GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Bae Abertawe
Swansea Bay University Health Board

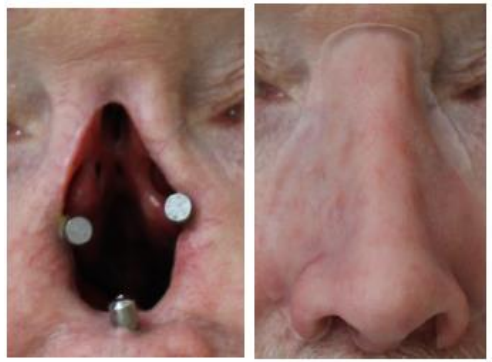
Medical Devices Regulations - Implementation and achievement of a certified Quality Management System

(11/11/2021 - Focussing on Quality, Safety, Competency and Training)

Dr. Rebecca Nix, Medical Device Regulation Compliance Lead

Rehabilitation Engineering Unit – Medical Physics and Clinical Engineering Directorate

Swansea Bay University Health Board

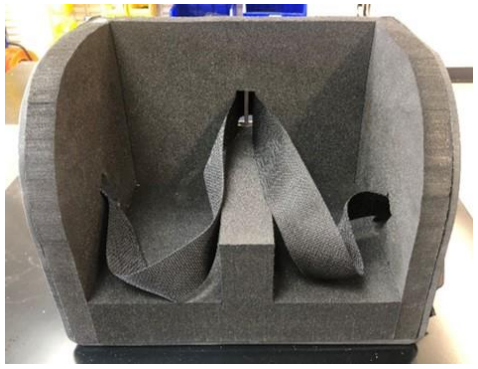


Presentation overview

- Context
  - Medical Devices and ‘in house’ manufacturing
  - Legislation ‘at the time’
- Quality Management Systems (QMS) implementation
  - Frameworks and approach to implementation
  - Monitoring progress
  - Challenges
- Next steps
  - Evolving legislation and influencing factors
  - MHRA Consultation on UK Legislation

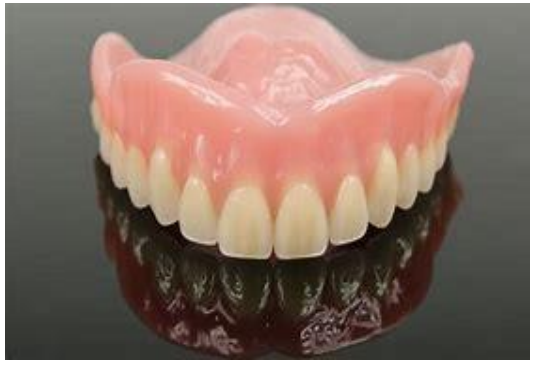
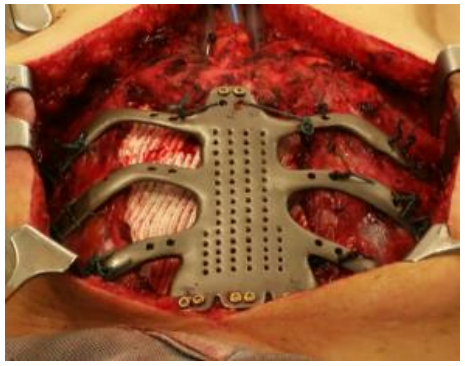
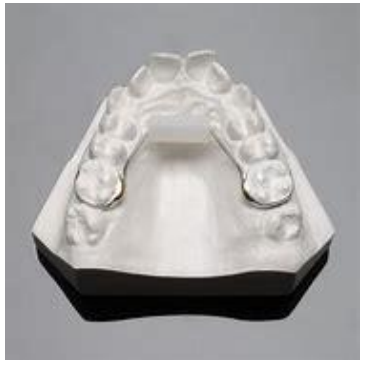
‘In house’ Medical Device Manufacturing

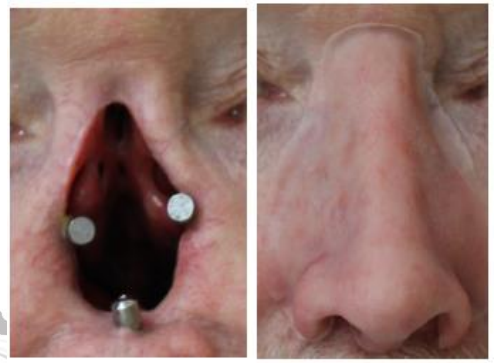
- **REU are considered to manufacture and modify medical devices under the EU Medical Device Regulations (EU 2017/ 745)**
  - Design and construct custom-made devices / appliances
    - Engineering solutions and adaptations to wheelchair seating
    - Special cushions and soft solutions for pressure care


‘In house’ Medical Device Manufacturing

- **MFL are also considered to manufacture medical devices under the EU Medical Device Regulations (EU 2017/ 745)**
  - Design and construct custom-made devices / appliances
    - Facial and body prostheses
    - Fixed and removable intra-oral prosthetics
    - Orthodontics

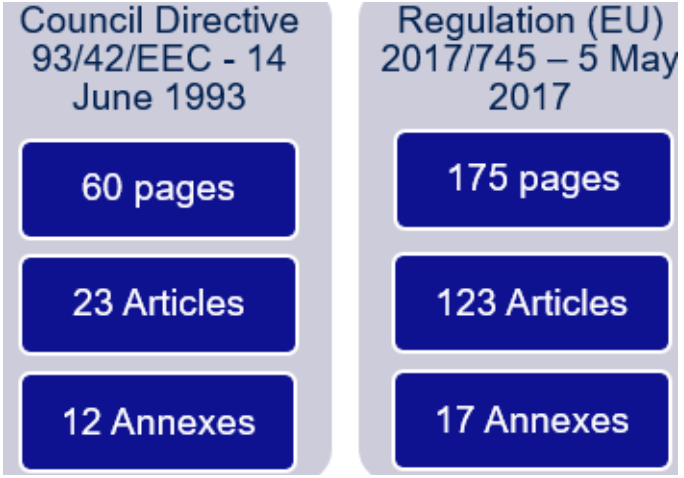






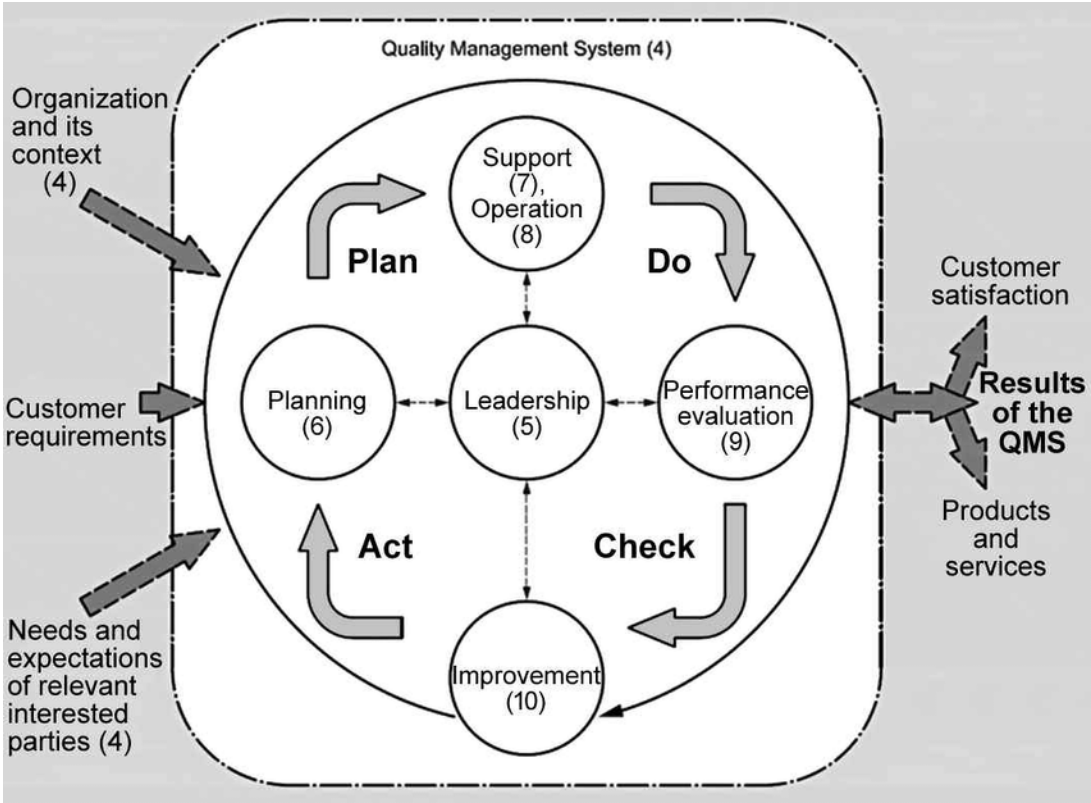
‘Medical device manufacturers’ are regulated

- Medical device manufacturers are regulated under the UK Medical Device Regulations (UK MDR)
  - Medical Device Directives (MDD)
  - Medical devices used in the same health institution as they are made were exempt

- **Medical device regulation in the UK was, and is changing.**
- New EU legislation, the Medical Device Regulations (MDR, EU 2017/745) – came in to force in May 2017 (May 2021)
  - Placed specific requirements on medical devices used in the same health institution (informally called the health institution exemption)
    - Compliance to the General Safety and Performance Requirements (GSPR)
    - Appropriate Quality Management System



What is a Quality Management System (QMS)?



