

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.

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1. **Changes in ARSAC membership**

The ARSAC membership has not changed since March this year. However within the next year two members of the committee will be completing their term of office and there will be the opportunity for new members to be appointed by The Appointments Commission; on behalf of Department of Health Ministers. Further details of this process will be included in future newsletters.

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 all 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, with a minimum of 90% of applications achieving this target. To monitor compliance with the standards, 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.

2007 Quarterly reports for completed applications within 60 days:

March	97.9%
June	98.8%
Sept	96%

Following the appointment of a new part time member of staff in March, all processes within the system are being reviewed so that this level of performance is maintained.

3. 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.

The following sections have just been revised and the reasons for this are set out below.

Appendix I Part A

Diagnostic reference levels for myocardial imaging

The ARSAC has decided to revise its diagnostic reference levels for myocardial imaging following acceptance of a paper by Richard Underwood by the European Journal of Nuclear Medicine. The paper entitled "The relationship between administered radiopharmaceutical activity in myocardial perfusion scintigraphy and imaging outcome" followed an ARSAC sponsored research study.

The study was based on a representative sample of UK patients and concluded that increasing activities upto 750 MBq led to better quality images, but increasing beyond this activity to 1000 MBq gave no useful benefit.

ARSAC has revised its diagnostic reference level values for technetium labelled sestamibi and technetium labelled tetrofosmin in line with these findings to 800 MBq and 800 MBq for a two day rest – exercise protocol and to 400 MBq and 1200 MBq for a one day protocol. The Notes for Guidance have been amended to reflect this. Administered activities may need to be adjusted up or down for patient size or weight but it is expected that adjustments made with regard to administrations of 800 MBq and 1200 MBq will be smaller than those required for administrations of 400 MBq.

Image quality is thought to be superior with a two day protocol, particularly with gated studies, and this is the preferred approach. It is acknowledged however that a one day protocol may be required for some patients and should remain an option.

Where certificate holders originally applied for myocardial imaging procedures by referencing the serial number in the ARSAC Notes for Guidance, or by applying for the functional group, then the use of activities up to these new diagnostic reference level values is automatically available and the certificate holder does not have to inform the ARSAC of changes to practice.

Appendix IV Part B

Practical experience for PET imaging

ARSAC has for some years issued advice on the types and levels of theoretical training and practical experience needed by doctors and dentists who wish to

apply for a certificate to administer radioactive medicinal products as required under the MARS Regulations. This advice has taken the form of a core curriculum and suggested levels of practical experience. Numbers of procedures to be undertaken have been included as a guide, although it is recognised that competency should not be best assessed by consideration only of numbers of procedures undertaken. The core curriculum and practical experience suggested has been intended for those doctors who have not undertaken an appropriate training course developed by the Royal Colleges, or where such training courses do not include specific types of procedures.

The current Notes for Guidance include advice on additional requirements for those who wish to provide positron emission tomography services. They suggest applicants should be able to demonstrate active involvement in approximately 300 cases over a three month period in order to ensure experience of a representative case-mix.

This guide was based on the experience of those who have undergone training in the UK and abroad. Over the past twelve months however, ARSAC has reviewed this figure, taking into account changes in European standards and a survey of UK nuclear medicine trainees. The trainees had consistently indicated that the experience required was greater than that set by ARSAC and that continuity was crucial in developing competence.

As a result, ARSAC has decided to increase its requirements for practical experience from 300 to approximately 600 cases. It is expected for most applicants this will apply to oncology cases only. The Notes for Guidance have been amended to reflect this. This is to come into effect from 1 January 2008. Given the increase in throughput of modern PET CT services, this should be achievable within the same time period of about three months. Further advice will be developed for those wishing to undertake cardiac and neurological PET CT examinations – see below.

These changes have been discussed with the Royal College of Physicians and the Royal College of Radiologists. These Colleges are working towards a joint statement regarding experience for reporting PET CT images and ARSAC believes the changes outlined above are broadly consistent with this, although ARSAC has developed its experience requirements around a more comprehensive training need which extends beyond image evaluation,

Further information regarding training requirements for reporting will be available from the Colleges in the near future.

5. Hot Topics

a. NRES (formerly COREC)

Undertaking research in nuclear medicine requires that a specific research application is made to ARSAC, as well as submissions to the appropriate ethical committee. Increasingly research is multi-centred and will require an application to the National Research Ethics Service (NRES) operated by the National Patients Safety Agency (NPSA).

Previously ARSAC has worked with COREC in developing guidance on research applications using ionising radiation and is currently advising on an integrated approach under development by NRES.

The intention is to replace Part B4 of the ARSAC form and the one page summary of the ethics submission (which provide details of the research study to be undertaken) by information contained in the application form required by the

NRES. The ARSAC form will be generated automatically. Other parts of the ARSAC application form are applicant and site specific and cannot be generated from the NRES application. Applicants to ARSAC will need to submit original Parts A and C, signed as usual, along with the new NRES generated Part B4.

