1 Regional Medical Physics Service support for HSC Imaging Services – Current Context

1.1 Introduction

The Regional Medical Physics Service (RMPS) provides scientific and technical support services, including those for medical imaging, across the HSC Trusts. These services include:

- Medical Physics Expert (MPE) in Diagnostic Radiology and Nuclear Medicine to ensure the optimisation and safety of patient exposures
- Scientific and safety advice for the range of imaging modalities
- Radiation Protection services to assist HSC organisations to meet statutory requirements related to the use of ionising radiations
- Quality assurance services for all ionising radiation and MRI imaging modalities
- Management of the Cyclotron and Regional Radiopharmacy facility used for the production of radiopharmaceuticals for the majority of Nuclear Medicine departments across N. Ireland

The requirement for many of the services provided is set out in statutory legislation [1-6] and guidance [7-11] and Trusts are subject to inspection by relevant enforcing bodies HSE(NI), RQIA, NIEA and MHRA. The extent and resource required to deliver these services is heavily dependent upon a number of factors including

- The size and complexity of the installed user equipment base
- The complexity of diagnostic procedures delivered using the associated equipment and
- The encompassing legislative requirements

1.2 Developments in Imaging equipment and Services in HSC Trusts and impact on RMPS

On-going technological developments in imaging have resulted in an increasing use of imaging equipment in the clinical arena and the development of new imaging techniques.

Table 1 below presents the expansion of the imaging equipment base since 2000. The increase is particularly evident in areas such as CT, digital X-ray imaging and MRI.

Table 1: Trends in Medical Imaging Equipment in HSC Trusts

Equipment	**2000**	**2006**	**2008**	**2010**	**2011**	**2013/ 14**
CR/DR	4	41	72	99	108	178
CT	12	24	28	28	30	37
Image Intensifiers	N/A	N/A	N/A	95	96	98
MRI	2	9	11	11	11	13
Mammography (digital)	16	18	19 (2)	19 (3)	19 (5)	19 (5)
Dental (digital)	N/A	N/A	N/A	N/A	137 (56)	137 (90)
X-ray tube	N/A	N/A	N/A	N/A	235	232
Gamma Camera (SPECT CT)	11 (0)	13 (1)	13 (2)	13 (2)	13 (2)	13 (4)
PET CT	0	1	1	1	1	1

Key points indicated in table 1 include

- The computed radiography/digital radiography and MRI equipment base has increased from a negligible level in 2000 to being in widespread use across HSC in N Ireland
- The number of CT systems has increased by a factor of > 3
- The use of digital imaging has increased substantially and will eventually encompass all modalities including mammography and dental.

As well as an increase in the imaging equipment base technological developments in imaging have resulted in the increased complexity and capability of the systems deployed. An example of this is the increase in complexity is CT scanners; whereas in 2000 all CT scanners were single slice, in 2011 most scanners (28 out of 30) are multi-slice with the most prevalent being 64 slice. Also most of these systems employ advanced features to allow the control and optimisation of exposures such as some form of automatic exposure control for image acquisition and iterative image reconstruction techniques). The expanded features of these systems make the quality control and optimisation of these systems much more complex and time consuming and resource intensive than for previous generations of CT scanners.

The increase in the number of imaging facilities using ionising radiation has also had an impact on the demands for Radiation Protection services. Recent changes in legislation associated with the requirement for Radioactive Waste Advisers has also led to the need for additional resources to develop staff to provide this role.

Although the quality assurance of imaging equipment using ionising radiation is a statutory requirement there is no similar legal requirement applying to non-ionising radiation imaging equipment such as Ultrasound and MRI. However to help ensure safety, quality and clinical effectiveness of these techniques an effective governance process is essential. A number of relevant scientific and professional bodies have identified the need for the implementation of quality assurance programmes and the availability of scientific advice and expertise relating to the safe use of this type of equipment as part of an effective governance process. [12-15].

1.3 RMPS Workforce Plan (2011)

Medical Physics staff fall into two main professional categories

- Clinical Scientists
- Clinical Technologists.

Clinical Scientists undertake a graduate training programme, the Modernising Scientific Careers (MSC) 3 year post-graduate Scientist Training Programme (STP). Following completion of training, successful trainees are eligible for registration as a clinical scientist with the Health and Care Professions Council (HCPC) and undertake a combination of routine and development work during which they gain experience and further training. This can lead to higher specialist and professionally independent roles such as Medical Physics Expert (MPE), Radiation Protection Advisor (RPA) in specialised areas of Medical Physics.

