

# **ADMINISTRATION OF RADIOACTIVE SUBSTANCES ADVISORY COMMITTEE**

## **(ARSAC) ANNUAL REPORT FOR 2006**

### **Background**

1. Article 5(a) of EC Directive 76/579/Euratom (relating to basic safety standards of radiation protection) requires that a system of prior authorisation must be applied in respect of the administration of radioactive substances to persons for the purposes of diagnosis, therapy or research. This was implemented in the UK by the Medicines (Administration of Radioactive Substances) Regulations 1978.
2. Regulation 2 of the Regulations requires that any doctor or dentist who wishes to administer radioactive medicinal products should hold a certificate issued by Health Ministers. The Regulations also established a committee to advise Ministers on applications.

### **The Committee and its Working Party**

3. The Administration of Radioactive Substances Advisory Committee (ARSAC) was set up under Regulation 3(1) to:  
  
advise Health Ministers with respect to the grant, renewal, suspension, revocation and variation of certificates and generally in connection with the system of prior authorisation required by Article 5(a) of Council Directive 76/579/Euratom
4. The Committee members comprise medical doctors (a majority), scientists and radiographers all of whom are directly involved in nuclear medicine. All members are appointed by UK Health Ministers as independent experts in their own field. The chairman is a medical doctor. The Committee normally meets twice a year. A membership list is available on the ARSAC website at [www.arsac.org.uk](http://www.arsac.org.uk).
5. In addition to the Committee a small Working Party, composed of members of the Committee and some co-opted experts, meets to provide detailed advice on issues which have relevance to the Committee's work.

### **The certification process**

6. The bulk of Committee members' work is done throughout the year by post, advising the Health Departments on written applications from practitioners for certificates which will enable them to use specific radioactive medicinal products in diagnosis, therapy or research.

7. Applicants, normally of consultant status, who wish to administer radioactive medicinal products supply information in confidence in order that they can be assessed for their suitability to hold a certificate. This includes information on their training and experience as well as on the services (such as radiopharmacies and medical physics departments) that support them. In some cases there is a commercial element to applications involving research projects as they involve novel procedures.
8. Committee Members send comments on such applications in confidence to the ARSAC Support Unit. The Committee advises primarily on issues concerning radiation hazards and does not replace the functions of an Ethics Committee. However, ethical implications of research applications are taken into consideration.
9. Administrative functions of the certification process are undertaken by the ARSAC Support Unit, provided by the Radiation Protection Division of the Health Protection Agency. The Committee's advice on individual applications is considered by a Departmental official. If the application is considered appropriate a certificate is issued and authorised on behalf of Secretary of State by that official.
10. Certificates of five years duration are normally issued for diagnosis and therapy purposes, and two years for research purposes.

### **Performance in 2006**

11. In 2006, the ARSAC Support Unit processed 1,225 applications for certificates. Of these 99 % were processed within 60 days with a mean processing time of 27 days.
12. In March 2006, the Committee published the revision of its "Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources" previously issued in December 1998. The Guidance provides a guide to good practice in the UK for nuclear medicine and serves as a valuable source of information for other national and international organisations. The new guidance is available on line at the ARSAC website ([www.arsac.org.uk](http://www.arsac.org.uk)).
13. During the year, the Committee and its Working Party considered a number of issues relevant to nuclear medicine practice including training for those undertaking PET-CT scanning, use of MUGA scanning in research, holding certificates at remote sites and activities for cardiac scanning. In addition, they provided advice to government departments and agencies including DH and MHRA on the Medicines (Administration of Radioactive Substances) Amendment Regulations 2006 and the Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006.