**IQIPS 2023 Standard Statements Guidance**

This guidance document is designed by the Accreditation Clinical Advisory Group (ACAG) to provide organisations with a basic understanding of what the assessment team will be looking for in relation to each criterion across the standard. The organisations must have the systems documented and must be able to provide evidence that they are compliant to those systems across all locations, activity, and service delivery. There are some examples in place across some disciplines where this was felt to be helpful. The professional bodies or UKAS can be approached for more specific guidance as required.

**Leadership & Management**

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| **LM1 -** The healthcare provider is or must be part of a legal entity. |
| **Criteria 1 -** Be part of an entity that can be held legally responsible for its activities. |

Verification of legal entity authorisation whether through Companies House or government legislative records will be determined prior to assessment and confirmed with the customer to determine accuracy and any significant changes.

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| **Criteria 2 -** Be licensed to operate according to relevant international and UK regulatory frameworks. |

The service should ensure they are aware of whether they meet the regulatory requirements to hold a licence to provide the healthcare service. This can be found in DHSC Protecting and promoting patients interests document.

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| **Criteria 3 -** Where applicable, be clearly recognised in the published organisational structure of the parent organisation. |

Assessors will be looking for a clear organisational structure for both the service and the parent or overarching organisation where applicable. The structure will show clear lines of accountability and line management.

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| **Criteria 4 -** Have clearly documented processes in place to inform users, staff, and stakeholders of its purpose and core values (culture). This is normally defined and published as a mission, vision, and values statement. |

There will be a documented mission statement and values with evidence it has been shared with staff whether at corporate or localised level or both. The service should provide evidence of how it has shared the documents with users and stakeholders.

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| **LM2 -** The healthcare provider must define, document, and communicate governance arrangements including leadership, roles, responsibilities, and accountabilities. |
| **Criteria 1 -** A leadership and management team consisting of individual(s) with defined responsibilities and accountabilities for clinical and professional leadership, advice, budget control and risk management. |

You will need to demonstrate that the Service has allocation and publication of localised and strategic/operational roles, responsibilities and accountabilities for clinical and professional leadership, advice, budget control and risk management. This will include having a named person responsible for each area with a deputy as appropriate.

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| **Criteria 2 -** A leadership and management team that is visible, approachable, and available to staff. |

You will need to show how you are ensuring the management team is visible, approachable, and available for staff. Assessors will be asking staff during the assessment for their view and opinion.

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| **Criteria 3 -** The leadership team identify and document details of individuals with specific roles and responsibilities across the Quality Management System (QMS). |

Assessors will be looking for an understanding of how the service has identified the different roles and responsibilities across the QMS. The role and responsibilities should be published and will include having a named person responsible for each area with a deputy as appropriate and will be referenced in the Quality Manual.

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| **Criteria 4 -** All staff have:   * An agreed contract of employment. * A current job description/job plan that specifies his/her role, responsibilities, authorities, and relationships; |

Assessors will check that each member of staff has an agreed contract of employment, current job description and/or job plan which details the person’s role, responsibilities including any line management and areas of authority. You will also need to demonstrate that you have a process to ensure appraisal, professional objective setting, job descriptions and ongoing personal development plans are in line with the organisational timeframes (usually undertaken annually).

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| **Criteria 5 -** All staff understand their specific role and responsibilities, authorities, and relationships. |

Assessors will require evidence that staff understand all tasks required for the delivery of the service, with clear lines of management and accountability. Staff should be fully aware of any roles they are required to do and should not be required to carry out tasks they are not currently trained or competent to do and this will be verified through discussion with staff.

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| **Criteria 6 -** All staff understand the processes in place to manage conflicts of interest. |

While it is unlikely that any conflicts of interest will arise, you will need to demonstrate that there are documented processes in place to manage conflicts of interest and how this is addressed on an ongoing basis. Staff should be aware of the potential sources of conflicts such as, for example, where they have other employment or take on consultancy work for another organisation.

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| **Criteria 7 -** All staff understand how to differentiate and manage feedback and complaints. |

Assessors will be looking for training and learning for all staff. The service should have a robust process for collecting all patient feedback and staff should be aware of the process and be able to explain it to assessors. There should be a mechanism for all feedback and complaints to be fed back to the team with shared learning as required (links to PE4).

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| **Criteria 8 -** All staff can give feedback and raise matters of concern, in confidence, and without fear of recrimination. |

Assessors will be looking for evidence that you have robust and confidential systems to allow staff to raise concerns over any aspect of service delivery or clinical management without prejudicing their position, i.e., freedom to speak up, whistleblowing.

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| **LM3 -** The healthcare provider must operate within its quality policy and monitor performance against measurable quality objectives. |
| **Criteria 1 -** The leadership team develop and publish an appropriate quality policy and measurable quality objectives that are regularly reviewed. |

Assessors will want to see the service has a documented quality policy which details the overarching quality objectives for the year. The service should have measurable quality objectives which may be within the quality policy or separate but should then be referenced to the quality policy. The service should document how these are being monitored and evidence to show monitoring and any actions taken as a result should be available.

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| **Criteria 2 -** Agreed local targets and key performance indicators/outcomes for service activities and clinical procedures, in line with local and national targets e.g., outcomes of objectives, equipment breakdown times, staff retention rates, patient/client satisfaction rates, workloads etc; |

Assessors will want to see evidence that the service delivers an integrated patient pathway and that it meets any KPIs agreed locally or with commissioners.

Evidence of the outcomes of the service objectives will be reviewed here.

Staff retention should be monitored, and the service should engage in systematic succession planning which ensures that it can deliver safe and effective care.

An effective process should be in place for reporting equipment faults and managing equipment breakdowns and monitoring turnaround times.

Feedback from patients on their experience of the service can contribute to service improvement and development and assessors will want to see how the service is using the feedback.

Waiting times and DNA/WNB data will be reviewed as part of the patient pathway in CL1.3

**Respiratory & Sleep Example**

For Respiratory and Sleep Physiology, patients attending for urgent tests (e.g., pre-operative assessment, sleep studies in sleepy professional drivers etc)) and those on 2-week cancer waits (e.g., lung cancer) should be clearly documented.

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| **Criteria 3 -** Consistency in performance across the provider’s activities with internal and external benchmarking. |

Assessors will be looking for evidence of benchmarking performance against national and local targets and quality standards. Benchmarking should be considered across the different areas or activities provided by the service and not across the service.

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| **LM4 -** The healthcare provider must establish, implement, and maintain a quality management system (QMS). |
| **Criteria 1 -** Be described in a quality manual. |

Assessors will be looking for a comprehensive quality manual covering the QMS. Evidence that this quality manual has been shared with staff should be available.

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| **Criteria 2 -** Be sufficiently robust to ensure that staff only have access to the latest and current versions of documents. |

The quality manual should be document controlled and updated whenever a document in the QMS is reviewed. The assessors will be looking for a process to ensure this occurs and will review the quality manual as evidence that latest versions are available to staff.

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| **Criteria 3 -** Ensure availability of supporting documentation to include, but not be limited to:   * Processes (ways of working) for all activities * Pathways and clinical protocols * Records of resources (staffing, equipment etc) available to support delivery * Forms in use * Internal audits * Publications |

Assessors will be looking to assure the service has some form of overview of all their documentation covering the above and that this is noted in their Quality manual. This may be a master list of documents or other mechanisms.

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| **Criteria 4 -** Be subjected to regular management reviews, at least annually, to include at least the following:   * Quality improvement initiatives to include business planning. * Results and outcomes from user feedback and complaints. * Periodic review of referrals received. * Staff and stakeholder consultation and feedback. * Results and outcomes from internal audits. * Risk management reports, and update of risk register. * Reviews conducted by external organisations. * Objectives aligned to local and national performance targets with outcomes of inter-service comparison programmes/benchmarking. * Performance of suppliers. * Identification and control of non-conformities. * Follow-up actions from previous management reviews. * Changes to the volume and scope of work including capacity and demand, staffing, premises, equipment consumables and resources. * Where the healthcare provider is required to follow the QMS of a parent organisation, they must demonstrate that the parent organisation’s system is appropriately implemented and where necessary the management review output is taken forward to the parent organisation. |

Assessors will review documentation to show the service performs at least an annual management/business review. The documentation should show that each area listed is reviewed either at a single meeting or across a range of meetings. The documentation should be clear and include who should be in attendance, how the inputs to the meeting will be provided such as reports or presentations, and how the outputs will be recorded including actions and any targets/goals to be achieved during the year and how these will be monitored (e.g., minutes or a formalised management review document). .

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| **LM5 -** The healthcare provider must ensure that documents and records (including clinical records) are controlled. |
| **Criteria 1 -** Agreed format and media for documents and records. |

Assessors will be looking for a process to ensure the format of documents and records has been agreed with staff and stakeholders as required. All relevant information is included as detailed in LM5.4 and this includes any templates used by the service for reports or clinical records. Evidence of the media the documents and records are to be stored on or in is agreed with appropriate safeguards.

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| **Criteria 2 -** Data is processed, handled, maintained, and secured in line with applicable regulation and professional guidance. |

You should have processes in place in accordance with GDPR legislation and Electronic Communications Act. These are governed by *Data Protection Act 1998 [5] as well as the National Health Service Act 2006 [6], Section 251.* You should ensure a secure storage area for patient data and reports, and that electronic reports are backed up daily.

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| **Criteria 3 -** All documents and records supporting delivery of services are current, reviewed, approved and available. |

Assessors will be checking that the service has a process to ensure effective review of documents and to allow only current documents to be available, and that these are accessible to all staff. The documents should contain all the information in criteria 4 and be in date.

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| **Criteria 4 -** All documents and records created and revised contain:   * A title * Unique identifier on each page * Date of current edition, review, edition number * Page number to total number of pages * Authority for issue |

Assessors will be looking to ensure that all documents reviewed contain the required level of information and identification.

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| **Criteria 5 -** Appropriate controls for the identification, collection, indexing, access, storage, maintenance, and amendments of current and obsolete records and documents. |

Assessors will be looking for a documented process for the management of documents. The process should include processes for archiving and the management of obsolete documents. It should detail who can access which areas or documents and who can amend or updated documents. This should also include safe transportation of documentation if required.

There should be a process in place for the retrieval of data if the main IT system fails, and this local disaster recovery plan has been tested. This process including the local disaster recovery plan, will have been communicated to staff who are aware of the document and the expected process.

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| **Criteria 6 -** Documents and records are protected from unauthorised alterations and where necessary kept confidential. |

The service must demonstrate that it has systems in place to control and audit access to all documents including patient data to ensure that no unauthorised alterations can be made. Where there has been unauthorised access, you must demonstrate that this has been investigated with a Root Cause Analysis performed and any resulting actions implemented.

Assessors will expect to see processes for secure storage of personal and confidential files (paper and electronic).

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| **LM6 -** The healthcare provider must establish and review agreements for any outsourcing /subcontracting clinical services. |
| **Criteria 1 -** Specification of the minimum information needed for different types of agreements. |

Assessors will be looking for evidence of agreements which show the specification for the contract. The contract should specify clear performance targets, including quality appraisal, and the action to be taken if performance is not satisfactory. This may be for example, when using an outsourced calibration service or outsourcing own services.

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| **Criteria 2 -** Timely review of all agreements. |

You should have documented regular reviews as part of the contractual agreement for during the term of the agreement and the review prior to the agreement ending or being renewed

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| **Criteria 3 -** Assurance that the selected sub-contractor is competent to perform the activity for which it has been selected. If not accredited the healthcare provider will need to demonstrate how competency has been established and what criteria were used. |

Assessors will be looking for sub-contractors to be UKAS accredited for the service being provided. If the sub-contractor is not accredited the service should have evidence that the company are competent to deliver the service (can tie to FR5.1). If the service is providing clinical activity the evidence should include clinical competency of the staff providing patient care.

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| **Criteria 4 -** Maintenance of patient/client confidentiality. |

Assessors will want to be assured that the sharing of patient data between organisations is subject to a policy which ensures security and confidentiality are maintained, and which adheres to the Data Protection Act 2018 and Electronic Communications Act 2000

Contractors or any outsourced provider will have a documented process for the management of records which include how to maintain patient confidentiality.

