Why Do We Reprocess and Track RIMD?
Because dirty RIMD pose a risk to patients if:
• Debris is not removed
• Unchecked instruments fail in a procedure
• Some infectious agents cannot be removed totally
• Reduce cross infection
• Maintain the integrity of the Instruments
• Because we don’t know what’s next!!!

Which Guidance Governs or Influences What We do?
• Medical Devices Directive (93/42/EEC)
• Medical Devices Directive (93/42/EEC) Annex 12
• HSE Code of Practice for Decontamination of Reusable Invasive Medical Devices (RIMD).
  Version 1.0 (Illustrated), 2007 (revised version including a separate Loan RIMD aspect due for release April 2010)
• Outside Southern Ireland?
  – HTM 01 01 – Part B (Draft) (Loan Set Management)
  – SHTM – Loan RIMD
What Information Might A Hospital Be Asked To Evidence?

- Date introduced
- Equipment Lot, Batch and unique ID
- Compliant Decontamination Process
- Maintenance and Service History of CSSD Equipment
- Access to accompanying reprocessing and usage instructions for the device
- Evidence that staff have been trained on how to handle, disassemble and reassemble complex MDD

Tracking high risk items in both manual and computerized tracking systems

- High Risk Items – Posterior Eye & Neurological RIMD
  - Prion transmission potential
- Medical Device Categories Class 2B and 3
  - Long term invasive devices and implantable devices – Product recall

Responsibilities For Proving Compliance?

- Should a patient suspect that a contaminated device has caused a medical complication, it is the hospitals responsibility to prove that the appropriate steps have been taken.
- In the case of an MD recall, it is the responsibility of the hospital to co-ordinate notification and recall to patients
What this means in terms of practical approaches to reviewing set and item history. Single site and multiple site use.

- All sets and LOT history's need to be processed under a master code, otherwise how can a system build a solid history of use?
- Tracking one LOT through a compliant process doesn't build enough history to know if the set is safe to use.

Your Own RIMD

- Unique code on a set of instruments?
- Same code and process used through each LOT
- The set never leaves your site to be used somewhere else
- The unique code on the tray is used to track to use on patient records
- Your reprocessing equipment is validated and maintained to the regulatory standards
- Only appropriately trained staff handle complex medical devices
- Instructions for use of category 2b and 3 medical devices are always available to theatres for reference.

Why Be Concerned With Instrument Migration?

- Checking identifies lost items
- Reduce the chance of cross infection
- Critical in high risk sets to avoid Prion transmission
- Should an adverse incident occur, you can minimize quarantined items to a specific tray, rather than them all!
Combating instrument Migration

- Single instrument marking and tracking
- Speed of reprocessing – faster or slower?
- Does this stop migration?
- Pro’s and Con’s?

Cultural Change

- CSSD
- Theatres
- Analyze the current situation – non conformance reporting
- Identify weak areas
- Implement corrective procedures
- Re-assess
- Change

Continual review

Loaned RIMD

Let’s think about what we have discussed in the context of loaned equipment. For the purpose of this session, let’s go through the questions looking at what we do and what we don’t know!

- Unique code on a set of instruments?
- Same code and process used through each cycle
- The set never leaves your site to be used somewhere else
- The unique code on the tray is used to track to use on patient records
- Your reprocessing equipment is validated and maintained to the regulatory standards
- Only appropriately trained staff handle complex medical devices
- Instructions for use of category 2a and 3 medical devices are always available to theatres for reference
Manual and Computerised Traceability

- If I receive a request from the following sources, can I track back to every patient use:
  - Let's consider the questions in the context of:
    1. No-traceability system
    2. A manual traceability system
    3. A computerised traceability system
    4. A computerised traceability system linked to a theatre management system

  - Request from theatres with patient number?
  - Request from theatres with a unique code on a set of instruments?
  - Request from the IMB on a product recall?

How Can We Meet The RIMD Requirements Of The Hospital But Still Meet Our Regulatory Needs and Patient Care Delivery?

- How do we manage our RIMD stock
- Do we know what we have and how often it is used
- Do we loan equipment from other sites, and if so why?
- If we don't loan from other sites why is this, and would we benefit from having access to more RIMD?

Commercial loans sets and Inter-hospital loans - the need for such items and the tracking considerations

- Lack of RIMD creates the need for these services
- Can you track them to the same level as your own RIMD
- Are you confident regarding the history of the RIMD you are borrowing?
Why Are Unique Tray & Instrument Codes Important

• A tray or instrument code needs to be unique to all users
• All tracking systems work on databases, so you can’t risk entering a non-unique number
• So what does that mean to my department?

Current Options For Tracking Equipment

<table>
<thead>
<tr>
<th>Barcode</th>
<th>Item Description</th>
<th>Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>1234567</td>
<td>General Basic Tray</td>
<td>Hospital Site</td>
</tr>
<tr>
<td>1234567</td>
<td>Arthroscopy Set</td>
<td>Another hospital's set or a loan set</td>
</tr>
</tbody>
</table>

• Scanning in:
  - Scan the non-unique barcode - conflict with an existing number
  - Process on a generic barcode
  - Create a new barcode to track the single process
  - Create a new barcode and type each line item into your T&T system

How A Central Database Can Help

- Host your data
- Work with all hospitals to provide access and integration
- Help you obtain, manage and generate your GS1 codes and tray tags
So What Benefits Do Unique Tray and Instrument Codes Deliver?

- Seamless RIMD Tracking for Commercial Loan Sets
- Seamless RIMD Tracking for Inter-Hospital Loan Sets
- Business Continuity Planning

Re-coding is not as complicated as it first appears - Manual Users

- For Manual Tracking Systems:
  - Tag and code your trays with GS1 codes, description and location – MS1 can provide the tools you need to do this
  - You can then deploy a business continuity plan with a partner site and share your sets with traceability
  - This will add to your current traceability

Re-coding is not as complicated as it first appears - Computerised T&T users

- For Computerised Tracking Systems:
  - Tag and code your trays with GS1 codes, description and location - your track and trace provider will show you how to associate the new code with your existing number
  - You can track inter-hospital loans
  - You can deploy a business continuity plan with a partner site and share your sets with traceability
  - This will add to your current traceability
What do you see as the advantages and disadvantages of sharing R1MD?

If all sites could share instrumentation compliantly, what would this mean for healthcare in general?

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