The Association of Renal Technologists

Best Practice Guidelines for Renal Technologists

Developed by Gareth Murcutt on behalf of the ART Committee.

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1.0 Introduction

1.1 Introduction and Overview

People working on haemodialysis (HD) and related equipment provide an essential service with many aspects critical to the safe treatment of end stage renal failure patients. In their current format the guidelines are principally intended to cover the work of NHS renal technologists but may be developed in the future to help those commissioning technical support.

Once established, a set of guidelines can be used by technical teams to highlight areas of concern and help obtain the necessary budget or management support to improve

Most renal technologists and service engineers enjoy a reputation for having a 'can-do' attitude, and these guidelines should not generally be used as a reason to avoid a particular task. The exception is where the person due to carry out the task feels there is a reasonable chance of a breach of either patient safety or health and safety policies.

The guidelines are not an attempt to be a line by line manual on how to manage a renal technical service, as there are many different operating models, any of which may be valid. Rather they aim to be a framework or template, outlining the principles of operation whilst giving examples of best practice.

1.2 Governance

The overriding governance body for NHS providers is the Care Quality Commission (CQC). The CQC publish a framework document titled *NHS Provider Compliance Assessment* of which *Outcome 11 (Regulation 16): Safety, availability and suitability of equipment* is the most pertinent to the scope of practice of renal technologists. A copy of this is included in Appendix A.

One major aim of the Renal Technologist's Guidelines is to provide evidence to support a Trust's CQC returns. As such each guideline is linked to the appropriate sections of the CQC document and the same colour coding is as the CQC is used throughout. Thus if a renal technical team audit themselves (or preferably two different teams audit each other) using these guidelines the 'grades' obtained may be fed directly into a CQC return.

1.3 Scope of the guidelines

There are many areas of work worthy of inclusion that do not appear in this version of the draft. For example, fluid quality is left entirely to the Renal Association Guidelines, now that ART has a significant role in drafting these. These guidelines are seen as a starting point and it is hoped they will evolve and develop over the coming years. In time they should tie in well with the ART Training Scheme as well as other ART projects such as CPD and Scope of Practice.

The guidelines are broken down into 4 separate sections:

1. Working Practice (WP)
2. Quality Assurance (QA)
3. Home dialysis (HHD)
4. Training (TR)

1.4 Audit

It is not known how many renal technical services audit themselves (or each other) despite it being one of the main tools used across industry and healthcare to achieve an improvement in service. This is arguably the most important challenge facing renal technologist teams and it is hoped these guidelines can provide a framework against which an audit can be performed.

It would be useful exercise to field test the document whereby some technical teams can use the guidelines to audit their work and provide feedback on whether they are practicable. It would also allow them to be refined as well as providing ideas on how to develop better audit data needed to judge compliance.

2.0: Best Practice Guidelines for Renal Technologists

Guideline Data	**Guideline N^{o}: WP1.** **Version: Draft 13.6** **Verified Date:** **Review Date: xx/xx/2016**
Guideline	Technologists should be provided with an accurate description of faults or errors before commencing work on an HD machine.
Rationale	In order to provide a safe and timely repair service it is vital that technologists are provided with accurate information on the nature of the fault. Ideally, repair requests should be entered by service users directly onto the equipment database, however if paper fault forms are used they should include an error code (or similar) or a good description. This should preferably be written but may be verbal in the case of HHD patients.
Best Practice	All faults reported via electronic database with traceable work history for each job.
Acceptable Practice	Electronic database or fault forms always used to report equipment faults.
Near Acceptable Practice	Electronic database or fault forms usually used to report equipment faults.
Unacceptable Practice	Fault messages not routinely provided.
CQC Outcome	Applicable to 11A, B, C, D, E, F
Exclusions	HHD patients and carers
Comments	Poor information may lead to a fault being missed and a piece of equipment unknowingly being returned to service in an unsafe state. Fault descriptions such as “Broken” increase the likelihood of this scenario.
Applicable guidance	
Other References	
Audit Data	Fault reporting and repairs audited and/or published/discussed with service users. Database can be used to audit fault reports.