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| **Criteria 5 -** Monitoring and review of performance against contract requirements, including remedial actions. |

You will need to evidence regular and systematic reviews of performance against contract requirements, and monitoring for cost-effectiveness. Actions to taken when performance is not satisfactory are recorded and monitored to show improvements or a move to review the contact.

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| **Criteria 6 -** Transparency of outsourcing/subcontracting to users and in clinical service outputs. |

Where applicable, assessors will be looking for evidence of communication with service users and referrers if the users are to have their care provided by an outsourced or subcontracted provider. Referrers and users should have the option of declining as appropriate

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| **LM7 -** The healthcare provider must provide competent advisory services. |
| **Criteria 1 -** Communication to users and stakeholders on the range and choice of clinical procedures currently available, and on emergent practice. |

The service will have documented processes that ensure effective communication to users and stakeholders about the range of activities they provide, and this will also include how the service can gain advice from those external sources to benefit their activity or patients. Where appropriate, the service will actively signpost patients to available communication and social support services: including the provision of information. Processes for provision of information should be documented.

The service can demonstrate that there are processes in place for reviewing emerging clinical practices, technologies, drugs, and investigative and treatment approaches. The service will have examples such as trials of new technologies or feasibility studies and can provide information on improvements in service delivery and quality where new practice has been implemented.

**Audiology Example**

There are many hearing self-help and voluntary societies that offer support to patients for example Action on Hearing Loss, NDCS, and local support organisations. Assessors will be looking for evidence that you ensure patients and carers are made aware of and have access to these support groups. Where appropriate, the service should evidence liaison with medical specialists (ENT/AVP) to ensure that patients attending medically led clinics receive the same level of information.

**Respiratory and Sleep Example**

British Lung Foundation (BLF)

Asthma UK

Sleep Apnoea Trust Association (SATA)

Motor Neurone Disease Association (MNDA)

**Vascular Example**

Circulation Foundation

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| **Criteria 2 -** Communication on clinical, professional, and logistical matters. |

You will need to demonstrate that you have a system in place to inform patients of the next steps in their pathway. Systems in place for effective communication with professionals for clinical, logistical guidance for example MDT meetings, commissioning, expert input

**Audiology Example**

Assessors will want to see evidence that information is provided to support young people with the transition between paediatric and adult hearing and balance services. Where a service is outside of their scope of practice (I.e., bone conduction hearing aids and implants or wax removal) there should be information available to the patient with regards to their options and how they can obtain these options.

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| **Criteria 3 -** Users and stakeholders can access advice on interpretation of results. |

You should be able to demonstrate a clear communication pathway between clinicians, referrers and services users to support their understanding of any report or result as required.

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| **Criteria 4 -** Sufficient capacity for staff to attend multidisciplinary meetings with users/ stakeholders about patient/client management. |

The Service should provide evidence of multiagency and multidisciplinary working within health (GP, ENT) and social care. For children this should extend to timely joint working with other wider healthcare professionals (I.e., Speech and Language) and education services.

Assessor will be looking for services attending planning and support meetings to provide service information and direction to strategic meetings with stakeholders. These could be to discuss service developments, improve local relationships (I.e., with care homes), pathways changes or service improvements.

**Example**

Staff rotas should include time for staff to attend regular multidisciplinary meetings with the wider Teams (e.g., surgeons/radiologists/nurse specialists

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| **LM8 -** The healthcare provider must identify, manage, and eliminate non-conformities by taking corrective actions. |
| **Criteria 1 -** Designated responsibilities for non-conformities. |

Assessors will want to see that there are defined roles, responsibilities and accountabilities for nonconformities and associated actions for the service for both preventative and corrective actions.

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| **Criteria 2 -** Training for staff to detect and record non-conformities. |

Assessors will be looking for training records with updates as required for all staff. The records should show that staff have been informed of the possible range of nonconformities clinical and non-clinical. Your incident reporting processes may well need to be included here as these are the non-conformities that require corrective actions. Staff should be trained in required processes for reporting non-conformities. There should be documented processes in place to manage non-conformity. This may well reference or include the incident reporting and management processes.

**Criteria 3 -** Review of data/information to determine where future non-conformities could occur (e.g., as part of clinical review meetings such as ‘Discrepancy’ or ‘Morbidity and Mortality’.

Assessors will be looking for a documented process to show the service is proactively looking for future possible non-conformities. The process could include audit results, MDT meetings, harm reviews, competency assessments patient feedback etc

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| **Criteria 4 -** Immediate actions are taken to mitigate the effect of non-conformities. |

You will be required to evidence that action has been taken immediately following a nonconformity to address the initial impact. This may include your incident reporting logs alongside any lower-level localised non-conformities.

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| **Criteria 4 -** Root cause analysis to determine the reasons for and extent of the non-conformity. |

All nonconformities should be investigated, with RCA performed looking at the extent and impact of the nonconformity. The result should be disseminated to staff.

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| **Criteria 5 –** Determine and document the root cause/s and extent of the non-conformity or potential non-conformity. |

Assessors will be looking for evidence that a root cause investigation has been performed and documented and that following this the service has looked at the extent of the non-conformity across the wider area. For example, if 3 documents were noted to not have effective document control the expectation would be to determine the root cause of why this has occurred and then consider whether this is also an issue across further documentation

**Criteria 6 -** Further actions are taken to remove the root cause and prevent reoccurrence of the non-conformity or future non-conformity.

Assessors will be looking for evidence that all corrective and preventative actions based on the investigation have been taken to eliminate and prevent re-occurrence of the non-conformity.

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| **Criteria 7 -** Mechanism(s) for recording non-conformities and resultant changes in practice. |

Assessors will check that your service has a recording process for all nonconformities, root causes and any changes in practice to allow monitoring. This may be 2 separate systems if using an organisational incident reporting system where lower-level non-conformities may not be captured.

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| **Criteria 8 -** Mechanisms for communicating non-conformities and resultant changes in practice to relevant users, staff, and stakeholders. |

Resultant changes in practice from the root cause investigation must be communicated to staff, service uses and stakeholders as appropriate. The process should show that staff have read, understood and implement the changes in practice.

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| **Criteria 9 -** Regular review of non-conformities to identify trends. |

Assessors will be looking for evidence of trends analysis of nonconformities, root cause and the resulting actions. This will also form part of management review.

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| **Criteria 10 -** Criteria are available to determine the following in the case of a clinical non-conformity:   * Whether clinical activities should be halted. * Whether reports should be withheld. * Who authorises the recommencement of any halted clinical activities; The need for previously released results to be recalled. * The medical significance of a non-conformity to patient/client management. * Responsibilities for reporting the non-conformity to the relevant referrer, users, staff and for escalating to the regulatory authority and/or equipment manufacturer as appropriate. |

Assessors will be looking for documented evidence that there are clear criteria as noted above for all possible clinical nonconformities. Evidence that clinical nonconformities have been reviewed against criteria and actions taken as a result should be available.

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| **LM9 -** The healthcare provider must evaluate and audit the effectiveness of their QMS including clinical activities. |
| **Criteria 1 -** The QMS including clinical activities is evaluated and assured with a regular audit cycle. This would usually be annually. |

Assessors will want to see evidence of systematic review of clinical and non-clinical practice in the audit schedule. The schedule should be regularly reviewed, and changes made depending on the previous year and the annual plan for the service. This will also form part of management review.

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| **Criteria 2 -** Use of different audit methods (vertical, horizontal and/or witnessing) to comprehensively cover the requirements of this standard. |

Assessors will be looking to see a range of audit methods across the audit schedule and across the clinical and non-clinical activities in the QMS.

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| **Criteria 3 -** The scope, criteria, methodology and frequency of audits are defined, documented, and reported in an agreed format. |

Assessors will want to see evidence of a clear audit policy, schedule and calendar. Evidence of a standard report format to ensure replication or reaudit is possible as required. Evidence of changes to frequency based on the outcome and root cause.

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| **Criteria 4 -** That the service assures appropriate training in audit. |

Assessors will be looking for evidence to show that staff involved in performing and reporting audits and root causes have had appropriate training to ensure repeatability by others if required.

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| **LM10 -** The healthcare provider must manage internal and external major incidents. |
| **Criteria 1 -** Availability of an agreed, published and up to date business continuity plan. |

The service should have a business continuity plan which is published, and staff are aware of the contents and where to find it. There may be a wider organisational plan however there should also be a local level plan to incorporate the service level areas of potential service impact.

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| **Criteria 2 -** That staff are aware of their roles and responsibilities in the event of a major incident and are provided with accessible up-to-date contact details, key action prompts and appropriate training. |

All staff should be fully trained in any emergency policies and should have access to appropriate facilities and equipment. Assessors will check that you have systems in place to ensure an appropriate response to incidents. This response will include informing patients and/or carers when such incidents have occurred.

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| **Criteria 3 -** Management of the return to routine service following the incident, including management of any backlog. |

Assessors will be looking for a documented process of the steps required to return to ‘normal’ service following a major incident. The documentation should include regular reviews and triggers for action should progress be slower or faster than planned. Any backlog of patients should be included with any harm reviews or actions required to ensure patients are safe while waiting.

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| **Criteria 4 -** Accessibility of counselling and support services. |

Occupational health support should be offered to staff where necessary or access to support services if provided by an outside agency

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| **Criteria 5 -** Analysis and review of performance following a major incident. |

All incidents should be investigated with an root cause to allow an appropriate action plan. A formal report should be shared with staff and stakeholders as appropriate.

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| **Criteria 6 -** Regular review and communication of any changes to major incident procedures and action plans. |

Assessors will be looking to see evidence that major incident plans are reviewed and updated as required. Changes must be communicated to staff with evidence that staff have read, understood, and have no concerns implementing.

**Clinical**

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| **CL1** - The healthcare provider must define and deliver its services from referral to discharge or further management. |
| **Criteria 1 -** Publication of the diagnostic and interventional service(s) description, range of clinical activities offered, and their locations. |

Assessors will be looking for documented information which is shared with service users, referrers, and stakeholders. The information will detail the range of diagnostics and interventions offered; they should include access criteria if appropriate. If the service has a range of locations the information should be clear for each location ensuring only activities offered at a location are shown. This could be in a service specification or on organisations website.

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| **Criteria 2 -** Publication of evidence-based agreed pathways developed with stakeholder involvement. |

Assessors will want to see evidence of documented systems in place to manage a patient’s journey through the service which meet the requirements of the commissioned pathway and/or the NHS Constitution. Agreed pathways from the patient journey should be based on up-to-date evidence and/or best practice. There should be an agreed definition of what constitutes an urgent case, and there should be a process to ensure these patients are seen in a timely fashion according to clinical need.

This should include agreed pathways for on-wards or backwards referral when required as part of that patients pathway, so patients are informed and have access to wider options (i.e., medical, implant, therapy) where appropriate

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| **Criteria 3 -** Agreement and publication of metrics and key performance indicators (KPI) for monitoring the patient pathway e.g. Did Not Attend (DNA), Referral to Treatment (RTT) and report turnaround. These could be based on a review of relevant guidelines, clinical pathways, quality standards and benchmark data. |

Assessors will look for evidence that waiting times for all procedures meet the requirements of the commissioned pathway. Patients will be informed about appointments in a timely fashion and there will be systems in place to ensure appointments are made at times convenient to patients, minimising attendances where appropriate, and can be easily changed (if applicable). There should be documented agreed definitions of what constitutes an urgent case (e.g., 2 weeks), and these should be seen in a timely fashion according to need.

Assessors will want to see evidence that the service delivers an integrated patient pathway including defined pathways to wider support or advanced care. Services should demonstrate communication mechanisms between other healthcare partners.

Where appropriate, the service should evidence liaison with medical or surgical specialists for example, integration of diagnostic tests within consultant-led “one-stop” clinics.

You will need documented evidence of the systems you have to manage the provision of follow up and ongoing care to patients. Aftercare will include the provision of advice, and the maintenance or replacement of faulty equipment (e.g., nebulisers, CPAP etc). The provision of aftercare should reflect the clinical and social needs of the patient; face to face aftercare should be provided if needed.

