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SMART HEALTHCARE ENGINEERING
2023-1-RO01-KA220-HED-000159985

Co-funded by
the European Union

PREVENTION AND FAILURES IN HOSPITAL FACILITY MATERIALS: SPECIFIC STANDARDS AND GOOD PRACTICE RULES

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INTRODUCTION

In the use of medical materials, compliance with the rules of good practice is essential to ensure the safety of patients and medical personnel, as well as to maintain the efficiency and longevity of the equipment.

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INTRODUCTION (II)

These rules focus on several key aspects: inspection and verification of materials, inventory management and traceability, staff training and education, and implementation of sterilization protocols.

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RULES OF GOOD PRACTICE IN THE USE OF MEDICAL MATERIALS

Physical Integrity Check

All materials and equipment must be visually inspected for physical defects such as cracks, wear, or damage caused by improper handling.

Electronic and mechanical equipment must be tested to ensure proper functionality and to detect potential operating problems.

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FUNCTIONALITY TESTING

Performing functional tests to confirm that medical equipment meets technical specifications and functions as intended.

Use of medical simulators to verify equipment performance under controlled conditions.

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COMPLIANCE WITH STANDARDS

Verification of compliance of materials and equipment with relevant standards such as ISO 13485, EN 13795, and ISO 11607.

Ensuring that all certifications and documentation are up to date and appropriate.

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COLLABORATION WITH SUPPLIERS

The hospital works closely with suppliers of medical supplies to ensure the quality and compliance of the delivered products.

This includes negotiating technical specifications, checking compliance certificates and evaluating supplier performance.

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INVENTORY MANAGEMENT

Implementing an inventory management system that monitors inventory levels and prevents shortages or excesses is essential.

Using barcodes to track medical supplies and ensure proper stock rotationon a first-in, first-out basis is ideal in a hospital.

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TRACEABILITY OF MATERIALS

Ensuring full traceability of materials by maintaining detailed records of batches, expiry dates and usage of each product.

Implementing effective recall procedures to be able to react quickly if a batch of materials is identified as defective or unsafe.

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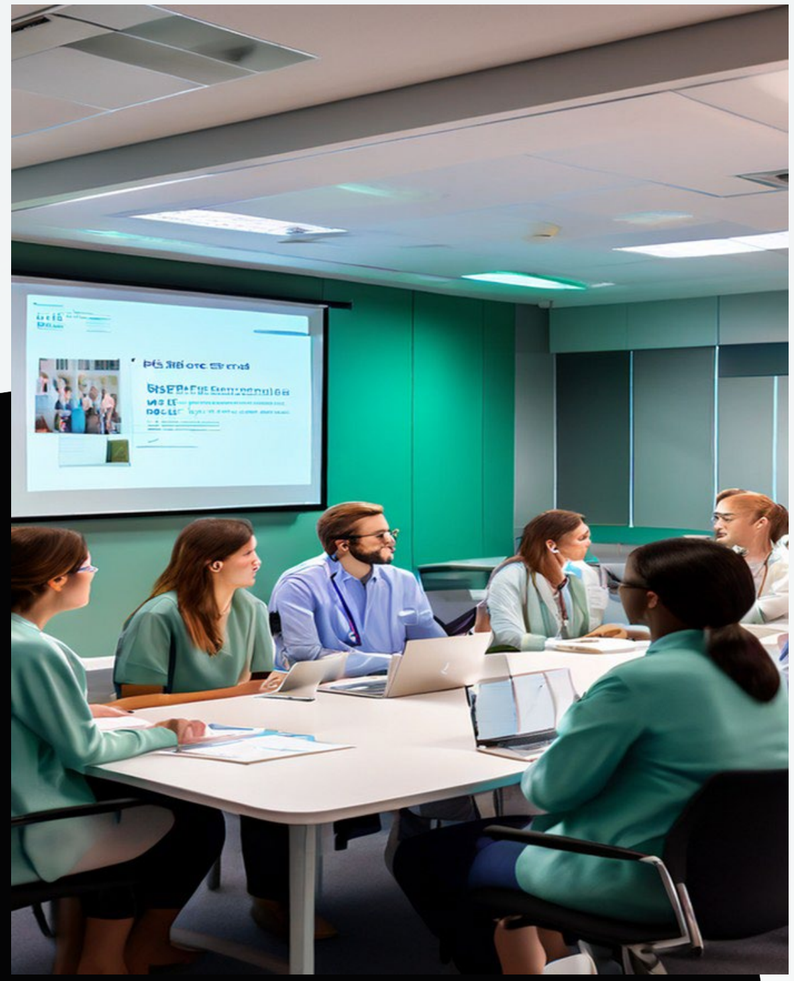
TRAINING AND STAFF TRAINING



Providing initial training sessions for new employees to include instruction in the proper use of medical supplies and equipment.

