Guide for STP Trainees : Medical Device Risk Management and Governance

Learning Outcome Subject	Code	Competency	Examples of evidence	Other competencies which may be demonstrated by this evidence
Medical Device Management Strategy	DRM1-C-1	Undertake a comprehensive review of the institution's medical device management policy against the prevailing national standards and professional best practice.	Review of own local medical devices policy and also awareness of MHRA document 'Managing medical Devices'. Document the local Medical devices governance structure (s), including Point of Care equipment, and Medical device education.	DRM7-C-3, DRM-C-13
	DRM1-C-2	Outline the key elements of a medical device management strategy and the associated service delivery.	Have awareness of the medical device lifecycle and present and explain one taken from local documentation or other literature, Awareness of ISO 55000 and the NHSSC blueprint. Summarise contents of NHSSC Blueprint and the NHS supply chain assessment tool.	
	DRM1-C-3	Navigate and interpret the IEC 60601 electromedical family of standards, including collateral, particular and performance standards.	Ability to articulate the key features of the IEC 60601 family and different elements, including part 1, collateral and part 2's. Attendance at the Liverpool Electrical Safety Testing course and awareness of IPEM report 90. Devise a Medical Electrical Stystem on paper ensuring compliance with the 60601 standard in terms of electrical safety.	
	DRM1-C-4	Navigate and interpret the healthcare-related risk management standards, including consideration of at least the following specific examples of medical device risks encountered. • Medical Device Decontamination • Equipment on loan	Summarise the contents of IPEM report 95 and requirements indicated in chapter 9 of MHRA document 'Managing medical devices' which relates to decontamination. Also review of local 'Loans and donations' policy.	
Optimisation of Medical Device Effectiveness and Efficiency	DRM2-C-1	Produce material that demonstrates specialist expertise in a range of medical equipment types and aids: • clinicians • technical colleagues to maximise the effectiveness and safe operation of devices, covering all the following areas: • training guides • addressing hazards • improved maintenance • quality assurance/performance checks • risk reduction.	Summarise the contents of IPEM report 95 and 110 and requirements indicated in chapters 6+7 of MHRA document 'Managing medical devices' which relates o Training. Participate in the Risk assessment of Medical devices in terms of training and maintenance. Write maintenance checklists.	DRM7-C-2, DRM4-C-2, DRM4-C-1
	DRM2-C-2	Identify limitations of clinical devices and suggest alternative solutions.	Lead participate on a Medical device Selection and Procurement exercise. Participate in clinical/Technical evaluation of a range of medial devices and critically appraise all solutions.	DRM2-C-2, DRM3-C-1, DRM3-C-2, DRM3-C-3, DRM3-C-4, DRM3-C-5, DRM3-C-6, DRM3-C-8, DRM-C-4
	DRM2-C-3	Design processes to ensure prescribed patient medical devices are effectively introduced and managed.	Considering medical devices in the community/home environment, give a good practical example and produce a checklist of key factors to consider prior to deployment.	
	DRM2-C-4	Critically appraise the technical and information governance issues arising from a complex medical installation in a networking environment.	Partipate in the commisioning process of newly selected medical devices that are to be interconneted to a medial network and integrated with software systems. Ensure awareness of the ISO 80001 standard.	