Assessors will want to see that your service has a policy (if localised reflecting organisational policy where relevant) for DNAs or Was not brought (WNBs) and cancellations of appointments and that the latter contains a definition of “reasonableness.” You will need to show that these policies are implemented, enforced, monitored, and reported on and that appropriate action is taken if rates are higher than national or local standards. Consideration for children and adults who are unable to attend alone should be made (if known), the risk of reduced access to health care should be reviewed when actioning patients who were not brought to their appointment (e.g., by notifying the referrer).

Assessors will be looking for capacity and demand reviews looking at current and actual demand along with capacity to generate plans for development. These should be budgeted for to ensure their benefits are sustainable. Evidence that you can identify bottlenecks and backlogs with associate actions should be available and any changes made to working practices should involve staff and users of the service.

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| **Criteria 4 -** Performance is communicated to users and stakeholders, as appropriate. |

Reports on performance of KPIs are shared with service users and stakeholders e.g., 6-week diagnostic wait target.

Every reasonable effort should be made to ensure that there are regular meetings between the multidisciplinary team where applicable.

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| **CL2 -** The healthcare provider must manage referrals and prepare patients/clients for their clinical activity. |
| **Criteria 1 -** Mechanisms for the referral process are clearly communicated. |

There should be documented referral criteria for all services provided and these should be clearly and consistently applied especially where there are commissioning contractual requirements. There will be evidence of an annual review with commissioners if appropriate and that any required changes are made following the review. The referral criteria will be clear about the local protocols for patient management. There should be systems and processes in place to ensure these criteria are applied as referrals are received. If the referral process differs from NHS to private these differences will need to be apparent and documented.

The needs of children accessing services are fundamentally different from those of adults and evidence will be needed to show that specific processes to meet children’s needs are in place. Referrals will be from professionals and carers who will need to have clear written indications as to when and where a child needs to be referred to a service. The child is reliant on adults to bring them to the appointment. Assessors will want to see evidence that the service makes every effort to ensure attendance for example by using text messaging, liaison with Health Visitor services etc. Referral criteria and referrer distribution lists need to be reviewed at a defined time by the organisation.

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| **Criteria 2 -** Requests are vetted in advance of the appointment. |

There should be documented referral guidelines which outline the systems and processes in place for the vetting, justification, and prioritisation of referrals. These might include triaging patients into routine, surveillance, or urgent work streams to ensure urgent cases can be seen in a timely fashion and should consider any commissioning access criteria. There should be a documented system for triage relating to professional guidance. Examples of urgent referral groups may include patients requiring diagnostics prior to major surgery. Other examples include referrals for patients on a cancer pathway or patients with suspected obstructive sleep who work in occupations requiring constant vigilance.

All referrals should be vetted in advance of the appointment to ensure patients are triaged into an appropriate pathway. Inappropriate referrals should be audited, and a standard process applied to reduce them if necessary. When insufficient or incomplete referral information is provided and the service can’t determine if the patient meets their access criteria, you must have processes to obtain the information or return the request and you must inform the referrer to support improvement in future referrals. Audit of the referral process will be reviewed by the assessor and should include actions taken to improve referral quality.

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| **Criteria 3 -** Request forms seek appropriate information including:   * Patient/client identification details (e.g., full name, hospital number, date of birth etc). * Name and contact details of the person making the request (who must be authorised to sign and request the specific clinical activity). * The clinical activity (e.g., test or intervention) being requested including the specific anatomic site, where relevant. * Clinically relevant information pertaining to the requested activity. * Date of the request. * Requirements for specified equipment, drugs (including dose), radioactive medicinal products and/or reagents if relevant. * Additional information to support patient/client needs e.g., need for wheelchair access, interpreter, infection status and any known allergies. |

There should be documented referral guidelines outlining the information which should be provided with a referral including as a minimum the above. Clinically relevant information should include statements related to access criteria if appropriate. The service should document how they manage referrals that do not have the minimum requirements stated.

You will need to demonstrate that patients are encouraged to communicate their individual requirements and preferences before, during and after their examination or procedure and that they can ask questions.

All patients should be treated as individuals and their specific requirements should be identified and addressed.

If your service uses drugs (definition of drugs includes oxygen) or contrast media, assessors will check that there are written protocols to ensure clinically relevant information and if appropriate a prescription is included with the referral. They will check that all staff know how to access these protocols and are made aware of any changes.

**Respiratory and Sleep Example**

Examples of commonly used drugs used in lung function services include bronchodilators (e.g., salbutamol), oxygen, bronchoconstrictor agents (e.g., methacholine, mannitol) and antihistamines.

**GI Physiology Example**

Local anaesthetic (e.g., Xylocaine spray) may be used by some GI Physiology services.

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| **CL3 -** The healthcare provider must assure the technical quality of clinical activities. |
| **Criteria 1 -** Patients/clients are correctly identified, and appropriate consent is obtained. |

Assessors will be looking for specific process and application of a policy to ensure that all staff are aware of their own and others’ responsibilities for patient identification at each stage in the patient’s journey. Specific processes should be in place to identify and protect vulnerable adults and children. Assessors will want to see evidence that all staff responsible for clinical care are aware of their role regarding informed consent and you will demonstrate that you implement a system to ensure patients’ consent to any examination or procedure and this is documented. For example, records of written consent may be filed/scanned together with reports, and confirmation of verbal consent noted on the test report. This links to PE3.

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| **Criteria 2 -** Equipment has been calibrated and/or serviced and is fit for purpose. |

You will need to demonstrate that you have a process in place to systematically review and document the installation, calibration, operation, and performance of equipment. These should be grounded in current best practice and reflect statutory requirements and link to FR5.

Documentation will include records to confirm all equipment is verified through servicing and/or calibrated at the recommended intervals and that daily checks are carried out on all equipment to best practice guidance. There should be evidence of regular servicing and safety testing of equipment where applicable. Staff should be aware of policies and guidelines and know how to access them. A documented quality assurance (QA) and quality control (QC) programme for all equipment should be in place.

**Respiratory and Sleep Example**

The calibration of spirometer devices, gas analysers, pressure transducers, exercise monitoring equipment and calibration required for polysomnography studies.

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| **Criteria 3 -** Availability of appropriate positioning and supporting devices to ensure the integrity and quality of the clinical activity. |

Where relevant there should be evidence that equipment such as headrests, couches, arm rests or pillows for example in use during a test are managed safely and appropriately to ensure the best clinical outcome.

**Audiology Example**

Caloric testing requires an appropriate couch that can be adjusted to ensure patient is set at relevant angles. Real ear measurement speakers must be set at an appropriate height and distance which may require speaker stands.

**Cardiology Example**

ECHO – Couch in use needs to have a moulded seat attached for scanning to BSE standard, documentation of maximum weight adhered to (i.e., for CP and patient combined), including processes for provision of a bariatric couch if required.

**Respiratory and Sleep Example**

Lung Function – Patient should be seated appropriately during tests, and a chair with arms is recommended.

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| **Criteria 4** - Availability of protocols for each clinical activity. Protocols must:   * Be evidence-based and appropriate. * Fully describe the critical procedural steps. * Include diagnostic criteria and uncertainty of measurements, as appropriate. * Include arrangements for safe sedation, analgesia and or anaesthesia where necessary. * Include health and safety considerations, contraindications and infection control. * Include guidance for onward referral, management of incidental or clinically urgent findings, and post-procedure care. |

Protocols should be developed, agreed, maintained, and applied for all activity undertaken in both service led and medically led clinical settings. Assessors will expect you to be using professionally recommended or National/International protocols including guidance and International Organization for Standardisation (ISO). Evidence that the professional protocols are supported by local documents to ensure all the requirements above are documented. There should be specific protocols for infants and children or those with complex needs, taking account of their particular needs.

Assessors will look to ensure that the uncertainty of measurement is considered across each activity delivered whether this is documented in a standalone policy or within the specific clinical protocols. The documentation should show that the service is aware of all the potential uncertainties (qualitative and quantitative) around each test and that staff when questioned will have an understanding of the impact of any uncertainty on the test result. The service should determine if any uncertainties are likely to be critical to the outcome of the test and as a result what they should do in those circumstances. At this stage there is not an expectation that services will develop an uncertainty budget for each test but they should consider where this is nationally available using this in their documentation.

Protocols and guidelines should be easily accessed by all staff (including agency staff) within the service. documentation should evidence communication to staff (using channels such as training sessions or team meetings) and assurance that staff have read, understood, and are implementing protocols.

**Neurophysiology Example**

Physiologist Led Nerve Conduction Studies

The protocol should as a minimum meet the standards set out by the BSCN/ANS.

Consultant/Spr Led NCS/EMG

Protocols should include evidence of consent process for needle EMG, and consideration of health and safety precautions. Although a standard protocol would include the taking of an appropriate clinical history, relevant clinical examination, and performance of NCS and or EMG, it is not expected that specific nerves or muscles to be tested are stated

**Vascular Examples**

Awareness of Uncertainty of measurement will include knowledge of likely sources of error. For example, knowledge of axial resolutions prior to selection of an appropriate probe for a vein mapping assessment, and the appropriate use of rounding in reported measurements. Inclusion of data from local QA processes (e.g., assessment of resolution at different depths for each machine, may also inform reported values. Where the diagnosis is more qualitative than quantitative inclusion of levels of certainty may be based on perceived image quality. Staff should have an understanding of the impact of technique on minimising potential errors, e.g., reducing the time between collection of values used to calculate ratios thereby minimising the effect of systemic circulatory fluctuations.

Induction processes for new staff should include information related to accessing protocols and guidelines. Evidence to show these have been reviewed should be available.

Assessors will want to see a patient centred approach embedded within protocols.

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| **Criteria 5 -** Regular review of protocols, communication of protocol changes to relevant staff, and training on the changes where necessary. |

Protocols should be regularly reviewed. Assessors will be looking for evidence of adherence to national standards (for example BSA, BSE) (Cardiac: BHRS / BSE) (Respiratory = ARTP, ATS/ERS, ARTP Sleep, AASM) (Vascular = SVT) where these are available. All protocols should have review dates and there should be processes to flag up when documents are reaching target review dates. Protocols additionally may be reviewed upon publication of new guidance papers. Procedures where national standards exist should be followed.

Where no national standards are available, the service should demonstrate adherence to local protocols and guidelines for treatments and interventional procedures. Local protocols and guidelines must be evidence based and be regularly and systematically reviewed.

Assessors will want to see evidence that you have a system in place for giving all appropriate members of the team information about the protocols they should be using. This system should include a documented mechanism (e.g., team meeting, training session, email etc). for updating staff when protocols are revised or changed and to show staff have read, understood, and are following the updated protocols.

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| **Criteria 6 -** Competent and appropriate supervision of staff. |

You will need to demonstrate that a robust system is in place to monitor appointed and locum staff and ensure they remain qualified, registered, and competent for their current roles. Assessors will be looking for evidence that you have a system to ensure staff maintain clinical competence for the range of procedures, interventions and non-clinical areas as detailed in their job descriptions.

This may also relate to consultants if they are involved in part of the accreditation activity.

Supervision should only be provided by staff who are evidenced as competent in the area being supervised and have appropriate competency in supervision or mentoring. This links to FR6.

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| **Criteria 7 -** Quality control measures are in place to ensure that the intended outcome of the testing/measurement/assessment stage is achieved, and that if there is a problem with quality, data is not released for reporting before the patient/client is discharged from the service. |

You will need to demonstrate that you have systems in place to ensure that the patients have achieved their intended outcome before being discharged. The outcome will depend on the pathway and assessors will expect a range of QC measures to be in place.

Diagnostic tests you perform should meet appropriate quality standards.

**Neurophysiology Example**

There would be an expectation of overall servicing of equipment which would include either external or internal assurance using a calibrated signal generator.

**Audiology Example**

In clinic settings (both audiology and medically led) assessors will be looking for assurance that all hearing tests will be performed in acoustical appropriate conditions and take account of national and international guidance. The system you have in place will have explicit guidelines for performing domiciliary hearing tests where acoustical conditions cannot be guaranteed including actions to be taken as required.

If electrophysiological assessment is carried out with young children, protocols and test strategy should be routinely peer reviewed to ensure compliance with national guidance.