Guideline Data	Guideline N^{o}: WP2. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	Before returning a medical device to clinical use a technologist should be confident that it is safe for use.
Rationale	Medical equipment has the potential to cause harm to patients and staff. A technologist should perform whatever tests they believe are required to ensure that all risks to patients and staff are minimised. The tests could vary depending upon the nature of the fault and the device but could include functional checks, chemical or microbiological tests, leak tests or possibly a visual inspection for blood spillages.
Best Practice	All technologists have appropriate resources for them to be confident any device they are returning to use is safe. All equipment is appropriately checked before returning to use. Details are recorded
Acceptable Practice	All technologists have appropriate resources for them to be confident any device they are returning to use is safe. All equipment is appropriately checked before returning to use. Details are recorded
Near Acceptable Practice	All technologists have appropriate resources for them to be confident any device they are returning to use is safe. All equipment is appropriately checked before returning to use. Details are usually recorded
Unacceptable Practice	Technologists lack resources to ensure patient and staff safety
CQC Outcome	Applicable to 11A, C, D, E, F, G
Exclusions	
Comments	Resources could include training, time (which may be achieved by having spare equipment), spare parts, test equipment, cleaning materials etc. Appropriate checks need to be determined by the type of equipment and the nature of the fault.
Applicable guidance	Manufacturers recommendations, MHRA guidance, local policies
Other References	
Audit Data	Traceable equipment history. Breakdown data. Incident reports

Guideline Data	Guideline N°: WP3. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	Before returning an HD machine to clinical use, appropriate electrical safety tests shall be completed as part of a PPM or after the replacement of a higher-risk component.
Rationale	An electrical safety test should be part of PPM schedule because a failure of the earthing system on an HD machine could seriously compromise electrical safety. Replacing a higher-risk component (e.g. power supply, heater bar) or significantly disturbing the earthing system should be followed by appropriate testing. The exact regime should be decided locally on the basis of manufacturer's recommendations, and knowledge of equipment and risks.
Best Practice	Local policy agreed, documented, implemented and monitored. Use of a recognised, calibrated electrical safety tester and documented recording of parts replaced and tests carried out completed.
Acceptable Practice	Local policy agreed, implemented and monitored. Use of a recognised, calibrated electrical safety tester and recording of parts replaced and tests carried out completed.
Near Acceptable Practice	Local policy agreed, implemented and monitored. Use of a recognised, calibrated electrical safety tester and parts replaced/tests completed.
Unacceptable Practice	No local policy agreed or not documented, implemented and/or monitored. Electrical safety tester not usually available or not routinely calibrated. Recording of parts replaced/tests completed not auditable. Engineers not trained in electrical safety of medical devices
CQC Outcome	Applicable to 11A, C, D, E, F
Exclusions	
Comments	Due to the number of different situations faced by renal technologists, exactly what tests should be done in certain situations should be decided locally. Technologists should have a good understanding of the risks associated with electrical safety.
Applicable guidance	IEC 601-1 (2012) IEC 601-2-16 (2010) Equipment manufacturers guidance Safety tester manufacturers guidance
Other References	
Audit Data	Documented, traceable calibration records for all meters. Database or spreadsheet of planned calibrations/verifications. Audit minutes.

