# IQIPS Standard 2023

## Introduction

This Improving Quality In Physiological Services (IQIPS) standard is based upon IQIPS standard v1 2012, revised to map to ISO15189, BS70000, QSI and CQC quality statements.

The purpose of this standard is to ensure that healthcare providers deliver physiological services that are accurate, effective, safe, efficient, responsive, accessible and sustainable. Achieving these goals requires:

- An effective leadership and management structure (clinical and administrative) including an appropriately designed quality management system;
- Administrative and clinical practices appropriate to the patient/client population including children
- Review of existing and new clinical practice to develop and improve the service;
- Provision of appropriate information and support for patients/clients and carers with due regard to differences in socio-economic characteristics, including effective feedback systems for patients and carers;
- Effective management of risks and emergencies;
- Appropriate and adequate facilities, equipment and consumables;
- Motivated and competent staff;
- The integration of sound business planning principles.

The healthcare provider must develop and maintain systems that are grounded in best practice, in line with professional guidance, and statutory and commissioning requirements. The healthcare provider must review its systems regularly, make corrections, and log changes. The provider must learn and take appropriate actions from its reviews and disseminate findings to support wider service improvement. Where necessary this standard will be supplemented by additional discipline-specific guidance from the relevant professional body.

## Scope

This standard specifies the requirements for quality and competence in Audiology, Clinical Neurophysiology, Cardiac Physiology, Respiratory & Sleep Physiology, Vascular Science, Ophthalmic & Vision Science, Gastrointestinal Physiology and Urodynamics. The standard may also be useful in other disciplines.

## Terms and definitions

**Advisory Services** - services that provide information relating to diagnosis, management, and patient support.

**Clinical activity** - this includes:

- Preparations conducted before a procedure;
- A test/measurement/assessment/examination that is performed on a patient/client;
- Methods for capturing data relating to a patient/client;
- Reporting the findings from an interaction with a patient/client;
- Any onward management which may include interventional/rehabilitation activity and monitoring of the outcome of the activity

**Corrective action** - action taken to remove the root cause of a problem causing a nonconformity

**Diagnostic criteria** - clinical decision values / clinical reference ranges

**Healthcare Provider** - organisation that provides clinical services(s)

**Manager(s)** - person(s) with overall responsibility for providing clinical services(s)

**Measurement Uncertainty** - the degree of doubt about a value. Uncertainty is usually expressed as the range within which the true value can be said to lie with a specified level of confidence. For example, if a person's height is given with 95% confidence as 160.0 +/- 0.5 cm this means there is a 5% chance it is more than 160.5 cm or less than 159.5 cm.

**Non-conformity** - failure to fulfil a requirement

**Preventative action** - action taken to eliminate the cause of potential nonconformities to prevent their occurrence

**Quality Management System** - a formalised system that documents processes, procedures and responsibilities for achieving quality policies and objectives. This helps coordinate and direct an organisation's activities to meet user, stakeholder and regulatory requirements and assure continual improvement

**Quality policy** - a short document published by management that establishes what quality means to the organisation

**Quality manual** - document that describes the organisation's quality management system

**Referral** - the entry point to service pathway which may include both self-referral and stakeholder referral

**Stakeholders** - includes commissioning bodies, professional bodies, clinicians, patient representative groups, patients and others, where appropriate

**System** - an agreed way of doing things that is documented, consistently implemented and regularly monitored

**Users** - patients/clients, their carers and referrers

# Leadership and Management domain

**The purpose of the Leadership and Management domain is to ensure appropriate leadership and managerial controls to support the healthcare provider's staff to deliver clinical services. This is achieved through an effective leadership and management structure (clinical and administrative).**

| **LM1 The healthcare provider is or must be part of a legal entity** | |
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| The healthcare provider for specific clinical services can be either autonomous or part of a larger parent organisation. It must where applicable: | |
| LM1.1. | Be part of an entity that can be held legally responsible for its activities; |
| LM1.2. | Be licensed to operate according to relevant international and UK regulatory frameworks; |
| LM1.3. | Where applicable, be clearly recognised in the published organisational structure of the parent organisation; |
| LM1.4. | 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. |