Hearing services will be expected to demonstrate that – where not clinically contra-indicated – it is using an objective and evidence-based validation procedure to measure hearing aid function such as REM (Real Ear Measurement) following the national guidance. Other measures such as the test box to assess hearing aid function should be used where REM is contra-indicated. Using tools which do not give objective and evidence-based data is not good clinical practice and will not meet the criterion. Assessors will also look for evidence that the patient’s hearing improvement outcome is being measured using an objective validated tool (such as GHAB/DP/COSI/IOI-HA or speech testing).

Complex services should demonstrate that they are recording outcomes and the amelioration of symptoms through, best practice guidance supported by locally developed documents. The use of psychological questionnaires or other measures of behavioural benefit can be useful.

**Respiratory/Sleep Example**

All procedures should be performed in line with the service policies. If measurements are recorded that do not meet the recommended quality, acceptability or reproducibility criteria, these clinical measurements may still be useful in-patient management, and the assessor would expect to see appropriate technical comments made to the clinical report to alert the interpreting officer. Any non-compliance with pre-test instruction (e.g., unable to discontinue medication as advised) should be recorded. Any changes to the test performance or measurement setting should be recorded.

Assessors would want to see evidence of review, including audit and checking of reports and interpretation.

**GI Physiology Example**

All procedures should be performed in line with service policies, using equipment that is clean, calibrated and serviced according to manufacturer guidance. Any non-compliance with the test instructions (e.g., failure to discontinue medication) or adaptations to the testing protocol (e.g., patient position) should be recorded on the test report and considered when interpreting the results. Anatomical factors that may influence the test measurements (e.g., previous anti-reflux surgery) should also be recorded on the test report and considered when interpreting the results.

**Vascular Example**

Any non-compliance with procedures laid down in protocols should be acknowledged in the report, especially where this may have an impact of recorded values or the scope of the diagnosis (e.g., patients who are unable to lie flat for ABPI assessment, where body habitus prevents assessment of the iliac vessels). Assessors will want to see a range of audit activities to assure the quality of the diagnoses and that they meet the needs of the referrer (e.g., image, inter-observer agreement, and report quality audits as well as comparison to other imaging modalities and/or surgical findings). Analysis of the findings of quality audits should have demonstrable positive impacts.

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| **Criteria 8 -** Results are reported in an appropriate time frame. |

Assessors will look for an auditable documented process for reporting with evidence of reporting turnaround times as documented in the QMS. This will include timeframes for the results including urgent or unexpected results. Evidence of compliance will be reviewed by the assessors.

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| **CL4 -** The healthcare provider must ensure the clinical and technical quality of records, interpretations, and reports. |
| **Criteria 1 -** Defined responsibilities for reporting clinical activities. If certain clinical activities are not reported then an agreement for transferring responsibility for the evaluation must be in place. |

Assessors will check that roles and responsibilities are clearly defined, assigned, and published for all activities involving diagnostic interpretation and reporting in your service.

**Neurophysiology Example**

Physiologist Led Nerve Conduction Studies

The conclusion should be written either by a consultant Clinical Neurophysiologist, or by a physiologist who has been suitably trained and assessed. Where conclusions are not written by the physiologist performing the test, a clinical history should be documented, waveforms should be readily available to be inspected by the reporter, and any patient factors that may affect the results should be documented (such as patient height, presence of ankle oedema, difficulty in achieving supramaximal stimulus).

There should be a procedure in place for unexpected results or more complex clinical presentations being discussed with a Clinical Neurophysiologist.

There should be evidence of the assurance of competence of any physiologist staff to perform studies – for example, training portfolio having been reviewed and observation of studies. Assessors will want to see evidence of regular audit of the quality / accuracy of physiologist led studies and reports. Interventions should be put in place if there are any issues found relating to their quality.

Consultant/Spr Led NCS/EMG

Assessors will want to see evidence that a relevant history has been taken from the patient, and clinical examination performed. Reports should include the results of the nerve conduction studies +- electromyography, and appropriate conclusions.

There should be evidence of quality control of consultant studies / reports, beyond GMC appraisal – for example, MDTs, double checking/signing reports, peer review, formal audit or direct observation.

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| **Criteria 2 -** Adequate numbers of competent reporting staff are available and documented. |

Assessors will look for an auditable documented process for reporting. This should include staff who are authorised for reporting. The Service should demonstrate adequate numbers of reporting staff and there is adequate coverage for the services workload, sickness, holiday etc. This should extend to assurance of any outsourced reporting staff regardless of whether this is internal or external.

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| **Criteria 3 -** Reporting formats are agreed with referrers and stakeholders. |

You should be able to demonstrate that you have agreed the structure and content of reports through local consultation with key stakeholders such as GPs and other referrers, local commissioners, and patient representative groups, where this is appropriate.

Generic Example

A service may include a question in their stakeholder survey to ask if they are happy with report format

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| **Criteria 4 -** Availability of locally agreed reporting structures/templates to reporting staff, including those external to the healthcare provider. |

Assessors will be looking for evidence to confirm that staff can access local protocols for reporting and that they use the appropriate reporting tools such as report templates. This includes compliance with national guidance on reporting formats, descriptors, units etc where this exists. All reports should be in the agreed format even if the report is provided by an external provider on the service’s behalf. Staff should be using the correct interpretation guidelines for interpretation of diagnostic test results as detailed in the service policies

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| **Criteria 5 -** Clear identification of the report issuer. This is particularly relevant where outsourcing arrangements are used. |

The report should include the named individual who performed the test/interpreted the results if this is different to the author of the report. The report should clearly show the name of the report writer, the date of reporting and their designation and their location if the report is outsourced. If applicable, checking of any reports should also be clearly indicated.

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| **Criteria 6** - Reports include, as appropriate:   * Referral information * Date and time of clinical activity * The clinical activity performed * Relevant findings/observations, including unexpected findings * A conclusion and/or diagnosis * How certain the conclusion is, and advice on further diagnostic tests * Signature(s) with the name(s) of the reporter(s) and their position(s) |

Assessors will be looking for evidence to confirm that report templates include all appropriate information. Evidence of any variation should be documented and have reasonable justification.

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| **Criteria 7 -** Mechanisms for auditing reports and processes for feedback and remedial actions. |

A clear and auditable mechanism for communicating reports to referrers should be available. Assessors will want to see evidence of a protocol or policy for test performance, interpretation, and reporting. The protocol will include regular audit and peer review of diagnosis and interpretation. Evidence of the review mechanisms will be available with examples of feedback, and remedial action taken to improve quality as required.

Examples of test reports will reflect the scientific protocols for interpretation and reporting including compliance with national guidance on reporting formats, descriptors, units etc where this exists.

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| **Criteria 8 -** Access to a second opinion, where appropriate. |

There should be a clear and documented process for accessing a second opinion on the results and/or report, should this be required.

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| **Criteria 9 -** Deviations from the reporting requirements are justified, documented, and communicated to referrers. |

Assessors will look for an auditable documented process for reporting, with evidence that if the process is not followed that the reasons are clear, recorded and are reasonable.

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| **CL5 -** The healthcare provider must manage the release of reports. |
| **Criteria 1 -** Reports are issued by staff who are authorised to do so. |

Assessors will be looking for a documented process for reporting, detailing staff who are authorised to generate reports. Evidence of staff training, and competency should be available.

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| **Criteria 2 -** Definition of local agreed reporting timescales/turnaround times for each type of clinical procedure particularly those with critical, urgent, or unexpected findings. |

A clear and auditable mechanism for communicating reports to referrers should be available. You should be able to demonstrate a clear communication pathway between clinicians and referrers, which includes feedback and review to allow changes to patient management to be implemented.

You will need to demonstrate how patients are informed of how, when and from whom they will receive results or reports. Linked to CL3.8

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| **Criteria 3 -** Locally agreed mechanisms are in place for communication of reports. Communication mechanisms must be secure and monitored. |

Assessors will be looking for evidence to confirm that staff can access local protocols for reporting and communicating test results and that they use the appropriate reporting tools such as report templates. This includes compliance with national/international guidance on reporting formats, descriptors, units etc where this exists.

You will need to demonstrate that you have processes in place for communicating medical emergencies or urgent results. These will include clear guidelines for prompt referral to a medical team for an urgent medical opinion or the management of unexpected and clinically significant findings.

Assessors will want to be assured that the sharing of patient data between organisations is subject to a policy which ensures security and confidentiality are maintained, and which adheres to GDPR requirements.

**Audiology Example**

Indication of a glomus tumour on otoscopy.

**Vascular Example**

A new finding of a large abdominal aortic aneurysm or acute arterial disease identified during a venous assessment.

**Respiratory and Sleep Example**

This may be a patient presenting with severe symptoms, and abnormal test results requiring urgent review (e.g., pulse oximetry or blood gases showing severe respiratory failure, cardiopulmonary exercise test showing abnormal cardiac findings etc.).

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| **Criteria 4 -** Records are maintained of all reports including those transmitted by telephone. |

The assessor will be looking for a process of recording all reports within the patient record including those provided verbally. For example, if results are transmitted verbally, this may be annotated onto the clinical report, and copies of reports emailed to clinicians ASAP, requesting receipt of delivery.

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| **Criteria 5 -** Where an interim report is issued it is clearly identified as such and a final report is issued according to locally agreed timescales. |

Assessors will be looking for evidence that interim reports are clearly identified and distinguishable from a final report. There should be a clearly documented process for reporting and communicating test results including the timeframes expected. This is likely to be covered in one procedure across all the statements relevant to reporting. Evidence that staff are compliant with the processes will be reviewed by the assessors.

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| **Criteria 6 -** Timely identification of reporting backlogs/delays and associated patient/client risks with escalation to the highest level within the parent organisation. |

There should be a clearly documented process for reporting and communicating test results detailing the timeframe for the reports. Assessors will be looking for evidence that timeframes are monitored with documented actions should reports fall outside the expected time frames including harm reviews as appropriate.

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| **Criteria 7 -** Where amendments are made to an issued report, that the changes are authorised and dated. The revised report must be communicated to the referrer with a clear explanation of the reason for the amendment and the implications for the management of the patient/client including any necessary urgent actions and lessons learnt. |

There should be clearly documented processes for report amendment. If you amend results or reports after they have been released or if a further report is issued after the detection or notification of an error, you must be able to demonstrate that there is a clear auditable process which includes informing the referrer the reasons for the changes and any implications on patient care.

All amendments or new reports following release should be considered an incident and reported. Any incident or error which may affect patient care must be communicated without delay to the clinical team and the patient or their carer/keyworker. All incidents should be investigated using an RCA, with findings analysed and disseminated to staff. Resultant changes in practice must be communicated to staff.

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| **CL6 -** The healthcare provider must manage clinical information systems. |
| **Criteria 1 -** Confidentiality of patient/client data in compliance with national requirements for data protection. |

There are documented policies for the management of medical records and data/reports which include how to maintain patient confidentiality. Assessors will look for evidence that these are communicated to all staff and that all staff are aware of data protection policies and these are compliant with GDPR. There should be evidence of staff mandatory training in data protection/information governance.

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| **Criteria 2 -** Validation of any clinical information system(s) for the collection, processing, recording, reporting, storage, and retrieval of data. |

You should have a secure storage area for patient data and reports, and electronic reports should be backed up daily. There should be a process in place for the retrieval of data if the main IT system fails, and this local disaster recovery plan has been tested. This process including the local disaster recovery plan, will have been communicated to staff.

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| **Criteria 3 -** Any changes to the clinical information system(s) are authorised, documented, and verified prior to implementation. Where applicable, this includes checking the proper functioning of interfaces with other information systems, instrumentation and administrative systems used to deliver patient/client services. |

Assessors will be looking for a documented process detailing the expected steps when changes are required to information systems, for example a software upgrade on a clinical system. The processes should include who can authorise changes, verification of the system before changes go live and additional training needs as required.

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| **Criteria 4 -** Secure transmission of data. |

You should have a process in place for the secure transition and transportation of patient records in accordance with GDPR, and any local policy.

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| **Criteria 5 -** Availability of documentation (e.g., user guides), to support day-to day functioning of clinical information system. |

Assessors will check user guides, quick guides and general information on the systems used by the service. These should be accessible to staff who on questioning can locate and explain them.

