MEDICAL DEVICE REPROCESSING

CHAPTER 1 – QUALITY SYSTEMS

WHAT IS QUALITY?

- The concept of quality within healthcare is associated with the degree or grade of excellence involving a service or product, with the patient/client being at the center of every quality concern
- The success of the MDRD is dependent on the successful and competent fulfilment of the needs of the (internal) customer
- Competent quality products and services impact the operation of the department as well as all other hospital areas that utilize the MDRD

IT IS ALSO VITAL TO UNDERSTAND:

- Quality is not the only way to improve
- Some critical components of quality cannot be delegated
- Quality involves the collaborative process from all stakeholders involving time, effort and participation

STAKEHOLDERS

- MDRD Stakeholders are any individual or group with an interest in the performance of the MDRD unit. MDRD stakeholders can be divided into two groups:
- **Internal Stakeholders**: These include MDRD technicians, nursing units, diagnostic imaging, infection control, biomedical engineering, physicians, and other allied professional personnel.
- **External Stakeholders**: These include vendors, suppliers, government, professional associations, and the community.

EXTERNAL QUALITY CONTROLS

- At the federal and provincial government levels, healthcare quality standards determined by governing bodies such as the Canadian Standards Association (CSA), Accreditation Canada (AC), and the Provincial Infectious Diseases Advisory Committee (PIDAC) have been put in place to establish the quality system that all healthcare facilities in Canada are required to uphold. The standards are sometimes referred to as external controls. Department managers carry out these controls.

EXAMPLES OF EXTERNAL CONTROLS

- **Canadian Standards Association (CSA)**: The CSA plays a major role in determining the activities within an MDRD. All policies and procedures must be written and based on the current CSA standards. CSA sets many of the manufacturing and operating requirements for machinery and equipment. The MDRD is responsible and accountable for all standards of practice described in the CSA relevant to each function for which standards are provided

OTHER ORGANIZATIONS:

- As well as the following organizations influence daily activities in an MDRD by developing recommended practices related to infection prevention and control, instrument pack, basin handling and processing:

  - **The Association for the Advancement of Medical Instrumentation (AAMI)**
  - **Association of Operating Room Nurses (AORN)**
  - **Operating Room Nurses Association of Canada (ORNAC)**

WSIB

- **WORKPLACE SAFETY INSURANCE BOARD**
- In Canada, the WSIB is one regulatory body. The Workplace Hazardous Materials Information Systems (WHMIS) is one of its programs. As well, WSIB does on-site inspections to ensure that a safe working environment exists. The American equivalent to WSIB is the Occupational Safety and Health Association (OHSA): its standards are often used by Canadian healthcare facilities

WHMIS

- **WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEMS**
- WHMIS is a comprehensive plan for providing information on the safe use of hazardous materials used in Canadian workplaces. Information is provided by means of product labels, material safety data sheets (MSDS), and worker education programs
- The main components of WHMIS are **hazard identification** and **product classification labelling, MSDS,** and **worker training and education**

THE IMPORTANCE OF WHMIS

- WHMIS was developed by a steering committee with representatives from government, industry, and labour to ensure that the best interests of everyone were considered.
- WHMIS became law through a series of complementary federal, provincial and territorial legislation that became effective on October 31, 1988

WHMIS con't..

- The majority of the information requirements of WHMIS legislation were incorporated into the **Hazardous Products Act** and the **Hazardous Materials Information Review Act,** which were applied throughout Canada. Regulations made under these acts include:
  - **Controlled Products Regulations**
  - **Ingredient Disclosure List**
  - **Hazardous Materials Information Review Act Appeal Board Procedures Regulations**
  - **Hazardous Materials Information Review Regulations**

DID YOU KNOW…..