Clinical technologists may enter the professional as (1) graduates and undertake workplace based training or (2) via the MSC initiative which involves a three year undergraduate practitioner training programme (PTP) similar in structure to the STP. Clinical Technologists undertake routine protocol driven work or a combination of routine and more specialist duties

The Regional Medical Physics Service is currently reviewing its Workforce Plan whose objectives include

- to ensure the continuity and future delivery of Medical Physics services to HSC bodies
- to ensure a suitably trained and qualified workforce is enabled to exploit and respond to changes in medical technology for the benefit of the population of N. Ireland

- to ensure the optimum number and skill mix of staff to meet the challenges and deliver medical physics services.

This work identified an increasing gap between the staff resource available to the RMPS and that required to provide and develop the service to meet the increasing demand for imaging services. It was projected that the equipment base and the demand for services would continue to grow throughout and beyond the timeframe covered by the Workforce Plan (2011-16).

An action from the Workforce Plan was to identify, in conjunction with stakeholders, resources to meet the increasing demands on the Service. With the support of the HSC Trusts the Regional Medical Physics Service during 2012 submitted completed Investment Protocol Templates (IPT) to the Health and Social Care Board outlining resources required to address the shortfall and planning for future increasing demand. This was updated with the submission of a Revenue Business Case during 2014.

At present the RMPS is only funded to provide a scientific and quality assurance programme to ultrasound imaging units used in the Breast Screening Programme [16] in Northern Ireland. This only covers a small fraction (8 out of approximately 350 units) of the ultrasound imaging units in the HSC Trusts. Following on from requests for support from HSC Trusts the Workforce Plan also identified the need to develop a scientific support and quality assurance service for all HSC Ultrasound imaging systems. A case for this new service was developed and submitted as an IPT to the HSC Board in 2012 and updated with the submission of a Revenue Business Case during 2014

The Medical Physics services provided to clinical imaging services are included in Service Level Agreements (SLAs) with all the NI HSC Trusts. The previously submitted IPTs are designed to (1) address existing gap between capacity and service demand and (2) put in place improved arrangements to meet projected increasing demand.

2 Optimal Service and Gap Analysis - Development of Medical Physics support to meet the future demands of HSC Imaging Services

2.1 Introduction

An optimal Medical Physics Service is one that can respond proactively to the requirements of the clinical imaging services and delivers efficient and effective services to the required standards. The requirement for many of the services provided is set out in statutory legislation [1-6] and guidance [7-11] and Trusts are subject to inspection by relevant enforcing bodies HSE(NI), RQIA, NIEA and MHRA. Medical Physics services play an important role in assisting Imaging services meet legislative requirements, practice standards and guidelines, and help assure the quality and safety of imaging equipment and procedures.

Clinical imaging services in N. Ireland as part of this review process have emphasised that it is essential that they are underpinned by safeguarding and clinical governance arrangements and that the achievement of ISAS (Imaging Services Accreditation Standard) is an objective to help ensure this. A well resourced and responsive Medical Physics Service will play a key role in ensuring that these objectives are achieved and maintained.

Furthermore forth-coming quality standards such as the Academy for Healthcare Science Improving Clinical Engineering and Physical Sciences Services (iCEPSS) will identify a range of additional standards which Medical Physics services will be expected to comply with.

This section outlines a range of factors that will influence the demands for Medical Physics services and highlights the necessary developments to ensure that Medical Physics Services continue to remain capable of appropriately supporting clinical imaging services. The principal resource required for the delivery of Medical Physics services is specialist scientific and technical staff. The specific details on workforce requirements will be developed through the Workforce Planning stream of the Imaging review and only the main issues affecting the development of the service will be highlighted in this paper.

2.2 Description of the Gap and factors affecting demand for Medical Physics Services

This section outlines factors that will influence future demand for Medical Physics services

2.2.1 Imaging services capacity and the installed equipment base

As outlined in Section 1 there has been a large growth in the number of imaging systems in N. Ireland since 2000 with particularly large changes in MRI and CT and the almost universal introduction of digital radiography which was non-existent at the turn of the millennium. Also there has been the introduction of PET to clinical imaging. The increase in imaging systems is projected to continue in the coming years as the demand for imaging increases (Table 2). In addition the these PET demand continues to exceed capacity and this may lead to an additional PET/CT system. Coupled with the growth in the imaging equipment base there will be on-going technological developments which will increase the capability of imaging systems and lead to the introduction of new imaging techniques. Growth in these areas will increase the demand for Medical Physics Services.