- Understanding and meeting requirements
  - **(What needs to be done)**
- Considering processes in terms of ‘added value’
  - **(Is what we do necessary and worthwhile)**
- Obtaining results of process performance and effectiveness
  - **(How well things work and how efficiently)**
- Improving processes based on objective measurement
  - **(What can we do to improve)**

Which QMS framework? How to approach the project?

- The framework depends on:
  - the function of the organisation
  - the service itself, or the products or service that is delivered.
  - Different legislation and / or guidance will apply.
    - ISO 13485 – Quality Management Systems – Requirements for regulatory purposes
    - ISO 9001 – Quality Management Systems. Requirements.

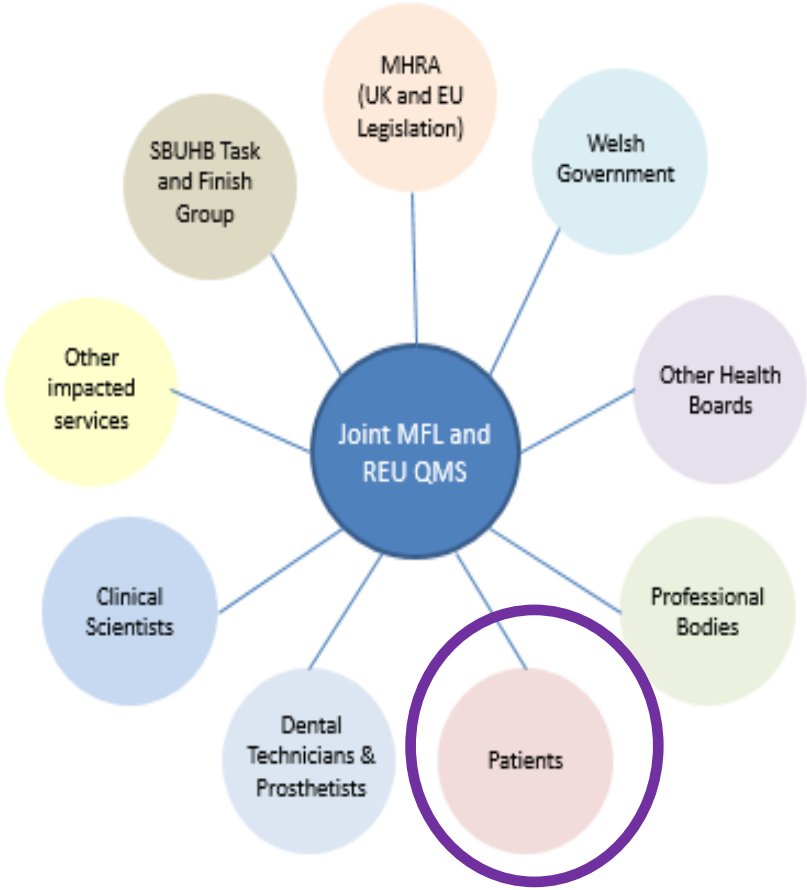
Approach to Implementation

- Identifying biggest areas of ‘risk’ within each service
  - Technical Information
    - Links to training and competence

- Identifying potential areas to share similar approaches
  - Document control (electronic document management system)
    - Links to evidence that QMS requirements are fulfilled e.g. training and competence

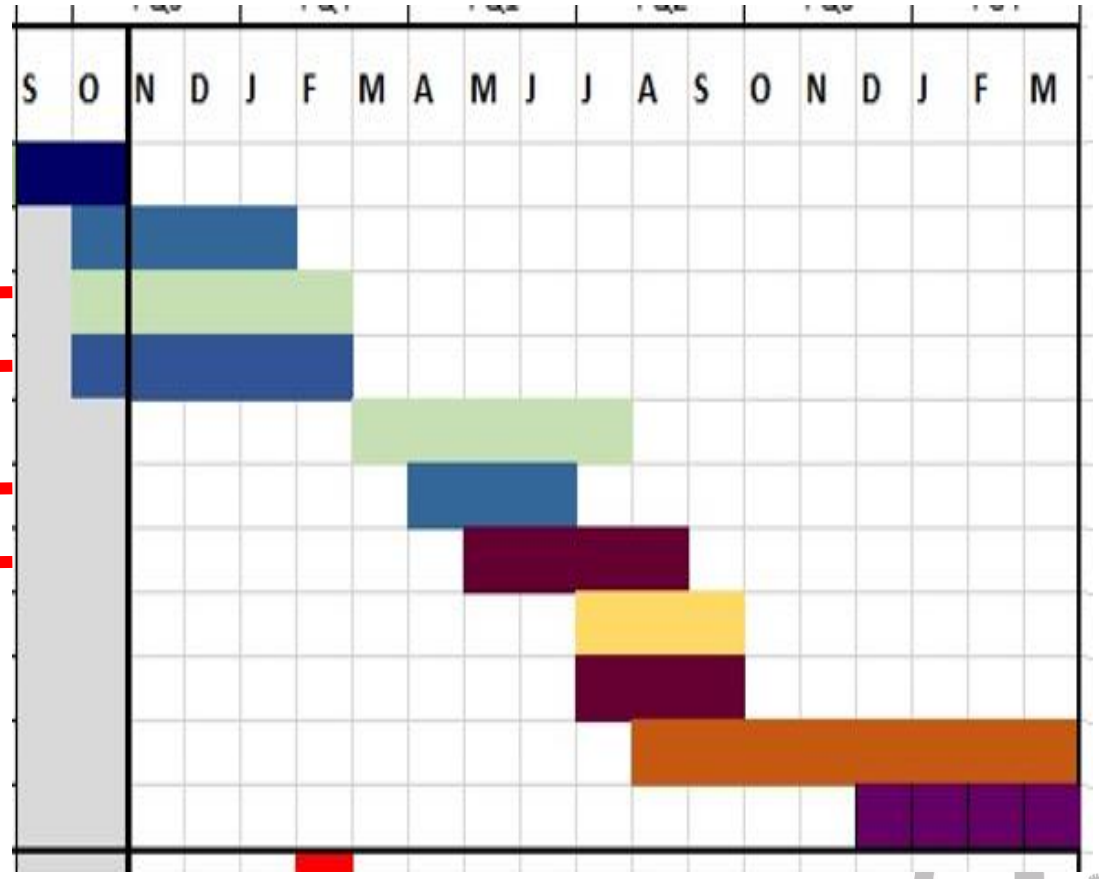
- Developing a plan
  - To be clear on timescales and sequence
  - To evidence that progress was being made

- Throughout - Identifying and managing the stakeholders



Implementation Plan

Critical Path Milestones
PROGRAMME
1. High Level Planning
2. QA Documentation and Process (Phase I)
3. Medical Device Documentation (Technical)
4. iPassport Implementation
5. Medical Device Documentation (Process)
6. QA Documentation and Process (Phase II)
7. Equipment Management Process
8. Procurement Management Process
9. Infrastructure Processes
10. Measurement, Analysis and Improvement Processes
11. Whole System Review / Assurance



