LM2 – Quality Management System.

a. The organisation should ensure effective functioning and continuous improvement of the Service (activities and processes) provided by having an appropriate quality management system that integrates all agreed processes and regular monitoring of effectiveness, whether at its permanent facilities or when using mobile units or outsourced services. The quality management system should be under the management of a named person and regularly reviewed to ensure it is effective and appropriate for the Service.

b. Service management should establish quality objectives, which through quality indicators, are measurable and consistent with the quality policy. These objectives should be communicated, understood, implemented and regularly reviewed. The communication strategy should include external as well as internal communications.

c. The quality management system must be designed and maintained to ensure that all necessary service documentation is accessible to personnel across all service delivery locations and that all technical and quality records are available for review by Service management.

d. Service management should assure itself of the effective functioning and continuous improvement of the Service by reviewing the quality management system at least annually. Where a service is required to follow the document management system of a parent organisation, the service must show that the parent organisation's system is implemented within the service.

e. A robust system should be in place to ensure that staff use only the latest and current versions of documents such as policies, procedures and report forms. The system should ensure that all documents are reviewed regularly and systematically and that all documents originating within the service and supporting the operation of the service are approved, authorised and current to avoid inadvertent use of any obsolete documents.

f. Medico-legal and research examinations and procedures raise particular issues. The service should have written published policies and processes to manage all such examinations and procedures, including robust policies and processes for the vetting and justification of requests.

g. The Service should have a documented procedure for the identification and management of non-conformities in every aspect of the quality management system. Records of nonconformities and corrective actions should be reviewed periodically by service management to detect trends, take preventative actions and ensure findings support budgeting and financial planning

h. Minimising clinical risk and managing incidents, errors and near misses arising from clinical activity are essential to the provision of a safe service. Effective risk management and error reporting systems are needed. Robust systems should be in place to ensure that all incidents, errors and near misses, including clinical incidents such as missed diagnoses, wrongly prescribed drugs or inappropriate treatment, as well as those which threaten the health and safety of patients, staff or others (including instances of violent or aggressive behaviour from patients or staff), are reported and recorded. Procedures should be in place to assess the degree of damage.

i. There should be written protocols and procedures to ensure that incidents and errors, including those resulting in overexposure to ionising radiation, are reported and investigated. The service should determine what represents a critical incident, though guidance suggests

that errors leading to mismanagement with resultant significant morbidity or mortality should be considered to constitute a critical incident. All clinical incidents should be recorded within the service and reported to the bodies within the organisation responsible for clinical governance. Procedures must be in place to assess the degree of harm. Incidents and near-misses must be investigated according to the guidance given by the relevant body, seeking expert advice as necessary such as from a Radiation Protection Adviser, and in accordance with organisational policy. Relevant bodies must be informed in compliance with legislation. Where appropriate incidents should be reported to the relevant regulatory body and referred to the relevant equipment manufacturer. Occupational health support should be offered to staff where necessary.

j. Robust systems should be in place to ensure that all incidents of overexposure, errors and near misses are reported and recorded. Incident forms must be readily available to staff who should be familiar with the process of use and completion. Any incident or error which may affect patient care must be communicated without delay to the clinical team, the patient or carer, and staff or others who may be affected. All incidents should be investigated, with findings analysed and disseminated to staff. Resultant changes in practice must be communicated to staff.

k. Outcomes and performance data for interventional procedures should be collected systematically and fully recorded locally. Data should be reported to national registries where these exist. Where complications occur, they should be recorded, categorised and analysed, with documented action taken to prevent recurrence of avoidable complications. Clinical outcomes and complications should be reviewed at formal meetings at least four times a year, with findings communicated to staff.

l. Robust systems should be in place to determine, assess and review regularly all risks in the service, clinical or operational, and to manage them actively. These systems should also identify near misses. For clinical risks, clinical review meetings such as Discrepancy or Morbidity and Mortality meetings can contribute to the process by affording a formal review of missed diagnoses, discrepancies of interpretation and reporting errors which, although potentially significant, have not resulted in patient harm. Services should develop mechanisms to respond to near misses by devising advice and processes to minimise the chance of recurrence.

m. There should be a comprehensive index of documents such as risk assessments available to staff. For all incident reporting, there should be an indication that trends are considered, analysed and acted on appropriately together with learning outcomes.

n. The Service and clinical imaging practice should be regularly audited and reviewed, in line with the guidance and audit tools developed by professional bodies such as the Royal College of Radiologists, the Society and College of Radiographers and the British Nuclear Medicine Society, and in consultation with service staff and clinical groups and specialties which make use of the service. The results of audit, discussion of current and emerging practice and feedback on the service should be disseminated to all staff involved in the service and others who use the service, and used to inform service development.

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