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Summary

Written with the Independent Practitioners Association (IDPA) this advice and guidance document provides support to independent practitioners who provide services to primary health care providers, the NHS and independent sector providers, corporate medical companies and, in some cases, directly to members of the public. These services include diagnostic imaging, screening, therapeutics and education.

1. Background

- 1.1 There is increasing demand on diagnostic imaging services to meet government targets, thereby accentuating the need for alternative high quality specialist services, offering provision closer to where people live, and helping relieve pressure on the acute sector. Furthermore, through Practice Based Commissioning (PBC), primary care clinicians are being provided with the resources and support to become more involved in commissioning decisions.
- 1.2 The Society and College of Radiographers has a legitimate interest in advising and providing professional guidance and support to independent practitioners engaged in the practice of providing diagnostic services. The Society and College of Radiographers recognises the need for policies for independent practitioners to ensure they provide the highest professional standards of care. This document supports the role of the independent practitioner in radiography and provides guidelines for professional practice for such individuals.
- 1.3 This document does not advise on legal and internal revenue matters for independent practice, nor on the setting up of private companies. Additional advice on these matters should be sought from appropriate sources.

2. Definition

2.1 The term Independent Practitioner encompasses all those members of The Society and College of Radiographers who are healthcare practitioners and provide services to primary health care providers, the NHS and independent sector providers, corporate medical companies and, in some cases, directly to the members of the public. These services include diagnostic imaging, screening,

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therapeutics and education.

3. Philosophy and Aims

- 3.1 The aim of an independent service is to provide both the patient and the client (clinician or purchaser) with a high quality of service. The service must ensure safe and effective patient care which complies with the relevant statutory instruments and clinical governance policies. Of particular relevance are current regulations controlling the use of ionising and other radiation and which enshrine the ALARP (As Low As Reasonably Practicable) principle.
- 3.2 Independent practitioners practise in a number of settings ranging across NHS Trusts, Health Boards, communities and the private sector. In each instance, independent practitioners will strive to deliver a high quality service for their patients. Government policy (for example as expressed in the publication 'Our Health, Our Care, Our Say: a new direction for community services')¹ will drive forward accountability for quality. Clinical governance will play a key role and places particular emphasis on lifelong learning, professional self-regulation, and the setting, delivering and monitoring of standards. The lonising Radiations Regulations 1999 (IRR99)² and the lonising Radiation (Medical Exposure) Regulations (2000; 2006)³,⁴ will impact significantly on practice and procedures for ensuring safety.
- 3.3 In a service where there is an ever-increasing demand on resources, difficult choices may have to be made which could influence the quality of service being offered. It is in the interest of patients, purchasers and professional staff that the service is of the highest quality. Individual independent practitioners have a duty to their patients to have due regard to their professional code of conduct in their practice and it is vital that an independent practitioner is not compromised in his/her professional role when dealing with a patient. Indeed, independent practitioners must work within the statutory obligations placed on all radiographers and it is no defence to claim that certain working practices remove professional responsibility from the individual. Independent practitioners must recognise and avoid conditions and practices that are inappropriate and ensure they develop and maintain high quality services at all times.

4. Models of Independent Practice

- 4.1 Independent practice may take any of the following forms:
 - self-employed
 - sole traders
 - partnership
 - limited liability partnerships (LLP)
 - limited liability companies (LLC)
- 4.2 Members are advised to seek advice from appropriate sources as to which model is suitable for their own particular practice. Further information on business models can be found at www.businesslink.gov.uk

5. Code of Conduct and Ethics

5.1 This document should be read in conjunction with the following documents:

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- Code of Conduct and Ethics (2008)⁵ published by the Society and College of Radiographers. These provide guidance to all levels of practitioners registered with the Society and College of Radiographers and are obligatory.
- The Standards of Proficiency for radiographers, published by the Health Professions Council (HPC)⁶.

Together, these documents set out the underpinning values and principles required to promote, maintain and disseminate the highest standards of professionalism including responsibility and accountability, thereby enhancing the good standing and reputation of the members of the Society and College of Radiographers.