Organization of regular training courses for all medical personnel, focused on updating knowledge and skills in the use of new technologies and materials.

In the Săcele Municipal Hospital, an annual training and professional development plan is carried out at the beginning of each year for all staff categories.

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STANDARDIZED PROCEDURES

The quality management service, together with colleagues from the hospital, deals with the development and implementation of standardized operational procedures for the use of medical materials, which are easily accessible and up-to-date.

Ensuring that the medical staff is familiar with the procedures and that they apply them consistently in their daily activities falls under the attributions of the person in charge of quality management.

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IMPLEMENTATION OF STERILIZATION PROTOCOLS

Regular checking of sterilization equipment to ensure proper operation ad efficiency of the sterilization process.

Use of chemical and biological indicators to monitor and validate sterilization processes.

Documenting sterilization test results and periodically reviewing these records to identify any deviations from sterilization standards.

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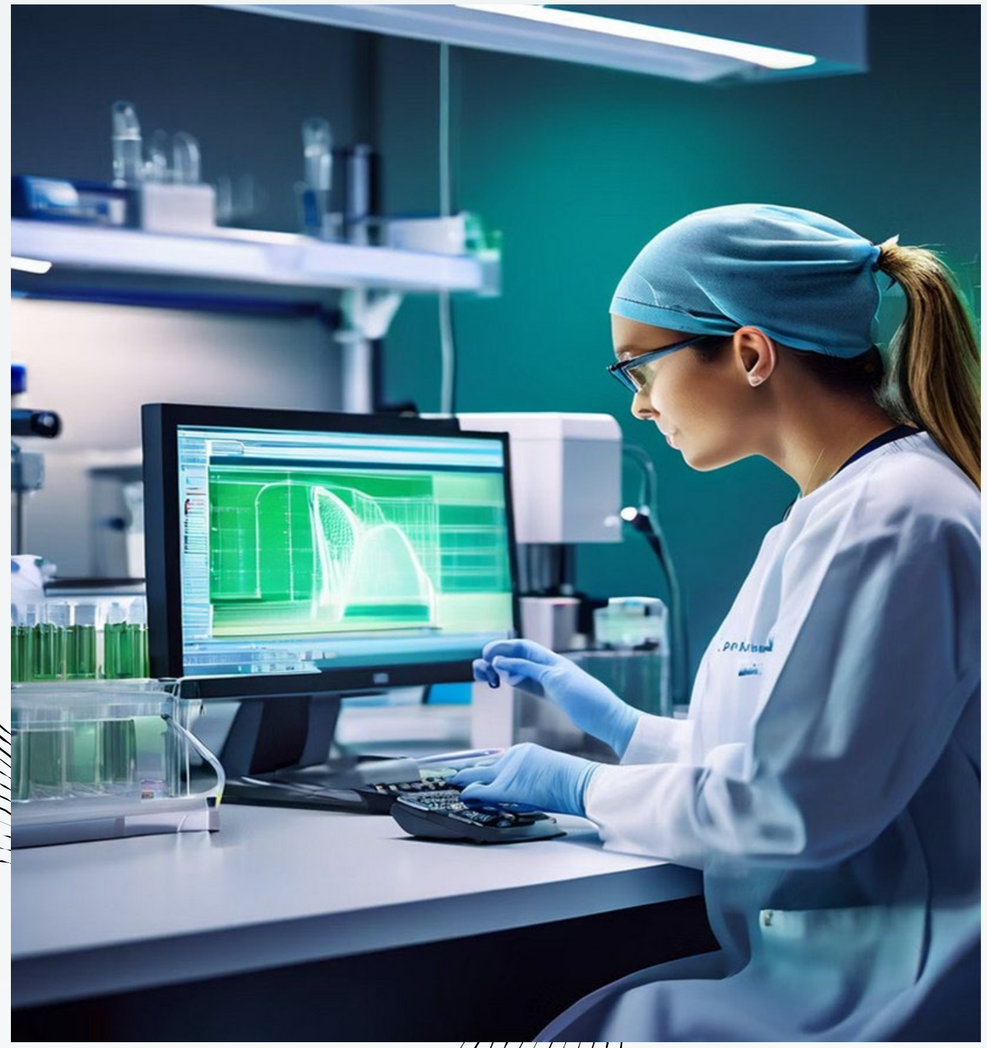
PRECAUTIONS



Implementing strict precautions for the handling and storage of sterile materials, ensuring that they are kept under appropriate conditions until the time of use.

Avoiding cross-contamination by using strict aseptic techniques and educating staff on the importance of keeping equipment sterile.