Equipment Acquisition, Acceptance Testing and Installation	DRM3-C-1	Apply engineering principles and practice to the evaluation and selection of medical devices.	Lead participate on a Medical device Selection and Procurement exercise. Write specifications and evaluations forms as part of a medical device procurement exercise, ensuring stakeholder engagement	DRM2-C-2, DRM3-C-1, DRM3-C-2, DRM3-C-3, DRM3-C-4, DRM3-C-5, DRM3-C-6, DRM3-C-8, DRM-C-4
	DRM3-C-2	Write a clinical specification as part of an equipment acquisition process, incorporating any technical standards and regulatory compliance.	Lead participate on a Medical device Selection and Procurement exercise. Ensure reference to applicable standards are included in the specification.	DRM2-C-2, DRM3-C-1, DRM3-C-2, DRM3-C-3, DRM3-C-4, DRM3-C-5, DRM3-C-6, DRM3-C-8, DRM-C-4
	DRM3-C-3	Develop evaluation criteria against which to test candidate devices.	Lead participate on a Medical device Selection and Procurement exercise. Develop clinical/Technical evaluation criteria ensuring stakeholder engagement. Awareness of chapter 3 of the MHRA document 'Managing Medical Devices'.	DRM2-C-2, DRM3-C-1, DRM3-C-2, DRM3-C-3, DRM3-C-4, DRM3-C-5, DRM3-C-6, DRM3-C-8, DRM-C-4
	DRM3-C-4	Develop and assess responses to pre-tender questionnaires.	Lead participate on a Medical device Selection and Procurement exercise. Critically appraise/compare and score tender responses	DRM2-C-2, DRM3-C-1, DRM3-C-2, DRM3-C-3, DRM3-C-4, DRM3-C-5, DRM3-C-6, DRM3-C-8, DRM-C-4
	DRM3-C-5	Arrange equipment trials to ensure devices meet clinical need and evaluate against established criteria	Lead/assist in a full selection/procurement exercise.	DRM2-C-2, DRM3-C-1, DRM3-C-2, DRM3-C-3, DRM3-C-4, DRM3-C-5, DRM3-C-6, DRM3-C-8, DRM-C-4
	DRM3-C-6	Evaluate commercially available equipment against clinical requirements.	Lead/assist in a full selection/procurement exercise.	DRM2-C-2, DRM3-C-1, DRM3-C-2, DRM3-C-3, DRM3-C-4, DRM3-C-5, DRM3-C-6, DRM3-C-8, DRM-C-4
	DRM3-C-7	Contribute to business case development and write a case for medical device acquisition encompassing key requirements.	Partipate in the replacement plans of key items of Medical devices, risk assessing where required. Attend and participate in Medical Equipment executive meetings	
	DRM3-C-8	Apply project planning methodologies to assist in the procurement and installation process.	Lead/assist in a full selection/procurement exercise.	DRM2-C-2, DRM3-C-1, DRM3-C-2, DRM3-C-3, DRM3-C-4, DRM3-C-5, DRM3-C-6, DRM3-C-8, DRM-C-4
	DRM3-C-9	Execute the installation process, including specifying all necessary acceptance tests and commissioning processes.	Familiarity of the requirements of chapter 5 of the MHRA document 'managing medical devices'. Participate in the commissioning of a range of different types of equipment in line with local procedures.	DRM3-C-9, DRM3-C-10, DRM3-C-11, DRM-C-5
	DRM3-C-10	Determine the ongoing maintenance arrangements for the device and associated life cycle issues.	Be familiar with local methodology for assessing maintetance intervals on medical devices. Establish a maintenance programme for a particular medical device alond with the training requirements for end users and technical staff on routine and user maintenance.	DRM3-C-9, DRM3-C-10, DRM3-C-11, DRM-C-5
	DRM3-C-11	Handle rejected items that fail acceptance testing.	Under supervision, follow local acceptance testing process and commsion a new device in accordance with work instruction. Record action on local equipment inventory. Be familiar with dealing with an item that fails an acceptance test and decribe the actions taken.	DRM3-C-9, DRM3-C-10, DRM3-C-11, DRM-C-5
Planned Maintenance and Repairs to Devices	DRM4-C-1	Apply engineering principles to the management of risk in designing and delivering maintenance programmes.	Summarise the contents of IPEM report 95 and 110 in terms of risk classification of medical devices. Follow local procedures in the risk classification of different models of medical devices	DRM2-C-1, DRM4-C-2, DRM7-C-2
	DRM4-C-2	Plan and manage preventive maintenance regimens for individual devices and the larger groupings of medical devices.	Summarise the contents of IPEM report 95 and 110 in terms of risk classification of medical devices. Follow local procedures in the risk classification of different models of medical devices	DRM4-C-1, DRM2-C-1, DRM7-C-2
	DRM4-C-3	Plan and participate in training and deploying the technical workforce to ensure coverage of all equipment types.	Attend a technical training course and create material which can be used to cascade knowledge to other members of the technical team.	
	DRM4-C-4	Specify, arrange and manage external service contract providers.	Familiarity of the requirements of chapter 8 of the MHRA document 'managing medical devices'. Particiapte in the procurement and selection of external maintenance provider ensuring appropriate level of cover and assessment of risk if utilisation of third party providers.	
	DRM4-C-5	Act as an expert on the use and interpretation of medical device safety tests as part of the maintenance process, including the resolution of anomalies.	Participate in the planned preventitaive maintenance of certain types of infusion devices, and re-calibrate where necessary.	
	DRM4-C-6	Design planned maintenance regimens for a range of medical devices.	Be familiar with local methodology for assessing maintenance intervals on medical devices, and show awareness of other such methodologies/tools for assessing maintenance risk of medical devices	DRM4-C-1, DRM4-C-2, DRM2-C-1

Planned Maintenance and Repairs to Devices	DRM4-C-7	Oversee workmanship standards on a range of medical devices.	Audit a group of staff members undertake a procedure withinin service and provide feedback on observations including non conformances and opportunities for improvement.	