Further information will be provided when this facility is available.

b. Cyclamen

The detection of radioactivity in individuals crossing international borders has been reported in both the scientific literature and the general media. In some cases, residual radioactivity following diagnostic nuclear medicine investigations has been detected. The ARSAC has discussed this matter with the appropriate UK authorities.

Throughout these discussions, it has been apparent that officials at the Home Office and HM Revenue and Customs have been sensitive to the difficulties this may raise with patients who have undergone nuclear medicine procedures as part of their care pathway or those who have participated in research using radioactive medicinal products. ARSAC has been working with these organisations in order that, when radioactivity is detected, HM Customs officials undertake their enquiries in a discrete and confidential manner.

Patients who have undergone therapy nuclear medicine procedures would be expected to carry information or instruction cards etc issued by their hospital but similar approaches have not been universally adopted for nuclear medicine patients following diagnostic procedures. It may be prudent for such individuals to do so, if they intend to cross international borders.

In discussions it has been agreed that the use of existing documentation is preferable to issuing additional information and therefore it has been agreed that the simplest and most effective way forward is for diagnostic nuclear medicine patients to be advised to carry their appointment letters. These should already include the address of the hospital or clinic, the type of scan to be undertaken and the date of the procedure.

With this in mind, ARSAC proposes that all nuclear medicine services amend their current appointment letters by adding the following text:

"It has come to our attention that there are extremely sensitive radiation detectors in place in some train stations, airports and seaports around the world. These monitors can detect extremely small quantities of radiation and it is just possible that, until the radioactivity from this test has completely left your body, you may trigger one of these detectors. In the unlikely event that this occurs, there is no reason to be concerned. Customs officials who operate these types of detectors are experienced in understanding what the detector has picked up, and after asking you a few simple questions and conducting a brief non-intrusive examination with a hand held detector, will let you pass on your way as soon as possible.

Different countries have different procedures and some may wish to see your appointment letter as part of this process. If you are planning to travel in the near future it is recommended you carry this letter with you. Please ask a member of the department staff for advice on how long your body is likely to retain traces of the radioactivity, and therefore whether carrying your letter will be necessary."

ARSAC suggests that patients who undergo procedures involving technetium agents should be advised to carry their appointment letters if they intend to travel within 7 days of the administration. For other longer lived radioactive medicinal

products in routine diagnostic use, patients should be advised to carry their appointment letters if they intend to travel within the next 3 months. For patients who have undergone therapy using long lived radioactive medicinal products (eg prostate seeds), it may be necessary to carry the letter, as well as other instruction cards etc, for a longer period – this should be assessed on a case by case basis.

Changes to patient information usually require hospital approval. It is hope that by adopting the standard text above approved by ARSAC, the Home Office and HM Revenue and Customs, that the processes required to make these changes can be approved with the minimum difficulty.

c. ARSAC work in progress

As part of this newsletter, information is provided on a number of pieces of work that the ARSAC is considering. In this newsletter, the work of three of the committee's sub-groups is described.

Discharges Strategy Review Subgroup

Defra has requested the assistance of ARSAC in gathering information to allow a broad estimate for projections of discharges as part of its discharge strategy. This will be chaired by Dr Chris Gibson. Defra has previously approached others regarding this work and is expected ARSAC will build on this.

PET CT Training Subgroup

As indicated above, the ARSAC has provided advice on training requirements for those who wish to hold certificates under MARS for PET CT studies. This advice has been designed to apply to those who offer comprehensive conventional nuclear medicine services and whose primary interests are oncology imaging with PET.

The Committee recognises the value of PET CT for cardiac and neurological investigations and expects the number of PET CT procedures in these areas will grow as facilities become available. It is aware also that some nuclear medicine specialists in these areas restrict their practice to cardiology and neurology and that guidance on PET CT training is required for these specific practices. ARSAC has established a subgroup to consider this and intends offering further advice in 2008. The subgroup is chaired by Dr Mary Prescott.

Operator Training Subgroup

On 17 November 2006, the Medicines (Administration of Radioactive Substances) Amendment Regulations 2006 came into force. These Regulations allow for the authorisation, by entitled and trained non-medically qualified staff, of nuclear medicine procedures as long as justification is consistent with guidelines issued by the certificate holder. This is consistent with the practice allowed under Regulation 6(5) of IR(ME)R 2000. Further detail is available by using the link in the ARSAC Newsletter of March 2007.

Following the issuing of these amendment regulations, the chairman of the Committee on Human Medicines (CHM) asked ARSAC to take a lead on developing standardised training for operators who would undertake authorisation and administration of radioactive medicinal products and other pharmaceuticals associated with nuclear medicine procedures. The ARSAC has established a subgroup, chaired by Mr Paul Maltby, to work with CHM and BNMS to achieve this.