Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

CUH
Ospidéal Ollscoile Chorcaí
Cork University Hospital

IDI
IRISH DECONTAMINATION INSTITUTE

Workshop: The nitty gritty of risk assessment - decontamination processes

IDI Managers Study Day April 12th 2012

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Aim & Objectives

Gain greater clarity, a deeper understanding and insight into the risk assessment process for decontamination RIMD

- Demystify risk assessment process
- Build on own experience
- Focus on the practicalities of risk assessment – (how is it done and how often is it done)

Risk management

- Proactive Risk Management →
  Risk Register

- Reactive Risk Management →
  Incident Management

What is **Proactive** Risk Management?

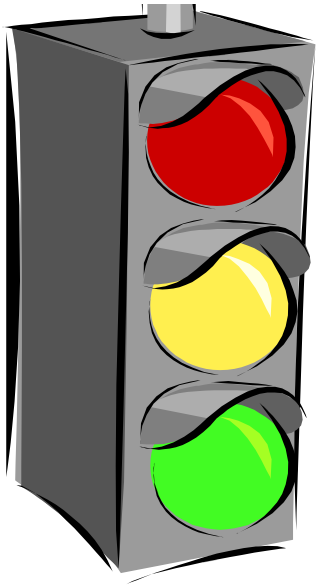
Work out what can go wrong and plan for the eventuality

→ spot a problem in the making and do something about it in advance

What is a risk register?

A risk register is a **database of risks** that face an organisation its staff and service users at any time.

Always changing to reflect the dynamic nature of risks and the organization's management of them.



Supporting Resources to Assist Risk Assessment Process

- HSE Decontamination Standards & Recommended Practices 2011
- HSE Risk Management in the HSE :An information Handbook Oct 2011
- HSE Risk Assessment Tool & Guidance (including guidance on application Oct 2011
- HSE Developing & populating a Risk Register- Best Practice Guidance Feb 2008

Resources where to get them

HSE Risk Assessments Docs via

- http://hsenet.hse.ie/HSE_Central/qualitypatientsafety/?importUrl=http://localhost:82/eng/about/Who/Quality_and_Clinical_Care/Riskmanagement/

HSE Decontamination RIMD Best Practice Guidance

- www.hse.ie/eng/Publications/services/Hospitals/

Importance of Professional Judgement

- Risk assessment and analysis can be a subjective process **relying on the knowledge and experience of the person making the analysis.**

- **Stakeholders & Team – should have clearly defined roles**

Completing the Risk Assessment **Form** Section 1

- **Administrative Area:**
- **Location:**
- **Section/Ward/Dept:**
- **Date of Assessment:**
- **Source of Risk:**
- **Unique ID No:**
- **Primary Risk Category:**
- **Secondary Risk Category:**
- **Tertiary Risk Category:**
- **Name Risk Owner: (BLOCKS)**
- **Signature of Risk Owner:**

Completing the Risk Assessment **Form** Section 2

RISK DESCRIPTION	IMPACTS/VUNERABILITIES	EXISTING CONTROL MEASURES	ADDITIONAL CONTROLS REQUIRED	PERSON RESPONSIBLE FOR ACTION	DUE DATE

Describe the Risk

ICC approach

- Describe the primary area of **Impact** if the risk were to materialise.
- Describe the **Causal Factors** that could result in the risk materialising.
- Ensure that the **Context** of the risk is clear
  - →is the risk 'target' well defined (e.g. staff, patient, department, hospital, etc.) and
  - → is the 'nature' of the risk clear (e.g. financial, safety, physical loss, perception, etc.)

Example of ICC Approach

- Potential injury to service users and staff **(impact)**

  due to old, unreliable & not fit for purpose steam sterilzer **(causal factor)**

  in the CDU **(context)**

Impacts & Vulnerabilities

- What is the likely harm that will occur if it does happen?
- HSE classified impacts into eight types of Harm

Completing the Risk Assessment **Form**
Section 2 continued
Existing Controls

RISK DESCRIPTION	IMPACTS/VUNERABILITIES	EXISTING CONTROL MEASURES	ADDITIONAL CONTROLS REQUIRED	PERSON RESPONSIBLE FOR ACTION	DUE DATE