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| **Criteria 6 -** Protection from unauthorised access, safeguards against tampering and data loss, investigation of non-compliances, and remedial action after non-compliances. |

The service must demonstrate that it has systems in place to control and audit access to data systems including when staff have left the organisation and removal of access. Where there has been unauthorised access, you must demonstrate that this has been investigated (e.g., RCA performed. Remedial actions taken to address the incident and prevent future nonconformity. Incident Reporting in line with policy.

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| **Criteria 7 -** Non-computerised systems should have safeguards against errors of manual recording and transcription. |

Assessors will be looking for a process that ensures all non-computerised clinical information is held securely. Processes should assure that patient identification is assured before any information is recorded and the information is clear and legible with appropriate identification of the clinician who has detailed the information including the date and time of the recording.

Evidence of a process for Information transfer to another system or transcribed should be auditable and documented and have additional safeguards to confirm that transfer or transcription is error free.

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| **Criteria 8 -** Information systems are operated in compliance with supplier specifications. |

Assessors will be looking for evidence that all the information systems used and operated by the service are used in an environment which meets the supplier specification for the specific information system.

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| **Criteria 9 -** Recording, investigation, correction and reporting of breaches of data integrity or system failures. |

Assessors will be looking for evidence that all incidents relating to the breaching of data, system failure or near misses should be clearly recorded. An investigation should be carried out and include an RCA with actions to correct incidents and prevent further nonconformity. A formal report to all appropriate stakeholders should be produced and shared for discussion and feedback.

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| **Criteria 10 -** Compliance with the requirements of this standard where information system(s) are managed and maintained off-site or sub-contracted. |

The service must provide evidence that any information system held, managed offsite or sub-contracted follows the requirements for information and data security set out in IQIPS 2023.

**Patient Experience**

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| **PE1 -** The healthcare provider must ensure that care is patient/client focused. |
| **Criteria 1 -** Equality of access. |

Patients and those accompanying them should have equal access to the service, feel valued, and be treated with respect, dignity, and compassion regardless of age, circumstances, or any other factor.

Your service will need to demonstrate that you manage the communication needs of your patients.

Access refers to both access to the service and physical access to premises and buildings so that patients with physical disabilities (e.g., blind, deaf, communication etc) or needing wheelchair access or assistance devices such as wheelchairs or hearing loop systems are accommodated.

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| **Criteria 2 -** Privacy, respect, dignity, and compassion regardless of age, gender, religion, culture, language, disability, circumstances, or any other factors. |

Assessors will check that all staff are aware of their responsibility to maintain patients’ privacy, dignity and security – this is likely to be through onsite observation of patient interactions. This includes up to date training in disability awareness and equal opportunity and diversity training or equivalent.

All staff should be able to demonstrate that they understand their responsibility for ensuring patients are treated with dignity and respect and that the service is patient centred.

Assessors will be looking for evidence that your service has systems to support a culture of patient respect. Practice should acknowledge and respond to the differing needs and values of patients, taking account of culture, religion, language, age, and disability. For example, patients should be greeted by a friendly efficient person; be informed about appointment waiting times; see staff wear name badges; not be obliged to undress in front of staff; and know that their belongings and information are secure.

Only essential staff should be present at the appointment unless permission has been sought. Examinations should be performed without interruption. Appropriate equipment and facilities for individual needs should be supplied, for example changing facilities and gowns where these are needed. Access to consulting rooms should be such that all patients can maintain their dignity during their appointment. You should actively seek patients’ opinion and ensure that any issues raised are addressed appropriately.

It is not necessary to always have an interpreter present, but services will need to plan for how they will communicate with patients who do not speak English. This might include access to onsite interpreters within the parent organisation, or telephone access to an interpreter service. The use of family members as interpreters should be discouraged to ensure patients feel able to share sensitive information and ensure it is kept private.

Staff should ensure patients are comfortable throughout their examination. Patients should feel that staff are approachable, courteous, trustworthy, friendly, responsive to their needs and supportive of their rights.

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| **Criteria 3 -** Patient/Client identity is confirmed throughout their contact with the service. |

Assessors will be looking for specific processes and application of policy to ensure that all staff are aware of their own and others’ responsibilities for patient identification at each stage in the patient’s journey. Specific processes should be in place to identify and protect vulnerable adults and children.

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| **Criteria 4 -** Chaperone provision. |

Assessors will be looking for evidence of a documented chaperone process. Chaperones can be formal and informal; the service should ensure this is made clear to the patient and ensure patient choice as appropriate.

Patients should be encouraged to include a significant other in their care regardless of their chaperone requirements.

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| **Criteria 5 -** Appropriate clinical management adapting to individual needs. |

You will need to demonstrate that patients are encouraged to communicate their individual requirements and preferences before, during and after their examination or procedure and that they can ask questions.

All patients should be treated as individuals and their specific requirements or goals should be identified and addressed.

**Audiology Example**

Staff working with those with complex needs should have specific training in place; all staff in audiology services should be trained in the communication needs of hearing-impaired people.

Appointment scheduling should include time for discussion and questions, and this should be carried out in a confidential, suitable environment. Good communication is vital to promote understanding and enable patients to make informed choices.

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| **Criteria 6 -** Counselling for those who become distressed during their contact with the provider, for example following bad news. |

Assessors will be looking for evidence of available support either within the service or provided by an outside agency for patients and their families. Assessors will be looking for a holistic approach when the service is providing news which has the potential to cause distress.

**Audiology Example**

Prognosis after a sudden hearing loss, diagnosis of a hearing impairment in a child etc.

**Cardiac Example**

End of life / palliative pathways to be in place in collaboration with HF & Arrhythmia team.

**Vascular Example**

Diagnosis of arterial graft occlusion where the patient is aware that likely treatment will be amputation of the limb.

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| **Criteria 7 -** Streamlined scheduling of appointments. |

Appointment and booking processes should comply with organisational policy and guidance and seek to reduce disruption to patients and their relatives or carers. You will need to demonstrate that patients are offered a choice of appointment time or can easily rearrange appointments. Specific needs should be considered, for example children should be seen in a paediatric setting or scheduled at the beginning of a list to reduce waiting time. Where possible, co-ordination of appointments should also be available, for example one stop clinical and investigation appointments or times to coincide with other appointments that the patient or family may have.

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| **Criteria 8 -** Opportunities to provide feedback. |

Feedback tools can be presented in various formats to consider your patient population and to encourage feedback from patients, their relatives, and carers (for example large print). Patients must be able to give feedback in a variety of ways and according to local policy, for example comments box, surveys, web tools, text survey and is linked to PE4.

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| **PE2 -** The healthcare provider must ensure that information is available for users and stakeholders. |
| **Criteria 1 -** Development of patient/client-friendly information. |

Assessors will be checking that there is documented policy relating to patient information development and review and that all patient information material is patient-friendly, current and has a review date. You will need to demonstrate that your patient information conforms to local styles and templates and is approved before release. It should reflect professional guidance where this exists and conform with the accessible information standard.

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| **Criteria 2 -** Lay involvement in the development and review of information. |

All material must involve lay people or patients during development and review. You will be expected to demonstrate your system for keeping patient information up to date and for involving lay representation.

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| **Criteria 3** - Availability of location-specific information including but not limited to:   * Address * List of available activities * Opening hours * Contact details * Parking arrangements |

Assessors will be looking for evidence of patient information relating to the locations. There should be an auditable documented process to assure patients are provided with information at the appropriate time. This could be detailed in a patient information leaflet, appointment letter or a link to a website.

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| **Criteria 4 -** Information is accessible in a range of formats and media and in various languages relevant to the population. |

You will need to demonstrate that information is tailored to the needs of your patient population and to the needs of each individual patient. It needs to be relevant to them and presented in a variety of media and languages to comply with legislation and good practice.

Services should have systems in place to ensure that patient information is presented according to best practice.

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| **Criteria 5** - Information addresses specific patient/client care aspects such as:   * Explanation of the procedure to include preparation, side-effects and or risks * Preventative measures to minimise risk e.g., infection, fasting requirements * How long the appointment is likely to take * Who is performing the examination/treatment/intervention * Access to interpretation and chaperones, if required * On arrival, the length of any known delay to appointments * Aftercare and return to normal activity * Communication of results and awareness of second opinions * Peer/self-help support information |

You will need to demonstrate to assessors how patients are told who will be present during an examination / procedure. This evidence may be collected through onsite observation.

The service should provide clear, relevant and up to date information in a range of formats about the safe use, storage and aftercare of devices and consumables issued.

There are many self-help and voluntary societies that offer support to patients and local support organisations. Assessors will be looking for evidence that you ensure patients and carers are made aware of and have access to these support groups.

You will need to demonstrate how patients are informed of how, when and from whom they will receive results or reports. Evidence of how patients can raise a concern regarding the content of reports or request a second opinion.

You will need to demonstrate that you have a system in place to inform patients, while they are still in the department, of the next steps in their pathway. This might include information about how long they might wait for their next assessment/procedure; checking if the patient has a follow up clinic appointment and informing them of who will discuss the next steps of their treatment.

**Audiology Example**

Assessors will want to see evidence that patients receive a copy of the individual management plan (IMP) in a timely way: this will reflect a locally agreed Key Performance Indicators (KPI).

Assessors will want to see evidence that information to support the transition between paediatric and adult hearing and balance services is provided to young people and their families.

Assessors will want to check availability of user manuals for hearing aids, safe use and disposal of batteries and other consumables.

**Respiratory and Sleep Example**

This may relate to the use of therapeutic devices such as nebulisers, CPAP and NIV devices and oxygen therapy equipment) and consumables (e.g., tubing, masks, nebuliser chambers etc.) This should also detail procedures for equipment failure, cleaning, and replacement of consumables. For example, patients may be given details in a range of formats, such as information leaflets or web links. There should be evidence that service users can contact the service for advice regarding devices and consumables.

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| **Criteria 6** - Communication to users in regards their responsibilities to:   * Notify the provider of appointment changes and cancellations * Providing feedback where expectations are not being met * Abiding by any behavioural codes of conduct |

Assessors will be looking for evidence of patient information relating to the above criteria. There should be an auditable documented process to assure patients are provided the information at the appropriate time in accessible formats.

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| **PE3 -** The healthcare provider must ensure that consent is obtained. |
| **Criteria 1 -** Valid informed consent for the specific clinical activity. |

The validity of consent does not depend on the form in which it is given. Written consent merely serves as evidence of consent: if the elements of voluntariness, appropriate information and capacity have not been satisfied, a signature on a form will not make the consent valid. Consent may be expressed verbally or nonverbally: an example of non-verbal consent would be where a person, after receiving appropriate information, holds out an arm for their blood pressure to be taken.

It is a general legal and ethical principle that valid informed consent must be obtained before starting treatment or a physical investigation, or providing personal care, for a patient. The clinician conducting the examination/procedure is responsible for ensuring that the patient has given valid consent. While there is no English statute setting out the general principles of consent, case law (‘common law’) has established that touching a patient without valid consent may constitute the civil or criminal offence of battery. An assessor will want to see evidence of a consent policy and evidence of assurance that staff comply to this.

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| **Criteria 2 -** Sufficient information is provided for valid consent, including information about risks. |

You will need to demonstrate that patients are fully informed regarding their examination/procedure and are given the opportunity to ask questions. For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question. The Mental Capacity Act 2005 requires that all practical and appropriate steps are taken to enable a person to make the decision themselves. These steps include the following: providing relevant information; communicating in an appropriate way; making the person feel at ease; supporting the patient. Some patients may wish to know very little about the examination – if information is offered and declined this should be documented.

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| **Criteria 3 -** Appropriate arrangements where the patient/client lacks the capacity to consent, for example, children and young people, vulnerable adults and users with intellectual disabilities. |

Assessors will expect to see evidence of the system used when obtaining consent from young adults, children, and vulnerable adults. Patients aged 16 or 17 are presumed to be capable of consenting to their own medical treatment. However, unlike adults, the refusal of a competent person aged 16–17 may in certain circumstances be overridden by a person with parental responsibility.