- The occupational health and safety components of WHMIS that apply to federal employees and others covered by the **Canada Labour Code (CLC)** are specified in the CLS and the **Canadian Occupational Health and Safety (OHS)** Regulations
- WHMIS is enforced by the **Labour Branch of Human Resources Development Canada** for federal workplaces, and by the provincial or territorial agencies responsible for OHS for most other workplaces

WHMIS RESPONSIBILITY

- Suppliers, employers, and workers all have specified responsibilities in the **Hazardous Products Act.**

  - **Suppliers**: Canadian suppliers are those who sell or import products. A controlled product must be labelled and include an MSDS for their customers according to the WHMIS legislation. The purpose of the labels is to **clearly identify the contents of the hazardous material,** and the MSDS is to **explain what the hazards are.**

WHMIS RESPONSIBILITES con't..

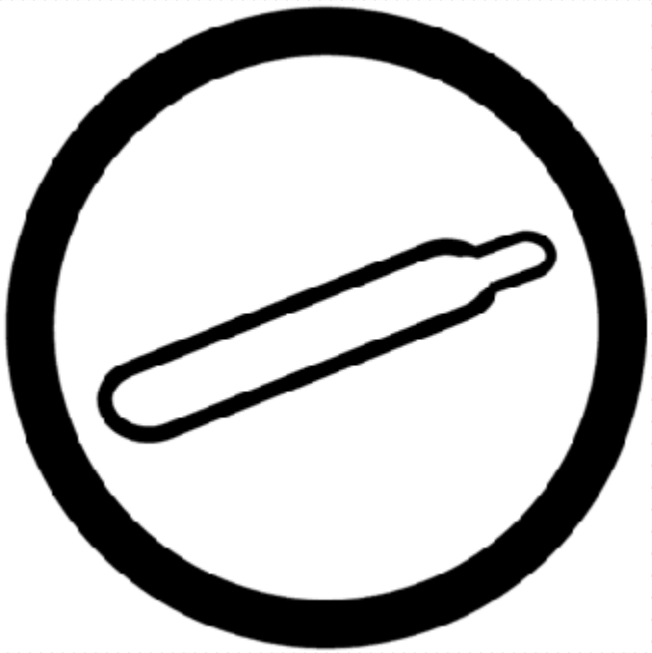
- **Employers**: Employers are required to establish education and training programs for workers exposed to hazardous products in the workplace. Employers must also ensure that the products are labelled and that the MSDS is presented for each product and that they are readily available to workers

- **Workers**: Workers are required to participate in the training programs and to use this information to help them work safety with hazardous materials. They must also inform employers when labels on containers have been inadvertently removed or not longer readable.

WHMIS CLASSIFICATIONS

- The term **'controlled product'** is given to products, materials, and substances that are regulated by WHMIS legislation. All controlled products fall into one or more of **six WHMIS classes.** All chemicals are grouped together with similar properties or hazards. The **Controlled Products Regulations** specifies the criteria used to place materials within each classification. There are **six classes,** and several classes have divisions or subdivisions. Each class has a **specific symbol** to help identify the hazard quickly.

CLASS A: Compressed Gas



- Any material that is normally a gas that is placed under pressure or chilled and contained by a cylinder is considered to be a compressed gas. These materials are dangerous because they are under pressure.

Compressed air, Carbon dioxide, Propane

Oxygen, Ethylene oxide, Welding gases

CLASS B: Flammable and Combustible Material

- Flammable means that the material will easily burn or catch fire at normal temperatures. Combustible material must usually be heated before they will catch on fire at temperatures above normal. Reactive flammable materials are those that may suddenly start burning when it comes in contact with air or water.

Propane, Butane, Acetylene, Ethanol, Acetone, Stoddard Solvent

Turpentine, Toluene, Kerosene, Varnish, Spray Paints

CLASS C: Oxidizing Materials

- Oxygen is necessary for a fire to occur. Some chemicals can cause other materials to burn by supplying oxygen. Oxidizers do not usually burn themselves, but they will assist fire by providing more oxygen, or they may cause material that normally does not burn to catch fire-this is called spontaneous combustion.