6. Liabilities

6.1 The European Convention on Human Rights (ECHR) and United Nations Conventions (UN) exist to enforce basic human rights and to provide statutory frameworks within which governments must act. The EHCR has been in existence since the 1950s but has been given further force through the Human Rights Act (1998)⁷ and The Scotland Act (1998)⁸ thereby enabling citizens to bring a civil action in the courts to enforce their rights as set out by ECHR. A radiographer, as with any professional person, is liable in common law for any injury caused to a client through breach of the employment contract and acts of wilful or professional negligence whilst carrying out his or her professional duties. This is in common with all persons who hold themselves, and the services they offer, out to the public as having special skills.

6.2 Liability and accountability

Independent practitioners are advised of their liabilities as follows:

- When a practitioner is self-employed (or similar) there will be no employer that is vicariously liable. Hence, provision for professional indemnity cover for allegations of negligence must be made.
- Independent practitioners acting as employers will be vicariously liable for the harm caused by the employees of their organisations.
- An employer is not liable for the acts of independent contractors; ie, self employed (or similar status) people who are working on under a contract to provide services.
- Independent Practitioners acting as employers have a duty to their employees under Health and Safety laws.
- 6.3 The above makes it imperative that all independent practitioners ensure that they are covered in terms of professional and vicarious liabilities and third party insurance.
- 6.4 It must be noted that this document does not cover legal matters. Independent Practitioners are strongly advised to seek legal advice from appropriate sources to clarify the full extent of their own particular legal position and liabilities. Further information may be obtained from www.thompsons.law.co.uk.

7. Operational Policy

7.1 Independent practitioners must have a written operational policy which embraces all aspects of their work. The working environment must be safe and must comply with all statutory health and safety requirements, such as the Health and Safety at Work Act (1974)⁹, Management of Health and Safety Work Regulation (1999)¹⁰ and IR(ME)R (2000; 2006)³,⁴. The following section identifies areas that need to be covered.

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- 7.2 All work must be monitored and verified in order to provide an efficient audit system.
- 7.3 A dose reduction policy, specifying appropriate mechanisms for ensuring that the dose to the patient is kept as low as reasonably practicable (ALARP principle), must be established. Similarly with ultrasound, the ALARP principle should be adhered to, thereby ensuring minimal exposure to ultrasound energy. For magnetic resonance imaging (MRI) scans, Specific Absorption Rates (SAR) should be minimised and the Medicines and Healthcare Products Regulatory Agency (MRHA) guidelines must be adhered to. Details can be found in the SCoR publication 'Safety in Magnetic Resonance Imaging' (2007)¹¹
- 7.4 Where independent practitioners have a direct role in the procedure there should be a protocol for reporting and interpretation of image quality.
- 7.5 There should be recognition of agreed referral sources (see Section 9.3).
- 7.6 Practice should be evidence based.
- 7.7 There should be protocols concerning all aspects of Health and Safety for patients, staff and members of the public, including those pertaining to the safe use of ionising radiations (where relevant) and to ensuring personal safety.
- 7.8 There should be due regard to quality assurance including safety, inspection and testing of equipment and the appropriate quality assurance procedures.
- 7.9 There must be a comprehensive training and development strategy. Independent practitioners must be aware of their professional responsibility to keep their practice current with respect to equipment/techniques and dose reduction/minimisation methods. Independent practitioners should maintain a reflective diary and must record all relevant continuing professional development (CPD) activities in accordance with the CPD policy of The Society and College of Radiographers and the statutory requirements of the HPC for CPD.
- 7.10 There should be a clear policy on the information to be issued to patients.
- 7.11 There should be a regular review of all equipment and an equipment replacement programme should be established.
- 7.12 There should be declared, unambiguous and acceptable levels of care for patients including statements on relationships, standards and facilities.
- 7.13 Patient/client confidentiality must be maintained at all times.
- 7.14 There should be due regard to ethical standards.

