in general
- non-fulfilment of prescribed limits
- non-fulfilment of specified aims and target values, etc.
- non-fulfilment of technical conditions of infrastructure (foreshots, leakage of dangerous substances, etc.)
- non-conforming contractors, whose environmental behaviour does not correspond with specified requirements
- complaints of the public regarding environment deterioration

- findings of the state administration authorities on non-fulfilment of tasks emerging from environmental legislation

In case of non-conformity there is checked the reason of its development (whether it is an operation fault or accident), seriousness and extent of negative impacts on environment fields, respectively responsibility. The head of the work site is responsible for review and correction of the non-conformity and he decides (possibly based on consultation with management representative for the EMS – this applies to more complex cases) on the way of settlement and he is responsible for performance of corrective measures so as to avoid repetition of the non-conformity. After realization of corrective measures he performs consequent control in a specified way and in specified term s or intervals and he records the results.

Corrective measures: they must correspond with seriousness and extent of impact on the environment. The corrective measures are set in cases of:

- establishment of non-conformities within the scope of realization of internal and external audits EMS
- establishment of non-conforming technological process, during regular or random control of operation, worksite, respectively during measuring of direct parameters (emissions, quality or quantity of waste, waste management, excessive quantity of waste, power consumption, leakage of harmful substances, etc).

Procedures for controlling the non-conformity and corrective measures include:

- efficient way of settlement of complaints regarding pollution of environment items
- investigation of causes of non-conformities, related to a product, process and environmental management system
- specification of corrective measures which is necessary for exclusion of causes of non-conformities
- application of operative management to arrange for a corrective measure to be adopted, realized and to be efficient.

Prevention in environment protection: it includes application of methodologies and performance of necessary changes of processes, efficient use of natural resources, exchange, replacement or saving of raw materials, material and power, with the aim of reducing negative impacts on the environment. The stimulus for initiation of a preventive measure may be:

- reaction to internal and external stimuli
- fulfilment of environmental aims
- measures to avoid accident situations

Improvement: it is performed by using the policy, corrective measures, preventive measures, by setting higher and higher aims and target values. In this way, the organization permanently improves the efficiency of EMS. The aim of the EMS level increase is to reach improvement of general environmental profile of the organization.

Permanent improvement can be reached mainly by the following methods:

- fulfilment of the EMS policy
- analysis of results reached and acceptance of measures based on the analysis
- review of reached aims by the management
- EMS efficiency and setting higher and higher aims and target values
- realization of preventive measures

In case of any EMS changes to occur due to corrective and preventive measures adopted, such changes must be recorded in related documents.

9 Zvláštní požadavky směrnice 93/42/EEC, / Special requirements of MDD 93/42/EEC

Special requirements towards production of medical devices according to the directive 93/42/EEC are described in directives QSM 21-01 and QSM 21-03.

The attachment of the CE mark is qualified by observing the procedure of conformity declaration according to the Appendix II.3, of the directive 93/42/EEC.

10 Zvláštní požadavky směrnice 2014/68/EU / Special requirements of PED 2014/68/EU

Special requirements towards production of pressure equipment according to the directive 2014/68/EU as amended re described in QSM 22-01.

The attachment of the CE mark is qualified by observing the procedure of conformity declaration according to the Appendix III, directive 2014/68/EU (module H, H1, full arrangement of quality with draft review and special supervision during final control; module G: individual piece checking).

Module H: The notified body carries out a formal audit of the quality system to ascertain whether it is in accordance with requirements, and draws a certificate. More, unannounced check inspections will be performed.

Module H1: The notified body carries out a formal audit of the quality system to ascertain whether it is in accordance with requirements, and draws a certificate. More, it performs the construction documentation approval.

Module G: The notified body carries out tests according to the Appendix III, module G.

The information on pressure device pressure device drawings and clear designation of the pressure device, operation instructions and documentation for the customer service. The information will be delivered to the user in time.

The representative for quality (PVJ) announces to the notified body all types of pressure devices that obtain the CE mark according to PED. In case of new devices this will be done after finishing the conformity assessment procedure, if there is available complete documentation for proving conformity with basic requirements.

The Quality management (ŘJ) informs the notified body immediately in case of critical changes of the quality system and in case of changes of pressure devices carrying the CE mark that could impeach the conformity with the basic safety requirements or that concern the specified conditions of use. Other changes of the quality management system or of pressure devices with CE mark that are related to the quality system of BMT Medical Technology s.r.o. will be submitted to the notified body in framework of the check and repeated audit.

