CareQuality Commission | The Regulation and Quality Improvement Authority | Healthcare Improvement Scotland | Arolygiaeth Gofal Iechyd Cymru / Healthcare Inspectorate Wales

IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS REGULATORY POSITION STATEMENT ON CLINICAL EVALUATION CEREBRAL PERFUSION CT

In May 2021, NHS England published its National Stroke Service Model and introduced the national optimal stroke imaging pathway (NOSIP).

In response to this, The Royal College of Radiologists (RCR) issued guidance in July 2024 – 'RCR statement on cerebral perfusion CT requesting and reporting for Radiology departments'. The relevant Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) enforcing authorities welcome this guidance to ensure safe and timely diagnosis and treatment access. This regulatory position statement has been developed in response to a number of enquires related to this imaging pathway.

For those services establishing the NOSIP, the IR(ME)R enforcing authorities would like to highlight regulatory considerations across the entire patient imaging pathway:

1. Responsibility for safe implementation of an imaging pathway lies with the IR(ME)R employer. The employer will require assurances that all elements of the imaging pathway have been considered.
2. Responsibilities of all duty holders should be clearly defined in employer's procedures, this includes the IR(ME)R referrer, IR(ME)R Practitioner and IR(ME)R operators. All individual duty holders must understand their responsibilities.
3. The IR(ME)R practitioners' primary role is the justification of individual exposures, to consider the potential detriment of the exposure against the potential net benefit to the individual. The employer's procedures should describe how the process for justification of referrals on this imaging pathway will be completed and evidenced. The employer must ensure any requirements for appropriate entitlement to authorise under authorisation guidelines is robust.
4. Entitled operators responsible for the practical aspects of the exposure should be appropriately trained and be supported by detailed clinical protocols, which they are required to follow.
5. In accordance with IR(ME)R, clinical evaluation means interpretation of the information resulting from an exposure including the outcome and implications.
6. If the employer confirms that the referring clinician is the most suitable individual to complete clinical evaluation of the exposure, these individuals must be entitled as an operator by an appropriate person and this should be detailed within employer's procedures (Schedule 2(b)).
7. Entitlement should be accompanied by an appropriately detailed scope of practice, with consideration of the initial training and ongoing training requirements to demonstrate competence. Special consideration may be required outside of normal working hours and any outsourced provision under co-operation between employers.
8. Any training on software used to support decision making as part of clinical evaluation will need to be recorded to demonstrate competency prior to entitlement. This would be in addition to the required training and competency for clinical evaluation.
9. The employer's procedure Schedule 2(j) should indicate where the clinical evaluation of the CT perfusion is recorded; clearly define the key criteria that make up the clinical evaluation; describe arrangements and timelines for any CT perfusion radiology reporting. Where AI is used to assist the rapid clinical evaluation of the CT perfusion scan, the employer's procedure should clearly highlight how this contributes to the

clinical evaluation and whether subsequent review of these types of exposures is required within a radiology report.

10. Any requirements for contemporaneous reporting to be accessible if the patient moves between services during their care pathway.
11. It is recognised that the acute stroke pathway may include other examinations using ionising radiation and the clinical evaluation requirements of these examinations should also be considered and detailed appropriately in employer's procedures.
12. IR(ME)R requires that software used to directly assist clinical evaluation must be held within a software inventory, acceptable performance criteria set and any measure put in place to improve inadequate or defective equipment.
13. CE certified Artificial Intelligence (AI) stroke software may be used within its intended purpose for acute ischaemic stroke care pathways. The employer and operators should be aware of the limitations of AI software, any changes due to major updates and other factors which may impact the software performance.
14. Employers are reminded that AI is an assistive decision tool and must consider how the operators responsible for clinical evaluation access the complete study and all images associated with the exposure to evaluate the AI software decision. In accordance with the regulations, operators should not solely rely upon AI for image interpretation.