



IPEM Recommendations for Clinical Scientist Support for PET-CT : Support Required for Fixed Site Performing FDG Oncology Studies

http://www.ipem.org.uk/ipem_public/article.asp?id=&did=&aid=3567&st=pct&oid=

1 INTRODUCTION

With the rapid expansion of clinical PET-CT in the UK there is an urgent need for guidance on the (state-registered) clinical scientist (CS) support required to deliver the service safely, effectively, in compliance with all relevant regulations, and to the necessary standards set by professional bodies, including 'Standards for delivering a PET service in the UK' (Report of the Intercollegiate Standing Committee on Nuclear Medicine, in 'PET-CT in the UK', RCR 2005).

These guidelines define the recommended minimum level of clinical scientist support required specifically for PET-CT based on a fixed site and performing FDG oncology studies only. A 'fixed site' is a unit where the scanner is permanently installed in a building, and does not include permanently sited mobile units. Additional and specialist scientific and engineering support will be needed where units are operating their own cyclotrons and/or undertaking research. This may be provided in partnership with manufacturers and academic units.

This document has been prepared by a group of clinical scientists from across the UK with extensive experience in PET-CT.

2 OVERVIEW OF CLINICAL SCIENTIST ROLES

The roles of clinical scientists in supporting the operation of a PET-CT unit at an established fixed site are given below. Where the role could be performed by someone other than a state-registered clinical scientist, this is stated. These roles are required for both PET and CT aspects of the operation. The degree of support will depend to a limited extent on the amount of involvement of manufacturer's engineering staff and applications staff and the level of IT/PACS support offered by host site, employer and/or manufacturer's IT staff. It should be noted, however, that the involvement of the Medical Physics Expert (MPE), or a state-registered clinical scientist acting under the supervision of the MPE, is required even if there is a high level of external support. This is to ensure that the service is provided in compliance with IRR 1999, IR(ME)R 2000 and ARSAC guidelines, and any additional requirements of the local NHS Trust Radiation Safety Policy.

Generic roles required for ongoing support of a unit that is already up and running

- Medical Physics Expert (MPE) as defined in IR(ME)R 2000 regulations
- Radiation Protection Advisor (RPA)
- Radiation protection supervisor (RPS) (This role could be performed by a radiographer/technologist)
- Scientific and technical support (Some, but not all, aspects of this role could be performed by manufacturers' service engineers)

Significant additional support is required for a limited period for

- Initial commissioning of new units and equipment, including PET-CT scanners
- Introduction and initial support of new protocols, procedures, research studies, tracers or radionuclides to existing units

The amount of ongoing support required will be greater when

- There is more than one scanner at the site
- Any research studies are performed including multicentre trials with standard established protocols.
- Complex/specialised procedures are performed (eg radiotherapy planning, quantification, use of tracers other than FDG, use of CT contrast)

If the different roles above are the responsibilities of different organisations then it is essential that there is an Operational Policy for the unit, which together with other Policies (e.g. Radiation Safety Policy, IRMER Policy) and Service Level Agreements clearly define the responsibilities of individual post-holders and the lines of responsibility for all staff.

3 ACTIVITIES CONSTITUTING THE MINIMUM CORE-LEVEL SUPPORT REQUIREMENT FOR AN FDG ONCOLOGY SERVICE AT AN UP AND RUNNING FIXED SITE

This is a list of the support activities that would typically be undertaken by a clinical scientist. In practice clinical scientists will also be required to perform activities that are not on this list.