| **LM2 The healthcare provider must define, document and communicate governance arrangements including leadership, roles, responsibilities and accountabilities** | |
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| The healthcare provider must deliver clearly defined clinical service(s) to meet the needs of the target population, whether at static, mobile and/or domiciliary settings. System(s) must ensure, where applicable: | |
| LM2.1. | 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. |
| LM2.2. | A leadership and management team that is visible, approachable and available to staff; |
| LM2.3. | The leadership team identify and document details of individuals with specific roles and responsibilities across the Quality Management System (QMS) |
| LM2.4. | All staff have:<br>• An agreed contract of employment;<br>• A current job description/job plan that specifies his/her role, responsibilities, authorities and relationships; |
| LM2.5. | All staff understand their specific role and responsibilities, authorities and relationships; |
| LM2.6. | All staff understand the processes in place to manage conflicts of interest; |
| LM2.7. | All staff understand how to differentiate and manage feedback and complaints; |
| LM2.8. | All staff can give feedback and raise matters of concern, in confidence, and without fear of recrimination. |

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| **LM3 The healthcare provider must operate within its quality policy and monitor performance against measurable quality objectives**<br>System(s) must ensure, where applicable: | |
| LM3.1. | The leadership team develop, and publish an appropriate quality policy and measurable quality objectives that are regularly reviewed; |
| LM3.2. | 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; |
| LM3.3. | Consistency in performance across the provider's activities with internal and external benchmarking. |

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| **LM4 The healthcare provider must establish, implement, and maintain a quality management system (QMS)**<br>The healthcare provider must establish an appropriate QMS to integrate all agreed processes, monitor their effectiveness and ensure continuous improvement of its service(s).<br>The QMS will: | |
| LM4.1. | Be described in a quality manual; |
| LM4.2. | Be sufficiently robust to ensure that staff only have access to the latest and current versions of documents; |
| LM4.3. | Ensure availability of supporting documentation to include, but not be limited to:<br>• Processes (ways of working) for all activities;<br>• Pathways and clinical protocols;<br>• Records of resources (staffing, equipment etc) available to support delivery;<br>• Forms in use;<br>• Internal audits;<br>• Publications; |
| LM4.4. | Be subjected to regular management reviews, at least annually, to include at least the following:<br>• Quality improvement initiatives to include business planning;<br>• Periodic review of referrals received;<br>• Results and outcomes from user feedback and complaints;<br>• Staff and stakeholder consultation and feedback;<br>• Results and outcomes from internal audits;<br>• Risk management reports, and update of risk register;<br>• Reviews conducted by external organisations;<br>• Objectives aligned to local and national performance targets with outcomes of inter-service comparison programmes/benchmarking;<br>• Performance of suppliers;<br>• Identification and control of non-conformities;<br>• Follow-up actions from previous management reviews;<br>• 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. | |

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| **LM5 The healthcare provider must ensure that documents and records (including clinical records) are controlled**<br>System(s) must ensure, where applicable: | |
| LM5.1. | Agreed format and media for documents and records; |
| LM5.2. | Data is processed, handled, maintained and secured in line with applicable regulation and professional guidance; |
| LM5.3. | All documents and records supporting delivery of services are current, reviewed, approved and available; |
| LM5.4. | All documents and records created and revised contain:<br>• A title;<br>• Unique identifier on each page;<br>• Date of current edition, review, edition number;<br>• Page number to total number of pages;<br>• Authority for issue; |
| LM5.5. | Appropriate controls for the identification, collection, indexing, access, storage, maintenance, and amendments of current and obsolete records and documents; |
| LM5.6. | Documents and records are protected from unauthorised alterations and where necessary kept confidential. |