Defined Medical Device Families

Ref.	Family	Sub-Family	Device(s) - Examples
1	**Accessories -Hardware**	Arm Supports	Elbow supports Gutters Pads
		Calf Supports	Calf Pads Calf Troughs Leg Rests
		Foot Supports	Foot Board Foot Box Foot Rest
		Foot Sandals	Food Sandals
		Head Support	Head Supports
		Lower Lateral Limb Support	Hip Guides Knee Pads
		Lateral (Trunk)	Lateral (Trunk)
		Pommels	Pommels
		Trays	Trays
2	**Accessories - Straps**		Ankle Hugger
			Calf Strap
			Chest Harness
			Foot Strap
			Groin Harness
			Postural Belt
			Protective Straps / Restraint
			Wrist Strap
3	**Back Support Hardware**	Backrest Hardware	Backrest Hardware
		Canvas	Canvas
		Infill (Inserts)	Infill (Inserts)
4	**Cushions**	Cushions	Cushions (Varying specifications)

- REU - eight Families in total (now nine)
- Family -> Sub-family -> Specific examples

5	**DSS**	Attachment Methods	ABS Shells Bracketry
		DSS Back	DSS Back
		DSS Base	DSS Base
6	**Mounting of Life Support (MOLS)**	Ventilator	Manufacturers Bag Bespoke Brackets
		Suction Machine	Laerdel Wall mounting bracket Bespoke brackets Karabiner Hooks.
		Pulse oximeter	Manufacturers Bag Bespoke brackets
		Feed Pump	Manufacturers Bag Bespoke brackets
		Oxygen cylinders	Rehabilitation Engineering Services (RMS) Oxygen cylinder carrier
7	**Soft Solutions**	Bead Bag	Bead Bag
		Memory Foam Pads	Memory Foam Pad
8	**Wheelchair System**	Baseboard (Including attachment)	Baseboard (Including attachment)
		Brackets (For special controls)	Brackets (For special controls)
		Mounting interface	Mounting interface
		Special Control	Special Control
		Wheelbase Modification	Wheelbase Modification

Defined Medical Device Families

Ref.	Family	Sub-Family	Device(s) - Examples
1	**Accessories -Hardware**	Arm Supports	Elbow supports Gutters Pads
		Calf Supports	Calf Pads Calf Troughs Leg Rests
		Foot Supports	Foot Board Foot Box Foot Rest
		Foot Sandals	Food Sandals
		Head Support	Head Supports
		Lower Lateral Limb Support	Hip Guides Knee Pads
		Lateral (Trunk)	Lateral (Trunk)
		Pommels	Pommels
		Trays	Trays
2	**Accessories - Straps**		Ankle Hugger
			Calf Strap
			Chest Harness
			Foot Strap
			Groin Harness
			Postural Belt
			Protective Straps / Restraint
			Wrist Strap
3	**Back Support Hardware**	Backrest Hardware	Backrest Hardware
		Canvas	Canvas
		Infill (Inserts)	Infill (Inserts)
4	**Cushions**	Cushions	Cushions (Varying specifications)

- REU - eight Families in total (now nine)
- Family -> Sub-family -> Specific examples

5	**DSS**	Attachment Methods	ABS Shells Bracketry
		DSS Back	DSS Back
		DSS Base	DSS Base
6	**Mounting of Life Support (MOLS)**	Ventilator	Manufacturers Bag Bespoke Brackets
		Suction Machine	Laerdel Wall mounting bracket Bespoke brackets Karabiner Hooks.
		Pulse oximeter	Manufacturers Bag Bespoke brackets
		Feed Pump	Manufacturers Bag Bespoke brackets
		Oxygen cylinders	Rehabilitation Engineering Services (RMS) Oxygen cylinder carrier
7	**Soft Solutions**	Bead Bag	Bead Bag
		Memory Foam Pads	Memory Foam Pad
8	**Wheelchair System**	Baseboard (Including attachment)	Baseboard (Including attachment)
		Brackets (For special controls)	Brackets (For special controls)
		Mounting interface	Mounting interface
		Special Control	Special Control
		Wheelbase Modification	Wheelbase Modification

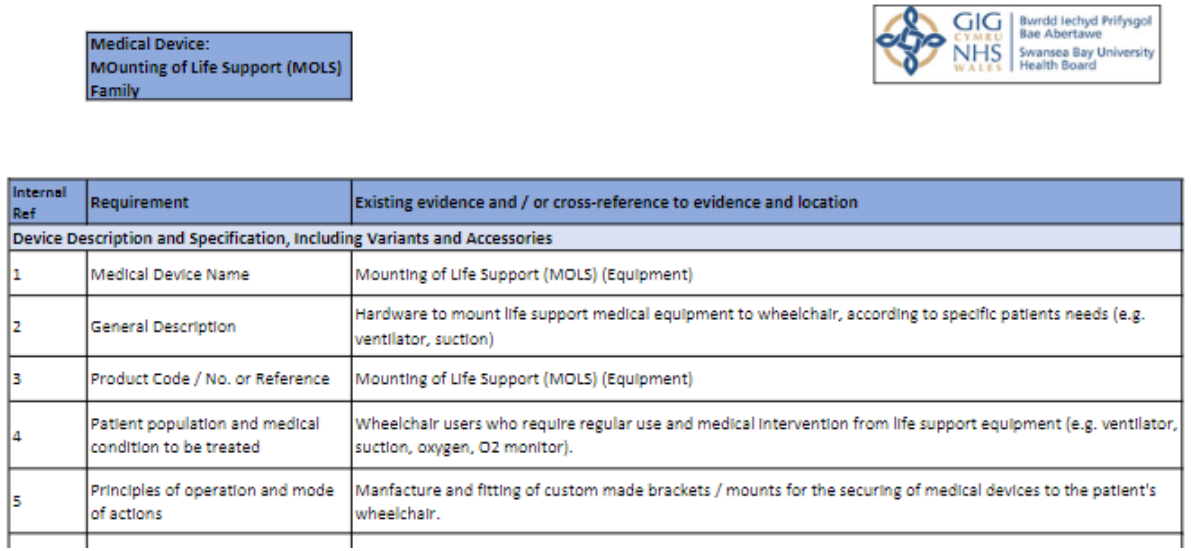
Example technical file

- Descriptor – Mounting of Life Support (MOLS)

- Risk Classification
  - Classification document (IPEM)

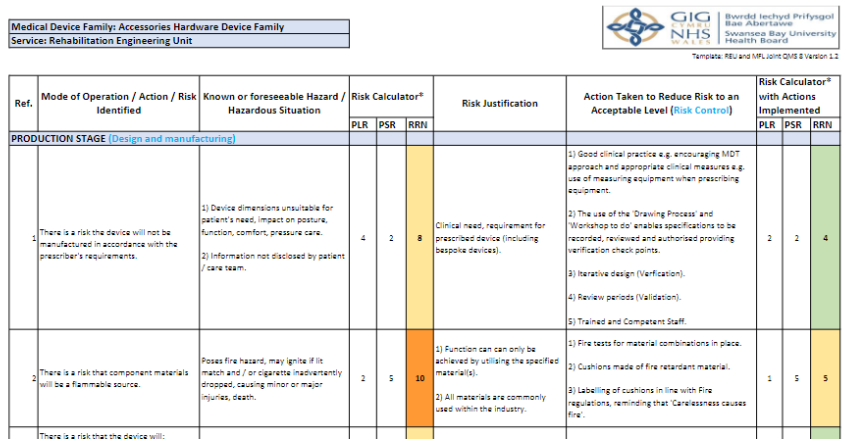
- General Safety and performance Requirements
- Risk Management Plan
  - Production
  - Storage . Transformation
  - Useage
  - Post market surveillance

- Patient Notes (Clinical Detail)
- Service Records (Design and Manufacture Detail)



Medical Device:
MOunting of Life Support (MOLS) Family

Internal Ref	Requirement	Existing evidence and / or cross-reference to evidence and location
Device Description and Specification, Including Variants and Accessories		
1	Medical Device Name	Mounting of Life Support (MOLS) (Equipment)
2	General Description	Hardware to mount life support medical equipment to wheelchair, according to specific patients needs (e.g. ventilator, suction)
3	Product Code / No. or Reference	Mounting of Life Support (MOLS) (Equipment)
4	Patient population and medical condition to be treated	Wheelchair users who require regular use and medical intervention from life support equipment (e.g. ventilator, suction, oxygen, O2 monitor).
5	Principles of operation and mode of actions	Manfacture and fitting of custom made brackets / mounts for the securing of medical devices to the patient's wheelchair.



