

Administration of Pharmaceuticals in Nuclear Medicine

Members will wish to be aware of amendments to three Statutory Instruments that have direct implications for nuclear medicine departments.

- 1. Statutory Instrument 2006 No. 2806. The Medicines (Administration of Radioactive Substances) Amendment Regulations 2006**
- 2. Statutory Instrument 2006 No. 2807. The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006**
- 3. Statutory Instrument 2006 No. 2523. The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006.**

The issuing of these Regulations follows consultation exercises undertaken by MHRA and DH during 2005 and 2006 and subsequent advice provided by the Administration of Radioactive Substances Advisory Committee (ARSAC).

1. The Medicines (Administration of Radioactive Substances) Amendment Regulations 2006.

These Regulations came into force on 17th November 2006. They are published in full at https://www.legislation.hmsso.gov.uk/si/si2006/uksi_20062806_en.pdf

The intention of the Regulations is to explicitly make legal the authorisation of a nuclear medicine exposure by an operator in accordance with guidelines issued by the ARSAC certificate holder, acting as the practitioner for the exposure. This approach is allowed under IR(ME)R 2000 Regulation 6(5).

Such guidelines allow trained operators to match patient specific medical data with generic clinical indications and an associated clinical investigation and to authorise exposures accordingly. The responsibility for the justification of the exposure is considered to remain with the practitioner, who in nuclear medicine exposures is the ARSAC certificate holder.

This approach has for some time been a common practice for administration of radiopharmaceuticals in many nuclear medicine departments. Unfortunately it does not satisfy requirements under the Medicines Act that pharmaceutical administrations must be made under patient specific directions.

These new Regulations identify the operator under IR(ME)R 2000 and allow this duty holder to administer radioactive medicinal products under directions which are not patient specific, as long as the operator acts in accordance with procedures and protocols, including guidelines issued by the ARSAC certificate holder, and the radioactive medicinal products are not controlled drugs.

2. The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006

This Order came into force on 17th November 2006. It is published in full at https://www.legislation.hmsso.gov.uk/si/si2006/uksi_20062807_en.pdf

As part of the consultation process on amendments to the MARS Regulations, it was suggested that a similar facility should be made for non-medical staff to authorise the administration of certain other medicinal products, where these are an integral part of the nuclear medicine investigation.

This Order therefore allows for prescription only medicines (POMs), such as frusemide or thyroid blocking agents, that are an essential part of some nuclear medicine examinations, to be administered by an operator, even though they are not radioactive and so are not covered by MARS. The conditions under which such a practice is conducted are the same

as those laid out above, ie the operator acts in accordance with procedures and protocols, including guidelines issued by the ARSAC certificate holder, and the medicinal products are not controlled drugs

The effect of this Order is regularise practices which have been common practice in many departments. Many users have for some time followed the advice of the BNMS Radiopharmacy Group, which has been on the BNMS web site since 2004, which indicates that such pharmaceuticals should be described in the written protocols of the department.

Some departments have made use of patient group directions (PGD) to enable non-medical staff to administer non-radioactive pharmaceuticals such as frusemide. This has been an acceptable practice, but as it only applies to registered healthcare professionals, it could not be applied in departments where nuclear medicine technicians inject and carry out scans. The new Order means that this approach is no longer necessary.

3. The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006

These Regulations came into force on 1st November 2006. They are published in full at https://www.legislation.hmso.gov.uk/si/si2006/ukSI_20062523_en.pdf

These Regulations establish that referrers and practitioners should be registered health care professionals. Such registered health care professionals should be members of professions regulated by a body defined in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002. In practice, this means that radiographers, who are so trained and entitled by their employer, in nuclear medicine departments may act as operators and referrers for all investigations involving ionising radiation, and practitioners for investigations involving ionising radiation other than those using radioactive medicinal products. In contrast, technicians can only be entitled to act as operators at the moment, but this anomaly will be removed when technicians become a registered profession.

In addition, the Regulations identify the Commission for Healthcare Audit and Inspection as the appropriate authority for England, and as a consequence it becomes the body with inspection and enforcement responsibilities. The Regulations also update references to ethics committees, in line with Part 2 of the Medicines for Human use (Clinical Trials) Regulations 2004.