FR 3 – The service implements and monitors systems to install and maintain equipment to deliver the service.

a. Central to effective delivery of the service is the appropriate installation and management of equipment and consumables for all aspects of the service. Policies and protocols for this purpose should be grounded in current best practice and reflect statutory requirements and the guidelines and instructions of the parent organisation. Staff should be aware of policies and guidelines and know how to access them.

b. All equipment (both ionising and non-ionising) should be identified on an inventory or asset register with: date of installation; type of equipment; expected working life; capital depreciation rate; and replacement value.

c. Policies and processes should be in place to assure the: installation, calibration, operation, quality assurance, maintenance, and replacement of all types of equipment used for imaging and interventional radiology purposes, including that used in the acquisition of diagnostic images through RNI (see also standard statements CL2, CL3 and SA1-SA4). Formal acceptance tests as required by legislation and the manufacturer must be performed before equipment is put into service. Equipment use and operation should conform to manufacturers' guidelines and national legislation.

d. All equipment should be subject to regular performance checks with a combination of in-house checks and in-depth checks undertaken by a suitably qualified individual, in accordance with current legislation and guidance. Certified expert specialists such as a Radiation Protection Advisor (RPA), MR Safety expert (MRSE) or Laser Protection Adviser (LPA) must be involved as required. There should be a system of work in place for a clear handover of equipment after service, maintenance or repair before it is placed back into service use. A quality assurance (QA) programme for all imaging equipment should be in place. This might include criteria of acceptable performance for both new and older equipment and the adoption of suspension levels for equipment using ionising radiation. Special consideration should be given to QA programmes for equipment which is used for children or procedures likely to give high radiation doses to the patient, such as fluoroscopy used for interventional cases and CT.

e. All equipment, including ancillary equipment, should be well maintained, in good working condition and clean. Equipment should be maintained and repaired under formal service agreements which should be reviewed regularly for effectiveness and value for money. Maintenance records and registers should be held and kept up to date.

f. Ancillary equipment used in MRI examination rooms should be certified and clearly labelled in accordance with recognised labelling systems as being MR-conditional or MR-safe, and staff should have a clear understanding of the difference. Foam pads should be provided to ensure the patient is separated from cables and the bore to protect from burns.

g. Protective equipment, such as shields, lead glasses and lead rubber aprons should be available, clean, maintained to agreed standards, checked regularly and replaced when necessary. A variety of shields should be available for patients and staff, including shields of sizes appropriate for children, as relevant.

h. IT equipment and software used in the service such as IT equipment, Radiology Information Systems (RIS) and PACS monitors should be included in QA and maintenance programmes.

i. A clear system should be in place for reporting faults and managing equipment breakdowns and repairs, in line with legislation and organisational policy. Robust processes should be in place to ensure that safety warnings and alerts are circulated to staff, formally acknowledged, and acted on within specified timescales.

References

The Royal College of Radiologists. *Picture archiving and communication systems (PACS) and guidelines on diagnostic display devices, Second edition.* BFCR (12)16 London: The Royal College of Radiologists, 2012. https://www.rcr.ac.uk/picture-archiving-and-communication-systems-pacs-and-guidelines-diagnostic-display-devices-second

The Royal College of Radiologists. *Picture archiving and communication systems (PACS) and quality assurance, Second edition***.** BFCR (12)15 London: The Royal College of Radiologists, 2012. https://www.rcr.ac.uk/picture-archiving-and-communication-systems-pacs-and-quality-assurance-second-edition

The Royal College of Radiologists. *Guidelines and standards for implementation of new PACS/ RIS solutions in the UK.* BFCR (11)4 London: The Royal College of Radiologists, 2011. https://www.rcr.ac.uk/guidelines-and-standards-implementation-new-pacsris-solutions-uk

Institute of Physics and Engineering in Medicine. *Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems Report 91.* London: Institute of Physics and Engineering in Medicine, 2005. https://www.ipem.ac.uk/ScientificJournalsPublications/IPEMReportSeries/AvailablePublications.aspx (purchase)

Medicines and Healthcare Products Regulatory Agency. *Managing Medical Devices: guidance for healthcare and social services organisations*. MHRA, 2015. https://www.gov.uk/government/publications/managing-medical-devices

Medicines and Healthcare Products Regulatory Agency. *Devices in Practice: checklists for using medical devices.* London: MHRA, 2014. https://www.gov.uk/government/publications/devices-in-practice-checklists-for-using-medical-devices

Medicines and Healthcare Products Regulatory Agency. *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use* London: MHRA, 2014. https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use

Health and Safety Executive. *Equipment used in connection with medical exposure: Guidance Note PM77* (Third edition), 2006.

http://www.hse.gov.uk/pubns/guidance/pm77.pdf

Department of Health and Social Care. *Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017* June 2018
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/720282/guidance-to-the-ionising-radiation-medical-exposure-regulations-2017.pdf

NHS England. *Monitor's Strategy 2014-17: helping to redesign healthcare provision in England*. London: Monitor, 2014
https://www.gov.uk/government/publications/monitors-strategy-for-2014-to-2017

National Audit Office (NAO) Report, 2011. *Managing high value capital equipment in the NHS in England***.** http://www.nao.org.uk/wp-content/uploads/2011/03/1011822.pdf

Reporting Adverse Incidents:
There is a different way to report a device dependent on the UK country involved.

England: *Report a problem with a medicine or medical device.*
https://www.gov.uk/report-problem-medicine-medical-device

Wales: M*edical Devices-Reporting Adverse Incidents.*
http://www.wales.nhs.uk/sites3/page.cfm?orgid=465&pid=56203

Scotland: *How to report an adverse incident.* http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric-1/adverse-incident-reporting/

Northern Ireland: *NIAIC Reporting an Adverse Incident* https://www.health-ni.gov.uk/articles/reporting-adverse-incident *(accessed July 2018)*

Legislation

The Ionising Radiation (Medical Exposure) Regulations 2017 SI2017 No1322
http://www.legislation.gov.uk/uksi/2017/1322/pdfs/uksi_20171322_en.pdf

The Ionising Radiations Regulations 2017 SI2017 No 1075
http://www.legislation.gov.uk/uksi/2017/1075/pdfs/uksi_20171075_en.pdf

The Ionising Radiation (Medical Exposure) Amendment Regulations 2018 SI2018 No 121
http://www.legislation.gov.uk/uksi/2018/121/pdfs/uksi_20180121_en.pdf

The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 SI 2018 No17
http://www.legislation.gov.uk/nisr/2018/17/pdfs/nisr_20180017_en.pdf

The Ionising Radiations Regulations (Northern Ireland) 2017 SI2017 No 229
http://www.legislation.gov.uk/nisr/2017/229/pdfs/nisr_20170229_en.pdf

The Control of Electromagnetic Fields at Work Regulations 2016 SI2016 No. 588
http://www.legislation.gov.uk/uksi/2016/588/pdfs/uksi_20160588_en.pdf

The Control of Artificial Optical Radiation at Work Regulations 2010 SI2010 No. 1140
http://www.legislation.gov.uk/uksi/2010/1140/regulation/5/made
The Pressure Systems Safety Regulations 2000. www.opsi.gov.uk/si/si2000/20000128.htm

Public Services (Social Value) Act 2012.
http://www.legislation.gov.uk/ukpga/2012/3/enacted

Websites

Medicines and Healthcare Products Regulatory Agency. www.mhra.gov.uk/index.htm

The Colleges will aim to update the reference list regularly to ensure that the information provided is as current as possible. Please note these links refer to external organisations and, as such, the Colleges are not responsible for the content or maintenance of these external sites.