Medical Device Family: Accessories Hardware Device Family
Service: Rehabilitation Engineering Unit

Template: REU and MPL Joint QMS 8 Version 1.2

Ref.	Mode of Operation / Action / Risk Identified	Known or foreseeable Hazard / Hazardous Situation	Risk Calculator*			Risk Justification	Action Taken to Reduce Risk to an Acceptable Level (Risk Control)	Risk Calculator* with Actions Implemented		
			PLR	PSR	RRN			PLR	PSR	RRN
PRODUCTION STAGE (Design and manufacturing)										
1	There is a risk the device will not be manufactured in accordance with the prescriber's requirements.	1) Device dimensions unsuitable for patient's need, impact on posture, function, comfort, pressure care. 2) Information not disclosed by patient / care team.	4	2	8	Clinical need, requirement for prescribed device (including bespoke devices).	1) Good clinical practice e.g. encouraging MDT approach and appropriate clinical measures e.g. use of measuring equipment when prescribing equipment. 2) The use of the 'Drawing Process' and 'Workshop to do' enables specifications to be recorded, reviewed and authorised providing verification check points. 3) Iterative design (Verification). 4) Review periods (Validation). 5) Trained and Competent Staff.	2	2	4
2	There is a risk that component materials will be a flammable source.	Poses fire hazard, may ignite if lit match and / or cigarette inadvertently dropped, causing minor or major injuries, death.	2	5	10	1) Function can can only be achieved by utilising the specified material(s). 2) All materials are commonly used within the industry.	1) Fire tests for material combinations in place. 2) Cushions made of fire retardant material. 3) Labelling of cushions in line with Fire regulations, reminding that 'Carelessness causes fire'.	1	5	5
3	There is a risk that the device will:									

Document Control

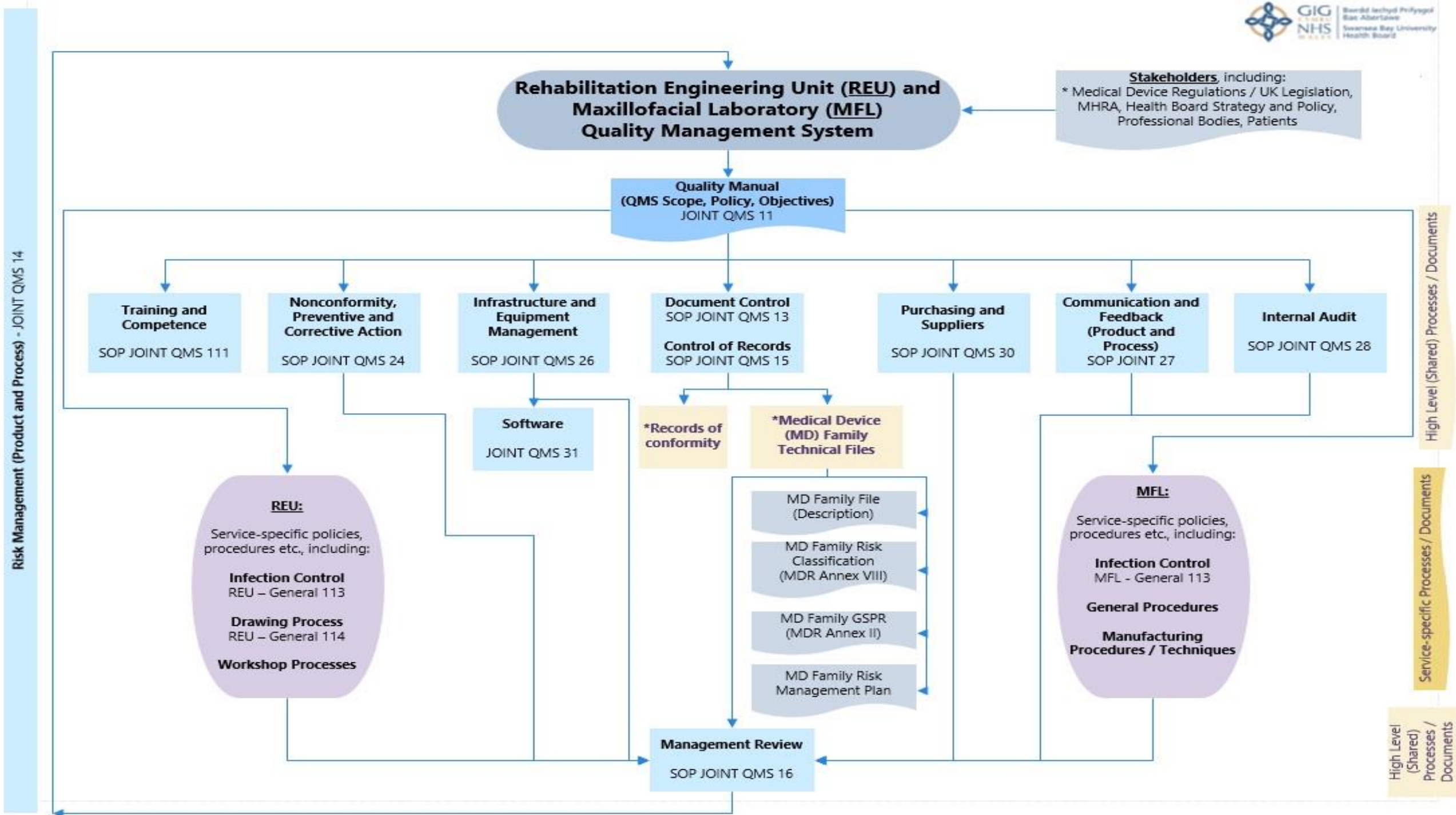
Document Type	|	Technical Information
Index Number	|	REU - General 48
Version Number	|	1.0
Title	|	MD File - MOLS Family
Author	|	Benjamin Lee
Authorised By	|	Benjamin Lee
Authorised On	|	18-Sep-2020

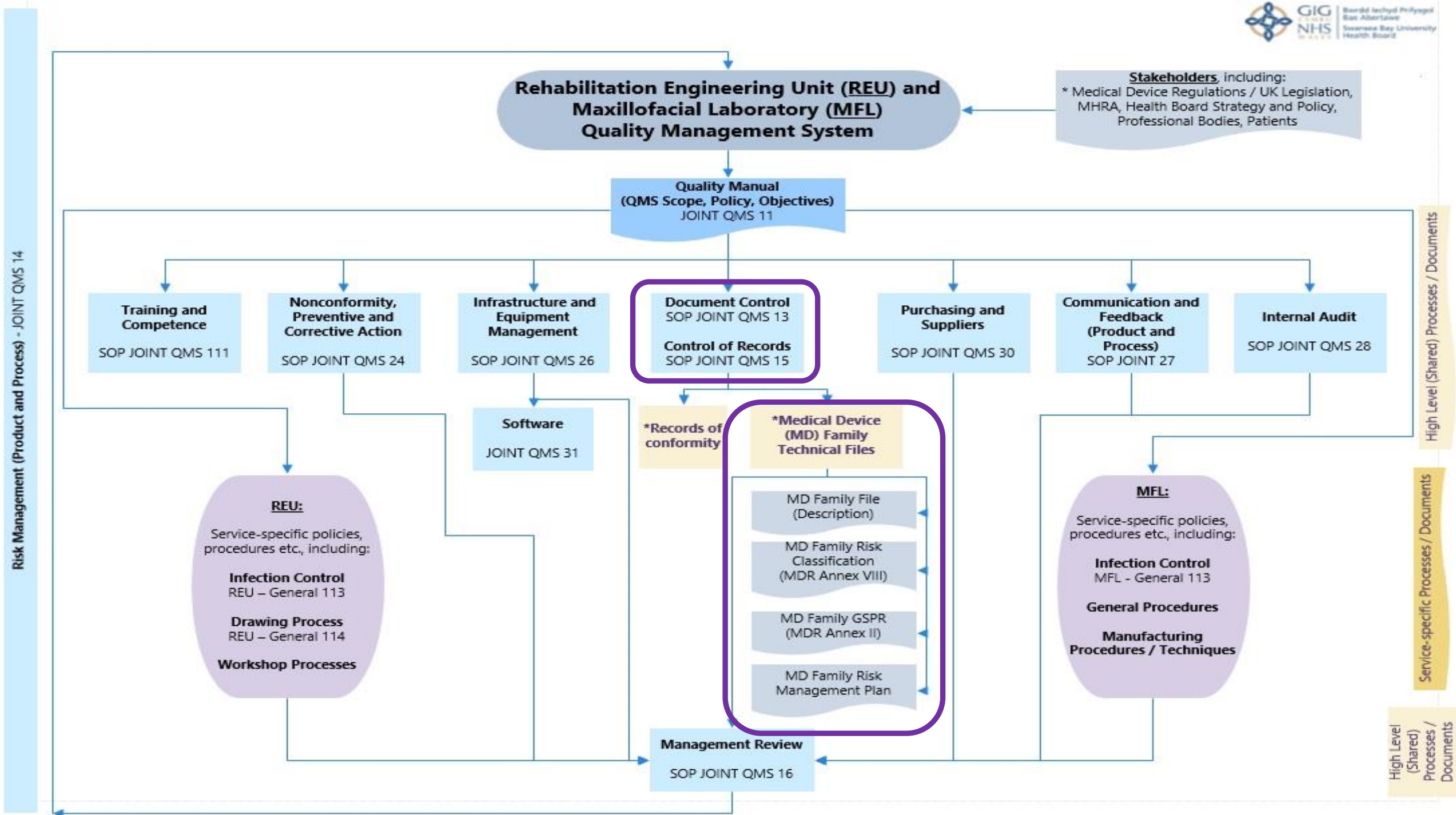
Document Type	|	Technical Information
Index Number	|	REU - General 48
Version Number	|	1.0
Title	|	MD File - MOLS Family

