

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 where appropriate.

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

Any enquiries about the content of the Newsletter should be directed by e-mail to the ARSAC Secretariat.

Issue 4: November 2009

Contents

1. Changes in ARSAC membership
2. Support Unit update
3. Hot Topics
 - a. PET/CT training for cardiac and neurological investigations
 - b. Research ARSAC applications using IRAS
 - c. Administered activity for SLNB techniques
 - d. ARSAC work in progress

1. Changes in ARSAC membership

The following were appointed to the Committee in June 2008:

Dr Lorenzo Biondi;	Consultant in Nuclear Medicine, Great Ormond Street Hospital for Children, London
Mr David Jones;	Superintendent Radiographer, Wrexham Maelor Hospital, Wrexham
Dr Wai Lup Wong;	Consultant Radiologist, Mount Vernon Hospital, Northwood

In early 2010 ARSAC will advertise the following additional vacancies:

- 5 Nuclear Medicine Specialist positions – of which 3 should have training and experience in therapeutic applications of nuclear medicine
- 1 Radiopharmacist position
- 2 Medical Physicist positions

As the ARSAC is an advisory body to the Department of Health (DH), all appointments are made via the Appointments Commission. This ensures that the appointment process is open, fair and impartial and that appointments are based solely on merit. Further details will be published on the ARSAC website.

2. Support Unit update

The Support Unit is required to meet performance standards set by 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.

2008/2009 Quarterly reports for completed applications within 60 days:

	2008	2009
March	100%	97.8%
June	97.9%	97.7%
September	98.4%	97.9%
December	100%	-

In August 2009, the ARSAC Secretariat employed a full-time Senior Nuclear Medicine Physicist, Louise Homer. Louise originally started work at the Support Unit, 1 day per week in 2007 and has gained a good understanding of the work involved in the certification process. In her new role, Louise will offer additional scientific support to the Committee and will be taking part in the work detailed in section 3d of this newsletter.

3. Hot Topics

a. PET/CT training for cardiac and neurological investigations

The ARSAC Notes for Guidance include advice on additional training requirements for those nuclear medicine specialists who wish to be certificated for PET/CT oncology procedures. In 2007, ARSAC established a PET/CT training sub-group to consider training requirements for cardiac and neurological PET/CT.

ARSAC recognises that there are relatively low numbers of centres that provide cardiac and neurological PET/CT services across the UK. Because of the low volume of work for both clinical indications, an applicant would need to demonstrate:

- Working within a specialised unit for the serial applied for
- Provide assurances of availability of MDT and adequate back-up services e.g. second read from an established centre
- Predict adequacy of through put to maintain competency
- Provide an external audit of start-up activity

To assist applicants, the following training requirements have been established:

Neurological PET/CT

Theoretical:

- Knowledge, experience and certification relating to SPECT imaging for the brain
- Fundamental aspects of PET/CT imaging
- Specific understanding of neurological PET/CT (consistent with the RCP syllabus for nuclear medicine)

Practical:

- Visit to established neuro PET/CT centre (2-3 cases per week) for approximately 4 to 6 weeks to establish practical competence etc
- Practical Experience / Image Interpretation
- Mentored review of 50 cases (including library cases) for each indication

Cardiac PET/CT

Theoretical:

- Knowledge, experience and certification relating to SPECT cardiac
- Fundamental aspects of PET/CT imaging
- Specific understanding of cardiac PET/CT (consistent with the RCP syllabus for nuclear medicine)

Practical:

- Visit to established cardiac PET/CT centre (approx 20 cases per week) for approximately 4 weeks to establish practical competence etc
- Practical Experience / Image Interpretation
- Mentored review of approximately 100 cases (including library cases), undertaken during attachment

b. Research ARSAC applications using IRAS

From the 1st of September 2009 the Integrated Research Application System (IRAS) became the only method of completing new online submissions to Ethics Committees. A research ARSAC certificate is required for research projects involving the administration of RMPs over and above that involved in routine diagnostic or therapeutic management. Each applicant for a research ARSAC certificate must submit Parts A, B4 and C of the full ARSAC application form and a one-page summary of the trial. Part B4 can be generated by the IRAS and substituted for that section of the full form. If the IRAS B4 is used, the one-page summary is no longer required.

There were initial teething problems with the auto-generated Part B4, however we believe these have now been resolved and correct completion of the project information in IRAS will automatically generate most of the information required to complete Part B4. All populated fields are read-only and can only be amended by agreement with the project owner and lead radiation experts for the study. The local certificate-holder should enter their name and any additional information about local variations in clinical practice in the field highlighted.