Oxygen/ozone, Liquids/nitric acid/Perchloric acid

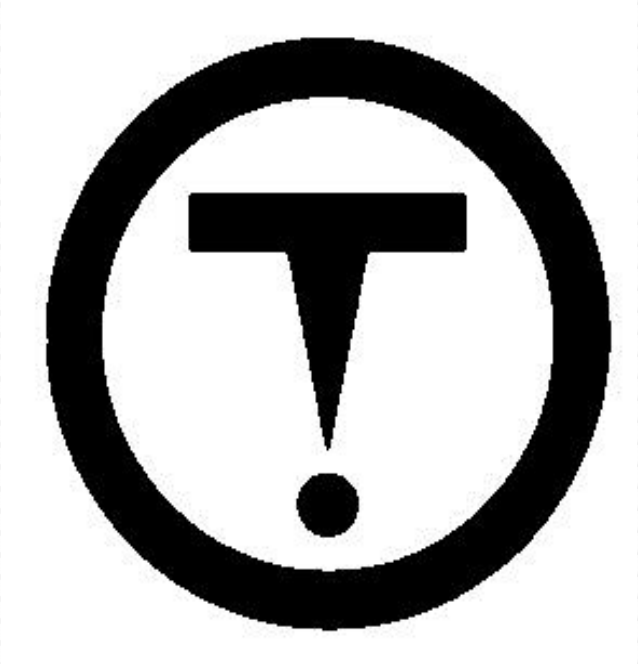
Solids/potassium permanganate/Sodium chlorite

CLASS D: Poisonous and Infectious Materials (3 Divisions)

- These materials are very poisonous and immediately dangerous to life and health. Serious health effects such as burns, loss of consciousness, coma, or death within just minutes or hours after exposure are grouped in this category

Division 1: Materials causing immediate and serious toxic effects	Carbon monoxide, sodium cyanide, Sulphuric acid, Toluene-2, Acrylonitrile

CLASS D: Poisonous and Infectious Materials



- These materials are also poisonous, but their effects are not always immediate, may only be temporary, but may still have very serious consequences such as cancer, allergies, reproductive problems, irritation/sensitization. Chronic effects have resulted from exposures over a period of time.
- **Subclass D2A**: Very toxic. Chemical has been shown to be carcinogenic, embryo toxic, teratogenic mutagenic. Reproductive toxic, or chronic toxic
- **Subclass D2B**: Toxic. Products produce sensitization of the skin, skin or eye irritation, chronic toxic effects, and mutagenic to non-reproductive cells.

Division 2: Materials causing Toxic Effects	Asbestos fibres, mercury, acetone, benzene, lead, cadmium

CLASS D: Poisonous and Infectious Materials

- These materials are organisms that support the toxins they produce, which cause diseases in people or animals. Included in this division are bacteria, viruses, fungi, and parasites. As these organisms can live in the body tissues and fluids, they should be regarded as toxic

Division 3: Biohazardous Infectious Materials	AIDS/HIV virus, Hepatitis B, Salmonella

CLASS E: Corrosive Material

- Corrosive is the name given to materials that can cause severe burns to skin and other human tissues, such as the eye or lung and can attack clothes and other materials, including metal. Corrosives are grouped in this special class because their effects are permanent.

Sulphuric and nitric acids, bases such as ammonium hydroxide and caustic soda

Other materials such as ammonia, chlorine, and nitrogen dioxide

CLASS F: Dangerously Reactive

- A material is considered to be dangerously reactive if it shows 3 different properties or abilities:
1. If it can react very strongly and quickly with water to make a toxic gas
2. If it will react with itself when it gets shocked or if the temperature or pressure increases
3. If it can vigorously coagulate, breakdown, or lose extra water such that it becomes a more dense material

If a material is dangerously reactive, it will be described as unstable.

Ethyl acrylate, Vinyl chloride, ethylene oxide, picric acid, anhydrous aluminum chloride

MATERIAL SAFETY DATA SHEET (MSDS)

- An **MSDS** is a document that contains information on the potential hazards of a chemical product and how to work safely with it. It is an essential starting point for the development of a complete health and safety program. It also contains information of the use, storage handling, and emergency procedures related to the hazards of the material. The **MSDS** provides additional details not included on the label.