Existing Controls

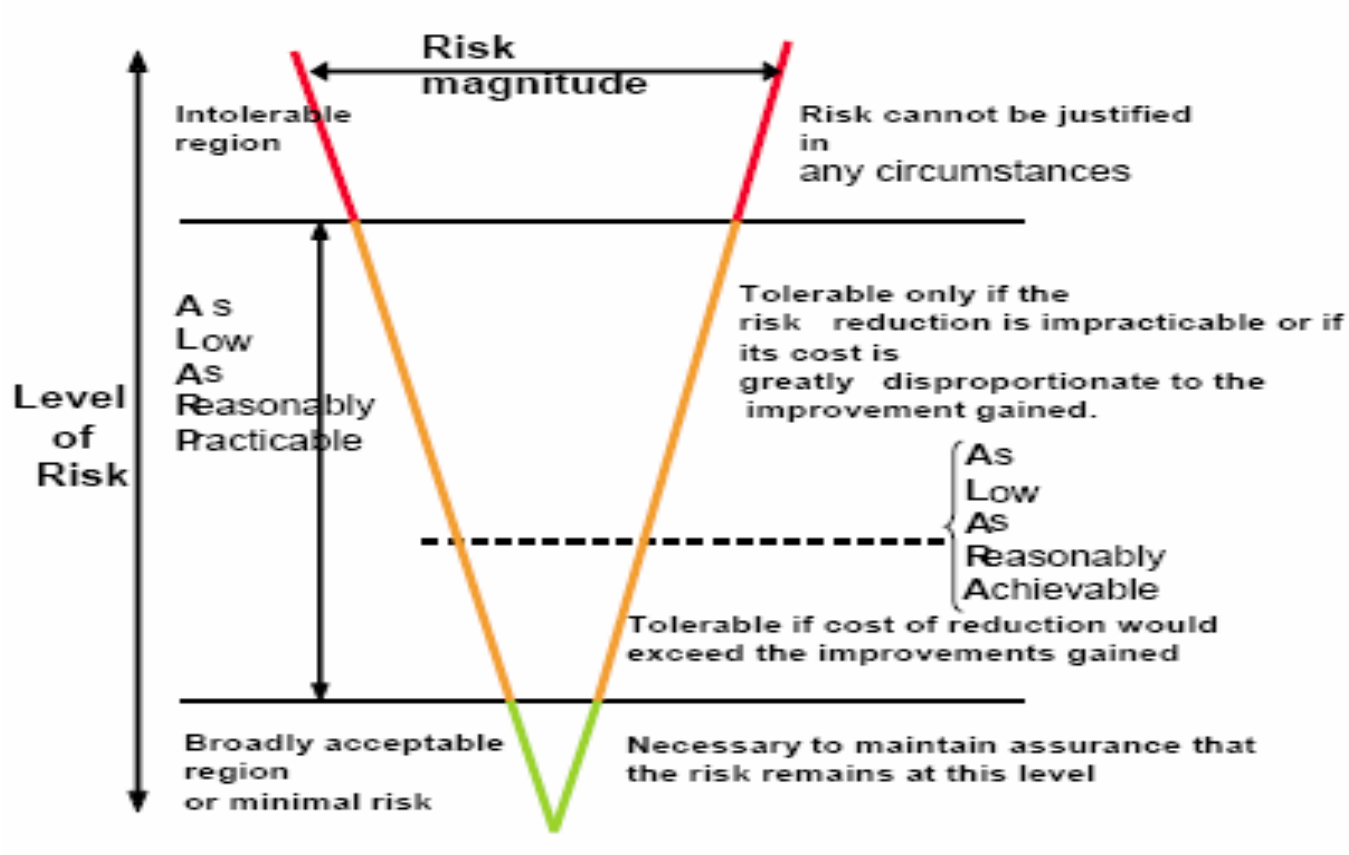
Need to consider

- Adequacy
- Method of implementation
- Effectiveness

in minimizing risk to low as is reasonably practicable level → LRPL

- in a safety context it is often required to make the adverse impacts of a risk as low as is reasonably practicable level

As low as is reasonably practicable (ALARP) Principle



Additional Controls Required

Work through hierarchy of controls
higher up the more reliable

- Elimination
- Substitution
- Engineering Controls
- Administrative Procedure and safe work practices
- PPE – last control measure to be considered

Completing the Risk Assessment **Form**
Section 3 Risk Analysis

INITIAL RISK			RESIDUAL RISK			STATUS
Likelihood	Impact	Initial Risk Rating	Likelihood	Impact	Residual Risk Rating	

HSE's Risk Assessment Tool

- To **reduce subjective biases** as far as possible and **make the process more objective** the HSE's Risk Assessment Tool should be used when analysing risk.