8. Clinical Governance

- 8.1 Clinical governance was defined in the 1998 consultation document "A First Class Service: Quality in the New NHS" $(p33)^{12}$ as:
- 'a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.'
- 8.2 The ethos of Clinical Governance has been embedded throughout this document. However, the key components and themes that promote good clinical governance are stated here for clarity:

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- Patient, public and carer involvement, to include analysis of patient/professional involvement and interaction, and strategy, planning and delivery of care.
- Strategic capacity and capability, including planning, communication and governance arrangements, and cultural behaviour aspects.
- Risk management; incident reporting, infection control, prevention and control of risk.
- Staff management and performance; recruitment, workforce planning, appraisals.
- Education, training and continuing professional development to include professional re-validation, management development, confidentiality and data protection.
- Clinical effectiveness; clinical audit management, planning and monitoring, learning through research and audit.
- Information management; patient records and other record keeping.
- Communication; patient and public, external partners, internal, board and organisation-wide.
- Leadership throughout the organisation, including Board, Chair and non-executive directors, chief executive and executive directors, managers and clinicians.
- Team working within the service, senior managers, clinical and multi-disciplinary teams, and across organisations. NB Independent practitioners have a professional responsibility to interact with other health care professionals and to seek feedback. Responsibilities within a skills mix environment are described in the document 'Team working within clinical imaging: A contemporary view of skills mix' (RCR SCoR 2007)¹⁴.

8.3 While these components and themes are aimed at sizeable healthcare organisations, they are, nevertheless, relevant themes that every independent practitioner and small independent practice will need to consider to ensure they have relevant policies and procedures in place.

9. Overall Standards

9.1 Standards

Independent Practitioners are expected to develop, implement and monitor policies, embracing the standards below. This will serve to assure patients and purchasers that the service offered by the Independent Practitioner is of the highest quality.

Specific objectives of the service relating to the following must be laid down in writing:

- Provision and maintenance of high quality care
- Provision of the service on a routine and regular (and possibly emergency) basis
- Consultation and co-operation with other health care professionals concerning the provision of the service
- Conduct of professional activities in accordance with the standards set by relevant professional organisations
- Compliance with all relevant Health and Safety regulations, including IRR992, IR(ME)R 2000 regulations³, and IR(ME) Amendment Regulations 2006⁴.
- Provision of a courteous and considerate service to patients including the need to respect privacy, confidentiality and to cater for cultural, language and other differences.

9.2 Information Governance

9.2.1 Health records are confidential. They should be shared only on a need-to-know basis. Information governance ensures necessary safeguards for, and appropriate use of, patient and personal information. There should be systems in place to protect the confidentiality and security of patient information and provide access to relevant information only to those who need it. In practice, this is addressed through three fundamental principles – **confidentiality, integrity and availability**.

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- Confidentiality Information must be secured against unauthorised access.
- Integrity Information must be safeguarded against unauthorised modification.
- **Availability** Information must be accessible to authorised users at times when they require it.
- 9.2.2 In order to maintain these principles, the following standards must be observed
 - All patient information should be recorded factually, lawfully and as transparently as possible to allow the public to
 - understand the reasons for processing personal information
 - give their consent for the disclosure and the use of personal information
 - gain their trust in the way the service provider handles the information
 - understand their rights to access information held about them.
 - Patients' medical records and reports from imaging examinations must be stored in a secure
 place within a specified time and a duplicate record kept. This may be in paper or digital
 format such as Picture Archiving and Communications systems (PACs). It is a legal
 requirement that a report be produced for all examinations.
 - Films or other hard copy images must be provided for all examinations except where it has been agreed and documented that this practice is inappropriate.
 - Films and records must be kept in accordance with agreed local policy and to comply with statutory requirements.
 - Particular attention must be given to insurance, indemnity, public liability and data protection.

9.3 Referrals

- 9.3.1 Independent practitioners must only accept requests for examinations from Registered Health Care Practitioners (ie, they must be registered under a statutory regulatory body in the UK). Requests must be properly authorised in accordance with established criteria, national guidelines and evidence based practice and the examination requested must be of benefit to the patient. The request must contain sufficient clinical information to justify the examination. Independent practitioners may carry out alternative or additional examinations where, in their professional judgement, these are appropriate to the patient's condition.
- 9.3.2 Independent practitioners may accept self-referrals for relevant examinations and in accordance with guidance produced by the Society and College of Radiographers. It must be noted that **there is no mechanism for self-referral under the IR(ME)R 2000 / 2006 legislation**^{3,4}.
- 9.3.3 Independent practitioners **must use their own professional judgement** and not carry out any imaging where, in their professional opinion, the risk to the patient is greater than the benefit obtained by the procedure. It is good practice to go back to the referrer in cases where this is in doubt.
- 9.3.4 The independent practitioner should ensure that the client has been assessed appropriately prior to undertaking the examination.
 - In order to obtain sufficient clinical information, the practitioner will need to formally evaluate and record risk factor data through a 'lifestyle/health' questionnaire.
 - The examination should take place in a clinically appropriate environment.
 - Patients must be fully informed of the implications of their examinations and the importance of disclosure of results to their general practitioner / referrer.
 - A copy of the results, risk assessment and information given to the patient is sent to the referrer for their records, so ensuring continuity of care. This is an important standard for the protection of the public.
 - The independent practitioner maintains full records for future reference.