Ongoing Support

- Support for diagnostic procedures - advice and ongoing review for existing procedures and protocols, Support of physicians and implementation of their requirements.
- Quality Assurance for PET, CT and PET-CT - ongoing performance monitoring and review of all QA programmes, policies, procedures and SOPs, ongoing support to mechanisms for clinical governance, audit and regulatory compliance
- Radiation Protection - support RPS in maintaining systems/infrastructure for radiation protection, ensuring compliance with regulations, addressing immediate and ongoing radiation safety issues and incidents, individualised advice (including dosimetry) for non-standard cases
- Equipment – ongoing monitoring and review of equipment QA programmes; especially PET-CT scanners, action on results of individual QC procedures as required. Trend analysis, and repetition of commissioning tests if appropriate to troubleshoot problems. Support for ongoing schedule of PET detector calibration procedures, required as defined by MPE's recommendation with regard to clinical use of system
- Equipment - ongoing applications support for PET-CT scanner and associated workstations (may be provided in part by manufacturer's applications specialist)
- Equipment - first line troubleshooting, especially for PET-CT scanner(s) – e.g. diagnosis and resolution of artefacts, investigation of problems with scanner/computing/data transfer
- Equipment - liaise with manufacturer on complex fault diagnosis and resolution, especially for PET-CT scanner(s) (could be performed by radiographer/technologist in some cases)
- Equipment - preventative maintenance & fault repair (usually carried out by service engineer)
- Equipment – installation and commissioning of (non-major) new equipment and software, and upgrades
- Training - ongoing education and training of staff including radiographic and technical staff (parts of this role could be performed by manufacturer's applications specialist). Staff will need to undertake significant preliminary and on-going training to remain effective in this relatively new and fast changing technology.
- IT - ongoing support for software, systems and infrastructure (some, but not all, aspects of this may be performed by site's/provider's IT support service and/or manufacturers). Maintenance of archiving and PACS where appropriate. Ongoing backup and system security (anti-virus etc) support. First line support/troubleshooting
- Setting up, quality control and data analysis for basic quantification using SUVs.
- EA, HSE, HCC and local site visits/inspections and associated preparation, follow up etc.
- Consequences of changes to legislation and guidance (eg need to convert RSA93 Best Practicable Means documents to waste strategy review/Best Available Technology documents - demonstrating waste minimisation etc)

Other requirements

- Clinical scientists must be provided with adequate opportunities for training, CPD and research activities in order to maintain their status of state-registered clinical scientist with the Health Professions Council (~10% FTE pro rata)
- Adequate provision must be made to maintain the required CS cover during periods of annual leave/sickness etc

4 ACTIVITIES REQUIRING SUPPORT ABOVE THE MINIMUM LEVEL

Additional FTE clinical scientist support will be required for the following. The level of support required will vary greatly with local circumstances. New developments will usually require full-time or increased CS support for a limited period and then increased support for a subsequent 'running in' period – eg for a period of several months following the installation of a new scanner.

Commissioning of the unit (limited period only)

- Radiation Protection – specification of shielding and facilities for dose limitation
- Environmental impact assessments and security review etc
- Equipment - installation, acceptance tests and commissioning of all equipment, including PET-CT scanner(s), critical exam
- Quality Assurance – establish QA programmes for all equipment, and definition of the required schedule of quality control and calibration procedures for each
- Regulatory Compliance - compliant standard operating procedures/policies for all relevant regulations (IRMER 2000, IRR 1999, RSA 93, MARS 1978, Health & Safety at Work Act 1974, Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2007, Data Protection Act 1998, Medicines Act 1968)
- Support for diagnostic procedures - specification of procedures and protocols required; including protocols for image data acquisition, reconstruction and processing, display and data transfer
- Training - education and training of staff including radiographic and technical staff (parts of this role could be performed by manufacturer's applications specialist)
- IT – installation and commissioning of IT systems; networks, workstations and associated hardware, data transfer pathways/protocols (may be performed by site's/provider's IT support service and/or manufacturers)
- Consequences of civil modification (change in use of rooms, move a wall etc)

Setting up new protocols/services (limited period only)

- Protocols and procedures for further applications – e.g. in cardiology and neuropsychiatry
- Procedures / protocols / approvals for non-standard tracers
- Procedures and supporting QC / calibrations for semi-quantitative and quantitative methods
- Procedures involving diagnostic CT protocols, +/- use of CT contrast agents and quantification
- Installation and commissioning of new equipment and software, and upgrades to same
- Protocols / data-handling / QC / clinical governance / regulatory approvals for clinical research and multicentre trials
- Use of PET in radiotherapy planning
- Additional scanners
- Complex research studies and development of new applications

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5 RECOMMENDATIONS

A minimum of 1.0 FTE clinical scientist is required to support an up and running FDG oncology service at a fixed site. This figure includes the ongoing support roles listed in section 2 above and all the activities listed in section 3 above. In practice different roles are likely to be performed by different individuals.

Note that the above recommendation is a *minimum* requirement and relates to support of an established service only. It does *not include* the clinical scientist input required for installation and commissioning of new services/equipment or significant service/research developments.

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