



Lather, Rinse, Reuse

A Reusable Device Audit Tool

**UHN Infection Prevention and Control Education Day
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(former chair - Re-Usable Medical Device Committee,
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Credits:

(Guidance Matrix Working Group)

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Agenda



- Background of the RMD
- Why a Guidance Matrix
- What is it?
- How is it used?

Health Canada Recommendations

(April 24, 2004)

Hospitals who clean, disinfect and sterilize RUDs should have in place:

- Procedures to ensure that RUDs are cleaned, disinfected and sterilized according to manufacturer's instructions
 - A mechanism to regularly review these procedures and ensure that they are being followed
 - A requirement, at the time of purchase, that manufacturers include complete instructions and, where necessary, adequate training for the cleaning, disinfecting and sterilizing of RUDs
 - A procedure to report to Health Canada any cases in which the manufacturer does not provide adequate instructions
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UHN Response

Creation of Re-Usable Medical Device Committee (RMD) reporting to Surgical Directorate

- Central Processing Department Managers and Education & Quality Coordinators
- Surgical Directors
- OR Managers / PCC's
- IPAC
- Medical Engineering
- Risk and Quality Management
- Plexxus (Purchasing – formerly SHSS)

Health Canada Recommendations

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 - A requirement, at the time of purchase, that manufacturers include complete instructions and, where necessary, adequate training for the cleaning, disinfecting and sterilizing of RUDs
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Re-Usable Medical Device Committee (RMD)

- Established strict requirements for validated manufacturer reprocessing instructions
 - Met with vendors to explain requirements
 - If instructions 'in doubt' required validation study data
 - Study data/validations not always available!!
(or extensive requirements involved....)
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Re-Usable Medical Device Committee (RMD)

- The result was:
 - ❑ 'Non-approval' of devices
 - ❑ No mechanism to approve 'in-house' innovations
 - ❑ Frustrated clinicians/committee members
 - ❑ Need to establish 'appeal' mechanism
 - ❑ Need to develop 'objective' data/criteria
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Re-Usable Medical Device Committee (RMD)

- November 2006 – UHN Quality of Care Committee becomes parent committee of RMD under sponsorship of Chief of Surgery
 - Received approval to develop audit tool (“Decision Matrix”) to assist in objective assessment of RMD’s for reprocessing
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Why a “Decision Matrix”

- RMD's becoming increasingly complex
 - Validated cleaning and sterilization instructions not always supplied or available from manufacturer
 - Need to enable and foster ‘innovation’ in surgical care
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Why a “Decision Matrix”

- PIDAC Best Practices Document – device specific instructions for cleaning/sterilization
 - CSA Standards – similar to PIDAC, however allows for institutions to develop internal review process that includes MDR, IPAC, Medical Engineering and Risk Management experts
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Guidance Matrix for Re-Usable Medical Devices (RMD)

