

Administration of Radioactive Substances Advisory Committee

Minutes of the 86th meeting, held on 23 May 2024 at the Novotel London Bridge, London

Present:

Chairman: Professor K Bradley

Members:

Ms K Adamson

Ms S Aldridge

Dr M Cooper

Dr A Craig

Dr K Dixon

Dr M Gaze

Mr D Graham

Dr A Henry

Dr N Hujairi

Dr P Julyan

Dr G Petrides

Dr S Rasul

Dr N Reed

Dr N Singh

Dr T Szyszko

Prof S Vinjamuri

Dr S Wan

Secretariat:

Mrs L Fraser (UKHSA)

Ms N Parkar (UKHSA)

Mr M Richardson (UKHSA)

Miss K Stonell (UKHSA)

Item 1 Welcome and apologies for absence

- 1.1 The Chairman welcomed members to the 86th meeting.
- 1.2 Apologies have been received from Dr Clare Beadsmoore, Dr John Dickson, Dr Neil Hartman, Mrs Clare Moody, Dr Shahid Rasul, Dr Arum Parthipun, Prof Jon Wadsley, Dr Tom Westwood, Dr Amina Powell (Maternity leave), Anncri Roberts (Scottish Gov).
- 1.3 The Chairman welcomed Dr Ann Henry and Dr Nick Reed to their first meeting. Dr Arum Parthipun (apologies) also joined the committee in April 2024.
- 1.4 The Chairman advised members that Dr Cooper will be standing down from the committee when her term comes to an end in July. A further update on membership will be provided at the next meeting.

Item 2 Declarations of members interests

- 2.1 The Chairman advised members that the declaration of members interests must be updated annually. This is published on the [members page](#) of the ARSAC website.
- 2.2 Members were asked to declare any changes to their interests since the last meeting. A full list of declarations will be added to website after the meeting. A declaration may be made now or at the start of any relevant item. Members should inform the ARSAC secretariat of any changes between meetings.

Item 3 Committee Protocols

- 3.1 The Chairman drew members' attention to ARSAC 02-24.
- 3.2 Members did not feel that the existing policy for reimbursement was flexible enough particularly as Members are unpaid and the distance/time required to travel is not taken into account. The Secretariat will feed comments back to UKHSA.

[Action: Secretariat]

Item 4 Minutes and notes of previous meeting

- 4.1 The Chairman asked members for corrections to the minutes of the previous meeting.
- 4.2 The minutes were accepted as an accurate record of the meeting and will be published on the ARSAC website.

[Action: Secretariat]

Item 5 Matters arising

- a) **Feedback from significant accidental or unintended exposure (SAUE) incident**

5.1 Mrs Fraser reminded members of discussions at previous meetings regarding the ¹³¹I therapy service which is currently suspended following an incident involving a pregnant patient. The CQC issued a prohibition notice under IR(ME)R and ARSAC revoked the employer licence. The CQC has closed the incident, but the prohibition notice remains in place, published on the CQC website. If a future employer licence application is received, ARSAC will engage with the CQC in the first instance.

b) Review of Ionising Radiation (Medical Exposure) Regulations 2017

5.2 Mrs Fraser reminded members that amendment regulations were being drafted and due to come into force later this year. Members will recall that the majority of the changes were minor, with a change to licence fees and allowing AI software to be used in an assistive capacity for clinical evaluation.

5.3 Following the general election announcement yesterday, there is uncertainty on the impact on the IR(ME)R amendment regulations. DHSC is making enquiries and the Secretariat will update members in due course.

[Action: Secretariat]

c) Application fees for licences

5.4 Mrs Fraser advised members that payment options for licence fees have been reviewed and it is not possible to implement a subscription model. However, the policy has been amended so that licences for NHS employers will now be released irrespective of whether the invoice for the fee has been settled.

d) ARSAC Notes for Guidance

5.6 The Chairman drew members attention to ARSAC 04-24 setting out the proposed updates for the 2025 edition of the ARSAC Notes for Guidance (NfG).

Section 3: Applying for a practitioner licence

Strengthen the guidance about submitting letters of support with initial practitioner licence applications to require this rather than “encourage” it.

5.7 The Chairman noted that, for therapies primarily, a letter of support is currently encouraged but not mandated. The Chairman also noted an increase in therapy applications which required a letter of support to resolve queries.

5.8 Members offered comments on the change. The Secretariat will review the application form and strengthen wording in the NfG.

[Action: Secretariat]

Update guidance for therapy applicants to ask how response to therapy will be assessed and documented.

5.11 Members offered comments on the change. The Secretariat will review the NfG and further draft questions for the application form.