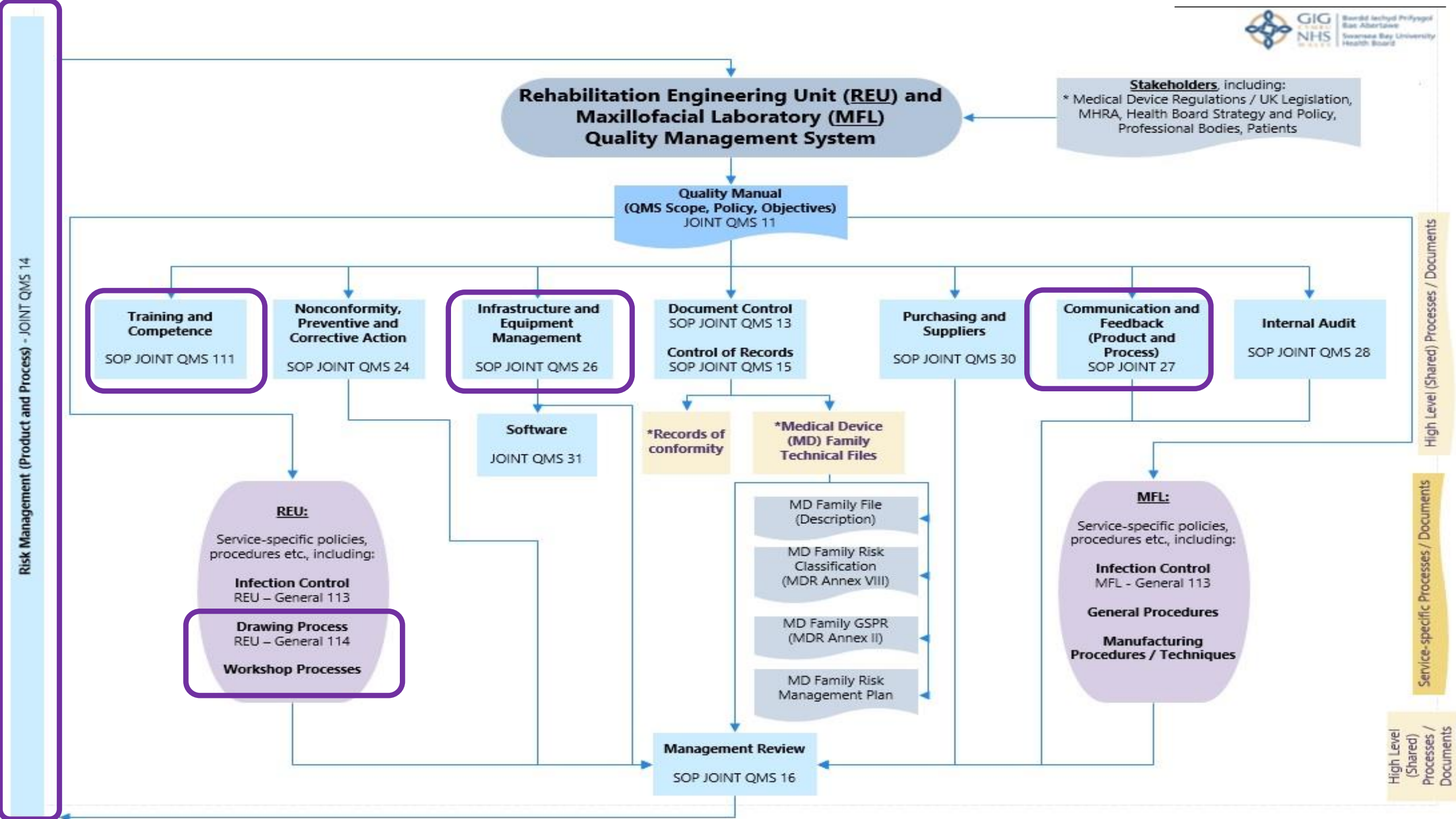
Medical Device:
MOunting of Life Support (MOLS) Family

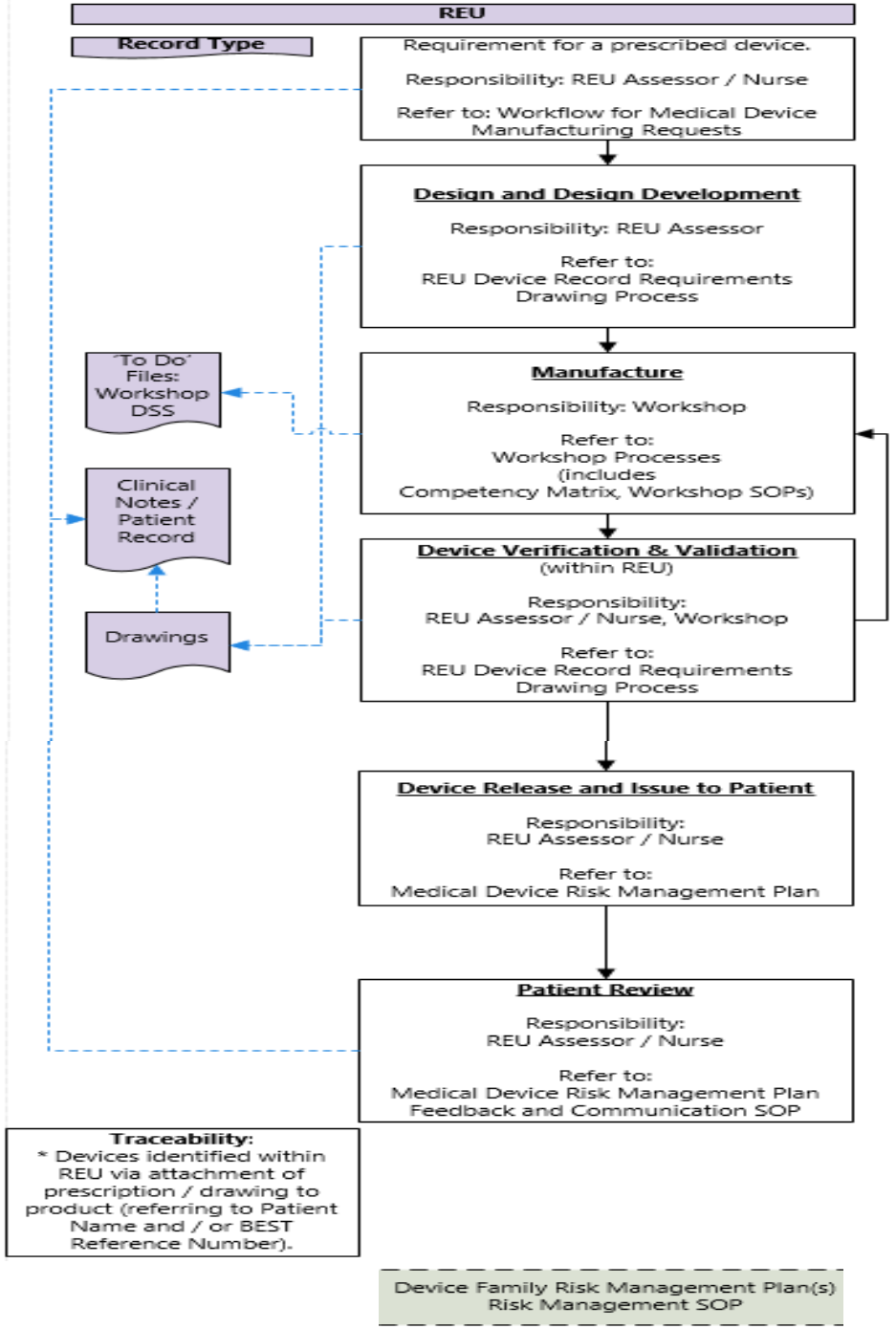
Internal Ref	Requirement	Existing evidence and / or cross-reference to evidence and location
Device Description and Specification, Including Variants and Accessories		
1	Medical Device Name	Mounting of Life Support (MOLS) (Equipment)
2	General Description	Hardware to mount life support medical equipment to wheelchair, according to specific patients needs (e.g. ventilator, suction)
3	Product Code / No. or Reference	Mounting of Life Support (MOLS) (Equipment)
4	Patient population and medical condition to be treated	Wheelchair users who require regular use and medical intervention from life support equipment (e.g. ventilator, suction, oxygen, O2 monitor).
5	Principles of operation and mode of actions	Manfacture and fitting of custom made brackets / mounts for the securing of medical devices to the patient's wheelchair.
6	Rationale for qualification as a device	The device meets the definition of a Medical Device as defined within Article 2.1 of the MDR (EU) 2017/745
7	Risk Class	Class I
8	Justification for application of HIE for each device / family	The target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market. Each device is prescribed, and custom-made, for an individual patient.
9	Evidence to support justification of HIE	Device features and performance designed for specific patient needs e.g. asymmetrical postures. Service requirements for lead times and control of compatibility of systems are additional factors.
10	Explanation of any novel features	N/A Requirements for novel features (by the clinician) could arise on a patient-by-patient basis, e.g. dimensions and component material.
11	Description of accessories / other devices or products to be used in combination	Wheelchair Seating System Attachment method