Analysing the risk – Six ?

- If this risk was to be managed effectively what controls would be required to be in place?
- What are the existing controls ?
- How effective are they ?
- Given the controls that are in place – how would you rate this risk?
- Are additional controls required? Y/N
- Is it ‘actual’ or ‘potential’ risk ?

Rating the Risk

- Risk is **analysed** and **rated** in terms of
  → **Likelihood** (how likely is it to happen?) &

→ **Impact** (what is the likely harm that will occur if it does happen?)

Rating the Impact

1. IMPACT TABLE	Negligible	Minor	Moderate	Major	Extreme
Injury	Adverse event leading to minor injury not requiring first aid.	Minor injury or illness, first aid treatment required <3 days absence < 3 days extended hospital stay Emotional Distress	Significant injury requiring medical treatment e.g. Fracture and/or counselling. Agency reportable, e.g. HSA, Gardaí (violent and aggressive acts). >3 Days absence 3-8 Days extended hospital Stay Emotional Trauma	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling Physical /emotional disability	Incident leading to death or major permanent incapacity. Event which impacts on large number of patients or member of the public (Emotional / Physical trauma)
Service User Experience	Reduced quality of service user experience related to inadequate provision of information	Unsatisfactory service user experience related to less than optimal treatment and/or inadequate information, not being to talked to & treated as an equal; or not being treated with honesty, dignity & respect - readily resolvable	Unsatisfactory service user experience related to less than optimal treatment resulting in short term effects (less than 1 week)	Unsatisfactory service user experience related to poor treatment resulting in long term effects	Totally unsatisfactory service user outcome resulting in long term effects, or extremely poor experience of care provision
Compliance with Standards (Statutory, Clinical, Professional & Management)	Minor non compliance with internal standards. Small number of minor issues requiring improvement	Single failure to meet internal standards or follow protocol. Minor recommendations which can be easily addressed by local management	Repeated failure to meet internal standards or follow protocols. Important recommendations that can be addressed with an appropriate management action plan.	Repeated failure to meet external standards. Failure to meet national norms and standards / Regulations (e.g. Mental Health, Child Care Act etc). Critical report or substantial number of significant findings and/or lack of adherence to regulations.	Gross failure to meet external standards Repeated failure to meet national norms and standards / regulations. Severely critical report with possible major reputational or financial implications.
Objectives/Projects	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over – run.	Inability to meet project objectives. Reputation of the organisation seriously damaged.
Business Continuity	Interruption in a service which does not impact on the delivery of service user care or the ability to continue to provide service.	Short term disruption to service with minor impact on service user care.	Some disruption in service with unacceptable impact on service user care. Temporary loss of ability to provide service	Sustained loss of service which has serious impact on delivery of service user care or service resulting in major contingency plans being involved	Permanent loss of core service or facility. Disruption to facility leading to significant 'knock on' effect
Adverse publicity/ Reputation	Rumours, no media coverage. No public concerns voiced. Little effect on staff morale. No review/investigation necessary.	Local media coverage – short term. Some public concern. Minor effect on staff morale / public attitudes. Internal review necessary.	Local media – adverse publicity. Significant effect on staff morale & public perception of the organisation. Public calls (at local level) for specific remedial actions. Comprehensive review/investigation necessary.	National media/ adverse publicity, less than 3 days. News stories & features in national papers. Local media – long term adverse publicity. Public confidence in the organisation undermined. HSE use of resources questioned. Minister may make comment. Possible questions in Daíl. Public calls (at national level) for specific remedial actions to be taken possible HSE review/investigation	National/International media/ adverse publicity, > than 3 days. Editorial follows days of news stories & features in National papers. Public confidence in the organisation undermined. HSE use of resources questioned. CEO's performance questioned. Calls for individual HSE officials to be sanctioned. Taoiseach/Minister forced to comment or intervene. Questions in the Daíl. Public calls (at national level) for specific remedial actions to be taken. Court action. Public (independent) Inquiry.
Financial Loss (per local Contact)	<€1k	€1k – €10k	€10 – €100k	€100k – €1m	>€1m
Environment	Nuisance Release.	On site release contained by organisation.	On site release contained by organisation.	Release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc.)	Toxic release affecting off-site with detrimental effect requiring outside assistance.