The Mental Capacity Act 2005 came fully into force in October 2007. It applies in England and Wales to everyone who works in health and social care and is involved in the care, treatment, or support of people over 16 years of age who may lack capacity to make decisions for themselves. It is largely based on previous common law and creates a single, coherent framework for decision-making, including decisions about treatment. The legal requirements in the Mental Capacity Act are underpinned by five statutory principles. One of these key principles is that any act done for, or any decision made on behalf of, a person who lacks capacity must be done, or made, in that person’s best interests.

The legal position concerning consent and refusal of assessment/treatment by those under the age of 16 is different from the position for adults. Children who have sufficient understanding and intelligence to enable them to fully understand what is involved in a proposed intervention will have the capacity to consent to that intervention. This is sometimes described as being ‘Gillick competent’. If a child is ‘Gillick competent ‘and is able to give voluntary consent after receiving appropriate information, that consent will be valid and additional consent by a person with parental responsibility will not be required. It is, however, good practice to involve the child’s family in the decision-making process where the child consents to their information being shared. Where a child under the age of 16 lacks capacity to consent (i.e., is not ‘Gillick competent’), consent can be given on their behalf by any one person with parental responsibility.

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| **Criteria 4 -** Consent is documented in the patient/client’s record where relevant. |

Evidence will be reviewed to show that staff have taken consent in whichever format is appropriate and this is recorded and audited for assurance including verbal consent. Assessors will require evidence that patients are able to consent for their test results to be distributed/shared.

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| **Criteria 5 -** Acknowledgment of the patient/client’s right to withhold or withdraw consent. |

Consent given, withheld, or withdrawn should be clearly documented in the patient record for all investigations, procedures, or interventions.

Although consent is implied regarding reporting test results for the benefit of patient care, it is important that patients are aware of who you will share their results with.

You will need to demonstrate that you implement a system to ensure patients’ consent to any examination or procedure and patients are able to withdraw consent or withhold consent for certain aspects.

If an adult with capacity makes a voluntary and appropriately informed decision to refuse investigation this decision must be respected (except in certain circumstances as defined by the Mental Health Act 1983).

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| **Criteria 6 -** Gaining consent when data is likely to be used for training or research purposes and/or if it will be shared electronically within or outside of the provider organisation. |

Assessors will look to see if there are processes in place to ensure GDPR and patients are informed and consent to data disclosure for research or teaching purposes.

Consent must be obtained and documented if data that is to be shared electronically within or outside of the provider organisation.

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| **PE4 -** The healthcare provider must manage feedback and complaints. |
| **Criteria 1 -** Feedback/complaints procedures and materials are available in a variety of formats and media. |

There should be a published complaints policy which clearly explains the process and provides names and current contact details for those responsible for receiving either verbal or written complaints. Details of the complaints process should be widely displayed in public areas of the service and should be readily accessible in different formats.

Assessors will expect a proactive approach to patient feedback with a documented process for gaining, reviewing, and managing feedback with patients being able to give feedback in a variety of ways, for example comments box, surveys, web tools. Feedback tools can be presented in various formats to consider your patient population and to encourage feedback from patients, their relatives, and carers (for example large print).

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| **Criteria 2 -** Confidentiality for those giving feedback and/or making a complaint. |

Patients must be confident that they can give feedback confidentially. Regular surveys are a useful method of obtaining patient feedback but consideration to confidentiality must be given. The service should consider a range of options to ensure patient confidentiality when seeking feedback.

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| **Criteria 3 -** Regular review of feedback and complaints with collation, analysis, actions, and dissemination to all relevant parties. |

Robust systems should be in place to ensure that all complaints are reported and investigated. Details of the complaint, investigation and findings should be recorded and analysed. Findings should be communicated to relevant parties, including the complainant and any staff involved. Information from complaints should be used to review service provision and details of remedial action or changes undertaken following complaints should be widely disseminated.

All patient feedback should be collated and analysed to better understand the patient’s experience of the service. Findings should be analysed, and appropriate action should be taken in every case, this might include documenting and informing those concerned of the reasons for not taking further action. Findings and any changes or initiatives implemented as a result of patient feedback should be disseminated to staff and patients.

The service might work with local Patient Advice and Liaison Services to obtain further feedback on the perspective of patients. Feedback and complaints will form part of the management review.

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| **Criteria 4 -** Involvement of users in the development and review of feedback and complaints materials, where relevant. |

Materials should be developed and agreed with patient/lay involvement to ensure they are in patient friendly language. All material should be reviewed at regular intervals. It is important to review materials and ensure they reflect the literacy levels of the population; community languages; alternative formats such as large print to ensure that they can be accessed by as many people as possible.

**Safety**

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| **SR1 -** The healthcare provider must manage all service risks. |
| **Criteria 1 -** An overall health and safety and risk management strategy that has been developed in collaboration with the parent organisation. |

Legislation and good practice guidance suggest that policies should be developed, agreed, maintained, and applied to minimise health and safety risks to patients, staff, and others. Assessors will be checking that the risk management processes are grounded in best practice and reflect professional guidance and statutory requirements where they exist. It is likely that some of these policies will be organisation wide, but you should have evidence that specific risks related to your service have been considered and included where appropriate. Policies and procedures will be expected to cover infection control, moving & handling, violence and aggression, risk management, health and safety, fire, waste management, COSHH, lone working.

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| **Criteria 2** - Risk assessments to identify:   * Risks associated with clinical activities e.g., infection control. * Non-clinical risks e.g., COSHH, moving and handling, violence and aggression etc. |

You will need to demonstrate that you have robust systems in place to determine, assess and regularly review all risks both clinical and non-clinical in the operation of the service. You will also demonstrate you have processes in place to actively manage risks.

You will need to demonstrate that you have conducted a risk assessment for all the procedures you conduct, and you have risk management systems in place for them. You will also need to demonstrate that recommended processes to minimise risk are being followed.

Assessors would want to see how you assure that risks associated with interventions are minimised. Having a process in place alone would not be sufficient, you should ensure that they are being acted upon in every case.

Regular risk assessments should be carried out in all areas of the service, with the results communicated to staff. Risk assessments should assess all areas of health and safety including, for example, VDU use, ergonomic desk assessment and the position of wires.

To provide a safe environment for patients, staff and others, the service must minimise and manage violent, aggressive, or abusive behaviour. A process should be in place to reduce the risk of violence and aggression, and the management of incidents which occur. Processes should be grounded in current best practice and reflect professional guidance and statutory requirements where they exist. Physical environment (including Ventilation systems) should be appropriate and safe for the procedure being performed.

Risks associated with moving and handling (this could be moving of patients or equipment etc) and infection control must always be highlighted on the risk register.

Assessors will want to ensure that the service implements policies to manage risks associated with hazardous substances. All new substances introduced into the service should be subject to risk assessment, with the results and implications reflected in the COSHH file or equivalent.

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| **Criteria 3 -** Maintenance of a comprehensive and up-to-date risk register to document, escalate and report risks, as necessary. |

Risk registers or equivalent should be maintained and up to date, assessors will review the document. This should register all risks or may be at Organisational level for high level risks with a localised register for local low-level risks. There should be an escalation process in place and assurance that accepted risks are monitored and reviewed at a defined interval. The service should be able to evidence that their risk management processes are effective. Where risks are not acceptably mitigated the service should show how these are being managed.

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| **Criteria 4 -** Tools are in place to record, report, investigate and manage adverse incidents and near misses within specified timescales. |

You will need to demonstrate that you have a process in place to deal with adverse incidents or near misses including timescales for investigating actions and reporting. These events might include someone fainting in a waiting room or clinical room, injury resulting from equipment handling, or any other event occurring within the confines of the service which could cause harm. All staff should be fully trained in the emergency call policy and you should have access to appropriate resuscitation facilities.

The service can demonstrate it has documented procedures for calling for medical assistance if this is needed during any service activity. Assessors will be looking for written protocols that ensure that incidents and errors are reported and investigated with an RCA and actions as appropriate.

Clinical incidents may include inappropriate treatment or treatment errors. Guidance suggests that errors leading to mismanagement should be considered a clinical incident. All clinical incidents should be recorded within the service and reported to the bodies within the organisation responsible for clinical governance. Other relevant bodies should be informed, in accordance with legislation and organisational policy.

If your service uses drugs (definition of drugs includes oxygen) or contrast media, assessors will check that staff caring for patients who receive drugs and contrast media are sufficiently experienced and competent to identify risk of adverse reaction. Staff should also be aware of contraindications to using a drug.

Incidents which threaten the health and safety of patients, staff or others should be reported and recorded in accordance with legislation and organisational policies. Occupational health support should be offered to staff where necessary. Instances of violent or aggressive behaviour from patients or staff should be reported and recorded in accordance with legislation and organisational policies. Incidents and errors relating to lifting and handling should be reported, investigated with a documented RCA, analysed with appropriate actions and findings disseminated to relevant parties and acted upon.

Any incident or error which may affect patient care must be communicated without delay to the clinical team and the patient or their carer/keyworker.

Resultant changes in practice must be communicated to staff. This may never have happened in your service before, but you still require a system in place to report and act upon incidents that may occur in the future. This ties in with LM8.

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| **Criteria 5 -** Management of patient safety alerts, and appropriate actions. |

Assessors will look for a documented process to ensure there is a mechanism for awareness of safety alerts and that these are reviewed and actioned. Safety alerts should be communicated with all staff and evidence of the process should be provided.

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| **Criteria 6 -** Regular health and safety training for all staff. |

Assessors will look for evidence of a formal and regular programme of health and safety training and review for staff. In addition to up-to-date training records for staff in general health and safety (including fire and basic life support) assessors will expect to see information displayed in a variety of ways to ensure staff maintain awareness of these issues. This could include relevant health and safety information displayed on notice boards, fire policy notices clearly displayed around the service and a clear display of emergency numbers.

All staff should undertake fire safety training according to local policy (ideally at least once a year) and an up-to-date record kept of their attendance. Staff should be properly trained in use of all H&S equipment and appropriate moving techniques. Training should be up to date and there should be a record of this training.

Records such as staff training in infection control and staff immunisation should be available.

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| **Criteria 7 -** Readily available, well-maintained health and safety and risk-reduction equipment and devices. |

Staff should be aware of the type, location, and safe use of, for example, fire safety equipment and first aid kits. Assessors will check that this equipment is readily available, appropriate, well maintained and regularly checked and serviced.

If it is your policy to move patients you should have equipment available that is maintained, appropriate for the task and correctly used.

You will need to demonstrate that you have a wide range and adequate stock levels of personal protective equipment (PPE) and clothing, including gowns/aprons, gloves, eyewear, and masks for dealing with hazardous substances and material and for use when clinical tasks warrant their use. Supplies of these should be properly managed and maintained. You will also need to demonstrate that staff know when and how (donning and doffing) to use this equipment. PPE should be available in a wide range of sizes and not used outside of its expiry date.

**Facilities and Resources**

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| **FR1 -** The healthcare provider must manage facilities and environment to support service delivery. |
| **Criteria 1 -** Sufficient suitable space to deliver all aspects of the service. |

Key room types should be fit for purpose, for example floor areas should be the statutory minimum, appropriate ventilation, noise, and light requirements should be satisfied.

Onsite, assessors will observe how effective working is facilitated by careful planning of appointment sessions and by the arrangement of rooms, facilities, and equipment. Equipment should be laid out to provide easy access and support safe working. The rooms should be easily accessible in the event of a medical emergency.

**Audiology Example**

Assessors will consider building/room requirements stated within any recommended guidance; dedicated paediatric testing rooms used for VRA and sound field testing must meet the requirements set out by the BSA. Rehabilitation rooms should have natural light/equivalent daylight bulbs. Available facilities should also include access to a wash hand basin with alcohol gel hand wash and an inductive loop system.

**Respiratory and Sleep Example**

All clinical rooms should be easily accessible in the event of a medical emergency (e.g., cardiopulmonary exercise testing). There should be adequate wheelchair access and space for additional staff and chaperones as required.

Sleep bedrooms for sleep studies (including MSLT/MWT) should be comfortable and provide patients with appropriate environment for high quality sleep and privacy. Environments should be appropriately lit and adequate reduction of noise to facilitate sleep.