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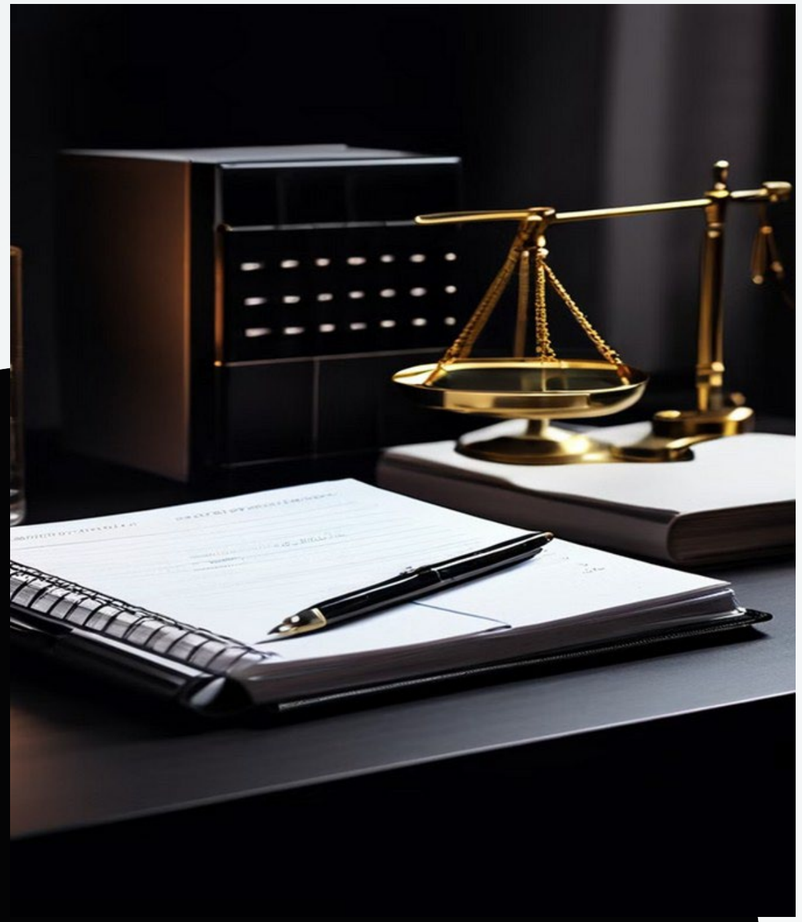
APPLICABLE STANDARDS



Săcele County Hospital has implemented a series of international and national standards to ensure the quality, safety and efficiency of the materials and equipment used within the institution.

These standards cover a wide range of issues, from quality management systems to technical specifications for medical equipment. The main standards that the hospital wishes to have implemented are detailed below.

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ISO 13485:2016 - QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES(I)

This is an international standard that specifies the requirements for a quality management system for medical devices.

The implementation of this standard ensures that the medical products and services offered by the hospital meet regulatory and customer requirements.

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ISO 13485:2016 - QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES(II)

Objectives

Compliance with international regulations: Ensuring that all medical devices comply with applicable regulations and standards.

Process improvement: Optimizing internal processes to improve the efficiency and quality of services provided.

Risk Management: Identifying and managing the risks associated with the use of medical devices

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ISO 9001:2015 - QUALITY MANAGEMENT SYSTEM (I)

This is an international standard that sets the criteria for a quality management system.

Implementation of this standard helps the hospital to continuously improve performance and ensure patient satisfaction.

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ISO 9001:2015 - QUALITY MANAGEMENT SYSTEM(II)

Customer Orientation: Focusing on the needs and expectations of patients to provide superior quality services.

Leadership and employee involvement: Fostering a work environment where leadership and employee involvement are encouraged and recognized.

Process-based approach: Managing activities and resources as interconnected processes to achieve efficient and quality results.

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ISO 14971:2019 - RISK MANAGEMENT FOR MEDICAL DEVICES

This international standard includes:

Hazard identification: Recognizing potential hazardsrelated to medical devices and assessing associated risks.

Risk assessment and control: Analysis and implementation of measures to control and minimize risks.

Monitoring and review: Continuous monitoring and review of risks to ensure that control measures are effective.

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ISO 11607-1 AND ISO 11607-2 - PACKAGING OF TERMINALLY STERILIZED MEDICAL DEVICES(I)

The implementation of these standards ensures:

Packaging integrity: Packaging must maintain the sterility of medical devices until they are used.

Performance testing: Packaging is subjected to rigorous testing to verify performance under varied conditions of use and transport.

Validation Process: Validation of packaging processes to ensure they meet specified requirements.

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EN 13795 - CLOTHING AND STERILE FIELDS FOR SURGERY(I)

This is a European standard that regulates the specifications and requirements for dressings and sterile fields used in operating theaters, and our unit applies these rules in the minor surgery room.

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EN 13795 - CLOTHING AND STERILE FIELDS FOR SURGERY(II)

The implementation of this standard contributes to:

Microbial cleanliness: Maintaining a low level of microbial contamination on the surface of materials.