[Action: Secretariat]

Section 5: Routine procedures

Strengthen ARSAC “recommendations” on dosimetry to “requirements”

- 5.13 Ms Parkar advised members that the guidance discussed here is included under the routine procedures sections of the NfG and additional guidance is in the research section. The Chairman noted a push for novel treatment early phase trials, so it is important to ensure the right balance without hindering routine practice.
- 5.14 Members offered comments on this change. The Secretariat will draft additional wording on image dose verification and to include details of involvement in relevant MDTs for patient management and selection.

[Action: Secretariat]

Include clarification that the procedure code for sentinel node (melanoma) imaging and probe studies includes Merkel cell carcinoma

- 5.16 This was included in a previous newsletter. The Secretariat will include this in the NfG.

[Action: Secretariat]

Section 6: Investigations in children and young persons

- 5.17 The Secretariat will remove reference to the use of pinhole collimators in the paragraph on sedation for investigations in children and young persons.

[Action: Secretariat]

Section 7: Pregnancy, conception and breastfeeding

- 5.18 Members agreed to the proposed changes.

[Action: Secretariat]

- 5.19 Members are asked to send any feedback or highlight any other areas to be addressed, including any procedures that should be removed, to the Secretariat, for review and approval at the November 2024 meeting.

[Action: All]

e) SimpleRad meeting

- 5.20 Mrs Fraser, Ms Parkar and Dr Dickson attended the workshop in Brussels organised by the European Commission on 10-11 December 2023 and fed back to the Committee.
- 5.21 The Secretariat will share the link to the report once published and will follow up with DHSC whether any equivalent work is being considered in the UK.

[Action: Secretariat]

Item 6 ARSAC Diagnostic Reference Levels (DRLs) for ¹⁸F-FDG for whole body tumour imaging and infection/inflammation imaging

6.1 The Chairman drew members attention to the draft article in ARSAC 05-24 for submission for publication. This includes the results of the survey for administered activity for ¹⁸F-FDG for whole body tumour imaging and infection/inflammation imaging. Ms Parkar reminded members that further work will be undertaken in due course to review other DRLs e.g. cardiac.

6.2 Members noted that the audit was only for PET. Members are asked to send any further comments to the Secretariat.

[Action: All]

Item 7 Members guide for assessing applications.

7.1 The Chairman drew members' attention to ARSAC 06-24, reminding members that this is an internal document to support the consistent review of applications. Proposed updates are track changed.

7.2 Members offered minor comments for update.

[Action: Secretariat]

Item 8 Practitioner training

a) Brain PET amyloid imaging

8.1 The Chairman drew members' attention to ARSAC 07-24 and the excerpt of guidance in the current NfG.

8.2 Members briefly discussed the guidance and agreed that the current requirements were not unreasonable or restrictive and therefore no further updates were required at this stage.

8.3 Mrs Fraser suggested additional clarification could be added to the NfG that 'authorisation' means that the applicant holds a licence for ¹⁸F-FDG imaging for differential diagnosis of dementia.

[Action: Secretariat]

b) Molecular Radiotherapy

8.4 Ms Parkar reflected on the current guidance in the NfG. Given there is an increase in therapy applications, members are asked to consider whether any changes to the guidance are required.

8.5 Members suggested that an additional sentence about CPD and plans for future CPD is included in the declaration. The Secretariat will amend the application form and the NfG will reflect the requirement for future plans for CPD.

[Action: Secretariat]

Item 9 Trends and issues on applications

a) HMDP for cardiac amyloid imaging

- 9.1 Mrs Fraser drew members' attention to ARSAC 08-24. The ARSAC position was established following consultation with National Amyloid Centre. Guidelines have been published recently which now includes ^{99m}Tc-HMDP as a suitable alternative for cardiac amyloid imaging. The Secretariat discussed this with one of the authors, at BNMS, who acknowledged there is now better evidence for ^{99m}Tc-HMDP. Members were asked to consider whether it should be added as a procedure code.
- 9.2 Members discussed this briefly noting that an amyloid lowering drug previously rejected by NICE is being evaluated. The current position that ^{99m}Tc-DPD is preferred for the diagnosis of transthyretin cardiac amyloid, would be maintained but committee will maintain a watching brief and consider any applications that are received.

b) Short employer licences issued

- 9.3 Mr Richardson reminded members of the basis on which short employer licences are issued. The expectation is that after two years there has been some progress in resolving the issues that led to the short licence being issued. There are currently 27 short licences in place for a number of reasons including equipment age, level of MPE support and non-adherence to UKRG drawing up guidance. The criteria applied by ARSAC has led to notable improvement or real action to improve service provision. Feedback is generally positive, and departments have been able to use short licences to support business cases. Members are asked to consider whether the current approach is still appropriate.
- 9.4 Members discussed the impact of the shortage of MPEs and that a short licence would not necessarily resolve this issue. Ms Parkar noted a pragmatic approach in these instances where, if the IPEM guidance is not met, the provision is questioned but it does not automatically result in a short licence being issued.
- 9.5 Members agreed that the approach to short licences was still appropriate but suggested some key metrics about the short licences would be useful in relation to response to the reasons for issue.