Rooms should have appropriate ventilation to ensure effective infection control within the environment. Temperature should be controlled as appropriate for many investigations (e.g., lung function testing, exercise testing).

**GI Physiology Example**

There should be appropriate ventilation to ensure infection control during aerosol-generating procedures. If available, aerosol-generating procedures should be performed in a clinic room which has specific documented negative pressure, to limit down time between patients. Patients undergoing Anorectal Physiology investigations should have suitable access to a toilet facility.

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| **Criteria 2 -** Enough suitable facilities for patient/client confidentiality and privacy and dignity. |

Access to consulting rooms should be such that all patients can maintain their dignity, privacy, and confidentiality during their appointment. You should actively seek patient opinion and ensure that any issues are addressed appropriately. Patients should have changing facilities and gowns where these are needed. Single patient investigation rooms should be available where possible to maintain confidentiality, privacy, dignity and reduce infection control risks.

Staff should ensure patients are comfortable throughout their examination. Any issues regarding patients’ comfort should be addressed immediately.

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| **Criteria 3 -** Appropriate access for users and staff who use wheelchairs, trolleys/beds, have impaired vision, hearing, or have other needs. |

You will need to demonstrate that you provide appropriate facilities for patients with disabilities, ensure appropriate access for wheelchairs, and disabled toilet facilities.

If you provide a service for children, you will need to demonstrate how their specific needs are met including toilet facilities.

**Audiology Example**

This also includes minimum floor area requirements for paediatric audiology assessment rooms as defined in BSA guidelines for visual reinforcement audiometry and sound field audiometry.

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| **Criteria 4 -** Management and monitoring of the condition of facilities and environment including cleaning and maintenance. |

Assessors will be looking to ensure that all areas are well maintained. Processes should be in place for regular routine checks of the condition and cleanliness of each area used by the service. The service should allocate funding within the annual budget for minor repairs and upgrades to the environment such as painting and structural alterations.

Assessors will review the departmental cleaning schedule and review any audit on environmental cleaning. Services should have processes to identify areas of non-compliance with the cleaning schedules.

Environmental conditions such as ventilation, temperature and lighting should be managed and controlled to ensure a comfortable environment for patients, staff, and others.

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| **Criteria 5 -** Display of relevant signage to notify users, staff and visitors of access and specific hazards. |

Assessors will want to see clear warning notices displayed in all areas that are potentially hazardous. Access to hazardous areas within the service should be controlled and restricted to authorised individuals only by, for example, interlocked or coded doors. Assessors will check that hazard warning signs, such as ‘wet floor’ signage are available and used throughout the service when needed. Fire exit signs should be clear and displayed in a variety of media, and there should be both auditory and visual fire alarms.

**Respiratory and Sleep Example**

Services will use gas sources, including compressed gas cylinders. Assessors will want to see appropriate signage to alert the presence of compressed gases.

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| **Criteria 6 -** Facilities and environment are fit for their intended purpose, in particular:  Criteria 6.1 - Clinical facilities:   * Records relating to environmental conditions that allow for correct performance (assure quality and integrity) of the clinical activity concerned e.g., noise reduction, ventilation, variable lighting and temperature, equipment performance. * Appropriate facilities for decontamination of equipment and consumables.   Criteria 6.2 - Reception, waiting and changing facilities:   * Sufficient and appropriate seating facilities for all patients/clients including space for those waiting in wheelchairs, needing bariatric support, waiting for hospital transport, as appropriate. * Appropriate waiting areas for children, vulnerable adults and their carers and those waiting on trolleys. * Screened areas for patients/clients dressed in gowns or those waiting on trolleys or in beds. * Secure storage facilities for patient’s/clients’ valuables.   Criteria 6.3 - Staff facilities:   * Sufficient and appropriate changing facilities for staff including those with disabilities. * Access to safe storage for personal items. * Access to toilet facilities and drinking water. * Storage of personal protective equipment. |

Assessors will seek assurance that all areas are well maintained with service contracts as required. Evidence of servicing for key items such as air conditioning, emergency lighting, cleaning schedule with appropriate audit to show conformity should be available.

During the onsite assessment assessor will look at the facilities to ensure access, signage and facilities meet the criteria detailed.

**Audiology Example**

Assessors will look for evidence that rooms with noise reduction adjustments or soundproof booth have assurance of monitoring of ambient noise against relevant BSA guidance or ISO standards to assure the facilities remain fit for purpose.

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| **FR2 -** The healthcare provider must have systems in place for the selection of external services and suppliers for equipment, reagents, drugs (includes contrast media), radioactive medicinal products and consumables. |
| **Criteria 1 -** Maintenance of an approved list of suppliers. |

Assessors will check evidence of a supplier list for all equipment, reagents, drugs (includes contrast media), radioactive medicinal products and consumables. The list should detail why the supplier is approved if it is not shown via a tendering process or national contract.

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| **Criteria 2 -** Availability of purchasing criteria that clearly describe the requirements for the product(s) and or service(s) to be purchased. |

Assessors will check that processes for procurement are grounded in current best practice with clear criteria to assure that products or services purchased meet the needs of the service and service users.

Policies will also reflect statutory requirements. If your service uses drugs (definition of drugs includes oxygen) or contrast media, there must be a system in place which is clearly defined, documented and available to all staff. Written protocols detailing what substances may be purchased and by whom.

**Audiology Example**

The procurement of hearing aids will reflect the current variety, choice and technological development of aids. A service will need to demonstrate why they are choosing a certain model.

**Sleep Physiology Example**

The procurement of CPAP devices may reflect the varying modes of operation requires, for example the purchase of fixed pressure and auto setting devices, the need for humidification and the possible scope for remote monitoring of therapy, as indicated in the recently published NICE Sleep Apnoea Guidelines. Patient interfaces (e.g., nasal masks, oronasal masks, nasal pillows etc) should be available in a wide range, including a range of sizes to meet the needs of service users, including patients with disability.

**Respiratory Example**

Many services use filters during lung function testing to reduce cross infection between patients. Services should specify the requirements for filters (e.g., type of filter, single patient use, compatibility with equipment, efficiency of filter, impedance etc).

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| **Criteria 3 -** Review of budgets/funding for equipment, reagents, gases, drugs, radioactive medicinal products, and consumables, at least annually, and where appropriate managed in conjunction with the parent organisation. |

This will define annual requirements and be shared with the parent organisation to agree an approach to funding. The expected lifetime of products or equipment will vary according to how much it is used, technological advances and changes in clinical need.

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| **Criteria 4 -** Regular monitoring of all purchases to ensure consistency with specified criteria. |

The assessors will look for evidence that the purchasing criteria detailed in FR2 criteria 2 are reviewed and there is an auditable documented process for assuring that products continue to meet the purchase criteria.

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| **FR3 -** The healthcare provider must receive, store, and manage equipment, reagents, drugs (includes contrast media), radioactive medicinal products and consumables. |
| **Criteria 1 -** Verification that the receiving location/facility has adequate storage and handling capabilities to maintain the purchased items in a manner that prevents damage and deterioration. |

Evidence to show how consumables and equipment etc. is received and stored will need to be demonstrated. If the service delivers activity across several locations, you will need to consider how stock is managed to deliver items across those locations.

If your service uses drugs (definition of drugs includes oxygen) or contrast media, assessors will check that all drugs and contrast media are stored correctly. Assessors will check that hazard warning signs, are available and used throughout the service when needed. You will need to demonstrate that all hazardous substances and materials are securely stored.

You will need to demonstrate that your service implements policies for the safe and secure storage, collection, transportation and disposal of sharps, spillages, cleaning agents and reagents etc.

**Audiology Example**

The service will have a system for the sustainable recycling of hearing aid batteries.

**Respiratory and Sleep Example**

Lung function laboratories use gas cylinders as part of routine testing. There should be an appropriate (and secure) storage area for charged cylinders and a process for transporting charged cylinders from storage areas to the laboratory and removal of empty cylinders. Gas cylinders should be appropriately secured in the lung function laboratory. There should be evidence (if applicable) of correct changing of gas cylinders or the process for getting them changed.

**Vascular Example**

Patients requiring oxygen will be managed according to the host organisational policy (e.g., requirements for accompanying medical staff for in-patients) and there will be appropriate secure storage for oxygen cylinders in clinical areas.

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| **Criteria 2 -** Verification of the performance of any new batch or shipment before use in clinical procedures. |

Assessors will look for processes to assure that equipment, reagents, drugs (includes contrast media), radioactive medicinal products and consumables are checked to assure quality before they are used or issued to patients.

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| **Criteria 3 -** Maintenance and routine implementation of an inventory control system. |

The service should have a stock management system in place and equipment inventory.

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| **Criteria 4 -** Appropriate instructions for use for all items are readily available. |

The service should provide clear, relevant, and up to date information in a range of formats about the safe use, storage and aftercare of devices and consumables issued.

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| **Criteria 5 -** Investigation and reporting of any adverse incidents or accidents that can be attributed directly to use of an item. |

Assessors will check that you have systems in place to ensure an appropriate response to all incidents. RCA should be performed for all incidents with appropriate actions and reporting. Reporting should include stakeholders, referrers, outside agencies, as appropriate. This response will include informing patients and/or carers when such incidents have occurred. Incident forms or the reporting process should be readily available to all staff.

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| **Criteria 6 -** Maintenance of records for each item that contributes to the performance of clinical procedures. |

Assessors will be checking that all equipment is well maintained, in good working condition and clean. Equipment should be maintained and repaired under formal service agreements which should be regularly reviewed and have a full associated QA log. Maintenance records and registers should be held and kept up to date and assessors will want to see these records.

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| **FR4 -** The healthcare provider must manage procurement, installation, and replacement of all equipment. |
| **Criteria 1 -** Any equipment used (including that on loan to patients/clients for use outside of the healthcare provider) meets the specific requirements of the clinical activities offered and the target population concerned (e.g., weight, age, disability etc). |

You will need to demonstrate that all equipment is procured specifically to meet the needs of the service’s target population, including the expected range of size and weight of patients.

Equipment used for the diagnosis and treatment of children, or patients with complex needs must be selected or modified appropriately.

You will need to demonstrate that you have personal protective equipment and clothing, including gowns, gloves, and masks for dealing with hazardous substances and material as appropriate.

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| **Criteria 2 -** Maintenance of an equipment inventory and rolling replacement programme Including software, upgrades (including diagnostic software) and accessory devices (e.g., couches, chairs etc). |

You will need to demonstrate that you have a rolling equipment replacement programme in place. All software used to include the electronic patient record should have a service agreement and a documented plan for upgrade or replacement. All equipment & items used by the service should be included, not just clinical items.

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| **Criteria 3 -** Regular review of equipment budget, at least annually, and where appropriate managed in conjunction with the parent organisation. |

This will define annual capital requirements, and this will be shared with the parent organisation to agree an approach to funding as appropriate. The expected lifetime of equipment will vary according to how much it is used, technological advances and changes in clinical need. Equipment must not exceed the maximum recommended age for equipment use where this exists. Assessors will be looking to ensure that processes for procurement are grounded in current best practice.

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| **Criteria 4 -** Acceptance testing upon installation and before use. |

You will need to demonstrate that you have a process in place to systematically review and document the installation, calibration, and operation of equipment before initial use when new or on return from repair. Processes should be grounded in current best practice and reflect statutory requirements and the manufacturers guidelines. A quality assurance (QA) and quality control (QC) programme for all equipment should be in place.

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| **Criteria 5 -** Maintenance of training and authorisation records for staff to operate specific equipment. |

Assessors will check records of staff training and a documented processes for authorising staff when new equipment is installed. If applicable there may be medical device training records in place.

If it is your policy to move patients, staff should be properly trained in using such equipment and there should be a record of this training.

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| **Criteria 6 -** Agreed minimum information is maintained for any equipment that contributes to the performance of clinical activity. The expectation is that records will include:   * Identity of the equipment. * Manufacture’s name, model and serial number or their unique identification. * Contact information for the supplier or the manufacturer. * Date of receiving and date of entering use within the service. * Location of the equipment. * Condition when received (new, used or reconditioned). * Manufacturer’s instruction manual. * Confirmation of acceptability for use. * Maintenance carried out and the schedule for preventative maintenance. * Performance records (reports/calibration certificates) that confirms ongoing acceptability for use. * Record of any damage to, malfunctions, modification and or repairs. |

The records above ideally will be held together but it is not expected that all with be within the same document.

