EXPLANATORY MEMORANDUM TO

THE MEDICINES (ADMINISTRATION OF RADIOACTIVE SUBSTANCES) AMENDMENT REGULATIONS 2006

2006 No. 2806

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), part of the Department of Health, and is laid before Parliament by Command of Her Majesty.

2. **Description**

2.1 These Regulations amend the Medicines (Administration of Radioactive Substances) Regulations 1978 ("the MARS Regulations") to allow persons who are operators in nuclear medicine procedures to administer or authorise the administration of radioactive medicinal products ("RMPs").

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None.

4. **Legislative Background**

4.1 These Regulations make further amendments to the MARS Regulations which restrict the administration of RMPs and implement a system of prior authorisation for administration of radioactive substances. In particular, Regulation 2 of the MARS Regulations prohibits the administration of RMPs except by a doctor or dentist holding a certificate issued by the Administration of Radioactive Substances Advisory Committee (ARSAC) or a person acting in accordance with his directions. The directions must be written and patient specific.

4.2 The amending Regulations make provision for the administration of RMPs where that administration is also a medical exposure under the Ionising Radiation (Medical Exposure) Regulations 2000 ("the IRME Regulations") . Provision is made for persons who are operators in nuclear medicines procedures under the IRME Regulations to administer or authorise the administration of RMPs. Operators must be acting in accordance with the procedures and protocols under the IRME Regulations and with written guidelines of an ARSAC certificate holder.

4.3 As RMPs are prescription only medicines, the Prescription Only Medicines (Human Use) Order 1997 is also being amended.

5. **Extent**

5.1 This instrument applies to all of the United Kingdom.

6. **European Convention on Human Rights**

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required

7. **Policy Background**

7.1 These changes are intended to reflect existing arrangements in place throughout the NHS and independent healthcare settings for the administration of medicines in nuclear procedures and ensure continuity in the provision of patient care.

7.2 The proposed amendments were subject to public consultation and advice to Ministers by the Commission on Human Medicines. A detailed analysis of the outcome of the public consultation exercise has been published on the MHRA website www.mhra.gov.uk In brief, there were 37 replies and the vast majority (33) expressed support for the proposals.

8. **Impact**

8.1 A Regulatory Impact Assessment has been not been prepared for these proposals because they do not impose a cost compliance on business, charities or voluntary bodies.

8.2 The impact on the public sector is to benefit patients.

9. **Contact**

9.1 Anne Ryan at the MHRA, tel 0207 084 2392 or e-mail: anne.ryan@mhra.gsi.gov.uk can answer any queries regarding the instrument.