For the purpose of planning the unannounced controls from the side of the notified body, the BMT provides the body with approximate production program of pressure devices.

11 Environmentální aspekty a environmentální profil organizace / Environmental aspects and envioronmental profile of the organization

11.1 Environmentální aspekty / Environmental aspects

The organization has created a documented procedure for identification of environmental aspects of its activities and products, it keeps the **Register of environmental aspects**, it considers impacts of the aspects and it updates the identified aspects and impacts.

The identification and assessment of environmental aspects on the basis of specified methodology and selection of important EA is one of the basic EMS elements. The EA arrangement represents a stable process, setting former, current as well as potential impacts (positive or negative) by which our organization affects the environment. The process also includes establishment of the way, in which our organization may be subject to influence of relevant regulations, laws, instructions and orders, the current and the future ones.

The process of EA identification and assessment can be divided into the following phases:

- selection of activities, services or products
- EA identification
- EA documentation and its quantification
- assessment of EA importance with impact on the environment using criteria

Activities or services of individual organization units must be clearly specified in such a way so as it is possible to use the EA identification method for establishment of all the EA that the company management may control and affect and that could have an impact on the environment. In the course of the EA identification, there is assessed the ordinary operation as well as extraordinary operation and potential conditions of emergency situations development, i.e. emergency operation.

Significant EA are a base for setting the environmental aims and target values and so even for improvement of environmental profile of the company. The impact of every significant EA to the environment must be monitored and assessed.

The way of identification and assessment of significance of environmental aspects of activities, services and products in individual organization units is described in the directive in QSM 23-06.

11.2 Environmentální profil / Environmental profile

On the basis of identified VEA there is further set so called Environmental profile of an organization, i.e. general assessment of the company influence and impact on the environment.

The indicators of the environmental profile (EPE) must be objective, verifiable and repeatable; they must be reasonable for activities, products and services of our organization and they must also be in compliance with our environmental policy.

The following rules must be obeyed while setting the EPE indicators:

- the EPE indicators must be practical
- the EPE indicators must be cost efficient
- the EPE indicators respectively their assessment must be technologically performable

The indicators of the environmental profile in the organization include for example the following:

- Total quantity of produced waste related to one production unit
- Total quantity of produced dangerous waste related to one production unit
- Total quantity of volatile organic substances emissions related to one production unit
- Total quantity of solid pollutants emissions related to one production unit
- Number of identified divergences established during internal and external audits
- Consumption of natural gas, electric power, heat, water, fuels and technical gases per production unit per calendar year
- Total volume of produced CO_2 and NO_x emissions per production unit per calendar year
- Mileage of service vehicles per production unit per calendar year
- Number of fulfilled aims in the EMS field per calendar year
- Sum of investment into the environment protection per calendar year

The resulting values of EPE indicators are inter-annually compared, always during the EMS review by the management and there is monitored the development in this field on long-term basis. The materials for EPE assessment and processed and presented by a management representative for the EMS.

12 Rozdělovník / Distribution list

All users of the program ISO PACK in the PC version.

In printed form according to the distribution sheet saved at Quality management (ŘJ)..

13 Přílohy / Appendixes

Not any

14 Související dokumentace / Conjoint documentation

ČSN EN ISO 9001: 2015	Systém kvality – model zabezpečování kvality při návrhu, vývoji, výrobě, instalaci a servisu / Quality system – model of quality guarantee during design, development, manufacturing and service
ČSN EN ISO 13485: 2016	Zdravotnické prostředky - Systém managementu kvality – Požadavky pro účely předpisů / Medical devices – Quality management systems – Requrements for regulatory purposes
ČSN EN ISO 14001:2015	Environmental Management Systems – Requirements with instructions for use
ČSN EN ISO 19011:2012	Směrnice pro auditování systému management / Regulations for Management systems auditing
ČSN EN ISO 14971:2012	Zdravotnické prostředky - Aplikace řízení rizika na zdravotnické prostředky / Medical devices – Application of risk management to medical devices
93/42/EEC	Směrnice Evropské unie pro zdravotnické prostředky / European union directive for medical devices
2014/68/EU	Směrnice Evropské unie pro tlaková zařízení / European union directive for pressure equipment
PŘ 2/2008	Jmenování pracovníků pro zavedení SJ / Appointing employees for quality system implementation

The actual list of conjoint quality system directives is available in the electronic form in ISO PACK and is not the part of the Quality manual.