	DRM4-C-8	Specify the calibration requirements for specific test equipment required to assist in the maintenance process.	Summarise local protocols/procedures relating to test equipment calibration. Understand requirements for Traceability to national standards, and how this is claimed for a selection of test apparatus in use.	DRM4-C-14
	DRM4-C-9	Specify the records necessary to support the maintenance process, including determination of records to comply with all of the following: • statutory requirements • prevailing national healthcare standards/NHS requirements • customer requirements • best professional practice • local needs.	Summarise the records requirements as documented in MHRA - Managing Medical Devices section 2. Be familiar with local policy on records and legal requirements.	
	DRM4-C-10	Provide expert advice on the cleaning and decontamination of medical devices as related to the maintenance process.	Be familiar with the requirements indicated in chapter 9 of MHRA document 'Managing medical devices' which relates to decontamination. Be familiar with local policy and procedures in terms of receipt of equipment into the workshop.	
	DRM4-C-11	Specify test equipment required for the workshop.	Spend time within the MEMS worshops ensuring exposure to the wide range of test appratus used. Summarise the test equipment requirements in order to service a selection of medical devices.	DRM4-C-13
	DRM4-C-12	Monitor the service records of technical staff to ensure they are comprehensive and legible.	Participate in the monthly audit of job records completed by technical staff, against the requirements defined in the relevant work instructions for entering a job.	
	DRM4-C-13	Oversee the correct use of hand tools within the workshop.	Spend time within the MEMS worshops ensuring exposure to the wide range of test appratus used. Summarise the test equipment requirements in order to service a selection of medical devices.	DRM4-C-11
	DRM4-C-14	Ensure traceability of product in the maintenance process.	Assist the workshop test apparatus calibration lead in the management of test equipment including internal verification, and how this can be traced back to national standards.	DRM4-C-8
	DRM4-C-15	Identify and minimise health and safety risks in the workshop and clinical environments while maintenance activities are undertaken.	Summarise the Health and Safety at work act, and the implications for Clinical Engineering departments. Assist the health and safety lead review month end status of health and safety actions and become familiar with the full breadth of health and safety considerations necessary.	
	DRM4-C-16	Ensure device modifications are undertaken appropriately.	Summarise section 3.5 of the MHRA document 'Managing Medical devices' which relates to Modification and changes in use. Ensure full risk assessment are conducted aswell as documented specification of the modification requirements	DRM4-C-17, DRM7-C-6
	DRM4-C-17	Advise on the appropriateness of in-house modifications and the necessity for risk assessment and the establishment of a design project.	with reference to an example, (may be theoretical) explain the key steps	DRM4-C-16, DRM7-C-6
Patient Safety	DRM5-C-1	Act as Department of Health Central Alerting System responsible officer, including ability to use the national database.	Summarise the responsibilities of the MDSO. Work with the trust MDSO in investigating the impact of an MHRA notice/FSN and ensure actions are implemented.	DRM5-C-2, DRM5-C-3, DRM5-C-5, DRM-C-11
	DRM5-C-2	Act as the MHRA liaison officer.	Summarise the responsibilities of the MDSO. Work with the trust MDSO in investigating the impact of an MHRA notice/FSN and ensure actions are implemented.	DRM5-C-1, DRM5-C-3, DRM5-C-5, DRM-C-11
	DRM5-C-3	Receive and determine actions associated with a national safety notice.	Summarise the responsibilities of the MDSO. Work with the trust MDSO in investigating the impact of an MHRA notice/FSN and ensure actions are implemented.	DRM5-C-1, DRM5-C-2, DRM-C-5, DRM-C-11
	DRM5-C-4	Investigate an incident	Summarise local processes for monitoring medical device incidents. Participate in an action plan/Root cause analysis in relation to a reported incident and discuss status at MDSO month meeting.	DRM5-C-6, DRM8-C-1, DRM7-C-5, DRM-C-12
	DRM5-C-5	Interpret safety alerts and extract key information, such as actions, deadlines and stakeholders.	Summarise the responsibilities of the MDSO. Work with the trust MDSO in investigating the impact of an MHRA notice/FSN and ensure actions are implemented.	DRM5-C-1, DRM5-C-2, DRM-C-3, DRM-C-11
	DRM5-C-6	Execute root cause analysis on a range of medical device-related incidents, emphasising where device performance has been compromised	Summarise local processes for monitoring medical device incidents. Participate in an action plan/Root cause analysis in relation to a reported incident and discuss status at MDSO month meeting.	DRM5-C-4, DRM8-C-1, DRM7-C-5, DRM-C-12

Medical Device Information System	DRM6-C-1	Apply engineering principles to classify and structure the institution's approach to medical device categorisation.	Summarise the Medical Device Type Categoration in terms of GMDN and UMDNS. Understand the requirments of GS1 and the impact this will have on Medical Device Categorisation.	