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| **LM6 The healthcare provider must establish and review agreements for any outsourcing /subcontracting clinical services.**<br>System(s) must ensure, where applicable: | |
| LM6.1. | Specification of the minimum information needed for different types of agreements; |
| LM6.2. | Timely review of all agreements; |
| LM6.3. | 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; |
| LM6.4. | Maintenance of patient/client confidentiality; |
| LM6.5. | Monitoring and review of performance against contract requirements, including remedial actions; |
| LM6.6. | Transparency of outsourcing/subcontracting to users and in clinical service outputs. |

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| **LM7 The healthcare provider must provide competent advisory services**<br>System(s) must ensure, where applicable: | |
| LM7.1. | Communication to users and stakeholders on the range and choice of clinical procedures currently available, and on emergent practice; |
| LM7.2. | Communication on clinical, professional and logistical matters; |
| LM7.3. | Users and stakeholders can access advice on interpretation of results; |
| LM7.4. | Sufficient capacity for staff to attend multidisciplinary meetings with users/ stakeholders about patient/client management. |

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| **LM8 The healthcare provider must identify, manage, eliminate and prevent non-conformities by taking preventative and corrective actions**<br>System(s) must ensure, where applicable: | |
| LM8.1. | Designated responsibilities for non-conformities and non-conformity prevention; |
| LM8.2. | Training for staff to detect and record non-conformities; |
| LM8.3. | 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'); |
| LM8.4. | Immediate actions are taken to mitigate the effect of non-conformities; |
| LM8.5. | Determine and document the root cause/s and extent of the non-conformity or potential non-conformity; |
| LM8.6. | Further actions are taken to remove the root cause and prevent reoccurrence of the non-conformity; |
| LM8.7. | The need for preventative action is evaluated and implemented when required; |
| LM8.8. | Mechanism(s) for recording non-conformities and resultant changes in practice |
| LM8.9. | Mechanisms for communicating non-conformities and resultant changes in practice to relevant users, staff and stakeholders; |
| LM8.10. | Regular review of non-conformities to identify trends; |
| LM8.11. | Results and effectiveness of preventative actions are reviewed and documented; |
| LM8.12. | Criteria are available to determine the following in the case of a clinical non- conformity:<br>• Whether clinical activities should be halted;<br>• Whether reports should be withheld;<br>• Who authorises the recommencement of any halted clinical activities; The need for previously released results to be recalled;<br>• The medical significance of a non-conformity to patient/client management;<br>• 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. |

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| **LM9 The healthcare provider must evaluate and audit the effectiveness of their QMS including clinical activities**<br>System(s) must ensure, where applicable: | |
| LM9.1. | The QMS including clinical activities is evaluated and assured with a regular audit cycle. This would usually be annually; |
| LM9.2. | Use of different audit methods (vertical, horizontal and/or witnessing) to comprehensively cover the requirements of this standard; |
| LM9.3. | The scope, criteria, methodology and frequency of audits are defined, documented and reported in an agreed format; |
| LM9.4. | That the service assures appropriate training in audit. |

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| **LM10 The healthcare provider must manage internal and external major incidents**<br>System(s) must ensure, where applicable: | |
| LM10.1. | Availability of an agreed, published and up to date business continuity plan; |
| LM10.2. | 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; |
| LM10.3. | Management of the return to routine service following the incident, including management of any backlog; |
| LM10.4. | Accessibility of counselling and support services; |
| LM10.5. | Analysis and review of performance following a major incident; |
| LM10.6. | Regular review and communication of any changes to major incident procedures and action plans. |

# Clinical domain

**The purpose of the Clinical domain is to promote timely, accurate and effective diagnosis and treatment. These are achieved by ensuring that administrative and clinical practices are appropriate to the patient/client population, that risk management is effective, and that the service develops and improves itself by reviewing existing and new clinical practices.**

| **CL1. The healthcare provider must define and deliver its services from referral to discharge or further management**<br>System(s) must ensure, where applicable: | |
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| CL1.1 | Publication of the diagnostic and interventional service(s) description, range of clinical activities offered, and their locations; |
| CL1.2 | Publication of evidence-based agreed pathways developed with stakeholder involvement; |
| CL1.3 | Agreement and publication of metrics and key performance indicators for monitoring the patient pathway e.g. Did Not Attend (DNA), Referral to Treatment (RTT). These could be based on a review of relevant guidelines, clinical pathways, quality standards and benchmark data; |
| CL1.4 | Performance is communicated to users and stakeholders, as appropriate; |

