The Radiographic Assistant Practitioner's role in Quality Control of Radiological Equipment

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Background

Assistant practitioners (APs) perform defined protocol-driven imaging examinations, working under the supervision of a Health and Care Professions Council (HCPC) registered radiographer. The supervision model will vary depending on the AP's area of work, their competence, and experience. The roles and responsibilities of the AP are clarified in the *CoR Education and Career Framework*[1] and in the SoR and Health Education England publication *Developing career pathways for diagnostic imaging support worker roles: guidance on roles and responsibilities*[2].

This update considers the impact of The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024[3] which came into effect on 1 October 2024 and reflects practice changes since 2019.

The Ionising Radiation (Medical Exposure) Regulations 2017[4] and The Ionising Radiation (Medical Exposure) (Northern Ireland) Regulations 2018[5] came into force on 6 February 2018 in accordance with the European Council Directive 2013/59/Euratom[6]. Both Great Britain and Northern Ireland regulations have the same requirements for quality control, therefore throughout this document these regulations will be jointly referred to as IR(ME)R. The Society of Radiographers (SoR) and the College of Radiographers (CoR) considers this a timely opportunity for employers (and radiography departments) to re-evaluate governance processes around the regulatory framework.

The SoR and CoR receive requests from the UK diagnostic radiography community pertaining to the scope of practice of the qualified AP. One such request is the need for guidance on the AP's role in quality control (QC) of radiological equipment. The SoR and CoR wishes to gratefully acknowledge the support and advice for the original 2016 guidance which was developed in collaboration with the Institute of Physics and Engineering in Medicine (IPEM) with support and advice from their Diagnostic Radiology Special Interest Group.

Introduction

QC is one component of a quality assurance programme. IR(ME)R Regulation 15 requires an employer who has control of equipment to implement and maintain a quality assurance programme, including the procedures and actions required to ensure equipment is working safely and to identify whether it is working at the desired performance level. Where radioactive substances are to be administered, QC measures should ensure the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime (Regulation 2 (g)). For the purpose of this guidance, the following interpretations are provided from IR(ME)R Regulation 2[3–5]:

"quality assurance" means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with generally applicable standards and quality control is a part of quality assurance;

"quality control" means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;

IR(ME)R requires the employer to ensure any diagnostic x-ray equipment is capable of restricting exposures in line with the 'as low as reasonably practicable' (ALARP) principle (Regulation 12: Optimisation). Regulation 15 requires employers to incorporate written procedures for the routine inspection and testing of equipment. As a minimum these should include:

- Adequate equipment testing before it is first put into clinical use
- Adequate equipment testing at appropriate intervals and after any major maintenance
- Appropriate measurements at suitable intervals to assess representative doses to persons undergoing medical exposures
- Adequate testing of devices capable of automatically controlling the radiation dose
- Adequate testing of devices used to indicate dose delivered to the individual undergoing the exposure
- Equipment performance criteria and the measures in place to identify defective equipment or poorly performing equipment, and any corrective action to be taken where required

The employer must also take all reasonable steps to prevent failure of equipment that could lead to greater than intended exposures of ionising radiation and to limit the consequences of such failure (Regulation 8). The amendments require that employers also take appropriate action in relation to systems for recording and analysing events involving, or potentially involving, accidental or unintended exposures proportionate to the radiological risk posed by the practice, and take any appropriate action in relation to such analyses (Regulation 8 (3) (a) and (b)).

Furthermore, each written procedure should:

- specify the frequency of testing
- contain a written protocol detailing how to perform the testing
- contain appropriate action level(s) for each test result
- identify the remedial actions required in the event that the action level(s) are exceeded
- make clear who has responsibility for carrying out the testing
- make clear who has responsibility for acting on adverse findings

Regulation 15 (3) (c) of IR(ME)R and Regulation 33 (3) of The Ionising Radiations Regulations 2017 (IRR 2017)[7] require the employer to undertake adequate performance testing at regular intervals and following any maintenance procedure, to ensure that the design, construction, installation and maintenance of the equipment enables restriction, so far as is reasonably practicable, of the exposure to ionising radiation of any person who is undergoing a medical exposure. The employer should consult the appointed Medical Physics Expert (MPE) about the QC procedure(s) and refer to the many guidance documents containing recommended standards for the QC of equipment[8–10]. Under IR(ME)R, it is for the employer to decide who undertakes the testing — this can be the employer's own staff or contractors.