9.4 Consent

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It is imperative that all radiographers are aware of the issues surrounding the gaining of consent from patients and others attending a diagnostic imaging or radiotherapy department. Radiographers have professional duties and responsibilities in terms of conduct, performance and ethics including a requirement to only undertake those tasks in which they are competent and for which appropriate patient consent has been obtained. The principle of consent to an examination carried out by a healthcare professional is the right of patients to determine what happens to their bodies. The radiographer who does not respect this principle is potentially liable to both legal action by the patient and by the Health Professions Council (HPC).

'The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later'. (Department of Health Nov 2001)¹⁴.

9.5 Policies and Procedures

The service must have dated, written policies and procedures to provide the framework for the service being provided. These must be based on current knowledge and principles. To achieve the standard the following must be observed:

- Policies and procedures are reviewed and updated at least annually and should be signed by all involved in the service and dated accordingly.
- Diagnostic imaging and interventional procedures are performed only upon written request from an approved referral source and the request contains sufficient clinical information to justify the examination (See also section 9.3 on referral).
- Written consent is obtained for all procedures and a chaperoning policy should be in place with regard to intimate procedures such as transvaginal or testicular ultrasound etc.
- All images are interpreted and reported in a timely fashion within an agreed scheme of work.
- Protocols relating to all imaging and interventional procedures are available.
- Procedures and Protocols as required under IR(ME)R 20003 2006⁴ are written and available.
- In case of abnormal findings, there should be a policy on referring clients into appropriate care management pathways in a timely fashion.
- In case of equivocal or difficult cases, there should be a mechanism for obtaining a second opinion. In situations where interpretation is not or cannot be provided, this is identified and an appropriate protocol is agreed with the referrer.
- In the event of an adverse incident, individual statements must be written and dated by all concerned as soon as possible after the event. These will be important in internal/external enquires that may follow.

9.6 Record Keeping

9.6.1 Good documentation and record keeping are synonymous. Effective patient care requires documentation of diagnosis, treatment and future plans so that there is sharing of communication for all practitioners for the benefit of the patient. Many civil cases arise after an initial event, and records are essential in terms of providing clarity, content, style, accuracy and comprehensiveness.

9.6.2 Records must be:

- made as soon as possible after the examination
- accurate, comprehensive and clear
- written legibly
- free of jargon
- signed and dated
- not be altered, unless there is a mechanism for the original report to be readable
- where changes or amendments of records are made, these need to be signed and dated at the time the change or amendment is made.

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9.7 Staff Development, Education and CPD

9.7.1 The service must be properly directed and staffed to achieve its stated goals and objectives. Practitioners are responsible for identifying, developing and maintaining the necessary skills and competences relevant to the service and its objectives and to ensure the provision of high quality of care.

To achieve the standard the following must be evident:

- the service is staffed by qualified, registered independent practitioners holding an accredited professional qualification appropriate to the speciality of the examination being performed
- there is a current written organisational chart, denoting clear lines of responsibility and accountability
- diagnostic images are interpreted by registered independent practitioners working in accordance with a scheme of work
- the IR(ME)R 2000/2006³, ⁴ legislation specifies four duty holders: Employer, Referrer, Practitioner and Operator. The roles and functional responsibilities of the various duty holders can be vested in one and the same person. However, it is a requirement that the Employer must ensure that the Practitioner and Operator be 'adequately trained' in accordance with Schedule 2 of the Regulations. In addition, entitlement to undertake any of the duty holder functions is the responsibility of the Employer and must be specified within agreed protocols
- there should be a continuing educational programme, supporting CPD and maintaining competencies in the relevant areas of practice. This should utilise professional and other resource material, and should also encourage research to ensure independent practitioners are fully aware of advances in practice
- all practitioners need to recognise and work within their own limitations and scope of practice
- all staff need to be aware of occupational hazards such as work-related musculoskeletal disorders and take measures to avoid/minimise them.