| **CL2. The healthcare provider must manage referrals and prepare patients/clients for their clinical activity**<br>System(s) must ensure, where applicable: | |
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| CL2.1 | Mechanisms for the referral process are clearly communicated |
| CL2.2 | Requests are vetted in advance of the appointment; |
| CL2.3 | Request forms seek appropriate information including:<br>Patient/client identification details;<br>• Name and contact details of the person making the request (who must be authorised to sign and request the specific clinical activity);<br>• The clinical activity being requested including the specific anatomic site, where relevant;<br>• Clinically relevant information pertaining to the requested activity;<br>• Date of the request;<br>• Requirements for specified equipment, drugs, radioactive medicinal products and/or reagents if relevant;<br>• Additional information to support patient/client needs e.g. need for wheelchair access, interpreter, infection status and any known allergies. |

| **CL3 The healthcare provider must assure the technical quality of clinical activities**<br>System(s) must ensure, where applicable: | |
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| CL3.1 | Patients/clients are correctly identified, and appropriate consent is obtained; |
| CL3.2 | Equipment has been calibrated, serviced and is fit for purpose; |
| CL3.3 | Availability of appropriate positioning and supporting devices to ensure the integrity and quality of the clinical activity; |
| CL3.4 | Availability of protocols for each clinical activity.<br>Protocols must: |

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| | • Be evidence-based and appropriate;<br>• Fully describe the critical procedural steps;<br>• Include diagnostic criteria and measurement uncertainty, as appropriate;<br>• Include arrangements for safe sedation, analgesia and or anaesthesia where necessary;<br>• Include health and safety considerations, contraindications and infection control;<br>• Include guidance for onward referral, management of incidental or clinically urgent findings, and post-procedure care. |
| CL3.5 | Regular review of protocols, communication of protocol changes to relevant staff, and training on the changes where necessary; |
| CL3.6 | Competent and appropriate supervision of staff; |
| CL3.7 | 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; |
| CL3.8 | Results are reported in an appropriate time frame. |

| **CL4 The healthcare provider must ensure the clinical and technical quality of records, interpretations and reports**<br>System(s) must ensure, where applicable: | |
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| CL4.1 | 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; |
| CL4.2 | Adequate numbers of competent reporting staff are available and documented; |
| CL4.3 | Reporting formats are agreed with referrers and stakeholders; |
| CL4.4 | Availability of locally agreed reporting structures/templates to reporting staff, including those external to the healthcare provider; |
| CL4.5 | Clear identification of the report issuer. This is particularly relevant where outsourcing arrangements are used; |
| CL4.6 | Reports include, as appropriate:<br>• Referral information<br>• Date and time of clinical activity<br>• The clinical activity performed<br>• Relevant findings/observations, including unexpected findings;<br>• A conclusion and/or diagnosis;<br>• How certain the conclusion is, and advice on further diagnostic tests;<br>• Signature(s) with the name(s) of the reporter(s) and their position(s); |
| CL4.7 | Mechanisms for auditing reports and processes for feedback and remedial actions; |
| CL4.8 | Access to a second opinion, where appropriate; |
| CL4.9 | Deviations from the reporting requirements are justified, documented and communicated to referrers. |

| **CL5 The healthcare provider must manage the release of reports**<br>System(s) must ensure, where applicable: | |
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| CL5.1 | Reports are issued by staff who are authorised to do so; |
| CL5.2 | Definition of local agreed reporting timescales/turnaround times for each type of clinical procedure particularly those with critical, urgent or unexpected findings |
| CL5.3 | Locally agreed mechanisms are in place for communication of reports. Communication mechanisms must be secure and monitored; |
| CL5.4 | Records are maintained of all reports including those transmitted by telephone; |
| CL5.5 | Where an interim report is issued it is clearly identified as such and a final report is issued according to locally agreed timescales; |
| CL5.6 | Timely identification of reporting backlogs/delays and associated patient/client risks with escalation to the highest level within the parent organisation; |
| CL5.7 | 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. |