Guideline Data	Guideline N°: WP4. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	All conductivity, temperature and pressure (CTP) meters used shall be covered by a valid calibration certificate and be kept in good working order.
Rationale	These are critical systems within HD machines and as such should be calibrated against accurate instruments. Patient safety and/or equipment reliability may be compromised if these systems are mis-calibrated. If a technologist/engineer has reason to question a meter's accuracy or reliability, local verification or recalibration should be completed depending upon local circumstances.
Best Practice	All relevant instruments routinely calibrated to traceable standards at all times. Calibrations planned, records kept and performance audited.
Acceptable Practice	All relevant instruments routinely calibrated to standards or accredited laboratory at all times. Calibrations planned, records kept and performance of instrument audited.
Near Acceptable Practice	Some instruments not routinely calibrated or verified against lab results and/or plans and records not audited.
Unacceptable Practice	Some/all instruments not routinely calibrated or verified as recommended by the manufacturer. Plans and records not audited.
CQC Outcome	Applicable to 11A, C, D, E, F, G
Exclusions	
Comments	If a meter showed erratic conductivity due to connection or electronic problems it should almost certainly be returned for repair and recalibration. If the same fault was caused by a fixable air leak local verification of performance may be adequate.
Applicable guidance	HD machine manufacturer's specification for accuracy of CTP systems. CTP meter manufacturer's specification Accreditation system
Other References	ISO 9001 Traceable standards – Accredited Laboratory – ACAS www.ukas.com/default.asp
Audit Data	Documented, traceable calibration records for all meters. Database or spreadsheet of planned calibrations/verifications. Audit minutes.

Guideline Data	Guideline N^{o}: WP5. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	Specialist OEM test equipment, software and/or calibration routines shall be used when calibrating and/or testing critical safety systems.
Rationale	Manufacturer's instructions should be followed when calibrating critical safety systems. OEM test equipment such as air-detector or blood leak calibration tools should always be used to calibrate these devices. If the machine includes a calibration routine in its software this should completed before returning the machine to use. Note: This specifically does NOT include CTP meters for which there are a number of valid suppliers.
Best Practice	All critical safety systems are calibrated using the appropriate OEM test equipment and software which itself is appropriately calibrated or within its 'use-by' date.
Acceptable Practice	All critical safety systems are calibrated using the appropriate OEM test equipment and software which itself is appropriately calibrated or within its 'use-by' date.
Near Acceptable Practice	Most critical safety systems are calibrated using the appropriate OEM test equipment and software. Some OEM test equipment occasionally outside its 'use-by' date.
Unacceptable Practice	Critical safety systems not calibrated or specialist equipment not used/not available
CQC Outcome	Applicable to 11A, C, D, E, F
Exclusions	CTP meters (see Guideline1.1). Test equipment used for indicative purposes.
Comments	Some air detector systems require the use of a bubble trap and water. It is up to the technologists professional judgment to decide if the system they are using is appropriate
Applicable guidance	Manufacturers Service Manuals and Technical Updates
Other References	
Audit Data	Correct service equipment available and appropriately calibrated. Audit minutes.

Guideline Data	Guideline N°: WP6. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	New OEM spare parts should be used during the repair of critical systems.
Rationale	Critical systems by their nature should always be repaired with new OEM spare parts. Second sourced (or second hand) spare parts may be used for non-critical systems (e.g. water tubing) as long as they are traceable and their use is justifiable.
Best Practice	All critical safety systems are repaired using new OEM spare parts. Any use of second-sourced or second-hand parts for non-critical systems is strictly controlled, traceable and justifiable.
Acceptable Practice	All critical safety systems are repaired using new OEM spare parts. Any use of second-sourced or second-hand parts for non-critical systems is strictly controlled, traceable and justifiable.
Near Acceptable Practice	All critical safety systems are repaired using OEM spare parts. Occasionally second-source or second hand parts are used and their use is not always recorded or justifiable.
Unacceptable Practice	Critical safety systems repaired with non-OEM or second hand spare-parts. Use of second-sourced or second-hand parts routinely not recorded or traceable.
CQC Outcome	Applicable to 11A, C, D, E, F
Exclusions	Generic items and consumables such as tubing, screws, fixings as long as they are fit for purpose.
Comments	It is acknowledged that risks can only be balanced and not eliminated. There may be occasions when the risk to service interruption is enough to justify the swapping of circuit boards between machines. The most important aspect is that everything done is recorded and traceable.
Applicable guidance	Manufacturers Service Manuals and Technical Updates. Manufacturers Spare parts lists
Other References	
Audit Data	Correct spare-parts available. Breakdown/downtime data. Traceability of any second-sourced or second hand parts used for non-critical systems clearly auditable. Audit minutes.