[Action: Secretariat]

- 9.6 Members briefly reflected on the requirements of the BSSD that an individual or group of individuals can act as MPEs if it is written into legislation. Members noted the MPE recognition scheme operated by RPA2000 only considers individuals. The Secretariat will follow up with DHSC.

[Action: Secretariat]

- 9.7 Mrs Fraser added that none of the short licences have been issued as a result of lack of practitioner support. The NfG states a requirement for at least one

practitioner, and more than one is recommended to allow for resilience.

c) Appropriate CRE reviewers for nuclear medicine research applications

- 9.8 Ms Parkar reminded members of guidance published by the HRA that ARSAC reviewed and agreed on limited circumstances when the Clinical Radiation Expert (CRE) reviewing a research study including nuclear medicine procedures did not need to be a licensed practitioner. The NfG also sets out guidance on when the CRE should be a licenced practitioner.
- 9.9 Applications continue to filter through where the CRE is not a licensed practitioner and it is unclear whether a licensed practitioner has fed into the review process. The Chairman acknowledged that for some novel treatments a CRE will never have held a licence.
- 9.10 Members offered the comments:
- 9.12 The Secretariat engages regularly with the HRA and will feed back member comments about the process.
- 9.13 Mrs Fraser suggested that cross referencing of CREs with licensed practitioners and a summary of who else has been involved is trialled for therapy research applications in the first instance. Mrs Fraser reminded members that any queries with an application can be raised with the Secretariat.

[Action: Secretariat]

- 9.14 Members suggested the same approach was applied for MPEs. Ms Parkar noted the ARSAC list of MPEs associated with NM services only includes the lead MPE so the Support Unit would not be able to cross check this in the same way.

Item 10 UKHSA update

a) Update on JIRA

- 10.1 Ms Parkar thanked members for their patience during the transition of JIRA. All members should now be able to access the portal and their applications for review. There are some minor issues to resolve including the email subscription service. The Secretariat will confirm as soon as this has been reinstated. In the meantime, there is a filter of all outstanding applications viewable in the confluence guidance and the dashboard highlights all assigned applications, but it does not differentiate between those already viewed.

[Action: Secretariat]

b) ARSAC application processing timescales

- 10.2 The output from JIRA includes number of applications, processing times and average resolution time for the last six months.

c) ARSAC annual report

- 10.3 Members will recall this is a standard template published each year setting out meeting dates, membership changes, data for applications/research approvals and publications.
- 10.4 Members noted an error in the November meeting date – amend from ‘2024’ to ‘2023’. This will be amended and published on the ARSAC website.

[Action: Secretariat]

d) National incident coding taxonomy

- 10.5 Mrs Fraser advised members that the UKHSA published the user guidance and national coding taxonomy for incident learning in clinical imaging, magnetic resonance imaging and nuclear medicine in April 2024. A system is being developed currently to receive data from local trust reporting systems either indirectly via NHS England LFPSE and Once for Wales, or directly from sites locally in Scotland and Northern Ireland. The data will be analysed and disseminated regularly to inform local analysis and share learning. This is separate to ARSAC but links into patient safety and therefore some shared learning.

Item 11 Nuclear medicine items from other committees/meetings

a) RCR

- 11.1 Dr Gaze advised members that there was no update of relevance to NM.

b) RCP

- 11.2 Mrs Fraser advised members that the group is developing a training credential for therapy.

c) ICSC

- 11.3 Dr Gaze advised members that he is no longer a member. Mrs Fraser advised members that Dr Amy Eccles is the new Chair. The last meeting discussed the regulation of physician associates which is not an issue in NM. The Chairman noted this is a growing area in Radiology. Mrs Fraser added that the RCP is going to develop guidance. Physician associates will be GMC registered.

d) UKRG

- 11.4 Dr Cooper advised members that the drawing up guidelines are being reviewed. Single doses are perceived as the gold standard but the emphasis is being shifted that both single and multi dose vial dispensing are equal and acceptable, and a risk assessment should be in place for whichever method is chosen.

e) BNMS

- 11.5 No one present to report.

f) SCoR

11.6 Prior to the meeting Mrs Moody confirmed there was no update of relevance to NM.

g) EANM physics committee

11.7 No one present to report.

Item 12 Date of next meeting

12.1 The next meetings will take place in November 2024 and May 2025. The Secretariat will issue a Doodle poll to determine availability.

[Action: Secretariat]

Item 13 Any other business

13.1 No items were raised.