

# ARSAC NEWSLETTER

This newsletter will be issued bi-annually following each ARSAC meeting. It will help to draw to the attention of those interested individuals, changes in nuclear medicine relating to your clinical practice. Items we expect to be included are changes to ARSAC, the Notes for Guidance and relevant legislation.

Please also periodically check the FAQ section on the website as this will also be updated as necessary.

**Issue 1 March 2007**

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## **1. Changes in ARSAC membership**

The following were appointed to the Committee in July 2006:

Dr J Ballinger;	Department of Nuclear Medicine, Guy's and St Thomas' Hospital, London
Dr JB Neilly;	University Medical Unit, Glasgow
Dr M O'Doherty;	Clinical PET Centre, St Thomas' Hospital, London
Dr JIS Rees	Radiology Directorate, University Hospital of Wales, Cardiff

## **2. Support Unit update**

The Support Unit is required to meet performance standards set by the Department of Health (DH). These standards monitor the time taken for applications to pass through both of the different stages of the process and also the overall time taken. A maximum time of 60 days for the whole process to be completed is stipulated by DH and performance reports are generated quarterly.

The staff in the Support Unit work extremely hard to achieve these targets with the help of the specialist sub-group ARSAC members who review the individual applications.

2006 Quarterly reports for completed applications within 60 days:

March	99%
June	99.5%
Sept.	96.6%
Dec.	99.5%

Although overall the performance standards are high there are known bottlenecks in the process and because of this the Secretariat, with DH support and in collaboration with Oxford Radcliffe Hospitals NHS Trust, has decided to appoint another member of staff.

We have successfully recruited a senior nuclear medicine physicist – Louise Homer - who will work at the Support Unit 1 day a week and the other 4 days at the Churchill Hospital in Oxford. By recruiting someone who is currently practising in nuclear medicine the Support Unit and Secretariat will also have more readily available access to information about developments in the field.

This role at the Support Unit will be varied but Louise will be involved in collating and analysing information received as part of the certification process, resolving queries, in allocation and developing radiopharmaceutical serials and recommending changes to the database. She will also be available for input into background information to the secretariat; preparing papers for working party and main committee meetings.

### 3. Changes to legislation

As many of you will be aware there have been amendments to some of the Regulations relevant to Nuclear Medicine practice, namely:

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

A summary of the changes and what they mean in clinical practice has been written by Paul Maltby and Richard Lawson in a recent paper; Administration of Pharmaceuticals in Nuclear Medicine available via the link below or on the BNMS web site.

[www.ARSAC.org.uk/newsletter/docs/reference\\_1.pdf](http://www.ARSAC.org.uk/newsletter/docs/reference_1.pdf)

### 4. Changes to Notes for Guidance revision March 2006

The current edition of the Notes for Guidance is held on the ARSAC web site and it will be necessary, periodically, to download a revised version to ensure that nuclear medicine services have available to them the most up to date copy of the Notes for Guidance.

#### Section 7 Conception, Pregnancy and Breast Feeding

##### Advice to Females of Childbearing Potential after Administration of Long-lived Radionuclides

In the December 1998 revision of the ARSAC Notes for Guidance, the period to avoid pregnancy after  $I^{131}$  therapy was given as 4 months. This value was based on the calculated dose to the fetus being maintained below 1mGy.

The 2006 Notes for Guidance Section 7 Table 7.1 revised this period to 6 months, and this change has led to a number of queries.

ARSAC's decision to change this guidance followed consideration of two factors:

1. between 1998 and 2006, the concept of dose constraints was introduced and became widely used – this was not taken into account in the 1998 revision of the ARSAC Notes for Guidance. Adopting a dose constraint of 0.3mSv for these exposures would have required an increase from 4 to 6 months for the period to avoid pregnancy.

2. ICRP 94, “Release of patients after therapy with unsealed radionuclides” was published in 2004. This notes that following I<sup>131</sup> therapy, the appropriate time to avoid pregnancy from a dosimetry point of view is 4 months. This is consistent with the ARSAC view of 1998. ICRP recommends however (section 13.5, para 184) that most female patients should be advised not to become pregnant for at least 6 months after therapy, based on the need to be sure that:

- a. the hyperthyroidism or cancer is controlled
- b. another treatment with radioiodine will not be needed when the patient is pregnant.