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| **FR5 -** The healthcare provider must calibrate and maintain equipment. |
| **Criteria 1 -** Use of an authorised/accredited body to conduct calibration. |

Assessors will look for evidence that the service performing calibration and maintenance of equipment should hold authorisation/accreditation for the types of calibration performed for the service therefore assuring their competence in this practice.

Currently accreditation or certification (ISO17025, ISO13485, ISO9001) is being taken as acceptable to determine authorised calibration provider, however if this is not evidenced then the service must ensure they gain evidence to support that the calibration provider is authorised/competent to perform the calibration activity. This may be by an external peer review with an accredited provider and/or external benchmarking of their calibration activity.

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| **Criteria 2 -** That calibration and maintenance takes account of conditions of use and manufacturer’s instructions. |

You will need to demonstrate that you have a process in place to systematically review and document the calibration, and performance of equipment including servicing. These should be grounded in current best practice and reflect statutory requirements and the guidelines and/or instructions of the manufacturer.

You will need to demonstrate that you have a process in place to document the calibration and performance of equipment as detailed in the criteria. Service documentation will include records to confirm all equipment is calibrated annually to international (ISO) standards and that daily checks are carried out on all equipment to international (ISO) standards or best practice guidelines if ISO standards are not available. Assessors will view evidence including Calibration Certificates and daily checks. Staff should be aware of policies and guidelines and know how to access them. A quality assurance (QA) programme for all equipment should be in place.

**Respiratory and Sleep Example**

Assessors will want to see evidence of staff performing daily quality control/calibration procedures (e.g., spirometers, gas analysers etc) in line with policy, and decision making to determine if the equipment is suitable for clinical measurement. This may include physical calibration (using certified calibration syringes, known gas mixes etc) and biological quality control procedures. Assessors will review calibration and quality control logs.

Assessors will also check that there are systems in place to ensure that other equipment e.g., height and weight measuring devices, barometers etc) are reading accurately.

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| **Criteria 3 -** Traceability between the equipment and the calibrated reference standard. |

Assessors will look for evidence that equipment used to calibrate the services own equipment has traceability to the reference standard. An authorised/accredited calibration body should be able to provide this. This will be designated on calibration certificates by demonstrating the UoM values and a statement of traceability may be noted. To ensure that calibration services meet the authority and traceability requirements, sites undergoing accreditation should ensure that their calibration provider can provide either:

Evidence of ISO 17025 accreditation through an accreditation body – demonstrated by accreditation status on the UKAS or other accreditation body website or their accreditation body/UKAS certificate, and evidence of your calibration certificates showing the appropriate statement of traceability and Uncertainty of Measurement data that confirms this for you.

**or**

Evidence of ISO 13485 certification through an accredited body, together with evidence of appropriate training for the person performing the calibration and again the certificates of calibration of your equipment providing the relevant traceability and UoM data

**or**

An in-date calibration certificate for their calibration equipment together with externally certified compliance with a quality management system (such as ISO 9001) and again the certificates of calibration of your equipment providing the relevant traceability and UoM data. The certification body providing this external verification of compliance with ISO 9001 must have accreditation with an accreditation body such as UKAS.

**or**

An in-date calibration certificate for their calibration equipment together with documented peer review evidence using an ISO 17025 accredited provider. It would also be good practice if not using an ISO17025 accredited provider for the calibration service to have a piece of equipment they calibrate also calibrated by an accredited service to show comparison of results thus assuring you of their accuracy and competence.

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| **Criteria 4 -** Verification of the measurement accuracy at defined measurement intervals. |

Assessors will look for an auditable documented process to assure equipment is reviewed to ensure any drift in performance is detected and acted upon as appropriate.

**Audiology Example**

Calibration certificates should be reviewed to see if there has been any drift to determine if this is significant whether test validity may have been compromised and recall of patients may be needed.

**Respiratory and Sleep Example**

Spirometers may be calibrated/verified at regular time intervals during the day, to ensure equipment is reading correctly to take into account factors that may impact on test performance should at changes in laboratory temperature or throughput of patients. Parameters such as ambient temperature and barometric pressure may also be remeasured.

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| **Criteria 5 -** Timely and accurate updating of correction factors as necessary. |

Assessors will need to see a documented process in place to ensure any correction factors are responded to in an auditable documented process following calibration and any evidence if available support this has been implemented effectively.

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| **Criteria 6 -** Safeguards to prevent adjustments or tampering that might invalidate clinical results. |

Assessors will be looking for evidence that the service has systems in place to prevent equipment being adjusted or tampered with including removal or changing of transducers is appropriate.

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| **Criteria 7 -** Reporting of faults and management of equipment breakdowns and repairs, in line with legislation, manufacturer’s guidelines and organisational policy. |

Assessors will be checking that all equipment is well maintained, in good working condition and clean. An effective process should be in place for reporting faults and managing equipment breakdowns and repairs. This should include provision for equipment replacement to maintain continuity of service.

Equipment should be maintained and repaired under formal service agreements which should be regularly reviewed and have a full associated QA log. Maintenance records and registers should be held and kept up to date and assessors will want to see these records.

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| **Criteria 8 -** Mechanisms to communicate health and safety warnings and alerts to staff, which are formally acknowledged, and acted on within specified timescales. |

Assessors will check systems to ensure H&S alerts are proactively monitored and staff are informed as appropriate. Evidence will be required of an auditable documented process for managing warnings or alerts or notifications once these have been received.

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| **Criteria 9 -** Regular review of electrical safety, emergency stop devices (where relevant). |

Assessors will review evidence including electrical safety certificates and records of equipment failure and maintenance. Staff will be asked to show they are aware and can comply with equipment safety policy.

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| **Criteria 10 -** Regular cleaning and decontamination of all equipment, including ancillary equipment following direct contact with patients/clients. |

Processes should be in place to ensure effective cleaning and decontamination of equipment as a matter of routine or following an incident. The service should have appropriate decontamination and segregation processes in place to ensure that patients with contagious or communicable diseases can be appropriately managed. These may be part of wider policies for the control of infections adopted through the wider organisation. Manufacturers’ specifications and recommendations should be considered.

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| **Criteria 11 -** Maintenance of training and authorisation records for staff who calibrate, clean, and decontaminate equipment. |

Assessors will look for evidence of staff competency in relation to daily, weekly, and monthly equipment checks and clearing. Evidence to show staff have been trained to decontaminate equipment routinely and following an incident should be available.

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| **Criteria 12 -** Timely Investigation and reporting of adverse incidents and accidents caused by defective equipment to manufacturers and relevant authorities. |

Assessors will check that you have systems in place to ensure an appropriate response to clinical incidents. This response will include informing patients and/or carers when such incidents have occurred. Incident forms should be readily available to all staff.

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| **Criteria 13 -** Labelling and removal from service of any equipment found to be defective. |

An effective process should be in place for reporting faults and managing equipment breakdowns and repairs.

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| **FR6 -** The healthcare provider must recruit, select, and train staff to assure competence. |
| **Criteria 1 -** Recruitment and selection criteria for each staff group in line with professional registration requirements. |

Even if staff recruitment, You will need to evidence recruitment processes and demonstrate that this is followed for all staff, including agency staff, students, and volunteers including where this is managed through another department within your organisation. Services should reflect guidance from professional bodies and from NICE where this is available.

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| **Criteria 2 -** Completion of pre-employment checks. |

All relevant employment checks must be carried out, including checks on qualifications, current professional registration, and eligibility for employment. Disclosure and Barring Service (DBS) checks and Independent Safeguarding Authority checks are required for staff whose work may bring them into contact with children or vulnerable adults. For new staff, involved in patient care DBS checks should be mandatory.

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| **Criteria 3 -** Verification that each member of staff including locum staff is qualified, trained and authorised (registered where necessary) to perform their intended functions and this is reflected in job description / job plan. |

Assessors will check that each member of staff has an agreed contract of employment, job description and job plan. You will also need to demonstrate that you assured the clinical competency of new starters including locum staff before working independently.

Staff should be fully aware of the tasks they are required to do and should not be required to carry out tasks they are not currently trained or competent to do. Evidence might include a training file with competency sign off for each member of staff, and a local register or evidence of an annual check that staff are still registered.

If you deliver an out of hours service (as defined in the Quality Manual), you will need to demonstrate that staffing levels are safe, appropriate, and adequate. Staff delivering out of hours must be fully supported and compensated in line with organisational policy. Implementation of an out of hours staff rota must be applied fairly across all staff. Colleagues, patients, and other departments must be clearly informed of the level of service provided and alternative/emergency arrangements if they exist. Services should be compliant with the services lone working policy.

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| **Criteria 4 -** Tailored induction training and supervision programmes are available specific to each role, circumstance and/or environment. For example, staff taking on new roles, temporary staff, those returning to work following extended leave and students. |

You need to evidence that you have a comprehensive induction programme for staff recruited to the service, including providing any additional education and training which might be required. Existing staff taking on new roles or returning after an extended absence should have an induction programme which includes any additional training required. This induction programme should include documented timescales for training that are adhered to. Staff should have their competency reviewed as part of their induction and should be authorised before working independently. Staff feedback on the induction programme should be gathered and acted on where appropriate.

**Audiology Example**

The plan will also cover any specialist roles such as the management of tinnitus or balance disorders or working effectively with patients with complex needs and learning disabilities. If you offer a paediatric audiology service, you will need to demonstrate that this team has the appropriate skills.

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| **Criteria 5 -** Collaboration with education institutions for education and training support to meet current and predicted staffing needs of the service. |

The service should plan education and training to support the current and predicted needs of the service, particularly for complex and developing examinations/procedures. This may be facilitated by links to, and involvement with, educational establishments and professional bodies/societies to support specialist training and development.

Support will include mentoring, team motivation and other leadership roles. This manager/lead may or may not be within the service but there must be a named individual who is responsible for supporting the service provide training.

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| **Criteria 6 -** Maintenance of records of staff training activities, professional qualifications, professional registration status, induction and refresher training courses attended, and certificates of competence with authorisation to carry out specific tasks. |

The service should be able to identify a named individual/s who is responsible for identifying and keeping records of the skill and competence of staff. You will need to demonstrate that a robust system is in place to monitor appointed staff and ensure they remain qualified, registered, and competent for their current roles. This means conducting an annual check that staff are still registered.

Staff CPD records should be reviewed by the service at least annually to ensure staff are able to maintain their professional registration.

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| **Criteria 7 -** Regular review of performance and assessment of competence for all staff. |

You will need to demonstrate that a robust system is in place to monitor appointed staff and ensure they remain competent for their current clinical and non-clinical roles which then references more formalised capability procedures. Assessors will also want to see records of competency assessments for all areas outlined in job descriptions for all clinical and non-clinical areas. The Organisation should consider documenting how they define staff competence which may include peer review, audit, CPD, retrospective review etc. and then evidence that staff are compliant to this covering clinical and non-clinical competency across all types of staffing including agency and return to work as well as full time resources.

Reviews of clinical records should reflect the work undertaken by the staff member and the number of records should reflect the amount of clinical activity performed.

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| **Criteria 8 -** Protected time for staff to engage in continuous professional development activities and to undertake improvement initiatives. |

You will need to demonstrate how you support staff to ensure they access CPD activities or personal development planning. This will also include demonstrating how you support the development of new skills and competencies.

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| **Criteria 9 -** Defined mandatory training is specified, available and completed for all staff. |

You will need to demonstrate that staff have access to appropriate learning opportunities to develop their abilities to help patients feel at ease during their contact with the service. This includes up to date training in disability awareness and equal opportunity and diversity training. Assessors will check evidence of formal prescribed and up to date training records for staff in your organisation which is likely to include general health and safety (including fire and basic life support), infection control, manual handling, information governance and consent. Staff should also be trained in conflict resolution and in the disposal of hazardous material identified in your COSHH review.

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| **Criteria 10 -** Systematic monitoring of staff retention and succession planning. |

Staff retention should be monitored, and the service should engage in systematic succession planning which ensures that it can deliver safe and effective care.