Mounting of Life Support (MOLS) (Equipment)
Hardware to mount life support medical equipment to wheelchair, according to specific patients needs (e.g. ventilator, suction)
Mounting of Life Support (MOLS) (Equipment)
Wheelchair users who require regular use and medical intervention from life support equipment (e.g. ventilator, suction, oxygen, O2 monitor).
Manfacture and fitting of custom made brackets / mounts for the securing of medical devices to the patient's wheelchair.


Rehabilitation Engineering Unit (REU) and Maxillofacial Laboratory (MFL) Quality Management System
Stakeholders, including:
* Medical Device Regulations / UK Legislation, MHRA, Health Board Strategy and Policy, Professional Bodies, Patients
Quality Manual (QMS Scope, Policy, Objectives) JOINT QMS 11
Training and Competence SOP JOINT QMS 111
Nonconformity, Preventive and Corrective Action SOP JOINT QMS 24
Infrastructure and Equipment Management SOP JOINT QMS 26
Document Control SOP JOINT QMS 13
Control of Records SOP JOINT QMS 15
Purchasing and Suppliers SOP JOINT QMS 30
Communication and Feedback (Product and Process) SOP JOINT 27
Internal Audit SOP JOINT QMS 28
Software JOINT QMS 31
*Records of conformity
*Medical Device (MD) Family Technical Files
MD Family File (Description)
MD Family Risk Classification (MDR Annex VIII)
MD Family GSPR (MDR Annex II)
MD Family Risk Management Plan
REU:
Service-specific policies, procedures etc., including:
Infection Control REU – General 113
Drawing Process REU – General 114
Workshop Processes
MFL:
Service-specific policies, procedures etc., including:
Infection Control MFL - General 113
General Procedures
Manufacturing Procedures / Techniques
Management Review SOP JOINT QMS 16
Risk Management (Product and Process) - JOINT QMS 14
High Level (Shared) Processes / Documents
Service-specific Processes / Documents
High Level (Shared) Processes / Documents


Rehabilitation Engineering Unit (REU) and Maxillofacial Laboratory (MFL) Quality Management System
Stakeholders, including:
* Medical Device Regulations / UK Legislation, MHRA, Health Board Strategy and Policy, Professional Bodies, Patients
Quality Manual (QMS Scope, Policy, Objectives)
JOINT QMS 11
Training and Competence
SOP JOINT QMS 111
Nonconformity, Preventive and Corrective Action
SOP JOINT QMS 24
Infrastructure and Equipment Management
SOP JOINT QMS 26
Document Control
SOP JOINT QMS 13
Control of Records
SOP JOINT QMS 15
Purchasing and Suppliers
SOP JOINT QMS 30
Communication and Feedback (Product and Process)
SOP JOINT 27
Internal Audit
SOP JOINT QMS 28
Software
JOINT QMS 31
*Records of conformity
*Medical Device (MD) Family Technical Files
MD Family File (Description)
MD Family Risk Classification (MDR Annex VIII)
MD Family GSPR (MDR Annex II)
MD Family Risk Management Plan
REU:
Service-specific policies, procedures etc., including:
Infection Control
REU – General 113
Drawing Process
REU – General 114
Workshop Processes
MFL:
Service-specific policies, procedures etc., including:
Infection Control
MFL - General 113
General Procedures
Manufacturing Procedures / Techniques
Management Review
SOP JOINT QMS 16
Risk Management (Product and Process) - JOINT QMS 14
High Level (Shared) Processes / Documents
Service-specific Processes / Documents
High Level (Shared) Processes / Documents


Risk Management (Product and Process) - JOINT QMS 14
Rehabilitation Engineering Unit (REU) and Maxillofacial Laboratory (MFL) Quality Management System
Stakeholders, including:
* Medical Device Regulations / UK Legislation, MHRA, Health Board Strategy and Policy, Professional Bodies, Patients
Quality Manual (QMS Scope, Policy, Objectives)
JOINT QMS 11
Training and Competence
SOP JOINT QMS 111
Nonconformity, Preventive and Corrective Action
SOP JOINT QMS 24
Infrastructure and Equipment Management
SOP JOINT QMS 26
Document Control
SOP JOINT QMS 13
Control of Records
SOP JOINT QMS 15
Purchasing and Suppliers
SOP JOINT QMS 30
Communication and Feedback (Product and Process)
SOP JOINT 27
Internal Audit
SOP JOINT QMS 28
High Level (Shared) Processes / Documents
Software
JOINT QMS 31
*Records of conformity
*Medical Device (MD) Family Technical Files
MD Family File (Description)
MD Family Risk Classification (MDR Annex VIII)
MD Family GSPR (MDR Annex II)
MD Family Risk Management Plan
REU:
Service-specific policies, procedures etc., including:
Infection Control
REU – General 113
Drawing Process
REU – General 114
Workshop Processes
MFL:
Service-specific policies, procedures etc., including:
Infection Control
MFL - General 113
General Procedures
Manufacturing Procedures / Techniques
Service-specific Processes / Documents
Management Review
SOP JOINT QMS 16
High Level (Shared) Processes / Documents



Medical Device Manufacturing

- Steps in Process
  - Requirement for a prescribed device
  - Design and Design Development
  - **Manufacture**
  - Device Verification and Validation (within REU)
  - **Device Release and issue to Patient**
  - Patient Review
  - Signposting to where evidence of these processes is stored.