Likelihood Scoring

TABLE 1: LIKELIHOOD SCORING

Rare/Remote (1)		Unlikely (2)		Possible (3)		Likely (4)		Almost Certain (5)	
Actual Frequency	Probability	Actual Frequency	Probability	Actual frequency	Probability	Actual Frequency	Probability	Actual Frequency	Probability
Occurs every 5 years or more	1%	Occurs every 2-5 years	10%	Occurs every 1-2 years	50%	Bimonthly	75%	At least monthly	99%

HSE Risk Matrix

3. RISK MATRIX	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare/Remote (1)	1	2	3	4	5

Evaluating Risk in Decontamination of RIMD

- Easy to identify what is definitely ‘unsafe’ or definitely ‘safe’
- In between there is significant gray area – which is dependent on the organism, the type of instrument and the immune statue of the patient/ service user

e.g. patient & tissue TSE/CJD risk category; dried out organic debris; final rinse water quality; site endoscope procedure; universal versus choose framework approach to decontamination standards

Evaluate the Risk

Depending on the risk rating and the adequacy of the current controls in place an evaluation must be made on whether to

- accept the risk,
- treat the risk by:
  - i) Avoiding the risk,
  - ii) Transferring the risk or
  - iii) Controlling the risk.

- ALARP Principle

Completing Risk Assessment **Form**
Section 3 **Risk Analysis & Evaluation**

- Existing control measurers
- Additional control measures required

INITIAL RISK			RESIDUAL RISK			STATUS
Likelihood	Impact	Initial Risk Rating	Likelihood	Impact	Residual Risk Rating	

Break Out Group Session

- Risk Assessment Exercise
- Feedback 30 minutes
- Followed by Discussion

Treat Risks / Improvement Action Plan

Aim of the Plan:

- Reduce the Level of Risk or Eliminate Risk if possible

1. Specific cost effective actions
2. Resource Requirements
3. Person Responsible
4. Time Frame
5. Performance measures
6. Reporting & monitoring Requirements

PDSA Tool

- it is vital that risks identified are addressed.
- a simple yet powerful the Plan-Do-Study-Act (PDSA) cycle tool for accelerating improvement.