Applicants should also note that an additional question (A3) has been added to the integrated dataset in a recent software revision. Investigators are now required to outline what steps will be taken to exclude women who are pregnant or who could become pregnant during the study.

The completed form should be submitted, along with signed Parts A and C of the full ARSAC application form, to the ARSAC Support Unit, Centre for Radiation, Chemical and Environmental Hazards, Health Protection Agency, Chilton, Didcot, OX11 0RQ.

ARSAC will accept research applications using either the IRAS method or the B4 section of the full ARSAC application form which is available on the website www.arsac.org.uk

Notifying amendments to ARSAC

ARSAC should be notified of any changes to the administration of radioactive materials during a study, e.g. dose changes, new modalities, new classes of study participant.

Such changes will normally meet the criteria for notifying substantial amendments to the Research Ethics Committee (or GTAC). It is the responsibility of the certificate holder to notify ARSAC of relevant changes to the trial protocol. Notification should be made by letter to the ARSAC Support Unit and should indicate that the Research Ethics Committee has been informed.

In a multi-site study, it is helpful if the trial co-ordinator can provide a template letter for all sites involved. ARSAC will contact certificate holders if any further information is required and/or the changes could affect existing certification.

Further guidance may be sought from the ARSAC Support Unit.

c. Administered activity for SLNB techniques

A discrepancy between the ARSAC DRL for breast SNLB and the advice published in the BNMS guidelines has been identified. The BNMS has now adjusted its guidelines so that the administered activity matches the ARSAC DRL and New Start recommendations. For breast SLNB, the activity to be used depends upon the time delay between administration and surgery. For patients undergoing imaging on the same day as surgery, the administered activity should be 20MBq, but for patients undergoing imaging the day before surgery, the administered activity should be adjusted according to the delay between imaging and surgery so that approx 10MBq in total is present within the patient at the time of surgical procedure.

Post administration, the activity remaining in the syringe should be assessed. The BNMS guidelines give further details of techniques to minimise the amount of residual activity within the syringe. Where appropriate, the ARSAC certificate holder may authorise an increase in the administered activity to ensure adequate imaging and detection in theatre.

Administered activity for SLNB for melanoma was discussed at the national consensus day held at St Thomas' Hospital in June 2009. Given the wide variability of lymphatic drainage in malignant melanoma, there are a number of occasions where the administered activity may need to be increased in melanoma SLN imaging above the current ARSAC DRL. ARSAC will provide further information on this topic following the publication of melanoma SLNB guidelines by the consensus group.

d. ARSAC work in progress

Review of Part C on Application form

The ARSAC Working Party has established a Working Group to rationalise the guidance available to the supporting staff who sign Part C of the ARSAC application form. This group will clarify the responsibilities of each person that is required to sign the various sections of the form and review the information included in the form. This group will be chaired by Dr Tom Nunan.

Therapy working group

This group has been set up to establish the training and competencies required for a range of therapy serials. This work will review the training requirements for serials listed in the ARSAC Notes for Guidance but will also include new therapies and procedures. This group will be chaired by Dr Valerie Lewington.

Paediatric doses / administered activity

Following the publication of the new EANM paediatric dosage card and the issues raised by Rixham and Roberts [1] in applying this new approach within the UK, the ARSAC is reviewing the weighing factors that are currently published in the Notes for Guidance.

The review will start by evaluating published literature on the subject of paediatric imaging in Nuclear Medicine. This will include subjects such as administered activity, image quality, motion correction etc. These results will inform the plan for a study evaluating image quality parameters vs administered activity for the most common paediatric imaging indications. The use of minimum administered activity levels will also be reviewed. This work will be carried out in conjunction with Dr Lorenzo Biassoni, Great Ormond Street Hospital, and other centres throughout the UK.

Medium/Long term review of 99Mo crisis

The BNMS, UKRG and ARSAC are working together to co-ordinate the UK response towards the recent Molybdenum crisis. The BNMS website is updated regularly with information on the crisis.

ARSAC is preparing a report for DH looking at medium to long term responses to the crisis. This will include making the best use of the activity that is available through better co-ordination of supply in the UK, and the use of new hardware and software options such as resolution recovery software to maximise image counts from lower administered activity. The report will also look alternative techniques such as PET/CT or MRI. It is intended that this report will be ready for publication in September 2010.

[1] The new EANM paediatric dosage card: how does it affect UK centres working under the ARSAC guidelines? Rixham PA and Roberts G, Nuclear Medicine Communications 30(4): 319-320 2009