Table 2: Forward projected trends in Medical Imaging Equipment in HSC Trusts

Equipment	**2014/ 15**	**2015/ 16**	**2016 /17***	**2017 /18***	**2018 /19***
CR/DR	218	258	270	270	270
CT	42	48	50	52	54
Image Intensifiers	100	102	104	106	108
MRI	17	19	21	22	23
Mammography (digital)	20 (20)	21 (21)	23 (23)	23 (23)	24 (24)
Dental (digital)	(137)	(137)	(137)	(137)	(137)
X-ray tube	240	240	240	240	240

2.2.2 Legislation and standards

A number of pieces of UK legislation govern the use of radiation in Medical Imaging procedures and are designed to protect patients, staff and members of the public from the effects of ionising radiation. In December 2013 the European Union adopted a revision of the Basic Safety Standards Directive [17]. It is expected that this will be implemented into UK law by early 2018 with a revision and updating of the legislation applicable to ionising radiation.

The exact nature and requirements of any new UK legislation are not known at this time. However the new directive does put a greater emphasis on the role of the Medical Physics Expert (MPE) in ensuring the safe and optimal use of radiation in diagnostic and therapeutic procedures and includes the need for member states to put in place processes for the certification of the MPE.

Imaging techniques such as MRI and Ultrasound do not use ionising radiations and are therefore not subject to the requirements of the Ionising Radiation Regulations. However good governance requires that these imaging systems and techniques should also meet applicable standards [12-15] and that there is sufficient oversight to ensure the optimal and safe use in the clinical environment.

Ultrasound systems are routinely used for patient diagnostic imaging purposes as well as assessment, monitoring and interventional guidance by a wide range of clinical specialities and are often used outside the confines of the Imaging Department. It is estimated that there are between 300 and 400 Ultrasound Imaging devices in use across the HSC.

The need for equipment quality assurance for ultrasound systems has been identified by a number of professional bodies in the field of Medical Ultrasound including the Royal College of Radiologists [14], the UK Association of Sonographers [15], The Society for Vascular Technology [18]. The Institute of Physics and Engineering in Medicine (IPEM) has issued national guidance on the Quality Assurance of Ultrasound equipment [13], which is endorsed by the above professional bodies.

At present there is no systematic quality assurance programme in place for the vast majority of ultrasound imaging devices in clinical use in N. Ireland. This represents a significant gap in the clinical governance and assurance processes for the services that utilise this imaging modality.

2.2.3 Technological developments

Advances in medical imaging technology will continue to significantly change the delivery of modern healthcare. The introduction of novel imaging technologies into clinical use will require sound evaluation of their clinical and cost effectiveness along with systems to ensure their safe and optimal use. Medical Physics will play an important role in ensuring that such technology adoption is safe, optimised and effective. To be able to support these developments the RMPS will require sufficient and suitably trained Clinical Scientists and Clinical Technologists.

2.2.3.1 Patient Dose Management

Other on-going technological developments will improve the efficiency and application of processes. An example of this is the management of the radiation doses to patients undergoing x-ray and CT examinations.

The recording, monitoring and audit of patient radiation doses for x-ray and CT examinations has been a legislative and good practice requirement for some time. This helps ensure that patient doses are not excessive and assists in optimisation of exposures.

Historically, data collection for patient dose audits has been performed by completing forms on paper and/or populating spreadsheets. Data collection consists of acquiring an appropriate sample of sets of patient exposure data for each common examination. The process can be disruptive, inefficient and time consuming and therefore limits the applicability and usefulness of dose audit as a dose management tool.

At present it is not clear if the planned revision of the Ionising Radiation Regulations will require individual institutions to submit dose data to a national registry to enable the estimates of population dose and Diagnostic Reference Levels (DRLs). However . recently the UK Committee on Medical Aspects of Radiation in the Environment (COMARE) in its 16th report on *Patient radiation dose issues resulting from the use of CT in the UK* [19] suggested that the Department of Health should include within the regulations a requirement for health care providers to submit patient dose data at a regular frequency.

Modern digital imaging equipment record measures related to patient dose in an electronic format. Commercial solutions are available to automatically and efficiently harvest this data from DICOM/RIS/PACS/MPPS.

2.3 Addressing the Gap - Developments in Medical Physics Services to support imaging services

This section outlines the areas of Medical Physics services which need to develop to ensure appropriate future support to Imaging Services

2.3.1 Development of the Medical Physics workforce

As outlined in section the demand for Medical Physics services is dependent on the size of the installed base of imaging equipment, technological developments and developments in legislation and standards.