	DRM6-C-2	Apply engineering principles to the specification, implementation and ongoing use of the medical device information system.	Summarise the importance of the Medical device inventory, identifiying all key requirements. Provide evidience that these requirements are being met with the local system.	
	DRM6-C-3	Analyse and interpret data from the system.	Participate with the end of month KPI analysis, showing evidence of the data that is extracted from the Medical Device inventory.	DRM6-C-7, DRM6-C-9
	DRM6-C-4	Be an expert user of the institution's medical device information system to display or extract all asset-related information.	Participate with the creation of Capital Medical Equipment equipment lists for Clinical Management Groups/Directorates to assist them with submission of capital bids.	DRM6-C-10
	DRM6-C-5	Access specific equipment types for information from the medical device information system, demonstrating an understanding of equipment classification.	Create lists of a selected 'Types' of Medical Equipment to allow for replacement plans. Understand the different financial classification of equipment in accordance with local 'Standing Financial Instructions'.	
	DRM6-C-6	Establish the institution's equipment holding by value and volume.	Create a list of all 'in service' Capital/Revenue equipment to enable assessment of value for each classification	
	DRM6-C-7	Design, produce and utilise key performance indicators for use in performance management of the medical device risk management and governance service	Participate with the end of month KPI analysis, showing evidence of the data that is extracted from the Medical Device inventory.	DRM6-C-3, DRM6-C-9
	DRM6-C-8	Maintain data integrity and security on the Institution's Medical Device Information System.	Summarise local systems of ensuring data integrity and security, i.e. access levels, audits etc.	
	DRM6-C-9	Use the Institution's Medical Device Information System to monitor progress on all service requests received.	Participate with the end of month KPI analysis, showing evidence of the data that is extracted from the Medical Device inventory.	DRM6-C-3, DRM6-6-7
	DRM6-C-10	Produce a range of complex, bespoke asset based reports.	Participate with the creation of Capital Medical Equipment equipment lists for Clinical Management Groups/Directorates to assist them with submission of capital bids.	DRM6-C-4
	DRM6-C-11	Undertake statistical analysis of device data to establish reliability of devices and cost effectiveness of devices through their life.	Use the Medical device inventory to determine the maintenance cost of a certain model of infusion pump. Undertake analysis to determine common causes of failure and devise action plan to reduce costs.	
Expertise in Medical Device Risk Management	DRM7-C-1	Apply medical device risk management knowledge and engineering principles to identify prevailing medical device-related risks within the institution.	Particpate in the Capital Medical Equipment bidding round process. Critically appraise some of the 'Cases of need' and justify the impact if the bid is not approved.	
	DRM7-C-2	Develop medical device risk management strategies for the institution.	Summarise the contents of IPEM report 95 and 110 in terms of risk classification of medical devices. Follow local procedures in the risk classification of different models of medical devices	DRM2-C-1, DRM4-C-2, DRM4-C-1
	DRM7-C-3	Develop a policy for the organisation to help manage risk.		DRM1-C-1
	DRM7-C-4	Execute a number of complex medical device- or service-related risk assessments.	Undertake a Risk Assessment in relation to use of third party maintenance contract service provider. Conduct a Risk assessment relating to a workshop working practice.	
	DRM7-C-5	Advise on practical risk management actions in medical device risk management and governance.	Participate in an action plan/Root cause analysis in relation to a reported incident and discuss status at MDSO month meeting.	DRM5-C-4, DRM5-C-6, DRM8-C-1, DRM-C-12
	DRM7-C-6	Authorise modifications to medical devices having analysed the associated risks.	with reference to an example, (may be theoretical) explain the key steps	DRM4-C-16, DRM4-C-17

Professional Advisory Services	DRM8-C-1	Implement interdisciplinary medical device risk management forums within the institution.	Attend and Participate in the local Medical Device Safety Officer meetings, devising relevant action plans and ensuring follow-up.	DRM5-C-4, DRM5-C-6, DRM7-C-5, DRM-C-12
	DRM8-C-2	Undertake medical device audits.	Participate in a trust wide Medical Device audit, or assist in a mini audit as per asset verification prior to renewing a maintenance contract. Awareness of the Capital finance capital asset verification, and why this is required.	