Guideline Data	Guideline N°: WP7. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	Manufacturer's recommendations shall be used as a basis for developing planned preventative maintenance schedules and programs.
Rationale	Manufacturer's recommendations for PPM procedures should be based on reliability data so are the most important factor when deciding PPM schedules and timing. However, local usage patterns such as disinfection routines may be require a schedule to be modified. Also component failure can be a function of both usage and/or time. If component failure is caused by usage it may be acceptable to replace it less often in a home dialysis installation, compared to a main renal clinic. Deviations from manufacturer's recommendations should be risk assessed.
Best Practice	PPM schedules strongly based on manufacturer's recommendations, fine tuned to the local operating environment, and all differences subjected to risk analysis. PPM compliance regularly audited
Acceptable Practice	PPM schedules strictly follow manufacturer's recommendations and compliance regularly audited.
Near Acceptable Practice	Clearly defined PPM schedules and compliance kept up to date but not regularly audited
Unacceptable Practice	No PPM schedule or schedule widely differing from manufacturer's recommendations in either content or timeliness. Compliance not regularly audited
CQC Outcome	Applicable to 11A, C, D, E, F, G
Exclusions	
Comments	PPM's are a vital aspect of equipment management If PPM compliance falls behind then breakdowns tend to increase. The best way to audit compliance is via an electronic database
Applicable guidance	Manufacturer's guidance and technical updates. Local operating conditions
Other References	ISO 9001
Audit Data	Documented, traceable PPM schedules and risk assesments. Database or spreadsheet of completed/upcoming PPM's.

Guideline Data	Guideline N^{o}: WP8. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	Technologists shall work to an agreed policy for managing equipment potentially exposed to Blood Borne Viruses (BBV's).
Rationale	Technologists working on HD equipment are at some risk from blood on external and internal surfaces and to some extent any post-dialyser fluid. Before commencing work on a machine, a technologist should be made aware of any unusual risks they are likely to face. This may be achieved by means of a sign or markings to differentiate certain equipment used by higher risk patients or by being provided with a decontamination form. A technologists should use universal precautions and will have appropriate PPE and cleaning equipment available. A clear protocol explaining how to decontaminate equipment, especially if the machine is to be moved from a higher to lower risk category must be available.
Best Practice	Clear and up to date agreed policies and protocols agreed and implemented. Universal precautions used when working on potentially contaminated equipment and PPE readily available. 100% use of decontamination forms by fault reporters.
Acceptable Practice	Clear and up to date agreed policies, protocols and PPE readily available. Universal precautions used when working on potentially contaminated equipment. Good use of decontamination forms by fault reporters.
Near Acceptable Practice	Clear and up to date agreed policies, protocols and PPE readily available. Universal precautions used when working on potentially contaminated equipment. Some use of decontamination forms by fault reporters.
Unacceptable Practice	No clear policy or guidelines available. PPE not readily available. Universal precautions sometimes used when working on potentially contaminated equipment Negligible use of decontamination forms by fault reporters.
CQC Outcome	Applicable to 11A, B, C, D, E, F, G
Exclusions	
Comments	The policy and/or protocols can be local but should be the based on National guidance and/or agreed with local infection control teams.
Applicable guidance	Department of Health, BBV guidance Local infection control policies HD machine manufacturer's guidance
Other References	
Audit Data	

