

RADIOLOGY DEPARTMENT

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**REGULATION OF TELERADIOLOGISTS AND TELERADIOLOGY PROVIDERS IN THE EU.**

I set out my views on this topic. My interest in this is derived from several sources.

- **General Medical Council Radiologist Assessor for Professional Performance Procedures, 2002 –**
- **Member, Royal College of Radiologists Standards Subcommittee 2003 –**
- **Adviser to Royal College of Radiologists on its Teleradiology publication (2004).**  
I enclose this as an attachment.
- **U.K. Representative, Union of European Medical Specialists (U.E.M.S.) Section of Radiology, 2001-**
- **Member, Royal College of Radiologists European Subcommittee, 2001 –**
- **Adviser to British Medical Association Radiology Subcommittee on European Affairs, 2001 –**
- **Major contributor to U.E.M.S. Section of Radiology Policy Statements**  
→ *Good Practice Guide for European Radiologists (2003)*  
→ *Risk Management of Radiology (2003)*  
→ *Teleradiology (2004)*
- **I have had a longstanding interest in improving patient safety through reduction in error in Radiologists' reports. I have written and lectured extensively on the topic.**

**Publications:**

**Radiological Error: Analysis, Standard Setting, Targeted Instruction and Teamworking.** R FitzGerald. (2005) *European Radiology*. 15; 1760-1767.

**Review: Error in Radiology.** R FitzGerald. (2001). *Clinical Radiology*, 56; 938-946.

**More knowledge sharing helps to eliminate errors.** R FitzGerald. (2005)  
*Diagnostic Imaging Europe*. August/September issue, page 48.

**Regulation and Revalidation of Teleradiologists.** R FitzGerald. (2006)  
*Newsletter of The Royal College of Radiologists* 87; 17-18.

**Lectures:**

*“Uncertainty, discrepancy and error in radiology: How can we do better?”* **European Congress of Radiology, Vienna, 8 March 2004.**

*“Impact of European legislation on UK Radiological Practice”*. **Royal Society of Medicine, London, 6 December 2004.**

*“Uncertainty, discrepancy and error in Radiology: How can we do better?”* **European Congress of Radiology, Vienna, 6 March 2005.**

*“Error in Radiology”* **Karolinska Institute, Stockholm, 17 May 2005.**

*“Radiological Error: Analysis, standard setting, targeted instruction and teamworking”*. **Management in Radiology Conference, Copenhagen, 5 October 2005.**

*“Radiological Quality Improvement – U.K. perspective”* **American College of Radiology Meeting, Sun Valley, Idaho, USA, 25 August 2006.**

*“Rehabilitation of Radiologists in Difficulty”*. **Management in Radiology Conference, Budapest, 6 October 2006.**

**REGULATION OF TELERADIOLOGISTS AND TELERADIOLOGY PROVIDERS**

- **E.U. citizens deserve legal certainty and protection regarding cross border healthcare.**
- **“European Competition Policy also helps to ensure a level playing field for economic actors providing and financing healthcare, and can contribute to the development and improvement of efficient services”** (section 2.3 Consultation regarding Community action on health services).
- **Cross border healthcare within the EU involves not only physical mobility of citizens and health professionals but also telemedicine** (section 2.2 – Consultation regarding Community action on health services).
- Teleradiology is a major component of telemedicine and is the method by which ever increasing numbers of scans and radiographs of E.U. citizens are being interpreted. Teleradiology provision within the E.U. often occurs across national boundaries. It also occurs from outside the E.U..

- **Patient protection and European competition policy for a level playing field both require E.U. Health Directive legislation in this area. Such legislation should address both the regulation of the individual teleradiologist and the regulation of the teleradiology provider.**

### **REGULATION OF TELERADIOLOGISTS:**

A teleradiologist who reports on medical images of E.U, patients should:

- Be registered with the Medical Regulatory Body of each E.U. Member State where his/her patients reside.
- Should be on the Radiology Specialist Register of the Medical Regulatory Body of each Member State where his/her patients reside.
- Should have individual insurance/indemnity cover for each of the Member States where his/her patients reside.
- Must have a proper knowledge of the language(s) of each Member State where his/her patients reside, as required by the E.U. Qualifications Directive 2005.
- Should have a “Certificate of Current Professional Status” when applying for registration with a Medical Regulatory Body.
- If providing teleradiology services for patients in a E.U. Member State, teleradiologists, wherever their location, should be subject to the same regulatory requirements as local Radiologists. Such specific national medical regulatory arrangements may include revalidation, recertification, relicensure, annual appraisal.
- Teleradiologists should be subject to the regulations applied to locum doctors by the Medical Regulatory Body in each Member State where his/her patients reside.