Anyone performing QC of radiological equipment is regarded as an IR(ME)R operator. When QC is undertaken, it is important that relevant aspects of IR(ME)R are adhered to — this includes compliance with the local rules and arrangements for personal monitoring.

Due to familiarity with the equipment and knowledge of the department in which they work, APs are well placed to undertake equipment QC. However, before APs can undertake this operator duty, IR(ME)R requires the following:

- that the AP is adequately trained as an IR(ME)R operator (according to Schedule 3), with provision made for ongoing training and continual professional development relevant to their scope of practice.
- that the AP is entitled, in accordance with the employer's procedures, to act as an IR(ME)R operator with a scope of practice that includes the QC tests they perform and the equipment on which they perform these tests.

- that there is a written protocol covering the practical aspects of the QC that is performed.
- that the AP, in their capacity as an IR(ME)R operator, follows the employer's procedures.

Entitlement under IR(ME)R

Entitlement of APs to perform equipment QC should not be considered until all other steps in this guidance have been completed. The entitlement should allow the AP to be identified, whether by name or designation. It should also include their defined scope of practice, including the tests they are permitted to undertake and the equipment on which they are permitted to perform these tests. The date on which they were entitled (or dates if it varies with equipment or test) and a schedule for a review of their training records and entitlement should also be included. Any consideration for entitlement should be supported by a clear line of accountability and a schedule for review of training records and entitlement. An AP undertaking QC tests must understand the relevance of the tests and measurements they record, know how and when to seek advice, and how to escalate out-of-tolerance results. Since the employer will have entitled radiographers as IR(ME)R operators, a good first step will be to use the same entitlement documentation and amend it to suit APs.

Written procedure

A detailed protocol is required for each test that is being undertaken. The protocol should include sufficient information as to allow the test set-up and technique to be accurately reproduced. It will, therefore, require detailed information on the following for each test being undertaken:

- the test equipment to be used
- the positioning of the x-ray equipment and test equipment
- the exposure factors
- the result to be recorded following the test, including where to record it
- the action level(s)
- the remedial actions required in the event that the action level(s) are exceeded
- if the remedial action is to escalate it to senior staff, their contact details should be included
- if the remedial action is to withdraw the equipment from use, details on how that is to be communicated to all potential users should be included

- where to record details on the action(s) taken in the event that action level(s) are exceeded

The choice of action levels and remedial actions is a local decision that should be taken with expert advice. Usually this will have come from the MPE. In compliance with IR(ME)R, all procedures require periodic review. Therefore the protocol should be subject to regular review (generally annually, though to be decided locally). It should also be reviewed when the equipment is replaced, updated or modified in any significant way, or if there are concerns raised about the equipment's performance. In all cases the protocol should be updated as necessary.

Training

Adequate training involves both theoretical and practical elements. The theoretical elements must be cross-referenced against Schedule 3 of IR(ME)R to ensure adequate training as an IR(ME)R operator; much of this will have been covered in the AP's pre-qualification education as well as any further training to date. An understanding of the written procedure for QC testing of all equipment that is to be included in the AP's scope of practice is essential. Practical elements will involve meeting pre-determined competencies. The means of demonstrating and assessing competence should be identified and documented in advance of the AP's training. Competencies must include the correct recording and interpretation of the results with respect to the action level(s) and a demonstration of what to do when action level(s) are exceeded.

When the AP has covered the theoretical and practical components they may then be signed off as competent by a suitably trained IR(ME)R operator and entitled by the Employer. Provision must be made for ongoing training to maintain competence. Competence and ongoing training should be recorded in the AP's training records and signed and dated by the supervisor.

Following the employer's procedures

At this stage, an AP might be ready to be entitled by the employer or to have their scope of practice increased on an existing entitlement. As an IR(ME)R operator, they are legally responsible for the practical actions they undertake and must follow the employer's procedures at all times. The AP should be made aware of this prior to their being entitled by the employer and, as with other staff, they should know the limitations of their practice. The SoR and CoR expect that any AP in SoR membership maintains their place on the CoR Voluntary Register for Accredited APs[11]. Accredited APs in SoR membership are covered by the Professional Indemnity Insurance for all IR(ME)R duties providing there is evidence of adequate training, entitlement and compliance with the employer's procedures[12].

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