Institute of Physics and Engineering in Medicine

POLICY STATEMENT : The Role of the Clinical Scientist in Medical Lasers and Optical Non Ionising Radiation

1. Introduction

The use of optical non-ionising radiation is well established in healthcare having valuable and diverse applications across most medical specialties and their varied applications continue to increase with the development of new novel treatments and diagnostic techniques.

The close involvement of Clinical Scientists within this field is vital. Their scientific expertise combined with clinical and regulatory experience helps to provide, and to promote, quality clinical services, allowing them to advise on regulatory control and to help further development and research in the field.

The Clinical Scientist will be required to input into all aspects of the use of optical non-ionising radiation including equipment and site specifications, quality assurance, optimisation of techniques, safety, research and development and education and training. This document aims to give a brief overview of the role of a Clinical Scientist within this broad field.

2. Role in Equipment and Site Specifications

Lasers are now a well-established tool in the fields such as surgery, ophthalmology, dermatology, gynaecology and cardiology, amongst many other areas. Other sources of optical radiation are also have seen widespread use for many applications in the medical arena. These include ultra-violet phototherapy for the treatment of skin conditions, photodynamic therapy in the treatment and diagnoses of skin and other cancers and blue light for the treatment of neonatal jaundice and applications in dentistry to name a few. Broadband high powered intense pulsed light sources (IPLs) have also found widespread use in many dermatological applications as well as aesthetic medicine.

Non-ionising radiation has found widespread use in the medical sector for a wide variety of diagnostic applications, ranging from the relatively simple and ubiquitous pulse oximeters through to sophisticated optical coherence tomography systems widely used in ophthalmology and the emerging use of Raman Spectroscopy with its ability to detect biochemical changes at a molecular level.

Microwave, radiofrequency and infra-red radiation have long been used in hospitals to treat a variety of conditions through a hyperthermic reaction. Physiotherapy patients, for example, may obtain palliation and enhanced function to muscles and joints. The prognosis for some cancers can be improved by a synergism between radiotherapy and radiofrequency induced hyperthermia.

With these varied applications in mind, it is important that an experienced Clinical Scientist is involved at the earliest opportunity when new non-ionising radiation equipment is procured or hired, when new sites for their use are proposed or when existing sites are re-modelled.

The Clinical Scientist will work closely with the whole project team, which may include varied personnel from clinicians to architects, and then utilise their detailed knowledge of the interactions of specific wavelengths with tissues and building materials, their knowledge of technological developments in the field and regulatory experience to help ensure that timely and well-informed purchasing and site planning decisions are made.

This close involvement is important where higher risk sources are proposed, such as the use of a Class 3B or Class 4 laser, IPL, UV source or other equipment which may produce significant risk to patients or staff in the immediate proximity due to the presence of high levels of optical radiation. In such a case, the Clinical Scientist would be expected to inform risk assessments and make decisions on room layouts and operational procedures, the use and specification of Personal Protective Equipment (PPE) and, if necessary, the modification of existing facilities or the design specification of new ones.

Clinical Scientists may also liaise with clinical users as to the most appropriate equipment and treatment settings for the intended use but also provide technical advice. They are likely to be involved with the acceptance and commissioning of new therapeutic or diagnostic non-ionizing devices. Their responsibilities will range from overseeing the supplier's/installer's commissioning tests and in some circumstances carrying out a full set of appropriate independent measurements dependent upon the nature of and hazard posed by the particular device in question.

The Clinical Scientist will maintain suitable instrumentation for assessment of the various radiations in a manner traceable to national and international standards and be fully conversant with any relevant measurement protocols and techniques. Clinical Scientists input into Quality Assurance (QA) frameworks, playing an important role in the delivery of safe and efficient, quality services to patients and reassuring staff that equipment is working as it should. They provide advice on framework development, measurement techniques and may carry out quantitative measurements themselves. In terms of the life cycle of equipment, Clinical Scientists may carry out measurements on equipment at each stage of life. Acceptance testing may be carried out on newly procured or hired equipment before it is put in the routine service to endure it is fit for purpose and to carry out the necessary regulatory Risk Assessments. After that, regular monitoring of equipment performance may be undertaken to ensure quality and to calibrate sources. Testing may be carried out post-maintenance and before it is put back in to clinical service.

3. Safety

There are inherent risks involved in the use of non-ionising radiation sources to both patients and staff. Clinical Scientists play a crucial role in advising employers of their regulatory responsibilities with regard to relevant legislation and guidance and in advising them on their implementation. In the past, there was little regulation in this field, with management of risk being controlled by the Health and Safety at Work Act 1974 and the Management of Health and Safety at Work Regulations 1999. However, the publication of the Control of Artificial Optical Radiation at Work Regulations 2010 and other relevant guidance documents has put much more emphasis upon the safe use of these sources, laying down specific legal exposure limits for members of staff that employers must adhere to.

The Clinical Scientist will help the employer lay down the required policies and procedures at an organisational level for the safe use of these sources and advise on what other controls are required. Technical support and advice are provided for the assessment of non- ionising radiation hazards to ensure compliance with relevant UK legislation, Codes of Practice and Guidance Notes. For Class 3B or Class 4 lasers and their equivalents, this task may be undertaken as part of a Laser Protection Adviser role.

In summary, the role may involve the following:

- Informing the organisation's Optical Radiation Safety Policy
- Producing Local Rules and Working Practices
- Undertaking measurements to determine envisaged occupational exposure
- Carrying out Risk Assessments
- Determining the protection requirements of PPE
- Implementing and overseeing QA programmes
- Investigating Adverse Events
- Carrying out Regular Safety Audits

4. Education and Training

The Clinical Scientist involved in non-ionising therapeutic or diagnostic techniques has a role in keeping up to date with changes in legislation and the current scientific, technological developments in the field. Passing on this knowledge to other Healthcare Professionals is an important aspect of the Clinical Scientist's work. Clinical Scientists may be involved in teaching courses for the safe use of non-ionising radiation for local staff or for a broader audience where the basic physical principles, applications and safety measures may be taught. By developing a good professional relationship with staff in departments where non-ionising radiation is used, safe and scientifically based working practices can be promoted. The Clinical Scientist may, in addition, issue advice to external bodies either in respect of radiation safety or any other aspect of work. For laser safety, a number of institutions across the country run a 'Core of Knowledge' course as described in the MHRA guidance document 'Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices' Providing a good base knowledge in the safe use of lasers and IPL systems.

5. Research and Development

Clinical Scientists are essential to the continued improvement of existing non-ionising therapeutic and diagnostic techniques and also, to the development of new and innovative ones. Typically, they may become involved in local service development, for example, as part of the auditing process or by dissemination of work published in the scientific literature or at conferences. In addition, the Clinical Scientist may also be involved in scientific research relating to or directly involving current or developing techniques in medical lasers and other forms of non-ionising radiation.

6. Conclusions

The role of the clinical scientist in the use of non-ionising radiation in the medical sector is very important not only in ensuring the safe and effective treatment of patients, but also in protecting staff from the hazards posed by excessive exposure to non-ionising radiation. It is a constantly evolving field requiring the skills and knowledge to achieve these aims for existing and newly introduced potentially hazardous sources.

7. References/bibliography

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