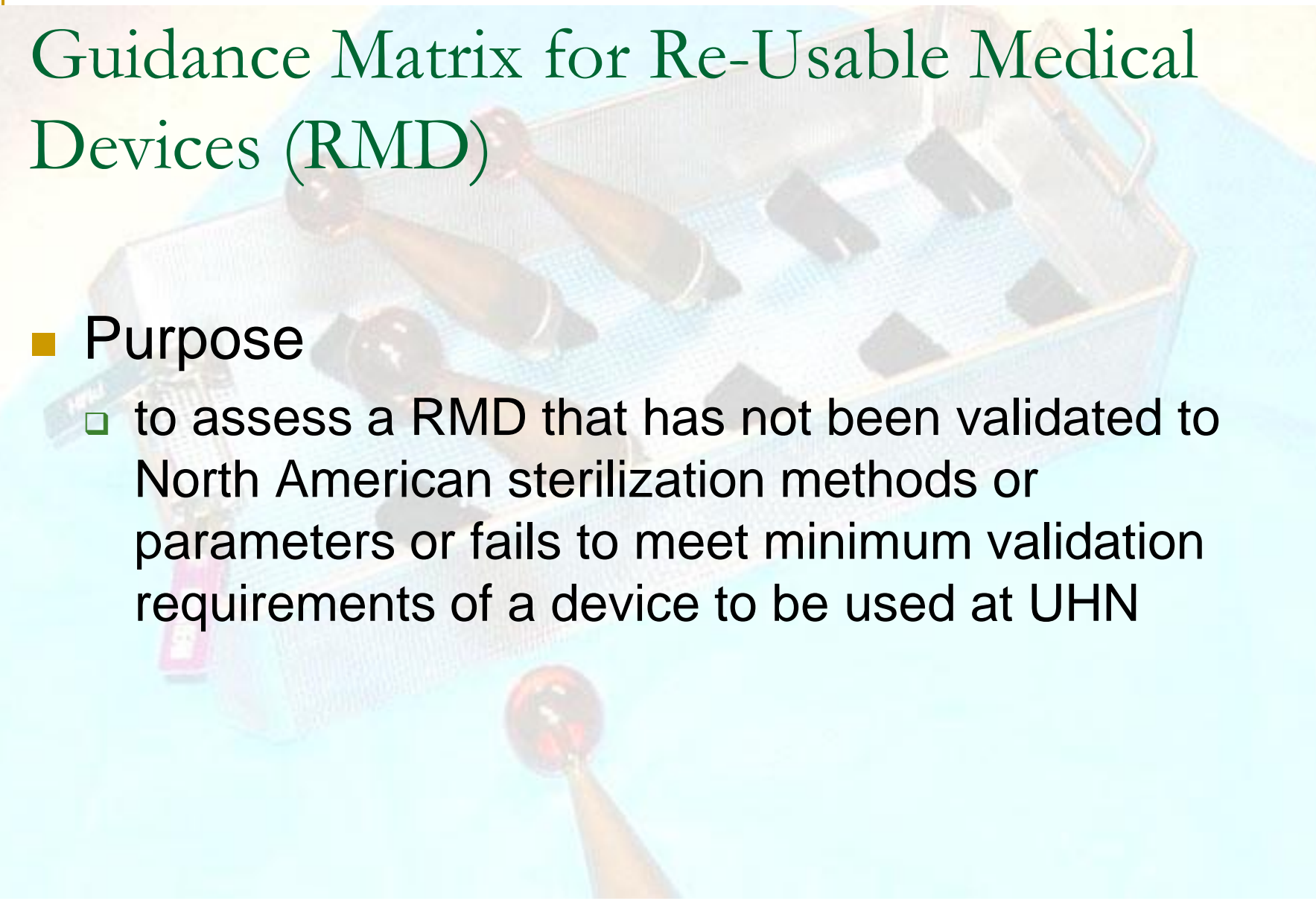
- Establish a working group (from RMD)
 - Literature search
 - Develop a model
 - Validate and test
 - Modify
 - Validate and test
 - Etc....
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Guidance Matrix for Re-Usable Medical Devices (RMD)

- Started as “Decision Matrix”
 - Testing and validation of tool showed that values are not ‘absolute’
 - Evolution to “Guidance Matrix” – a powerful objective tool to assist in evaluation of a medical devices’ ability to be safely cleaned and/or reprocessed within a health care facility
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Guidance Matrix for Re-Usable Medical Devices (RMD)

■ Purpose

- to assess a RMD that has not been validated to North American sterilization methods or parameters or fails to meet minimum validation requirements of a device to be used at UHN
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Guidance Matrix for Re-Usable Medical Devices (RMD)

■ Three Distinct Sections

- ❑ Section A - General Information (not part of Matrix)
- ❑ Section B - Mandatory Requirements (if minimal requirements not met – will NOT be reprocessed)
- ❑ Section C - Reprocessing Challenges (weighted scoring)