9 Categories of Information Necessary on a Canadian MSDS

1. Product information (product identifier, manufacturer and supplier names, addresses and emergency numbers)
2. Hazardous ingredients
3. Physical data
4. Fire or explosion and hazard data
5. Reactivity data (i.e., information on the chemical instability of a product and the substance it may react with)
6. Toxicological properties (i.e., health effects)
7. Preventative measures
8. First Aid measures
9. Preparation information

Did You Know…??

- MSDS sheets **must** be updated every **3 years** under WHMIS law for controlled products
- The **Manufacturer** is responsible to update the MSDS
- **All employees must have access** to MSDS documentation

WHAT IS QUALITY HEALTHCARE?

- **Quality Healthcare** is defined by the degree of excellence to which an organization meets the clients' needs and exceeds their expectations.
- **Each** healthcare facility needs to provide all the appropriate and necessary resources to strive to meet or exceed these standards.
- These resources form the employee health services (e.g., occupational health and safety, ergonomics, workers' compensation, etc.)

QUALITY HEALTHCARE…con't

- **Each** department that reprocesses reusable medical devices must have a quality system in place. The quality system **must** include:
  - Written policies and procedures that are regularly reviewed and updated, with documentation controls to ensure that everyone is using the most recent procedures
  - Personnel policies that specify staff qualifications, responsibilities and reporting relationships, and that support continual improvements
  - Continual improvements in all aspects of the facility's operations

QUALITY MANAGEMENT SYSTEM

- All healthcare facilities performing any reprocessing function **must** establish, document, and implement a **Quality Management System (QMS)** and maintain its effectiveness in accordance with the requirements of Canadian standards

QUALITY MANAGEMENT SYSTEM..con't

- **The main function** of the QMS is to establish consistency and control of the required processes and documentation to produce quality products that meet customer and regulatory requirements. A QMS gives assurance that the department's policies, procedures, and processes are in compliance with Canadian standards, and that its products and services will provide the highest possible degree of safety and quality to the patients and staff.

THE QMS MUST INCLUDE (11 Components):

- Policies and procedures reviewed at specified intervals
- A chart outlining the organizational structure of the MDRD responsibilities within the healthcare setting
- Requirements for management and staff qualifications, including roles, responsibilities, and accountability
- A process for continual improvement
- Customer-focused approaches, requirements, and services

THE QMS…con't

- A communication plan for internal and external stakeholders
- Performance indicators and a means to measure and monitor (e.g., audits performed by internal and external sources)
- A process for:
  - Change control
  - Management of adverse events
  - Management of drugs and products
  - Product recalls, either manufactured or purchased

THE QMS…con't

- Infection prevention and control
- Occupational and environmental health and safety
- A process for regular management review of:
  - Client issues and follow-up
  - Resources to ensure they are adequate
  - Key performance indicators (KPIs)
  - Any changes that could affect the QMS
  - Follow-up actions from a previous management review
  - Preventative actions based on risk analysis
  - Documented actions and objectives coming from the management review that will foster continual improvement

DOCUMENTATION AND RECORDS

- Each item/service should be documented with valid statistics that include:
  - A quality policy, plan, and key performance indicators (KPIs)
  - Procedures to achieve the KPIs
  - Procedures to control the processes
  - Procedures to evaluate process outcomes
  - Protocols for any required corrective actions
  - Records required by quality standards and any other documentation specified by national or regional regulations (e.g., Manufacturer's Instructions for Use (IFUs) for medical devices or reprocessing equipment)

CONTROL OF DOCUMENTS

- A document procedure must be established to ensure that documents and records required by the QMS are:
  - Reviewed and approved prior to use
  - Updated, revised, and reapproved as needed
  - Archived when obsolete, given suitable identification if retained for any purpose, and prevented from unintended use
  - Legible, readily identifiable, and retrievable
  - Identified if they are of external origin and their distribution controlled

The MDRD **must define** the period for which at least one copy of obsolete controlled documents should be retained

POLICIES AND PROCEDURES

- A policy is a guiding principle that is documented and used to set direction in an organization. The policies for reprocessing medical devices need to be integrated with the healthcare facility's existing policies.

