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The regulatory position in Europe: A British perspective

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In most cases, the current legislative and regulatory infrastructures for nuclear medicine in European countries are largely based on a range of Standards, Recommendations, Directives, Codes of Conduct and Documents from a number of international bodies and organisations. In addition however national legislation will always be formulated in accordance with the State's overarching legislative structure, also taking into account other acts and regulations which predate the international approach.

These international bodies include the International Commission on Radiation Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the Committee on Biological Effects of Ionising Radiation (BEIR), the International Atomic Energy Agency (IAEA), the European Commission (EC) and a range of international professional bodies.

The areas covered in legislation impinge on all aspects of nuclear medicine practice and include equipment design, manufacture of radiopharmaceuticals, transport, medical education, employment law, safety and security of radioactive substances, keeping and disposal of radioactive substances, public and employee safety, patient safety and conduct of clinical trials.

The safety of the public, employees and patients are of prime concern and the European Council Directives on Basic Safety Standards (96/29/Euratom) (1) and Medical Exposures (97/43/Euratom) (2) provide the basis for much of the legislation that will be encountered on a day to day basis in nuclear medicine. It should be noted however that clinical research is an integral part of nuclear medicine and therefore the less well-known Clinical Trials Directive (2001/20) (3) is also of relevance.

In Great Britain, a range of acts and regulations have been laid to implement these Directives and to provide a comprehensive legislative infrastructure for the safe practice of nuclear medicine. This includes; the Radioactive Substances Act 1993 (4) which addresses the keeping and use of radioactive material and the accumulation and disposal of radioactive waste; the Medicines Act 1968 (5) which considers sale, supply and manufacture of medicinal products; the Ionising Radiations Regulations 1999 (6) which provide for the safety of employees and the public; the Ionising Radiation (Medical Exposure) Regulations 2000 (7) which ensure the safety of patients; the Medicines (Administration of Radioactive Substances) Regulations 1978 (8) and the Medicines (Administration of Radioactive Substances) Amendment Regulations 1995 (9) which provide for a system of certification of nuclear medicine practitioners; and the Medicines for Human Use (Clinical Trials) Regulations 2004 (10) which protect the rights and safety of clinical trial subjects.

These acts and regulations are enforced by a number of regulatory bodies. This requires close collaboration to ensure consistent approaches across a number of areas where different regulations apply to the same clinical practices.

The regulatory bodies in Great Britain have a long established history of working with professional bodies, statutory advisory committees and in the future new Agencies. These organisations produce guidance documents which effectively define accepted practice in nuclear medicine.

References

1. Council Directive 96/29/Euratom (OJ No L159, June 1996)
2. Council Directive 97/43/Euratom (OJ No L180, July 1997)
3. Council Directive 2001/20/EC (OJ No L121, May 2001)
4. The Radioactive Substances Act 1993. London: HMSO
5. The Medicines Act 1968. London: HMSO
6. The Ionising Radiations Regulations 1999 (SI 1999 No 3232). London: HMSO
7. The Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000 No 1059). London: HMSO
8. The Medicines (Administration of Radioactive Substances) Regulations 1978 (SI 1978 No 1006). London: HMSO
9. The Medicines (Administration of Radioactive Substances) Amendment Regulations 1995 (SI 1995 No 2147). London: HMSO
10. The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 No 1031). London: HMSO