Guidance Matrix for Re-Usable Medical Devices (RMD)

■ General Information

- ❑ Validation forthcoming (to follow)
 - ❑ ‘Default Parameters’ failure to validate (Extended cycles required)
 - ❑ Frequency of use (patient impact)
 - ❑ Innovation
 - ❑ Elective vs. Emergent use
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Guidance Matrix for Re-Usable Medical Devices (RMD)

- **Mandatory Requirements**
 - ❑ Sign-off by senior regulatory official (in lieu of validation report)
 - ❑ Compliance with CSA safety standards
 - ❑ EN Fractionated steam validation on RMD contains lumens
 - ❑ Medical device licensing
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Guidance Matrix for Re-Usable Medical Devices (RMD)

- Reprocessing Challenges
 - General Validations
 - Validation for Cleaning
 - Instrument Criteria
 - Instrument Configuration
 - Instrument Complexity
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Guidance Matrix for Re-Usable Medical Devices (RMD)

■ Weighting

- Each criteria has a **weight value** based on the degree of challenge (3 = greatest, 1 = non-critical challenge)
- Evaluator assigns a value of 0, 1 or 2 corresponding to each criteria, where 0 represents no challenge and 2 represents greatest challenge
- Overall criteria value is the **weight X assigned value**

Guidance Matrix for Re-Usable Medical Devices (RMD)

■ General Validations

- ❑ Validation based on “equivalence”?
- ❑ Validation for set vs. individual component/RMD?
- ❑ Validation based on European (EN) pre-vacuum?
(ie. Fractional)
- ❑ BI (PCD) available to authenticate cycle?
- ❑ Validation load configurations?

Guidance Matrix for Re-Usable Medical Devices (RMD)

- Validation for Cleaning
 - ❑ Manual vs. automated cleaning?
 - ❑ Can it be disassembled?
 - ❑ Closed-ended lumens?
 - ❑ Retractable/sliding parts? Ball & socket design?
 - ❑ Hard to reach areas? (eg. Undercuts?)
 - ❑ Difficult to rinse materials? (eg. Plastics)
 - ❑ RO / sterile water rinse requirements?
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Guidance Matrix for Re-Usable Medical Devices (RMD)

■ Instrument Criteria

- ❑ Used invasively? (Spaulding)
 - ❑ Service considerations (eg. service after x uses?)
 - ❑ Reusable?
 - ❑ Wicking required? (eg. Bulldogs, clips)
 - ❑ Labour intensive setup in MDR?
 - ❑ Difficult lubrication required?
 - ❑ RMD contains threaded instruments?
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Guidance Matrix for Re-Usable Medical Devices (RMD)



■ Instrument Configuration

- ❑ Closed for sterilization?
- ❑ Contains springs and/or bearings?
- ❑ Lay-out in container? (eg. Metal on metal stacking)
- ❑ High mass?
- ❑ Dissimilar materials? (eg. Metal and wood/composite/other (pheneol))

Guidance Matrix for Re-Usable Medical Devices (RMD)