Guideline Data	Guideline N°: QA1. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	An electronic database shall be used to maintain equipment inventories and service history.
Rationale	To enable fully traceable and auditable equipment records all data should be stored electronically. Ideally this should be available to technologists at all sites where work occurs to allow them to see the service history of a piece of equipment they are working on.
Best Practice	All inventory and service history stored in an electronic database, accessible at all sites where work occurs.
Acceptable Practice	All inventory and service history stored in an electronic database, accessible at the main sites where work occurs. Possible for remote working technologists to access the database via a colleague at a main site.
Near Acceptable Practice	All inventory and service history stored in an electronic database, accessible at a single site where work occurs.
Unacceptable Practice	No electronic database in use to record inventory and service history of equipment.
CQC Outcome	Applicable to 11A, B, C, D, E, F, G
Exclusions	
Comments	
Applicable guidance	
Other References	
Audit Data	Database used as a primary reference source during audit.

Guideline Data	Guideline N°: QA2. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	Alerts from National Bodies such as the MHRA, NPSA, and renal rapid reporting system shall be shall be routinely monitored and assessed for relevance and priority.
Rationale	Patient safety may be compromised if these alerts are not monitored, assessed and actioned in a timely manner. Alerts may arrive by a variety of means such as email, the internet or via a local contact. The information should be regularly assessed for relevance and priority in light of local circumstances with respect to safety/risk and cost/benefit.
Best Practice	All information regularly assessed, documented and made available to engineers. Action timelines agreed, implemented and monitored.
Acceptable Practice	All information made available to engineers. Action timelines agreed, implemented and monitored.
Near Acceptable Practice	Information assessed and/or made available to engineers. Action timelines agreed and monitored. Decisions and actions not recorded/audited.
Unacceptable Practice	Information rarely assessed and/or made available to engineers. Action timelines not agreed and monitored. Decisions and actions not recorded/audited.
CQC Outcome	Applicable to 11D, E
Exclusions	1, 2
Comments	If a meter showed erratic conductivity due to connection or electronic problems it should almost certainly be returned for repair and recalibration. If the same fault was caused by a fixable air leak local verification of performance may be adequate.
Applicable guidance	MHRA Alerts NPSA alerts Rapid Renal Reporting System alerts
Other References	Local Incident Reporting systems
Audit Data	Documented, traceable records of TI, decision making process and progress reports.

Guideline Data	Guideline N^{o}: QA3. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	Technical information and updates from manufacturers shall be routinely monitored and assessed for relevance and priority.
Rationale	Manufacturers should issue routine technical information updates. These cover a vast range of topics from safety issues to enabling optional features or perhaps a change of spare part supplier. The information should be regularly assessed for relevance and priority in light of local circumstances with respect to safety/risk and cost/benefit.
Best Practice	All information regularly assessed, documented and made available to engineers. Action timelines agreed, implemented and monitored.
Acceptable Practice	All information made available to engineers. Action timelines agreed, implemented and monitored.
Near Acceptable Practice	Information assessed and/or made available to engineers. Action timelines agreed and monitored. Decisions and actions not recorded/audited.
Unacceptable Practice	Information rarely assessed and/or made available to engineers. Action timelines not agreed and monitored. Decisions and actions not recorded/audited.
CQC Outcome	Applicable to 11D, E
Exclusions	
Comments	It may not be possible/desirable/cost effective to implement every piece of manufacturers TI, however a system should be in place to assess and record this process.
Applicable guidance	Equipment manufacturer's technical information data
Other References	
Audit Data	Documented, traceable records of TI, decision making process and progress reports.