Protection against infection: Ensuring that sterile dressings and fields provide adequate protection against microbial contamination.

Barrier performance: Checking the performance of materials used to prevent the passage of microorganisms.

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IEC 60601-1 - GENERAL REQUIREMENTS FOR THE SAFETY OF ELECTROMEDICAL EQUIPMENT(I)

This is an international standard that specifies general requirements for the safety of electromedical equipment.

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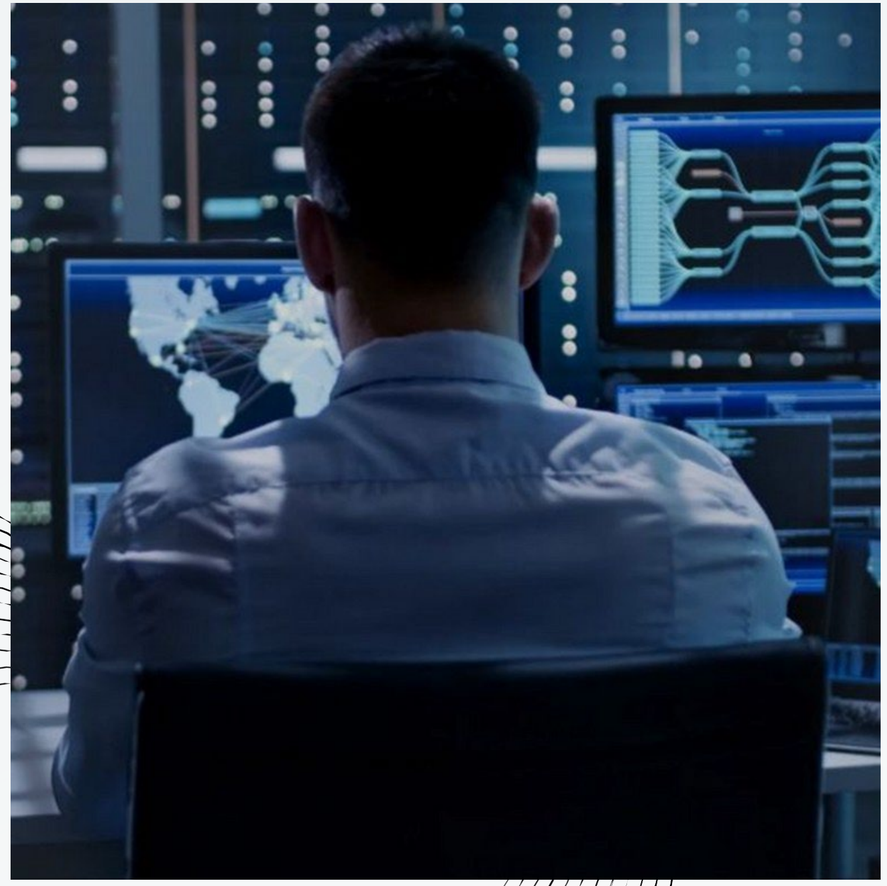
IEC 60601-1 - GENERAL REQUIREMENTS FOR THE SAFETY OF ELECTROMEDICAL EQUIPMEN(II)



Implementation of this standard helps to:

Electrical Safety: Ensuring that medical electrical equipment is safe to use and does not pose electrical hazards to patients and staff.

Electromagnetic compatibility: Prevention of electromagnetic interference that could affect the operation of equipment.

Mechanical and thermal performance: Checking the mechanical strength and thermal management of equipment to ensure safety in use.

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ISO 10993 - BIOLOGICAL EVALUATION OF MEDICAL DEVICES(I)

It is a series of standards that provide the requirements for the biological evaluation of medical devices.

Their implementation ensures:

Biocompatibility assessment: Testing of materials to assess biocompatibility and prevent adverse reactions in contact with human tissues.

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ISO 10993 - BIOLOGICAL EVALUATION OF MEDICAL DEVICES(II)

Toxicity testing: Identifying and evaluating the potential toxic effects of materials used in medical devices.

Standardized test procedures: Use of internationally recognized test methods to ensure consistency and comparability of results.

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CONCLUSION (I)

Compliance with the rules of good practice in the use of medical materials is essential to prevent failures and ensure a safe and efficient working environment in hospital units.

By implementing these rules, Săcele Municipal Hospital demonstrates its commitment to patient safety and the quality of the medical services offered.

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CONCLUSION (II)

The implementation of these standards in the Săcele Municipal Hospital will ensure that the materials and equipment used meet the highest quality and safety requirements.

These standards will not only protect patients and medical staff, but will also contribute to operational efficiency and continuous improvement of the services provided.

Commitment to these standards reflects the hospital's dedication to excellence and innovation in healthcare.

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Gracias por su atención
İlginiz için teşekkür ederiz
Vă mulțumesc pentru atenție!

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