This final factor was by far the most compelling reason for the change to a 6 month recommendation i.e. the basis for the change is on clinical considerations rather than on dosimetric grounds.

After further consideration, the ARSAC has decided to make a further change and recommends that females undergoing treatment with I<sup>131</sup> should avoid pregnancy for at least 6 months. This is consistent with ICRP advice.

### Appendix I Part A

It is expected that amendments to Appendix I will account for the most frequent changes to the Notes for Guidance and these will be highlighted and explained in each edition of the ARSAC Newsletter.

#### Lymph node and sentinel node imaging and probe studies

In March 2006, the serial for lymph node imaging (43a7iii) was replaced with four separate serials (43a7xi, 43a7xii, 43a7xiii and 43a7xvii) to reflect the development of sentinel node imaging and probe studies and the need for specific training for some of these techniques.

Lymph node imaging (43a7iii) has now been directly replaced with lymph node (lymphoedema) imaging (43a7xvii) and those certificate holders who have previously held 43a7iii will see that this will be replaced by 43a7xvii on renewal of their certificates.

Those wishing to undertake sentinel node imaging and probe studies, should ensure they hold the serials listed in the Notes for Guidance revision March 2006. If necessary, applications with evidence of appropriate training should be made to the ARSAC Support Unit.

Clarification regarding the diagnostic reference levels for all these investigations (activity per limb, activity for one and two day protocols) is given within Appendix I Part A on the web site.

Sentinel node imaging and probe studies for conditions other than those listed in the current Notes for Guidance should be submitted as research applications, unless the individual applicant has previous research experience or the body of evidence to support routine use has changed significantly.

## Appendix I Part C

### Treatment of arthritic conditions

The use of <sup>90</sup>Y colloidal silicate in aqueous solution for the treatment of arthritic conditions (OC6) is a well established technique and has been included within the Notes for Guidance for many years as a routine therapy serial. Recently, colloidal citrate has been used (OC52) as an alternative for this treatment and is available through established sources.

The Notes for Guidance have been amended to reflect this. Those certificate holders holding serial O6C may now use the citrate form without making a further submission to the ARSAC Support Unit. Revisions to the schedules of current therapy certificates are not deemed necessary. On renewal, certificates will reflect this change by including both chemical forms under serial OC6.

## **5. Hot Topics**

### **a. The use of MUGA and ECHO in research studies**

The Medicines (Administration of Radioactive Substances) Regulations 1978 (the MARS Regulations) state that any doctor or dentist who wishes to administer radioactive medicinal products to humans, whether for diagnosis, treatment or research must hold a certificate to do so issued by Health Ministers. To assist Ministers in their decisions, the Administration of Radioactive Substances Advisory Committee (ARSAC) assesses applications, including ones for research using radioactive medicinal products, for certificates.

The Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R) require that radiation doses from medical procedures should be optimised and that where possible, alternative techniques that do not result in radiation dose should be considered and used if appropriate.

It has come to the Committee's attention that research studies that include a requirement for assessment of left ventricular ejection fraction as an indicator of cardio-toxicity often provide the option of using echocardiography or MUGA scans to do so. MUGA scans result in a small radiation dose to subjects as they involve the injection of a radiopharmaceutical and therefore research studies using MUGA scans are subject to certification under the MARS Regulations.

The ARSAC is aware that echocardiography scanning is not provided routinely at all centres and that this technique is operator dependent. It is also noted that performance of high quality MUGA scans within a multi-centre study will require good quality control procedures to be in place both within each centre and across all participating centres.

In support of the IR(ME)R, the ARSAC is of the view that in such studies, wherever possible and where used for clinical practice, echocardiography scanning should be used in preference to MUGA scanning, that MUGA and echocardiography should not be optional within any participating centre and that ideally all centres participating in a study should adopt the same technique. This approach will reduce the radiation dose to individuals and aid consistency.