	DRM8-C-3	Provide advice on the requirements for a clinical trial involving a novel medical device.	Assist in the Clinical Engineering review of R+D study approval. Awareness of the ethics process and requirements for clinical evaluation as per Medical Devices Regulations. Awareness of MHRA document 'Clinical Investigations of Medical Devices - Guidance for Manufacturers'.	
	DRM8-C-4	Keep up to date with new technologies and developments within the field of medical device management.	Participate in meetings with company representatives in which new products are presented. Keep abreast of new technologies by reviewing journals and attending national conferences.	
	DRM8-C-5	Advise the institution on equipment replacement requirements.	Partipate in the replacement plans of key items of Medical devices, risk assessing where required. Attend and participate in Medical Equipment executive	DRM3-C-7
	DRM8-C-6	Participate in the clinical engineering response to a major business plan involving a significant medical equipment installation.	Partipate in a new build project which involves the requirments of a significnat amount of medical devices to be purchased.	

DOPS

		DOPS	Examples of evidence	Competencies which may share evidence with this DOPS
Medical Device Management Strategy		Undertake a review of the Institution's approach to Device Risk Management, identifying key features of the Medical Device Management policy, governance controls and local arrangements for device life cycle management	Observe Student reviewing MHRA guidance (Managing Medical Devices) and Trust Medical Devices Policy.	DRM1-C-1
		Navigate the IEC 60601-1 standard and associated collateral and particular standards.	Observe Student reviewing 60601 core standard.	DRM1-C-3
		Conduct a medical device related risk assessment	Observe The Student undertake a risk assessment in relation to a medical device e.g. modification, use of third party maintenance providers.	DRM7-C-4
		Clean and decontaminate a re-usable medical device	Observe Student decontam inate a medical device on return to the medical equipment library	
Optimisation of Medical Device Effectiveness & Efficiency		Implement a quality assurance regime for a medical device	Observe Student audit a process which forms part of the medical equipment management quality management system.	DRM4-C-7
		Implement IT and interconnectivity for a medical device installation	Observe student participate in discussions in relation to connection of new/existing medical devices to the trust network.	DRM2-C-4
		Select and utilise specialist test equipment, specifically including electro-medical safety testers, understanding the need for calibrated devices.	Observe Student undertake a medical electrical equipment safety check of a device which has patient connected appled parts	
		Undertake a risk assessment related to the utilisation of medical devices in complex clinical environments	Observe student participate in the risk assessment in relation to neonatal or peadiatric transport system to be used in an ambulance	DRM4-C-16
		Undertake a risk assessment related to the utilisation of medical devices in Theatres Me	Observe student participate in a risk assessment in relation to the introduction of a new model/type of medical device within the theatre environment	
		Undertake a risk assessment related to the utilisation of medical devices in Intensive Care	Observe student participate in a risk assessment in relation to the introduction of a new model/type of medical device within the intensive care environment	
		Outline a prescription for a medical device and develop specific guidance	Observe the trainee identifying the key medical device management issues when a prescribed device is to be issued to a patient. The dop may commonly take the form of advising a fellow healthcare professional.	
		Identify limitations of clinical devices and suggest alternative solutions	Observe Student score feedback from a medical device procurement exercise and develop material to justify decisions.	DRM3-C-1 - DRM3-C-6
		Design processes to ensure prescribed patient medical devices are effectively introduced and managed	Be familiar with relevant policies of when issueing home patients with medical deviecs and obseve student undertaking such a task in an area such as respiratory physiology.	