- They are written based on best practices and **must** conform to CSA Standards.

POLICIES AND PROCEDURES…con't

- Documented policies, including those for quality control for the following, are required for the reprocessing of reusable devices:
  - Staff and management responsibilities
  - Qualifications, education, and training of personnel
  - Infection prevention and control
  - Establishment and maintenance of procedures and protocols
  - Worker health and safety
  - Evaluation and purchase of medical devices and reprocessing equipment

POLICES AND PROCEDURES…con't

- Requirements for subcontractors (if used); whether they operate within or outside the healthcare facility
- Ongoing quality assurance and competency assessment to maintain compliance with procedures and protocols for medical device reprocessing
- Contingency planning (e.g., anticipating and preventing inventory problems), and arranging backup plans to cover temporary shortages and service interruptions
- Environmental conditions and infrastructure

PROCEDURES

- The purpose of a procedure is to ensure the consistency of each product, process and/or service provided.

- Procedures must be established to describe:
  - Each service or production process provided by the MDRD
  - All services or production process changes are outlined in the following steps:
    - Identification
    - Documentation
    - Review
    - Approval

STANDARD OPERATING PROCEDURES (SOPs)

- The healthcare facility should establish and maintain **Standard Operating Procedures (SOPs)** for the following:
  - **All steps of medical device reprocessing, including standard sterile storage and distribution**
  - **Reprocessing of devices according to their risk class and the written manufacturer's instructions**
  - **Management and reporting of occupational health-and-safety related accidents and incidents**
  - **Reassembly and functional testing of reprocessed devices**
  - **Lifecycle management of reposable medical devices and equipment (e.g., reprocessing, generators)**

SOPs…con't

- Identification and appropriate management of devices with design or material characteristics that make the devices difficult to clean (e.g., lumens less than **1 mm** in diameter, channels that are not freely accessible, devices that cannot be readily dismantled, etc.)
- Contingency plans for emergency situations (e.g., equipment shutdowns, steam or other utility shutdowns, large scale inventory loss, and natural disasters)
- Management of utilities critical to effective reprocessing (e.g., water and steam quality)
- Packaging in accordance with CAN/CSA Z314.10.1

IMPORTANT NOTES…

- Procedures should be maintained in a printed form (e.g., binders, manuals or monographs) or electronic format. **The procedures should be placed in a central location where they are readily available.**
- Procedures should also be reviewed and updated at intervals defined by the healthcare facility to remain current. The timeframe for this review and update should be stated in the healthcare facility's policies.

SENIOR MANAGEMENT RESPONSIBILTY

- Leadership requires skills that assist in the management of data, opportunity planning, establishment of priorities, and training of staff to implement improved processes. In order to develop strategies, assess client satisfaction, promote patient experience, effective leaders must define standards and serve as the hospital's quality committee.

Management Should Designate an Individual Responsible for:

- Ensuring that processes needed for the QMS are established, implemented, and maintained
- Reporting to management on the performance of the QMS and any need for improvement
- Ensuring the promotion of awareness of customer and regulatory requirements throughout the MDRD
- Liaising with external parties on matters related to the QMS

QUALITY CONTROL INDICATORS

- **The purpose of quality control indicators** are used to monitor how well the MDRD is meeting departmental objectives in adhering to CSA Standards in the reprocessing of medical devices.
- Examples of MDRD quality indicators include:
  - Sterilization procedures are CSA-approved based on mechanical, chemical, and biological indicators (BI) results
  - Instrument sets contain correct contents
  - Client/patient supplies and equipment are available, accessible, and in proper working condition at all times