■ Instrument Complexity

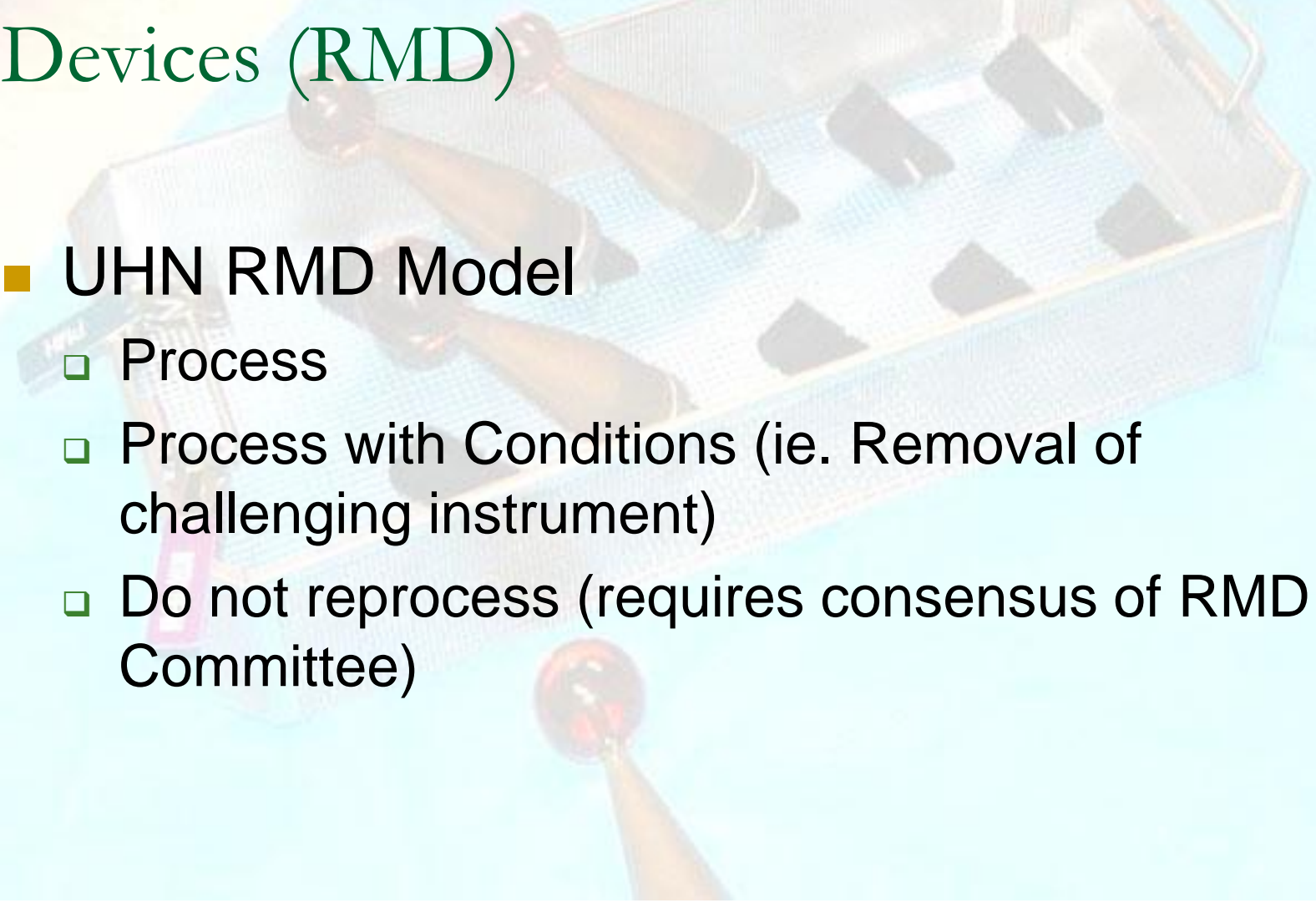
- ❑ Implantable device or used 'on' implantable device?
- ❑ Non take-apart multi-component?
- ❑ Custom built?
- ❑ Contains blocked holes?
- ❑ Lumen diameter < 3mm?
- ❑ Lumens with 90 degree bends?
- ❑ Lumens with more than 1 bend?
- ❑ Multi-layers tray/set > 25 lbs?

Guidance Matrix for Re-Usable Medical Devices (RMD)

- Total Maximum Value (144)
 - The greater the score – the greater the challenge
 - Scores not absolute – but a valuable and objective tool to assist with your evaluation
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Guidance Matrix for Re-Usable Medical Devices (RMD)

■ UHN RMD Model

- Process
 - Process with Conditions (ie. Removal of challenging instrument)
 - Do not reprocess (requires consensus of RMD Committee)
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Questions?

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