Guideline Data	Guideline N°: HHD1. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	HHD sites are consistently evaluated for suitability and safety before conversion work is approved. All work conforms to the relevant building and water regulations.
Rationale	Just because an HD machine can be fit into a room this does not mean the site is suitable for HHD. Other factors need to be considered such as storage for consumables and space to work safely. A standardised evaluation form should be available to help technologists give consistency and so that relevant details are recorded.
Best Practice	All potential sites are evaluated consistently using a standardised form before work commences. All work conforms to the relevant building and water regulations. Details of the evaluation visit are recorded electronically and readily available.
Acceptable Practice	All potential sites are evaluated consistently using a standardised form before work commences. Any deviation from the relevant building and water regulations is risk assessed and recorded. Details of the evaluation visit are recorded.
Near Acceptable Practice	All potential sites are evaluated consistently before work commences. All work conforms to the relevant building and water regulations.
Unacceptable Practice	Not all potential sites are evaluated consistently. Work may not meet the building or water regulations. Records of visits not available.
CQC Outcome	Applicable to 11 A, B, C, D, E, F, G
Exclusions	
Comments	It is acknowledged there are some practical difficulties with the IEC 601 guidance and the hardwiring of medical equipment in the home. Until this is fully resolved it would seem 'acceptable' that equipment is covered by a risk assessment.
Applicable guidance	Drinking Water Regulations (http://dwi.defra.gov.uk/stakeholders/legislation/) IEC 601
Other References	
Audit Data	Evaluation form available. Records available. Certificates of compliance available. Risk assessments available. Audit minutes.

Guideline Data	Guideline N°: TR1. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	Technologists should receive adequate training before working on medical equipment. Supervision of untrained technologists is essential.
Rationale	Medical equipment has the potential to cause harm to patients so anybody working on devices should have received appropriate training to help them achieve competency. This training would normally be achieved by attending a manufacturers training course but other methods may be acceptable and transferable skills are also recognised as providing competency. Supervision may take different forms for different tasks depending upon the level of risk involved.
Best Practice	All technologists attend appropriate OEM training courses where available. All other training (e.g. in-house train the trainer) is fully documented. Untrained technologists are supervised by an appropriate method.
Acceptable Practice	All technologists attend appropriate OEM training courses where available. All other training (e.g. in-house train the trainer) is fully documented. Untrained technologists are supervised by an appropriate method.
Near Acceptable Practice	All technologists attend appropriate OEM training courses where available. Some training is done in-house but not fully recorded. Untrained technologists are supervised by an appropriate method.
Unacceptable Practice	Not all technologists attend appropriate OEM training courses. In-house training not recorded. Untrained technologists not supervised appropriately.
CQC Outcome	Applicable to 11A, C, D, E, F, G
Exclusions	Some first-line equipment support may be covered by transferable skills alone.
Comments	Whilst attending an OEM course is obviously desirable, these vary in quality and cannot guarantee competency. Experience also has a role to play. Examples of transferable skills : A technologist should not have to attend a training course to fix 1. A drip from a water connector 2. Replace a smashed electrical plug. 3. A slightly different model of equipment (as long as they are aware of any differences). Supervision may be direct or indirect (telephone support) depending upon the nature of the equipment and problem.
Applicable guidance	ART training course http://www.artery.org.uk/site/2010/training/art-training-scheme---latest-updates? ART CPD scheme, Manufacturers recommendations
Other References	VRCT **http://www.vrct.org.uk/**
Audit Data	Training records, assessments and certificates. CPD documents.

Guideline Data	Guideline N^{o}: TR2. Version: Draft 13.6 Verified Date: Review Date: xx/xx/2016
Guideline	Technologists should maintain adequate knowledge and competences to ensure they can practice safely.
Rationale	Technologists should be able to demonstrate continuing competency by reference to a professional body CPD scheme.
Best Practice	All technologists attend appropriate training courses and maintain a record of CPD work undertaken, audited and accredited by a professional body.
Acceptable Practice	All technologists attend appropriate training courses and maintain an auditable record of CPD work undertaken.
Near Acceptable Practice	Technologists attend appropriate training courses and maintain a record of CPD work undertaken.
Unacceptable Practice	Technologists don't attend appropriate training courses or don't record CPD work undertaken.
CQC Outcome	Applicable to 11 A, C, D, E, F, G
Exclusions	
Comments	
Applicable guidance	ART training course. ART CPD scheme, Manufacturers recommendations and updates
Other References	ART CPD scheme: VRCT: **http://www.vrct.org.uk/**
Audit Data	Training records, assessments and certificates. CPD documents.