| **CL6 The healthcare provider must manage clinical information systems**<br>System(s) must ensure, where applicable: | |
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| CL6.1 | Confidentiality of patient/client data in compliance with national requirements for data protection; |
| CL6.2 | Validation of any clinical information system(s) for the collection, processing, recording, reporting, storage and retrieval of data; |
| CL6.3 | 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; |
| CL6.4 | Secure transmission of data |
| CL6.5 | Availability of documentation (e.g. user guides), to support day-to day functioning of clinical information system(s); |
| CL6.6 | Protection from unauthorised access, safeguards against tampering and data loss, investigation of non-compliances, and remedial action after non-compliances; |
| CL6.7 | Non-computerised systems should have safeguards against errors of manual recording and transcription; |
| CL6.8 | Information systems are operated in compliance with supplier specifications; |
| CL6.9 | Recording, investigation, correction and reporting of breaches of data integrity or system failures; |
| CL6.10 | Compliance with the requirements of this standard where information system(s) are managed and maintained off-site or sub-contracted; |

## Patient/Client Experience domain

**The purpose of the Patient/Client Experience domain is to ensure that the Service is patient-focused. This is achieved through respect for individuals and their specific requirements, and through effective mechanisms for feedback from service-users. A patient-focussed Service provides information and support that are appropriate for patients, clients and carers taking account of differences in culture, religion, age and other factors.**

| **PE1 The healthcare provider must ensure that care is patient/client focused**<br>System(s) must ensure, where applicable: | |
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| PE1.1. | Equality of access; |
| PE1.2. | Privacy, respect, dignity and compassion regardless of age, gender, religion, culture, language, disability, circumstances or any other factors; |
| PE1.3. | Patient/Client identity is confirmed throughout their contact with the service; |
| PE1.4. | Chaperone provision; |
| PE1.5. | Appropriate clinical management adapting to individual needs; |
| PE1.6. | Counselling for those who become distressed during their contact with the provider, for example following bad news; |
| PE1.7. | Streamlined scheduling of appointments; |
| PE1.8. | Opportunities to provide feedback. |

| **PE2 The healthcare provider must ensure that information is available for users and stakeholders**<br>System(s) must ensure, where applicable: | |
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| PE2.1. | Development of patient/client-friendly information; |
| PE2.2. | Lay involvement in the development and review of information; |
| PE2.3. | Availability of location-specific information including but not limited to:<br>• address;<br>• list of available activities;<br>• opening hours;<br>• contact details;<br>• parking arrangements; |
| PE2.4. | Information is accessible in a range of formats and media and in various languages relevant to the population; |
| PE2.5. | Information addresses specific patient/client care aspects such as:<br>Explanation of the procedure to include preparation, side-effects and or risks;<br>Preventative measures to minimise risk e.g. infection, fasting requirements;<br>How long the appointment is likely to take;<br>Who is performing the examination/treatment/intervention;<br>Access to interpretation and chaperones, if required;<br>On arrival, the length of any known delay to appointments;<br>Aftercare and return to normal activity;<br>Communication of results and awareness of second opinions;<br>Peer/self-help support information; |
| PE2.6. | Communication to users in regards their responsibilities to:<br>• Notify the provider of appointment changes and cancellations;<br>• Providing feedback where expectations are not being met;<br>• Abiding by any behavioural codes of conduct. |

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| **PE3 The healthcare provider must ensure that consent is obtained**<br>Procedure(s) must ensure, where applicable: | |
| PE3.1. | Valid informed consent for the specific clinical activity; |
| PE3.2. | Sufficient information is provided for valid consent, including information about risks; |
| PE3.3. | Appropriate arrangements where the patient/client lacks the capacity to consent, for example, children and young people, vulnerable adults and users with intellectual disabilities; |
| PE3.4. | Consent is documented in the patient/client's record where relevant; |
| PE3.5. | Acknowledgment of the patient/client's right to withhold or withdraw consent; |
| PE3.6. | 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. |