Equipment Acquisition, Acceptance Testing and Installation		Produce a plan, including the appropriate engineering evaluations to assess and evaluate a medical device against the specification produced to evaluate candidate devices E	Observe student contribute towards creation of a specification and organise/plan appropriate clinical/technical evaluations as to ensure objective assessment of a selection of medical devices	DRM3-C-1 - DRM3-C-6
		Plan a trial of a medical device in a clinical setting, including the design and application of device evaluation material.	Observe student contribute towards creation of a specification and organise/plan appropriate clinical/technical evaluations as to ensure objective assessment of a selection of medical devices	DRM3-C-1 - DRM3-C-6
		Evaluate a Pre-Purchase Questionnaire from a Supplier to inform the selection process	Observe the student assess/evaluate content of a PAQ form and any supplementary information returned from manufacture as part of local purchase approval process	
		Determine the acceptance test requirements and test the equipment prior to introducing the devices into service, describing the process for items that fail acceptance	Observe the Student undertake the full Accepance/commissioning process for a new item of medical equipment in accordance with local procedures which form part of quality management system.	DRM3-C-9
		Contribute to a complex installation of a medical device system	Observe the student partricipate in the full acceptance/commissioning process for a large installation of multiple devices in a theatres or intensive care area in accordance with local procedures which form part of quality management system.	DRM3-C-9
		Assess the planned maintenance requirements of a newly acquired device	Observe the student assess/score the maintenance risk classification of a new medical device type/model in accordance with local procedures and allocate PM schedule to device on trust medical device inventory.	DRM4-C-6
		Collate the data to be recorded on the institutions Medical Device Information System	Observe the Student undertake the full Accepance/commissioning process for a new item of medical equipment in accordance with local procedures which form part of quality management system.	DRM3-C-9
Planned Maintenance and Repairs to Devices		Carry out a range of planned maintenance and repairs to a range of medical equipment	Observe the Student participate with a repair and planned preventivice maintenance procedure on low/medium/high risk medical devices in accordance with local procedures that form part of a quality management system.	DRM4-C-6
		Manage the key components of the planned maintenance and repair process, illustrating the approach to maintenance plannning	Observe the student whilst working in the maintenance team, prioritise demand work requests in accordance with local processes/procedures that form part of a quality managament system.	
		Apply quality management systems, such as ISO 9001 to the workshop environment, contributing to internal audits	Observe student participate in local quality management meetings and participate in an audit of a core process such as acceptance, repair, preventative maintenance of medical devices.	DRM4-C-7
		Specify the calibration requirements for specific test equipment required to assist in the maintenance process, and advise on the management of calibration devices and test equipment	Observe Student particpate in a calibration meeting and also participating in an internal verification of a ietms of test apparatus and also revieiwing the calibration certificate of a item of equipment calibrated externally.	DRM4-C-14
		Select one or two devices to follow through the decontamination process	Observe student follow local processes and procedures and trust policy to decontaminate an item of equipment returned to the medical equipment library and also a review the decontamination certificate of an item of equipment returned to the workshop for repair/maintenance.	DRM1-C-4, DRM4-C-10
		Oversee the delivery of a series of planned maintenance visits to a range of clinical areas	Observe student arranging external engineer maintenance visits within critical care areas across the trust, ensuring equipment availability and access where possible. Ensure service records are provided and inventory updates as per local processes/procedures.	
		Develop a range of policies and procedures relating to device maintenance	Observe student lead/participate in the review of a current process or development of a new process which forms part of the local quality management system.	DRM4-C-1, DRM4-C-6
		Undertake risk based planned maintenance on a medical device	Observe the student assess/score the maintenance risk classification of a new medical device type/model in accordance with local procedures and allocate PM schedule to device on trust medical device inventory.	DRM4-C-1, DRM4-C-6
		Oversee workmanship standards on a range of medical devices, including the correct use of hand tools	Observe Student undertake a repair of an infusion pump which includes the use of tools and test apparatus.	DRM4-C-13

Patient Safety		Describe the Institution's approach to the handling of safety alerts. Review current safety alerts on the prevailing national distribution systems	Observe Student review a safety alert or Field Safety Notice and assess impact and devise action plan.	DRM5-C-3
		Assess technical matters that could impair device efficacy	Observe Student participate in discussions in relation to building plans that shall house medial devices, advising on necessary measures to ensure equipment functionality.	