Training and Competence

- *Ensuring staff have the skills, experience and competencies to undertake their roles and responsibilities, ensures that service provision **(including the manufacturing of medical devices)** is in line with the quality policy and objectives outlined in the Quality Manual.*

- ***Staff safety, patient safety***

Training and Competence - Staff

Training:

- New starter induction in line with Health Board Policy
- Mandatory training associated with individual roles managed through Electronic Staff Record *(ESR)*
- Local inductions to services / procedures
- QMS policies via iPassport – recording acknowledgement
- Evaluation of training through management / appraisal

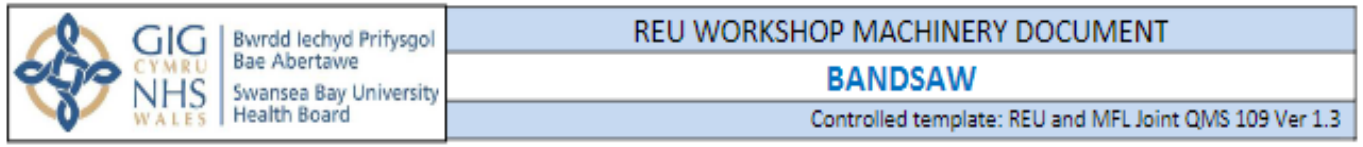
Competence:

- Maintaining professional body registration (where required)
- Continual professional development *(CPD)* evidence
- Competence evidence for specialist workshop equipment (where required)

Workshop Machinery

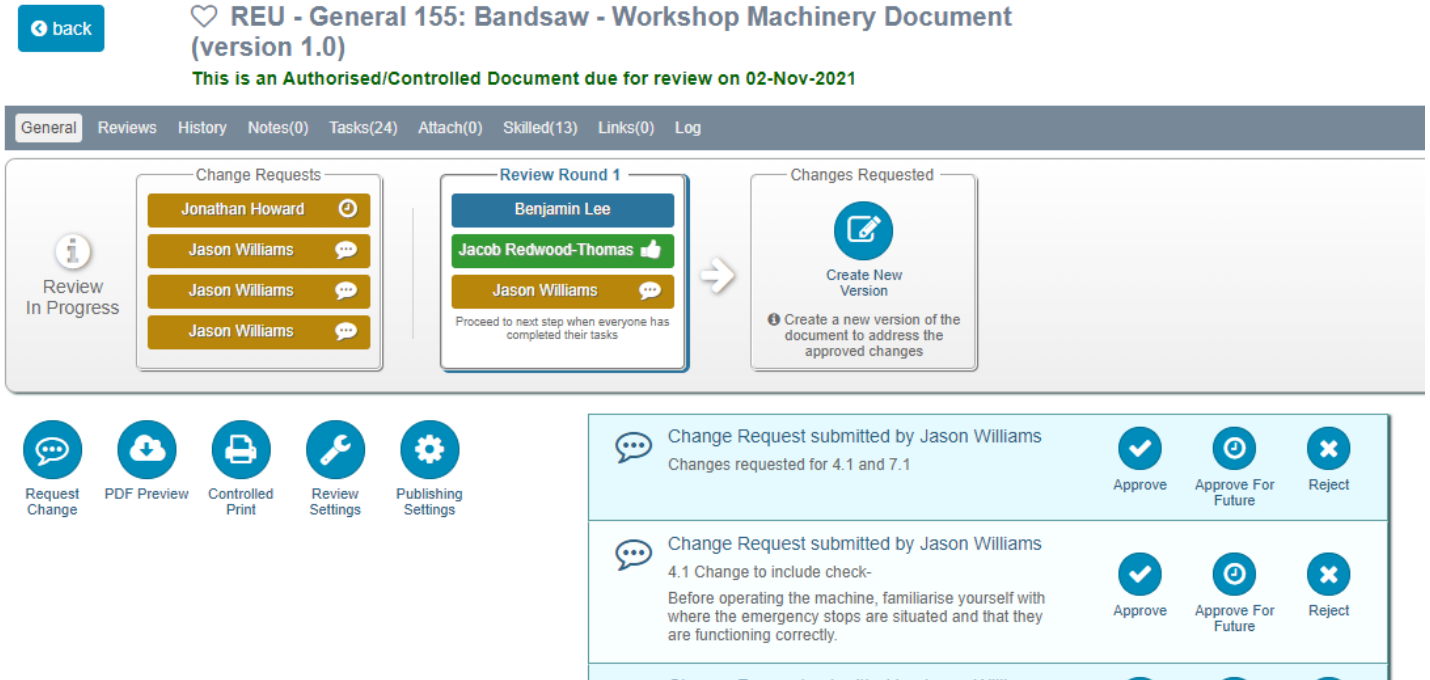
Documentation

- Each piece of machinery has its own ‘controlled’ documentation



1. Purpose

1.1. The purpose of this document is to provide information around the use of the Bandsaw and the competencies that have to be met for staff of the Rehabilitation Engineering Unit (REU) department to use the equipment.



Workshop Machinery

Training:

- Provided by a competent trainer on the content of the document

Competence:

- Assessed e.g. with ‘test pieces’ during training activity
- Refresher assessment (6 monthly)

Evidence:

- Via iPassport ‘Read and acknowledge’

REU Workshop Machinery Training Record

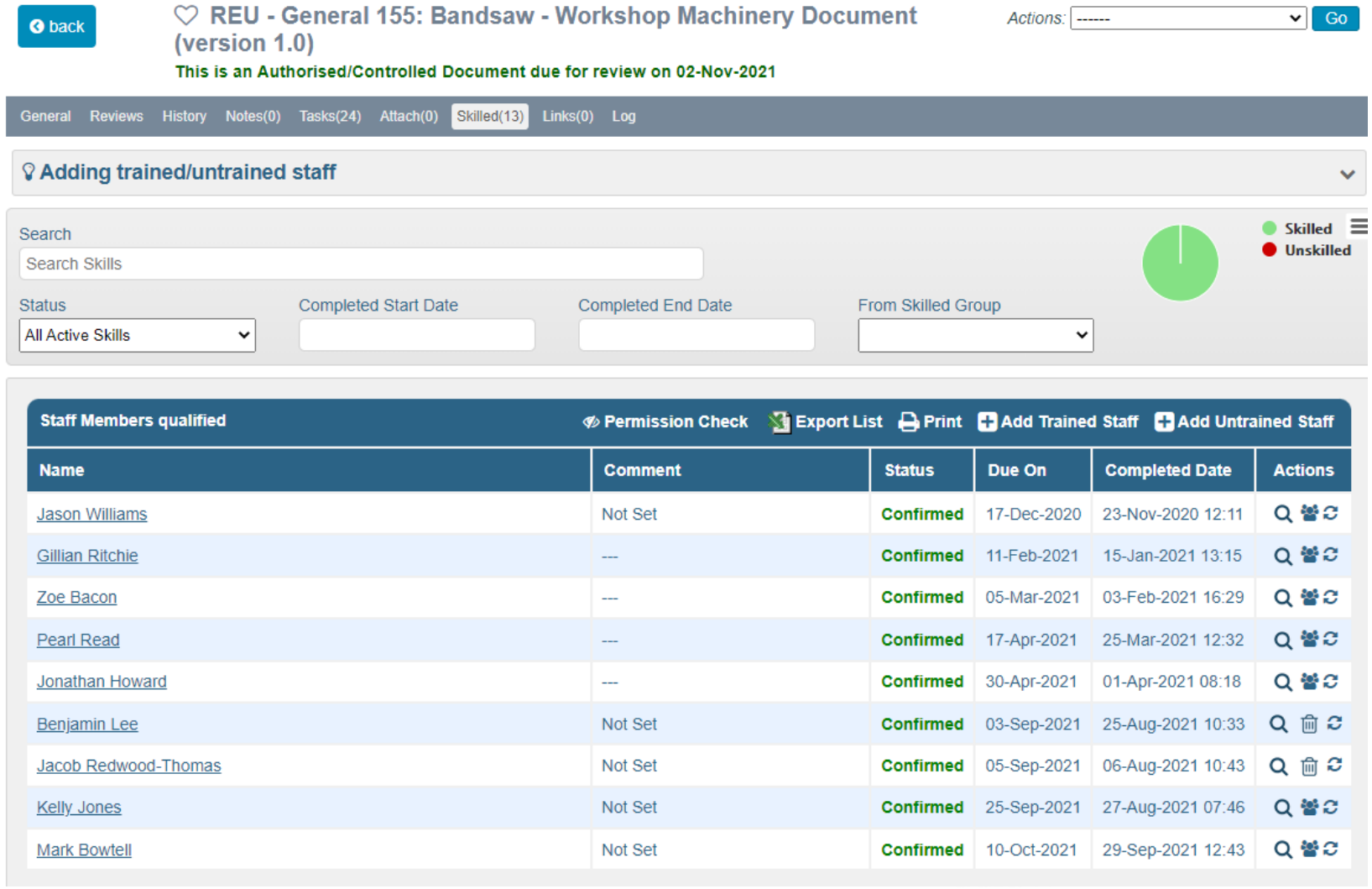
Equipment	Jason Williams	Lorna Tasker
Bandsaw		
CNC Foam Carve	23/03/2021	
Chop Saw		
Jig Saw		
Lathe		
Milling Machine		
Linisher		
Hot Wire Strip Heater		
Off Hand Grinder		
Pedestal Drill		
Powered Hand Tools		
Router		
Spray Booth		
TIG Welder		
Sewing Machine^		
3D Printer		

Key:	
Not machine competent	
Essential competencies	
Advanced competencies	
Refresher Training Required	DATE
Competencies in development	^
Awaiting Training/Sign Off	*

Workshop Machinery

Evidence:

- Via iPassport ‘task’
- ‘Read and acknowledge’
- Fully auditable, electronic approach



‘Training’ for patients and / or carers

- REU devices are ‘custom made’ (for individual, named patients)
- Consistency of information

Pressure **U**lcer **P**revention and **I**ntervention **S**ervice
Rehabilitation Engineering Unit
Specialist Rehabilitation Centre
Morriston Hospital
Swansea, SA6 6NL

Phone/Ffon: 01792 703609
Email/Ebost: SBU.PUPIS@wales.nhs.uk

RE: Provision of custom equipment

Patient name: ..... Date: ..... PUPIS Clinician: .....