The Regional Medical Physics Service has developed a Workforce Plan the objectives of which are

- to ensure the continuity and future delivery of Medical Physics services to HSC bodies
- to ensure a suitably trained and qualified workforce is enabled to exploit and respond to changes in medical technology for the benefit of the population of N. Ireland
- to ensure the optimum number and skill mix of staff to meet the challenges and deliver medical physics services.

The Workforce Plan identified an increasing gap between the staff resource available to the RMPS and that required to provide and develop the service to meet the increasing demand for Medical Physics services associated with medical imaging. This is particularly evident in medical imaging, where the gap had arisen mainly from the significant increases in the medical imaging equipment base and the increasing technical complexity. It is envisaged that the equipment base will continue to grow in both terms of number and complexity.

Whilst anticipated changes to Ionising Radiation Regulations are as yet unclear it is likely that these will result in additional demands for Medical Physics services. However there are a number of recent developments at EU and national level designed to support the implementation of the EU Directive in member countries that need to be taken into account. In 2014 the European Commission published RP174 [20] which presented guidelines on the role and training of the Medical Physics Expert (MPE). This publication also included guidance on MPE staffing in three defined specialities viz., Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy. The first two areas are directly relevant to imaging services. Application of this guidance indicated that in some specialities there is a significant local shortfall in Medical Physics staffing levels.

It is essential that workforce planning recommendations for Medical Physics staffing are implemented and an approach to commissioning its services is developed which is responsive to changes in demand.

Due to the well-recognised shortage of individuals with the required expertise in this specialist area, the staffing and filling of posts in Medical Physics has traditionally been difficult. The Modernising Scientific Careers (MSC) initiative describes training and career pathways for healthcare science staff. Included in this are higher training and career development pathways (e.g. Higher Specialist Scientist Training, Accredited Expert Scientific Practice) [21]. To ensure future sustainability of Medical Physics services it is essential that a regional approach to the commissioning of Medical Physics trainees (scientists and practitioners/technologists) is put in place.

2.3.2 Regional Service for quality assurance and scientific support for ultrasound imaging systems

As part of an effective governance system professional and other interested scientific bodies recommend the implementation of quality assurance programmes and the availability of scientific advice relating to the safe use of ultrasound equipment. As outlined above there is presently no regional scientific support or quality assurance for Diagnostic Ultrasound services / devices.

This represents a significant gap in the governance arrangements for the clinical use of ultrasound imaging systems. In order to address this gap it is recommended that a regional service to provide a quality assurance programme and scientific advice relating to the safe use for all of ultrasound imaging equipment is commissioned.

The previously submitted (to HSCB) revenue business case proposes that this service be provided by the Regional Medical Physics Service and be included as part of revised RMPS service level agreements with trusts across N Ireland. The proposed service would be:-

- Independent of manufacturers/suppliers of diagnostic ultrasound systems
- Meet QA program requirements as outlined in national guidance (4,5)
- Provide an expert scientific and technical advisory service for users of diagnostic ultrasound systems

With the current HSC ultrasound imaging equipment base it is estimated that a regional ultrasound QA and scientific support service could be provided by an additional team of 1 Clinical Scientist and 2 clinical technologists

2.3.3 Electronic Patient Dose management system

Section 2.2.3.1 identified the requirement for the management of patient dose in Diagnostic Radiology and outlined the present difficulties and limitations in its application.

Recent developments in standardising the reporting of patient doses by imaging modalities have prompted the development of electronic Patient Dose Management systems to manage the collation and analysis of this data. Such systems potentially provide greater efficiency in the process of dose audit and will further promote the development of improved exposure optimisation strategies. Furthermore in the event of future requirements by regulatory or accreditation bodies, for institutions to regularly submit patient dose audit data to dose registries, this process will be greatly facilitated with the availability of a patient dose management system.

There are currently a number of commercial Patient Dose Management solutions available which differ in how they collect and collate dose information and in how they deal with legacy systems manufactured before current data format standards were introduced. In the UK and the RepublicIreland a number of regions and Healthcare providers have already implemented such systems.

In order to modernise and improve the efficiency of patient dose management, improve radiation governance and the optimisation of doses to patients and facilitate the inclusion in any future national initiatives for monitoring patient doses it is recommended that an electronic Patient Dose Management system is introduced to N. Ireland. A scoping group including of representatives of Regional Medical Physics, Trust Radiology and IT services should be formed to scope the requirements and develop a business case for the implementation of a Regional Patient Dose Management System.

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