		Review a medical device incident & describe the reporting requirements to the Medicine and Healthcare products Regulatory Aency	Observe student gather all relevant information required to report an incident to the MHRA.	DRM5-C-4
		Describe the institutions approach to the handling of safety alerts	Observe student review local procedure in relation to management of medical device safety alerts and field safety notices	DRM5-C-5
		Execute root cause analysis on a range of medical device related incidents	Observe Student undertake a root cause analysis of an incident	DRM5-C-6
Medical Device Information System		Extract, analyse and interpret data from the Medical Device Information system, producing an analysis of capital and revenue assets held by the Trust, by value and volume,together with a replacement date analysis.	Observe Student extract data from the trust medical equipment inventory and devise a replacement plan including annual costs required for execution, in a form that can be presented to the trust capital equipment panel.	DRM6-C-6
		Use a Medical Device Information System to perform complex equipment management tasks, such as an analysis of last maintenance dates for all devices	Observe Student extract data from trust medical device inventory in relation to maintenance performance of high and medium risk medical devices.	DRM6-C-3, DRM6-C-7
		Use of a Medical Device Information System to produce Key Performance Indicators to measure the performance of the Medical Device Management Organisation	Create KPI data sets as per local processes which form part of quality management system.	DRM6-C-3, DRM6-C-7
		Undertake statistical analysis of device data to establish reliability of devices and cost effectiveness of devices through their life	Use the Medical device inventory to determine the maintenance cost of a certain model of infusion pump. Undertake analysis to determine common causes of failure and devise action plan to reduce costs.	DRM6-C-11
Expertise in Medical Device Risk Management		Draft a risk management strategy for the department	Observe the student undertake a risk assessment in relation to a new or ammended departmental process, such as electrical safety testingn intervals or ammendments to manufacturer preventative maintenance intervals	
		Identify means to ensure compliance with CQC requirements for the safety and availability of equipment	Observe the student review/present the CQC standards in relation to medical devices and provide an action plan to encourage compliance.	
		Undertake a project involving analysis of risk and proposal of solutions to mitigate involving a clinical department	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams	DRM4-C-16, DRM4-C-17, DRM7-C-6
		Modify a medical device and follow necessary procedure	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams.	DRM4-C-16, DRM4-C-17, DRM7-C-6
		Authorise modifications to medical devices having analysed the associated risks	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams.	DRM4-C-16, DRM4-C-17, DRM7-C-6
		Identify key patient risks that exist in the organisation in relation to the acquisition and use of medical devices	Observe student undetake a risk assessment in relation to the selection/procurement of a newly procured medical device model.	
Professional Advisory Services		Underake an audit of medical device use in clinical practice	Observe Student undertake a study of utilisation of an item of medical equipment.	
		Assess the impact of emerging regulation or standardisation	Observe Student present knowledge of new guidance to team members with examples of impact.	
		Use engineering principles to determine the best engineering solutions to effectively manage medical devices	Observe student come up with innovative solutions to a range of problems in relation to medical equipment management within the trust.	

OCEs

		OCEs	Examples of evidence	Competencies which may share evidence with this DOPS
Medical Device Management Strategy		Describe to clinical staff the reasons for control of medical devices and how this is achieved.	Observe Student participate in a formal discussion with clincial staff regarding a medical device related issues such as invetigating impact of new capital equipment purchase post installation.	DRM7-C-1
		Develop a practical application for a device management protocol in relation to a particular equipment type you're familiar with using information extracted from the standards. Present the protocol to colleagues	Observe Student present rationale behind risk classification of a new medical device and procedures followed to make decision on risk level. Also how classification could be validated.	DRM7-C-2
		Present findings of a risk assessment to clinical colleagues including recommendations to mitigate risk	Observe Student present risk assessment in relation to using a third party contractor for service/repair of their equipment.	DRM7-C-4
Optimisation of Medical Device Effectiveness & Efficiency		Develop training material to aid Technical and Clinical colleagues	Observe student create a competency document in relation to a new medical device introduced into the trust.	
		Attend an MDT meeting and advise on risk associated with a medical device use	Observe Student participate at MDT training meeting.	
		Participate in the resolution of clinical queries and explain possible solutions to clincial colleagues to ensure successful patient delivery	Observe Student participate in a technical issue possibly raised via an incident report or request for equipment replacement. Ensure issues are investigated and options are considered and appraised and solutions recommended, which are fed back to equipment owners.	DRM5-C-4
		Advise on the minimisation of risks associated with device usage	Observe the student investigate an incident and feedback to users ways to mitigate against further re-occurances.	DRM5-C-4
		Explain to clinical users how to effectively and safely configure and use the device	Observe Student provide training to clinical users on medical device set-up and configuration.	
		Develop training material contextualised for the audience, which may range from patients, professional users or practitioners involved in device maintenance	Observe Student produce and use material to train staff groups of varied experience on use ans application of a medical device.	
		Critically appraise the technical and information governance issues arising from a complex medical installations in a networking environment and present to collegues	Assess a medical network installation against requirements of 80001 standard and present conclusions and opinions on safety of the network and possible opportunities for improvement.	DRM2-C-4
Equipment Acquisition, Acceptance and Installation		Identify and articulate the clinical need behind an equipment acquisition to a MDT	Observe student discussing case of need relating to a capital equipment bid for equipment, with bidder as to understand criticality.	