3.0 Supporting Information

3.1: List of Related Web Links	
CQC Home	http://www.cqc.org.uk
CQC Guidance (pdf)	http://www.cqc.org.uk/sites/default/files/media/documents/guidance_about_compliance_summary.pd
CQC Outcome 11 (doc)	http://www.cqc.org.uk/sites/default/files/media/documents/PCA_OUTCOME_11_new.doc
ART Home	www.artery.org.uk
ART Training Scheme (req's login)	http://www.artery.org.uk/site/2010/training/art-training-scheme---latest-updates?
Bradford University Renal Technology modules	http://www.bradford.ac.uk/courses/view/?c=healthcare-science-clinical-engineering-bsc-3-years#2
VRCT	http://www.vrct.org.uk/
ART CPD scheme	
UKAS	www.ukas.com/default.asp

3.2 CQC Guidance document (2012)

NHS Provider Compliance Assessment

Safeguarding and safety

Outcome 11 (Regulation 16): Safety, availability and suitability of equipment

What should people who use services experience?

People who use services and people who work in or visit the premises:

- Are not at risk of harm from unsafe or unsuitable equipment (medical and non-medical equipment, furnishings or fittings).
- Benefit from equipment that is comfortable and meets their needs.

This is because providers who comply with the regulations will:

- Make sure that equipment:
  - is suitable for its purpose
  - is available
  - is properly maintained
  - is used correctly and safely in line with manufacturers' instructions
  - promotes independence
  - is comfortable.
- Follow published Guidance about how to use medical devices safely.

Ensure equipment is adequate

11A Provide evidence to demonstrate that people who use services are not placed at risk of harm because where equipment is provided or used as part of the regulated activity, the equipment is safe and appropriate as outlined in the section 11A.	Green ☒	Yellow ☐	Amber ☐	Red ☐

Summary of evidence to support the outcomes described in 11A

People are safe because, where equipment is provided or used as part of the regulated activity, the equipment is:

- **Available in sufficient quantities to meet the needs of people who use the service.**
- **Safe to be used.**
- **Suitable for its stated purpose.**
- **Compliant with all relevant laws.**
- **Installed, used and maintained correctly with reference to the specifications, manufacturer's instructions, legislation and appropriate guidance from expert bodies.**
- **Properly maintained, tested, serviced and renewed under a recorded programme.**
- **Stored safely and securely to prevent theft, damage or misuse.**

Based upon the following guidance for Outcome 11 taken from the CQC website:
People using the service and people who work in or visit the premises:
Are not at risk of harm from unsafe or unsuitable equipment (medical and non-medical equipment, furnishings or fittings).
Benefit from equipment that is comfortable and meets their needs. This is because providers who comply with the regulations will:
Make sure that equipment:
is suitable for its purpose
is available
is properly maintained
is used correctly and safely
promotes independence
is comfortable.
Follow published guidance about how to use medical devices safely.

11B Provide evidence to demonstrate the needs of people who use services are met because staff using any equipment do so in a way that has regard to their dignity, comfort and safety and promotes their independence.	Green ☒	Yellow ☐	Amber ☐	Red ☐

Summary of evidence to support the outcomes described in 11B

People's needs are met because staff using any equipment do so in a way that has regard to their dignity, comfort and safety and promotes their independence by:

- **Actively listening to their preferences and thoughts about the equipment they need and how it is used.**
- **Supporting the person to understand how and why the equipment is being used.**
- **Taking care in the way they use the equipment to make sure the person is comfortable and safe.**
- **Using the equipment in a way that ensures the person's privacy and dignity.**

Manage risk through effective procedures about equipment suitability

11C Provide evidence to demonstrate that people who use services are safe because where equipment is provided as part of the regulated activity, there are clear procedures followed in practice, monitored and reviewed.	Green ☐	Yellow ☐	Amber ☒	Red ☐