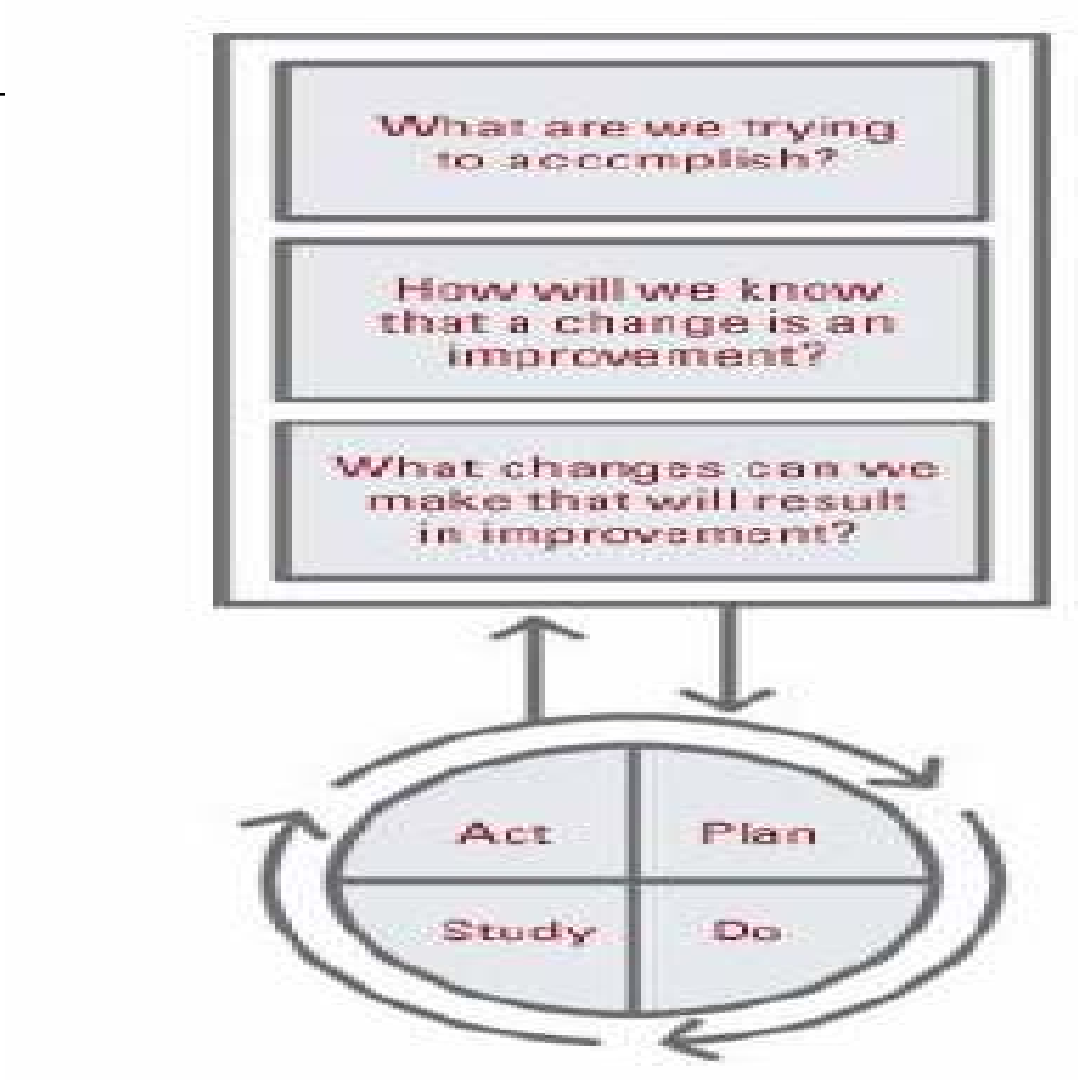
- **The model has two parts:**

- Three fundamental questions, which can be addressed in any order

- The PDSA cycle
  is used to test and implement changes in real work settings

  - guides the test of a change to determine if the change is an improvement.

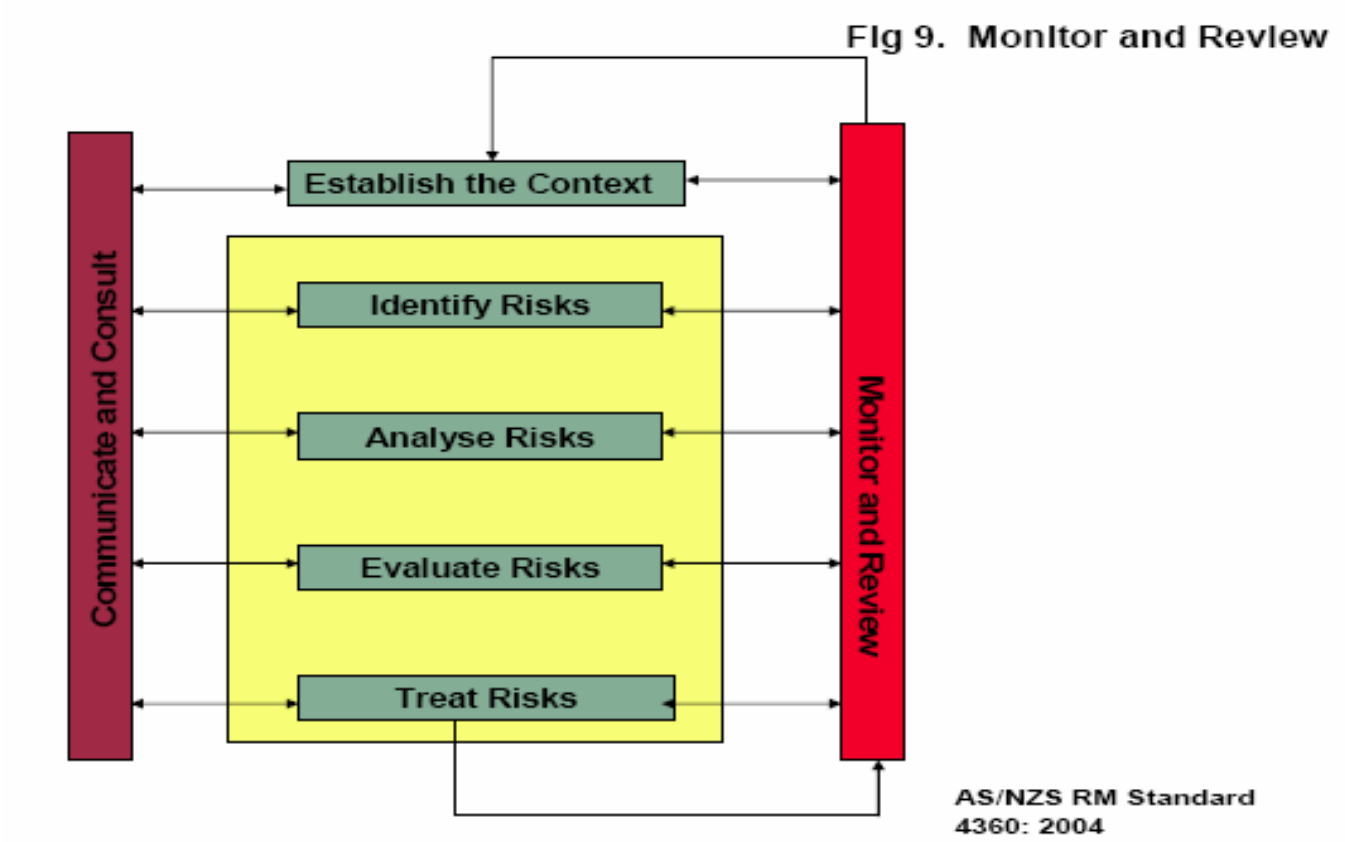
The ‘Plan, Do, Study, Act’ (PDSA) Cycle.