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| **PE4 The healthcare provider must manage feedback and complaints**<br>System(s) must ensure, where applicable: | |
| PE4.1. | Feedback/complaints procedures and materials are available in a variety of formats and media; |
| PE4.2. | Confidentiality for those giving feedback and/or making a complaint; |
| PE4.3. | Regular review of feedback and complaints with collation, analysis, actions and dissemination to all relevant parties; |
| PE4.4. | Involvement of users in the development and review of feedback and complaints materials, where relevant. |

## Safety and Risk Management Domain

**The purpose of the Safety and Risk domain is to ensure that the healthcare provider delivers the highest level of safety for all users. This is achieved through assessment and management of the risks associated with delivery of its services.**

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| **SR1 The healthcare provider must manage all service risks**<br>Systems must ensure, where applicable: | |
| SR1.1. | An overall health and safety and risk management strategy that has been developed in collaboration with the parent organisation; |
| SR1.2. | Risk assessments to identify:<br>• Risks associated with clinical activities e.g. infection control;<br>• Non-clinical risks e.g. COSHH, moving and handling, violence and aggression etc; |
| SR1.3. | Maintenance of a comprehensive and up-to-date risk register to document, escalate and report risks, as necessary; |
| SR1.4. | Tools are in place to record, report, investigate and manage adverse incidents and near misses within specified timescales |
| SR1.5. | Management of patient safety alerts, and appropriate actions; |
| SR1.6. | Regular health and safety training for all staff; |
| SR1.7. | Readily available, well-maintained health and safety and risk-reduction equipment and devices; |

## Facilities and Resources domain

**The purpose of the Facilities, Resources and Workforce domain is to ensure that the healthcare provider's resources are used effectively to provide safe, efficient, comfortable and accessible services. This is achieved through appropriate and adequate facilities (rooms and equipment); motivated and competent staff; and the integration of sound business planning principles.**

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| **FR1 The healthcare provider must manage facilities and environment to support service delivery.**<br>System(s) must ensure, where applicable: | |
| FR1.1. | Sufficient suitable space to deliver all aspects of the service; |
| FR1.2. | Enough suitable facilities for patient/client confidentiality and privacy and dignity; |
| FR1.3. | Appropriate access for users and staff who use wheelchairs, trolleys/beds, have impaired vision, hearing, or have other needs; |
| FR1.4. | Management and monitoring of the condition of facilities and environment including cleaning and maintenance; |
| FR1.5. | Display of relevant signage to notify users, staff and visitors of access and specific hazards. |
| FR1.6. | Facilities and environment are fit for their intended purpose, in particular: |
| FR1.6.1 | **Clinical facilities**<br>• 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;<br>• Appropriate facilities for decontamination of equipment and consumables |
| FR1.6.2 | **Reception, waiting and changing facilities**<br>• 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;<br>• Appropriate waiting areas for children, vulnerable adults and their carers and those waiting on trolleys;<br>• Screened areas for patients/clients dressed in gowns or those waiting on trolleys or in beds;<br>• Secure storage facilities for patient's/clients' valuables; |
| FR1.6.3 | **Staff facilities**<br>• Sufficient and appropriate changing facilities for staff including those with disabilities;<br>• Access to safe storage for personal items;<br>• Access to toilet facilities and drinking water;<br>• Storage of personal protective equipment. |

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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**<br>System(s) must ensure, where applicable: | |
| FR2.1. | Maintenance of an approved list of suppliers; |
| FR2.2. | Availability of purchasing criteria that clearly describe the requirements for the product(s) and or service(s) to be purchased; |
| FR2.3. | 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; |
| FR2.4. | Regular monitoring of all purchases to ensure consistency with specified 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.**<br>System(s) must ensure, where applicable: | |
| FR3.1. | 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; |
| FR3.2. | Verification of the performance of any new batch or shipment before use in clinical procedures; |
| FR3.3. | Maintenance and routine implementation of an inventory control system; |
| FR3.4. | Appropriate instructions for use for all items are readily available; |
| FR3.5. | Investigation and reporting of any adverse incidents or accidents that can be attributed directly to use of an item; |
| FR3.6. | Maintenance of records for each item that contributes to the performance of clinical procedures. |