Equipment:.....

Please use your device(s) as informed by the Clinician (Prescriber) to reduce the risk of pressure ulcer deterioration. **The device(s) should only be used for the above named person.**

With new equipment, **please check your skin regularly**, both where the original pressure area is, and any areas contacting the device. **Should any reddening / other issues occur please remove the provided equipment and seek support immediately -**

- **Local nurse team (e.g. district nurses) for wound-related problem**
- **Posture and Mobility (Wheelchair) Service on 01443 661799 for wheelchair equipment**
- **PUPIS on 01792 703609 for bespoke devices**

Please seek advice if you are unsure of how to set-up/ use your device, or, if the device is not working as intended.

- When used correctly, the provided device(s) should provide pressure relief, comfort and promote healing of pressure related issues to optimise health outcomes.
- Check the direction and location the device is placed in is as prescribed.
- If your device is faulty or damaged, please contact the PUPIS team as soon as possible. Damage can prevent the device working as intended.
- Avoid placing other covers or items on top of your device(s), as they will reduce its effectiveness.
- The device should be used in a clean and safe environment that prevents contact with materials, equipment, or animals that could cause damage. Removable covers are machine washable at 40°C and should be kept clean.

Assurance of Progress, Opportunities for Knowledge Exchange

- Active collaboration and knowledge exchange – Internal and external to SBUHB
  - Welsh Government-Led MDR Forum (now chaired via HEIW)
  - NHS Wales Medical Devices Consultant
  - RESMAG
  - Improvement Cymru
  - Other Health Boards (within Wales and England)
  - Within SBUHB (other Services, Q&S Forums, Medical Device Regulation Task and Finish Group)

Assurance of Progress, Opportunities for Knowledge Exchange

- Active collaboration and knowledge exchange – Internal and external to SBUHB
  - Welsh Government-Led MDR Forum
  - NHS Wales Medical Devices Consultant
  - RESMAG
  - Improvement Cymru
  - Other Health Boards (within Wales and England)
  - Within SBUHB (other Services, Q&S Forums, Medical Device Regulation Task and Finish Group)

  - **Newly created Medical Device Regulation Compliance Lead role (housed within MPCE)**

External certification

- Identification of an appropriate external body to undertake an assessment
- Utilised United Registrar Systems (URS) UK-based Certification Body

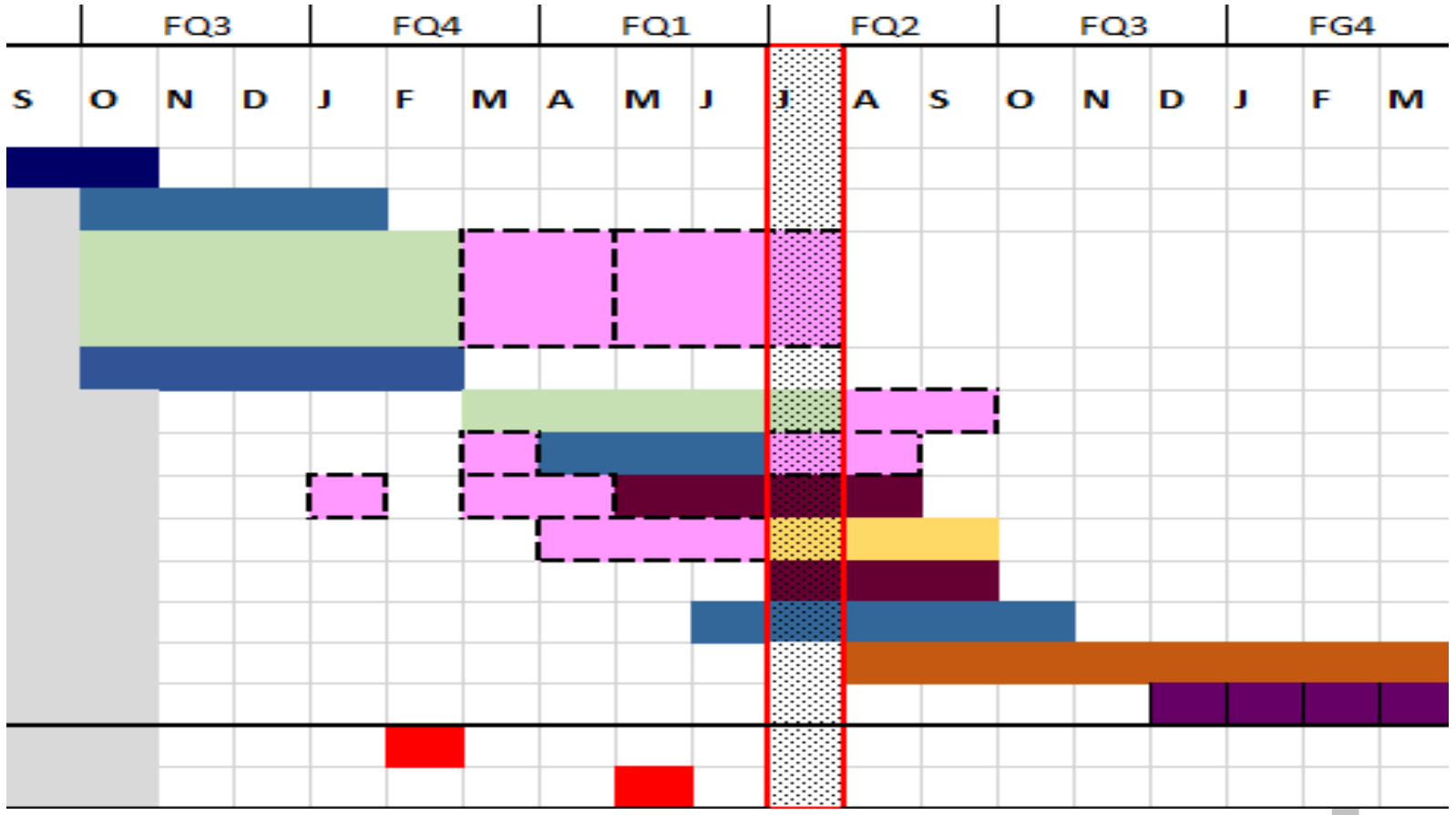
- Feb 2021 – Stage 1 Assessment – 1 Day
- April 2021 – Stage 2 Assessment – 5 days

- Successful certification of the QMS to ISO 13485

- 2022 and 2023 – Surveillance Assessment - 3 Days
- 2024 – Reassessment – 5 Days

Progress – Not always to plan!

Ref.	Stage
1	High Level Planning
2	QA Documentation and Process (Phase I)
3	Technical Documentation (Medical Device)
4	iPassport (QMS documentation only)
5	Process Documentation (Medical Device)
6	QA Documentation and Process (Phase II)
7	Equipment Management Process
8	Procurement Process
9	Infastructure Process
13	QA Documentation and Process (Phase III)
10	Measurement & Analysis Processes
11	Whole System Review / Assurance
12.1	Notified Body Checkpoint I
12.2	Notified Body Checkpoint II



Next Steps

- For REU and MFL:
  - Continual improvement and development of the joint QMS
- For Swansea Bay
  - Health Board wide resource – Medical Device Regulation Compliance Lead to support wider services and beyond
- For the UK
  - Medical device legislation is evolving….
  - **Consultation open until 25th November**

Acknowledgements

Justin McCarthy

REU (SBUHB)

Dr. Lorna Tasker

Pearl Read

Dr. Mark Bowtell

MFL (SBUHB)

Peter Llewelyn Evans