## **b. Guidelines on Holding a certificate at remote sites.**

Certificates issued under the Medicines (Administration of Radioactive Substances) Regulations 1978 (MARS) are issued to doctors and dentists where Health Ministers are reasonably satisfied regarding:

- (i) the knowledge, experience, competence and skill of the applicant
- (ii) the availability of suitable equipment and facilities
- (iii) the availability of suitably qualified staff

Certificates therefore are issued on a site specific basis.

The established model for the certification of nuclear medicine services is based on an ARSAC certificate holder, employed by an NHS Hospital Trust, holding certificates at his/her hospital site.

Four regularly occurring exceptions to this are:

- a. when a Hospital Trust has multiple sites each providing nuclear medicine services – for flexibility a certificate holder may hold certificates at each site within the Trust
- b. when a certificate holder provides services at a private hospital
- c. when a hospital has insufficient workload to justify a comprehensive nuclear medicine service
- d. when a certificate holder has specialist expertise that is required for patients at a number of hospital sites, each of which cannot provide a specialist competent in this area. Until recently, the most common example of this was the availability of nuclear medicine expertise for therapy administrations.

Whilst not ideal, these exceptions have tended to involve a certificate holder holding certificates at only a few sites, all within close geographical proximity to the certificate holder's main base. In general the Committee has been content that adequate levels of supervision can be maintained.

Recently, three additional circumstances have become increasingly common:

- a. the provision of mobile PET services has expanded at a greater rate than the availability of comprehensive expertise with this modality. This has resulted in certificate holders having certificates for many "sites" that the mobile service visits. Whilst in the longer term this is expected to be rectified, with local certificate holders undertaking PET training, in the shorter term this may become more common, stimulated by the Government's policy on independent sector provision.
- b. increased mobility of NHS consultant staff has resulted in certificate holders wishing to maintain interest in research projects initiated by them at hospitals that they have since left. In some cases, this involves supervision of research students at their previous hospitals
- c. increased collaboration between sites each offering different elements of a research study has resulted in lead researchers (and certificate holders) wishing to remain responsible for studies at a number of sites.

MARS Regulation 2(1) states

"No person shall administer to a human being (otherwise than to himself) any radioactive medicinal product unless he is a doctor or a dentist holding a certificate issued by the Health Ministers for the purposes of Section 60 of the Act in respect of radioactive medicinal products (hereinafter referred to as a "certificate") or a person acting in accordance with the directions of such a doctor or dentist"

**In cases where others work under the written directions of the certificate holder, this implies that the certificate holder has some level of managerial control of the processes under which the administrations take place and of the staff that undertake them. The certificate holder must be able to provide adequate supervision of individual administrations, as appropriate**

Where applications are made for certificates to be held by individuals operating at a site remote from their normal place of employment, a number of criteria should be considered:

- (i) the level of supervision that can be provided at the remote site by the applicant
- (ii) the contractual arrangements that can be put in place to allow the applicant to fulfil his/her responsibilities under the Regulations in terms of staff undertaking functions under the applicant's written directions and the safety of patients or others
- (iii) the need for the certificate to be held by the applicant rather than by a local certificate holder

In considering this last criterion, due attention should be paid to the following:

- (i) is there specific local expertise relating to the application in existence such that a remote certificate holder is not necessary
- (ii) in the case of research applications (extensions), is the research already underway under a certificate previously issued to the applicant
- (iii) if so what impact would there be on the research and those involved in this research if the certificate is allocated to a different, local doctor or dentist

The level and scope of responsibility relating to the certificate holder has not previously been clearly defined. It is proposed that the certificate holder should be available to provide supervision regarding:

- (i) the justification of the exposure of individuals
- (ii) contraindications to the justification of exposure of individuals
- (iii) the optimisation of the exposure through adherence to protocols under which the administration and subsequent investigations (utilising the radioactive medicinal product administered) are conducted and
- (iv) any necessary deviations from standard protocols on a case-by-case basis

In the case of research applications, any decisions relating to the granting of a certificate under the Regulations to an applicant for a remote site should not have impact on decisions regarding the appropriateness of the applicant to supervise elements of the research, other than the administration of radioactive medicinal products, or those undertaking such research.