9.8 Facilities and Equipment

There should be suitable space, equipment and adequate supplies for the safe performance and delivery of all services provided.

9.8.1 To achieve the standard the following must be observed:

- the implementation of radiation safety measures is supervised by the equipment operator. The services of a Radiation Protection Supervisor/Radiation Protection Advisor (RPS/RPA) for IRR 1999² and a Medical Physics Expert (MPE) for IR(ME)R 2000/2006³, who is appropriately qualified and experienced must be available to provide specific support and advice to those responsible for the operation of equipment
- due attention is paid to product liability with respect to loan, purchase, modification or sale of equipment
- safety measures include safety precautions against electrical and mechanical hazards, fire and explosions as well as against radiation hazards
- all new work practices must be assessed as required under the Management of the Health and Safety at Work Regulations, 1999. This would include specific 'Prior Risk Assessment' if the work practice involves the use of ionising radiations. Safety measures also need to be followed to minimise work related disorders to staff
- all newly installed equipment is tested to ensure it meets agreed specifications and is 'Critically Examined' in accordance with IR(ME)R 2000, 2006³, and, where relevant, the Royal College of Radiologists standards for ultrasound equipment (2000)¹⁵
- all equipment is subject to a planned maintenance and replacement programme in accordance with statutory requirements
- all equipment and facilities conform to existing Health and Safety Regulations and relevant European Directives
- calibration of equipment and all safety measures followed are in compliance with statutory

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regulations

• there is a policy for infection control.

9.9 Monitoring and Evaluation

Health professionals should be able to assess the care they provide against established clinical standards by means of clinical audit. This will involve identifying and building on good practice, the assessment and minimising of risk and the investigation of problems and learning from that investigation. The service must assure the provision of high quality care by its involvement in evaluation activities.

9.9.1 To achieve the standard the following policies are observed:

- evaluation of the service compared to the standards laid out in this document
- evaluation of service compared to national standards
- evaluation of professional performance
- evaluation of incidents and accidents
- evaluation of the use of resources
- evaluation of waiting lists and times
- evaluation of Health and Safety policies, risk assessments, procedures and practices
- evaluation of radiation safety standards, compliance with regulations and evaluation of quality assurance procedures as required under IR(ME)R 2000 / 2006³,⁴
- provision of a mechanism for making and dealing with complaints which is clear and known to all
- collation of statistics on, for example, number of attendances, referrals, use of investigations, patient satisfaction and equipment failure
- where research is undertaken, assurance that patients' rights are protected and the research protocols have been approved by the relevant authorities.
- evaluation by independent assessors as necessary and at determined intervals

10. Marketing and Advertising

10.1 The College of Radiographers endorses the practice of independent practitioners advertising their services provided that any advertisement conforms to the British Codes of Advertising Practice and Sales Promotion. To achieve the standard the following criteria apply:

- advertisements should not be false, fraudulent, misleading, deceptive, self-laudatory, unfair or sensational
- advertisements should be dignified and professionally restrained

10.2 The health care practitioner/patient relationship is important, therefore due regard should be paid to the maintenance of the highest ethical standards in any advertising. Direct appeals to patients, either face to face or over the telephone, should be avoided. It is undesirable to use too many abbreviations which can be confusing to patients and clients. Comparative claims with other practitioners should not be made in respect of superiority of skills, equipment and/or facilities. The term 'specialist' should be restricted to those who have a defined specialist skill. Whilst it may be correct and proper for Independent Practitioners to be able to publicise their service and practice, they should act in a restrained and professional manner at all times.

Further information can be obtained from the Advertising standards authority at www.asa.org.uk/asa/codes

10.3 As regulated healthcare professionals, Independent Practitioners must also comply with the requirements of the Health Professions Council and the guidance of the Society and College of

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Radiographers with regard to advertising their services.

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