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| **FR4 The healthcare provider must manage procurement, installation and replacement of all equipment**<br>System(s) must ensure, where applicable: | |
| FR4.1. | 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); |
| FR4.2. | Maintenance of an equipment inventory and rolling replacement programme Including software, upgrades (including diagnostic software) and accessory devices (e.g. couches, chairs etc); |
| FR4.3. | Regular review of equipment budget, at least annually, and where appropriate managed in conjunction with the parent organisation; |
| FR4.4. | Acceptance testing upon installation and before use; |
| FR4.5. | Maintenance of training and authorisation records for staff to operate specific equipment; |
| FR4.6. | Agreed minimum information is maintained for any equipment that contributes to the performance of clinical activity. The expectation is that records will include:<br>• Identity of the equipment;<br>• Manufacture's name, model and serial number or their unique identification;<br>• Contact information for the supplier or the manufacturer;<br>• Date of receiving and date of entering use within the service; |

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| | • Location of the equipment;<br>• Condition when received (new, used or reconditioned);<br>• Manufacturer's instruction manual;<br>• Confirmation of acceptability for use;<br>• Maintenance carried out and the schedule for preventative maintenance;<br>• Performance records (reports/calibration certificates) that confirms ongoing acceptability for use;<br>• Record of any damage to, malfunctions, modification and or repairs. |

| **FR5 The healthcare provider must calibrate and maintain equipment**<br>System(s) must ensure, where applicable: | |
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| FR5.1. | Use of an authorised/accredited body to conduct calibration; |
| FR5.2. | That calibration and maintenance takes account of conditions of use and manufacturer's instructions; |
| FR5.3. | Traceability between the equipment and the calibrated reference standard; |
| FR5.4. | Verification of the measurement accuracy at defined measurement intervals; |
| FR5.5. | Timely and accurate updating of correction factors as necessary; |
| FR5.6. | Safeguards to prevent adjustments or tampering that might invalidate clinical results; |
| FR5.7. | Reporting of faults and management of equipment breakdowns and repairs, in line with legislation, manufacturer's guidelines and organisational policy; |
| FR5.8. | Mechanisms to communicate health and safety warnings and alerts to staff, which are formally acknowledged, and acted on within specified timescales; |
| FR5.9. | Regular review of electrical safety, emergency stop devices (where relevant); |
| FR5.10. | Regular cleaning and decontamination of all equipment, including ancillary equipment following direct contact with patients/clients; |
| FR5.11. | Maintenance of training and authorisation records for staff who calibrate, clean and decontaminate equipment; |
| FR5.12. | Timely Investigation and reporting of adverse incidents and accidents caused by defective equipment to manufacturers and relevant authorities; |
| FR5.13. | Labelling and removal from service of any equipment found to be defective. |

| **FR6 The healthcare provider must recruit, select and train staff to assure competence**<br>System(s) must ensure, where applicable: | |
|---|---|
| FR6.1. | Recruitment and selection criteria for each staff group in line with professional registration requirements; |
| FR6.2. | Completion of pre-employment checks; |
| FR6.3. | 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; |
| FR6.4. | 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; |
| FR6.5. | Collaboration with education institutions for education and training support to meet current and predicted staffing needs of the service; |

| | |
|---|---|
| FR6.6. | 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; |
| FR6.7. | Regular review of performance and assessment of competence for all staff; |
| FR6.8. | Protected time for staff to engage in continuous professional development activities and to undertake improvement initiatives; |
| FR6.9. | Defined mandatory training is specified, available and completed for all staff; |
| FR6.10. | Systematic monitoring of staff retention and succession planning. |