Summary of evidence to support the outcomes described in 11C

People are safe because, where equipment is provided as part of the regulated activity, there are clear procedures followed in practice, monitored and reviewed. Wherever necessary these include:

- **Identification, assessment and review of risk.**
- **Where risks are identified, a plan for how these are to be managed.**
- **How the equipment is maintained and used.**
- **Ensuring that all staff involved in using the equipment have the competency and skills needed, and where this is not possible, know what to do to ensure the people remain safe.**
- **How staff will know what to do when a person who uses services refuses to allow use of the equipment.**
- **The arrangements for adverse events, incidents, errors and near miss reporting. These should encourage local and, where applicable, national reporting, learning and promoting an open and fair culture of safety.**
- **The training of people who use services about any equipment they are given to use themselves.**

- **Best interest meetings with people who know and understand the person using the services to ensure that treatment and care are taken that reflect the person's best interest.**
- **What will happen in the event of electricity, water or gas supply failure, or other emergencies, that affect the equipment used to meet the needs of people who use services.**

11D Provide evidence to demonstrate that where people who use services receive care, treatment or support that involves the use of medical devices, the provider has clear procedures that are followed in practice, monitored and reviewed for the use of medical devices as outlined in section 11D.	Green ☐	Yellow ☒	Amber ☐	Red ☐

Summary of evidence to support the outcomes described in 11D

Where people who use services receive care, treatment or support that involves the use of medical devices, the provider has:

- **Clear procedures that are followed in practice, monitored and reviewed for the use of medical devices. Wherever they are required these procedures include:**
  - **implementing guidance issued by experts or professional bodies in relation to the medical devices used**
  - **acting on alerts from an expert or professional body or a product manufacturer.**

11E Provide evidence to demonstrate that people who use services receive care, treatment and support from a service that takes into account relevant guidance including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).	Green ☐	Yellow ☒	Amber ☐	Red ☐

People who use services receive care, treatment and support from a service that:

Takes into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications (see appendix B).

- **MHRA DB2008(03) Guidance on the safe use of lasers, IPL systems and LEDs**
- **MHRA DB 2006 (4) Single-use Medical Devices: Implications and Consequences of Reuse (MHRA, 2006)**
- **MHRA DB 2006(5) Managing Medical Devices: Guidance for health**

care and social care organisations (MHRA, 2006)

- Safety alerts, rapid response alerts, guidance and directives relating to equipment published by expert and professional bodies including:
  - National Institute of Clinical Excellence
  - National Patient Safety Agency
  - Medicines and Healthcare products Regulatory Agency
  - Royal Pharmaceutical Society of Great Britain
  - DH
  - Product manufacturers
- DH IRMER Guidance and Good Practice Notes
- Mental Health Act 1983 and Mental Health Act Code of Practice (DH, 2008 relating to seclusion facilities)

Providing personalised care through the effective use of medical devices

	Green	Yellow	Amber	Red
11F Provide evidence to demonstrate that people who use services receive care, treatment and support with medical devices that meet the requirement outlined in section 11F.	☐	☒	☐	☐

Additional prompts for specific service types

DCC DCS DEN RCA RSM SHL SLS

	Green	Yellow	Amber	Red
11G Provide evidence that demonstrates that people who use services are safe because when equipment is used in a person's own home, staff address any concerns in a timely manner where they have identified problems around the safety of the equipment.	☒	☐	☐	☐
11H Provide evidence that demonstrates that people using services are not at risk of harm because the equipment used for resuscitation or other medical emergencies is available, accessible for quick use and where necessary, is tamper proof.	☒	☐	☐	☐

Summary of evidence to support the outcomes described in 11H

People who use services receive care, treatment and support that:
Ensures equipment required for resuscitation or other medical emergencies

is available and accessible for use as quickly as possible. Where the service requires it, this equipment is tamper proof.