### **Language Testing**

**Article 53 of the 2005 European Union *Qualifications Directive*** states that “persons benefiting from the recognition of professional qualifications shall have knowledge of languages necessary for practicing the profession in the host member state”.

**The European Court of Justice ruled in case C-424/97 Haim II** that the reliability of a dental practitioner’s communication with his patients and with the administrative authorities and professional bodies were such that linguistic testing was justified.

Thus there is no E.U. legal barrier to linguistic testing of teleradiologists who report on medical images of patients in another Member State. There has never been any legal obstacle to testing linguistic competence of teleradiologists resident outside the E.U..

Linguistic competence has particular relevance to teleradiologists. If reporting imaging examinations at a distance by teleradiology, the clinical contact between the referring doctor and

the reporting Radiologist is substantially reduced and the need for adequate linguistic competence is even more important for patient safety.

### **E.U. Healthcare Professionals Crossing Borders Agreement, 2005**

Details of this may be accessed on:

<http://admin.uems.net/uploadedfiles/678.pdf>

This agreement is due to be implemented by the end of 2007 and will require E.U. Medical Regulatory Bodies to proactively exchange information when they have restricted a healthcare professional's right to practice because of a serious performance, conduct, health or criminal issue.

It also includes a ***“European Template for a Certificate of Current Professional Status”***. Teleradiologists registered in another E.U. Member State should be required to provide such a European Certificate from his/her Medical Regulatory Body before obtaining registration in another E.U. Member State. Teleradiologists outside the E.U. should have an equivalent certificate.

### **Communication Requirements of Teleradiologists**

A teleradiologist who reports medical images of E.U. patients must be required to be able to communicate directly with referring Radiology Departments and Clinicians in order to discuss the clinical background and unexpected diagnosis which may be relevant to the timely management of a patient. The contact phone number of the reporting teleradiologist should be provided on the report. A definitive report is mandatory with the electronic signature of the reporting teleradiologist. Teleradiologists who report medical images of E.U. patients should be subject to the same error feedback, clinical incident reporting, root cause analysis, audit and other forms of Clinical Governance as apply to local Radiologists.

### **REGULATION OF TELERADIOLOGY PROVIDERS**

Teleradiology companies which provide reporting of medical images of E.U. citizens:

- Should be registered with the Healthcare Commission or equivalent in each E.U Member State where their patients reside, and be subject to its regulations/standards.
- Should be subject to the same Member State Regulations as apply to Medical Locum Agencies.
- At the conclusion of every doctor's employment, teleradiology providers should be required to make a brief standardised return to the relevant national Medical Regulatory Body.
- Teleradiology Providers should ensure that teleradiologists reporting imaging of patients in a particular Member State comply with the regulation, revalidation, annual appraisal and other national Clinical Governance Regulations of that Member State.

- When a teleradiologist changes employer or contracting organisation between revalidation/relicensure cycles, the previous teleradiology provider should provide the new employer with a standardised record outlining the practitioner's current position in relation to the elements contributing to relicensure/revalidation.
- Clinical evaluation and data should be provided to the reporting teleradiologist.
- Teleradiology providers must comply with the requirements of the Euratom 97/43 Directive including Justification, and optimisation of imaging technique.
- Reports from Teleradiology Providers should be integrated with the patient's notes, electronic records, Radiology Information Systems and should be capable of review by clinicians and at multi disciplinary team meetings as easily as if the reports were generated locally.
- Teleradiology Providers should have close communication with the Radiology Departments who produce the medical images.
- Teleradiology Providers should ensure security and privacy of transmitted patient data comply with E.U. and National Directives.
- Teleradiology Providers should conduct regular user/clinician surveys. Robust audit procedures should be in place to check the quality and accuracy of reports and the overall therapeutic and clinical impact of the service.
- Teleradiology providers should have adequate medicolegal and insurance cover.

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Attachment: Teleradiology – A Guidance Document for Clinical Radiologists. Issued by and available on Royal College of Radiologists website [www.rcr.ac.uk](http://www.rcr.ac.uk)

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