# Revised IQIPS Standard (mapped to IQIPS v1)

| Leadership and Management | IQIPS v1 2012 |
|---|---|
| LM1. The healthcare provider is or must be part of a legal entity | AY1, AY2 |
| LM2. The healthcare provider must define, document and communicate governance arrangements including leadership, roles, responsibilities and accountabilities | C1 all domains across standard, FR3 |
| LM3. The healthcare provider must operate within its quality policy and monitor performance against measurable quality objectives | FR5, FR6C5, CL1C2 |
| LM4. The healthcare provider must establish, implement, and maintain a quality management system, QMS | Whole standard |
| LM5. The healthcare provider must ensure that documents and records (including clinical records) are controlled | Extra, plus , CL7 |
| LM6. The healthcare provider must establish and review agreements for any outsourcing /subcontracting clinical services | FR6C5 |
| LM7. The healthcare provider must provide competent advisory services | CL1C3, CL3C5, PE1C6, PE4C6 |
| LM8. The healthcare provider must identify, manage, eliminate and prevent non-conformities by taking preventative and corrective actions | Extra plus SA1C6,SA2C7,SA3C5, SA4C4,SA5C7,CL6C5, |
| LM9. The healthcare provider must evaluate and audit the effectiveness of their QMS including clinical activities | CL8 |
| LM10. The healthcare provider must manage internal and external major incidents | Extra plus SA5C3,C7, CL6C3,C5 |
| **Clinical** | |
| CL1. The healthcare provider must define and deliver its services from referral to discharge or further management | CL1C2,C3, , FR5C2 |
| CL2. The healthcare provider must manage referrals and prepare patients/clients for clinical procedure(s) | CL1C4,C5,C6, CL5C4, PE4C5 |
| CL3. The healthcare provider must assure the technical quality of clinical procedures | CL2C2,C3,C4,CL4C3,C4,C5, PE4C5, FR2C3, FR4C3, CL3C5 |
| CL4. The healthcare provider must assure the clinical and technical quality of records, interpretations and reports | CL3 |
| CL5. The healthcare provider must manage the release of reports | CL1C7, CL3C5,C6,CL7C4, PE1C5 |
| CL6. The healthcare provider must manage clinical information systems | CL7 |

| Patient/Client Experience | |
|---|---|
| PE1. The healthcare provider must ensure that care is patient/client focussed | PE4,PE2 |
| PE2. The healthcare provider must ensure that information is available for users and stakeholders | PE1, CL9C6(Aud) |
| PE3. The healthcare provider must ensure that consent is obtained | PE3, CL6C4 |
| PE4. The healthcare provider must manage feedback and complaints | PE5, FR7 |
| **Safety and Risk Management** | |
| SR1. The healthcare provider must manage all service risks | SA1, SA2, SA3, SA4, SA5, ,CL4C2,CL5C3, CL6,CL9(Aud/Neuro/Uro/RS/Vas) |
| **Facilities and Resource** | |
| FR1. The healthcare provider must manage facilities and environment to support service delivery | FR1, PE2C3,C4, SA5C6 |
| FR2 The healthcare provider must have systems in place for the selection of external services and suppliers for equipment, reagents, gases, drugs (includes contrast media), radioactive medicinal products and consumables | FR2C2, CL5C2 |
| FR3. The healthcare provider must receive, store and manage equipment, reagents, gases, drugs (includes contrast media), radioactive medicinal products and consumables | FR2C5, CL5C6, CL6C3,SA2C3, SA5C6, CL9C6(Aud) |
| FR4. The healthcare provider must manage procurement, installation and replacement of all equipment | SA2C4, SA3C3, FR2C2,C3,C4,C5,C6,C7, CL9C2(A/N/U), |
| FR5. The healthcare provider must calibrate and maintain equipment | SA5C5, FR2C3,C5,C6,C7, CL6C3, SA2C6, SA1C5 |
| FR6. The healthcare provider must recruit, select and train staff to assure competence | SA5C4, FR3C2, C3,C4,C5,C6,C7,PE2C2 FR4C2,C3,C4,C5,C6,C7,C8, FR5C4,C5,C6, FR6C2,C3,C4,C6 |