Monitor & Review Risks

- Monitor & Review effectiveness of all steps of the risk management process
- Document & use Process Records of all stages, steps taken & decisions made
- Evidence of continual improvement & learning

Monitor & Review



Additional Controls (Actions) Update Form

*** Attach this form to original Risk Assessment Form**

Action Owner: _____
Unique Risk ID No: _____
Date of Update: _____

ACTION NUMBER	ADDITIONAL CONTROL (ACTION) SUMMARY UPDATE	PERSON RESPONSIBLE FOR ACTION (if changed)	Action STATUS {Behind Schedule On Schedule Complete}	NEW REVIEW DATE

EXAMPLE

Additional Controls (Actions) Update Form

*** original Risk Assessment Form attached**

Action Owner: Dr ---- Chair Endoscopy Users Group / Director Internal Medicine
Unique Risk ID No: INM -4

Date of Update: 28th June 2011

ACTION NUMBER	ADDITIONAL CONTROL (ACTION) SUMMARY UPDATE	PERSON RESPONSIBLE FOR ACTION (if changed)	Action STATUS {Behind Schedule On Schedule Complete}	NEW REVIEW DATE
1.	In progress due completion December 2012. The planning process for the development of the a new Endoscopy Reprocessing Unit (ERU) commenced in May 2011.The capital funding for the project has been approved.	CEO & ERU Steering Group	On schedule	Jan 2013

Management Procedures

- Departmental Level
- Service Delivery / Directorate Level
- Risk Management Dept→ Risk Register
- Organization Senior Management
- Regional Level
- Corporate Level – Quality & Safety & Risk

Reactive Risk Management

Incident Management

- Identifying actual accident or near miss
- Reporting
- Investigating
- Implementing recommendations
- Sharing the learning

Serious Incident

Any incident which involved or is likely to cause extreme harm or is likely to become a matter of significant concern to service users, employees or the public

Procedure for managing incidents

- Complete Local Incident Form → to Line Manager & Risk Manager
- Consider Risk Assessment and or System Analysis/ Case Review
- Complete Regional Incident Report Form → immediately following an incident; kept locally for local follow up and management

Failure to adequately decontaminate RIMD

Will

- increase the risk of transmission of cross-infection between patients
- Compromised the integrity of biopsy specimens
- Expose the patient to adverse consequences of non-sterile contaminants
- Damage RIMD and impede their effective function
- Increase costs unnecessarily

Summary

Questions & Discussion