		Write a clinical specification as part of an equipment acquisition process and present to colleagues	Observe student contribute towards creation of a specification and organise/plan appropriate clinical/technical evaluations as to ensure objective assessment of a selection of medical devices	DRM3-C-1 - DRM3-C-6
		Gain feedback from users evaluating equipment, including patient feedback	Observe student contribute towards creation of a specification and organise/plan appropriate clinical/technical evaluations as to ensure objective assessment of a selection of medical devices	DRM3-C-1 - DRM3-C-6
		Interpret, critically appraise and present evaluation findings to multi-disciplinary teams.	Observe student present outcome of a procurement exercise to the trust medical device standardisation group or equivalent.	
		Contribute to the final device selection forum	Observe student present outcome of a procurement exercise to the trust medical device standardisation group or equivalent.	

Planned Maintenance and Repairs to Devices		Carry out maintenance in the clinical environment including liaison with clinical equipment users	Observe Student participate in a repair request for equipment within the ICU environment.	
		Explain to non-scientific staff the governance arrangements for a medical device to be removed form service as a result of a service failure or quality system non-conformity	Observe the student inform senior clinical staff that an item of equipment has failed electrical or functional tests and needs to be removed from service.	
		Plan and participate in training & deploying the technical workforce to ensure coverage of all equipment types	Attend a technical training course and create material which can be used to cascade knowledge to other members of the technical team.	DRM4-C-3
		Provide expert advice to clinical staff on the cleaning and decontamination of medical devices as related to the maintenance process	Observe student reject a decontamination form and advise on cause and suggestions to correct.	DRM4-C-10
		Advise on the appropriateness of in-house modifications and the necessity for risk assessment and the establishment of a design project	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams	DRM4-C-16, DRM4-C-17, DRM7-C-6
Patient Safety		Shadow personnel receiving and determining actions in relation to a number of safety alerts and report to your supervisor the considerations for staff and patient care	Observe Student review a safety alert or Field Safety Notice and assess impact and devise action plan.	DRM5-C-3
		Advise clinical colleagues on policy development to assist clinical governance and patient safety within the organisation	Observe student particpate in a trust policy review which includes medical devices.	
		Discuss with clinical colleagues the circumstances of an incident and attempt to establish the root cause.	Observe Student undertake a root cause analysis of an incident	DRM5-C-6
Medical Device Information System		Critically appraise the organisations categorisation of medical devices and report to colleagues	Partipate in the maintenance/training risk classification of a new model of medical equipment, justifying classification	DRM4-C-6
		Present to clinical colleagues an equipment replacement forecast derived from the Medical Device Information system	Observe Student participate in creating a revenue/capital equipment replacement plan for presentation to the trust medical equipment executive or equivalent.	DRM6-C-5
Expertise in Medical Device Risk Management		Draft a strategy to minimise the risks associated with modifying medical devices and present to colleagues	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams	DRM4-C-16, DRM4-C-17, DRM7-C-6
		Advise a clinical colleague on on a practical risk management actions in Medical Device Risk Management & Governance	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams	DRM4-C-16, DRM4-C-17, DRM7-C-6
		Carry out an "Outcome Guardian Audit" in a clinical area	Undertake a CQC readiness inspection of a clinical area focussing on medical device management issues, including providing feedback to clinical staff. Discuss the typical areas of focus such an inspection or audit, including a focus on how the trainee feeds back to clinical colleagues.	
Professional Advisory Services		Contribute to interdisciplinary forum to promote the safe and effective use of technology, e.g. Medical Device Advisory Groups	Attend trust medical equipment executive meetings and contribute to discussions on medical technology management.	
		Present recommendations to a multi disciplinary group on achieving compliance with a medical device guideline	Present outcome of local project in relation to change of practice at a local or national conference	

CBD

	CBD Example		Examples of evidence	Competencies which may share evidence with this CBD
DRM1	**Provide student with a real life MHRA alert/Field Safety Notice and discuss content, risk, priority and actions required and responsibility.**		FSN and action plan	DRM5-C-1 - DRM5-C-3
DRM2	**Provide student with a description of a medical device system and ask them to define safety aspects that will beed to be implemented to ensure compliance with the 60601-1 standard in terms of systems electrical safety.**		Diagram of system with safety measures shown	
DRM3	**Ask Student to present the CQC regulations that relate to medical devices and suggest stratergies to help with compliance.**		Awarness of relevant CQC standards	
DRM4				
DRM5				
DRM6				
DRM7				
DRM8				