QUALITY CONTROL INDICATORS…con't

- Sterilization indicators are properly maintained, logged, and reported for all sterilizers
- The use of Immediate Use Steam Sterilization (IUSS-Flash-sterilization) is performed utilizing CSA Standards and accepted practices involving documentation
- BIs accompany every load that require biological monitoring
- Complete and accurate contents on case-carts
- Correct and up-to-date surgeon pick cards

Management Control Monitors

- All directors, managers, supervisors, and lead technicians **must** be thoroughly trained in MDRD principles which include:
  - Policies, procedures, standards must have timelines and documented outcomes for quality control via written procedures and work assignment lists
  - All written procedures must be available to every MDRD technician for necessary review and referral
  - Quality control checks (technical, statistical sampling method that measures the quality of production) must be performed on a regular basis as determined by the healthcare facility

Management Control Monitors…con't

- Safety inspections promote quality and can assist to avoid accidents and keep staff healthy
- Safety inspection reports can provide information that may prevent accidents and prevent loss of working time and prevent increase of sick-time
- Safety Occurrence Reports (SORs) are useful in determining process trends (e.g., missing instruments from trays, bioburden in lumens, small instruments, etc.) SORs can also warn of possible poor-quality service
- Staff complaints

INTERNAL AND EXTERNAL AUDITS

- Management needs to review the quality system at **specific intervals**
- The use of periodic **external audits**, conducted by third-party agents outside the organization, should occur to measure progress and to identify areas for improvement
- **Internal audits** need to be performed periodically by appropriate personnel to verify the continuing effectiveness of the system. Audits need to be carried out according to an established program by trained staff who do not have direct responsibility for the procedures being audited.

HUMAN RESOURCES

- **Competency, Awareness and Training**
- Personnel performing work affecting product quality must be competent on the basis of appropriate education, training, skills, and experience
- **The four (4) areas that all MDRD technicians must consistently practice quality processes that are specific to the different areas within MDRD are:**
  - Decontamination area
  - Assembly area (Prep/Pack)
  - Sterilization area
  - Distribution area ('Case-Room')

TOTAL QUALITY MANAGEMENT (TQM) AND SIX SIGMA

- **Total Quality Management (TQM)** is an organizational-wide quality approach based on participation of all members that aims for long-term success through customer satisfaction and benefits to all members of the organization and society. TQM requires that the facility maintain quality standards in all aspects of its business and ensures that work procedures are correctly performed the first time and defects and waste are eliminated. TQM aims to improve the quality of the organization's processes, products, and services

SIX SIGMA

- The objective of Six Sigma is to deliver high performance, reliable outcomes, and value to the end consumer.
- It relies on data for the elimination of defects that measures how far a process deviates from perfection and how to eliminate waste, thereby improving efficiency

DIFFERENT CATEGORIES FOR SIX SIGMA IMPLEMENTATION

- Executive leadership and administrators responsible for establishing a vision. They must empower their team with the freedom and resources to explore new ideas and improvements.
- Champions drawn from upper administrative levels are responsible for implementation across the organization. They are mentors to Master Black Belts (known as quality leaders)

SIX SIGMA CATEGORIES…con't

- Master Black Belts are in-house expert coaches for the organization, and focus their time to Six Sigma efforts in guiding black and green belts
- Black Belts apply Six Sigma methodology to specific projects, and focus on project execution
- Green Belts incorporate Six Sigma responsibilities with other job obligations
- Orange Belts receive training that assists them to understand Six Sigma methodology

QUALITY SYSTEMS RESOURCE SITES

- CSA Standards: http://www.csa.ca
- Central Service Association of Ontario (CSAO):
  - www.csao.net
- Provincial Infectious Diseases Advisory Committee (PIDAC): http://www.publichealthontario.ca
- IAHCSMM: www.iahcsmm.org

QUALITY SYSTEMS RESOURCE SITES

- Operating Room Nurses Association of Canada (ORNAC): www.ornac.ca
- AORN (The Official Voice of Perioperative Nursing): www.aornjournal.org

Questions?