Administration of Radioactive Substances Advisory Committee

Minutes of the 87th meeting, held on 7 November 2024 at the Wesley Hotel, London

Present:
Chairman: Professor K Bradley

Members:
Ms K Adamson
Ms S Aldridge
Dr C Beadsmoore
Dr A Craig
Dr K Dixon
Prof J Dickson
Prof M Gaze
Mr D Graham
Dr A Henry
Dr P Julyan
Dr A Parthipun
Dr G Petrides
Dr S Rasul
Dr N Reed
Dr N Singh
Dr T Szyszko
Prof J Wadsley
Dr S Wan
Dr T Westwood

Secretariat:
Mrs L Fraser (UKHSA)
Mr M Richardson (UKHSA)
Miss L Burns (UKHSA)

Item 1 Welcome and apologies for absence

1.1 The Chairman welcomed members to the 87th meeting.

1.2 Apologies were received from, Prof Sobhan Vinjamuri, Mrs Clare Moody, Dr Neil Hartman, Dr Nabil Hujairi, Ms Nasreen Parkar (UKHSA), Dr Amina Powell (UKHSA), Priya Iype (DHSC) and Anncris Roberts (Scottish Government).

1.3 The Chairman gave thanks to Prof. Mark Gaze and Prof Sobhan Vinjamuri as this will be their last Committee meeting.

1.4 The Chairman advised members that following internal promotion, Laura Burns will be taking the notes for this meeting.

Item 2 Declarations of members interests

2.1 The Chairman provided an update to the current committee vacancies.

2.2 The Chairman relayed a message from the DHSC regarding proper conduct surrounding conflicts of interest and media engagement.

2.3 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.

Item 3 Minutes of previous meeting

3.1 The Chairman asked members for corrections to the minutes of the previous meeting.

3.2 The minutes were accepted as an accurate record of the meeting and will be published on the ARSAC website.

[Action: Secretariat]

Item 4 Matters arising

a) Committee protocol

4.1 The Secretariat confirmed that UKHSA will not be able to reimburse for 1st Class travel for attendance at committee meetings.

b) SimpleRAD meeting

4.2 There has been no update on the publication of the SimpleRAD report by the European Commission following the workshop focusing on therapeutic uses of radiopharmaceuticals. Corrections are currently being made and once complete, these will be published and made available to the Committee.

c) Members guide for assessing applications

4.3 The members guide for assessing applications was agreed at the last meeting and will be used for the induction of new members.

Item 5 ARSAC Diagnostic Reference Levels (DRLs) for ^{18}F-FDG for whole body tumour imaging and infection/inflammation imaging

5.1 The Chairman drew members attention to the draft article in ARSAC 11-24 and Annex A. Following on from the previous meeting, the secretariat has collaborated with members to produce a revised draft of the DRL paper for publication.

5.2 Members raised the question of whether variation in local DRLs across sites could present a barrier to participation in research studies. It was suggested that local protocols should allow flexibility in this regard.

5.3 There was a discussion on the importance of setting DRLs to exploit the performance of modern digital equipment which can then be used to support business cases for replacement of old, technically inferior equipment. The secretariat agreed that a caveat should be included in the paper, specifying that if equipment limitations meant that diagnostic image quality cannot be achieved with the specified dose, local adjustments can be made.

5.4 The Committee agreed to set the NDRL at 3.5 MBq/kg for ^{18}F-FDG for whole body tumour imaging and infection/inflammation imaging.

5.5 The Committee discussed if there was a need to review the NDRL for brain imaging with PET/CT. It was highlighted that weight-based scaling does not significantly impact imaging of the brain.

5.6 Members expressed the need for clearer and more definitive language and would provide suggested revisions to the secretariat.

[Action: Committee]

5.7 The secretariat would make final updates to the paper based on the discussion and submit to Nuclear Medicine Communications.

[Action: Secretariat]

Item 6 ARSAC Notes for Guidance

6.1 The Chairman drew members attention to ARSAC 12-24, Annex A. This includes the draft 2025 Notes for Guidance. Members provided the following feedback to the draft changes.

- Section 3.13 (f) - Updates regarding the submission of support letters for

new practitioners. It was confirmed that letters are only mandated for therapy related applications.

- Section 3.42 – requires some grammatical changes.
- Table 5.1: Minor updates and clarifications to existing procedures
- Sections 7.12-7.17 – Updates to include advice on avoiding conception after treatment with ^{223}Ra-Chloride.
- Section 7.16 – Proposed changes to this section to be submitted to the secretariat by the beginning of December.
- Section 7.21 – Wording changes regarding the administration of ^{123}I radiopharmaceuticals for breastfeeding patients. The original wording should remain until further work can be done on this.
- Table 7.1 – Clarification required on time frames to avoid pregnancy for 131I treatments. Further context is required detailing risks and safe intervals. This will be gathered by the secretariat and updated in the Notes.
- Section 7.23 – updated to be consistent with the second edition of the Medical and Dental Guidance Notes.
- Section 7.30-7.33 – minor updates to breastfeeding interruption times.
- Section 8.9 – clarification on thyroid blocking protocols

6.2 The Secretariat will update the Notes based on the feedback from the Committee discussion.

[ACTION: Secretariat]

6.3 Members provided an update on NHS England's updated service specification for molecular radiotherapy which includes guidance on dosimetry which should be addressed.

6.4 The Notes for Guidance already includes guidance on dosimetry however, ARSAC could issue a newsletter to highlight this area of regulations. Members suggested that this matter might be better handled in a more focused manner with senior members of NHS England.

[ACTION: Committee and Secretariat]

Item 7 Ionising Radiation (Medical Exposure) Amendment Regulations 2024

7.1 The Chairman drew members' attention to ARSAC 13-24 Annex A for the combined amended regulations. The regulations only apply to Great Britain, there is no update on when equivalent amendment regulations are expected in Northern Ireland.

7.2 Members were asked to consider whether the inclusion of software in IR(ME)R would impact the Employer licence application forms. The Secretariat would provide members with a statement agreed by the IR(ME)R regulators on this.

[Action: Secretariat]

Item 8 ARSAC assessment of impact of ^{131}I-mIBG supply issues

8.1 The Chairman drew members' attention to ARSAC 14-24 and Annex A. On 8 October 2024, the Department of Health and Social Care asked ARSAC to consider the impact on UK molecular radiotherapy services of the decision by GE Healthcare to discontinue the supply of ^{131}I-mIBG at the end of 2024. The Committee was asked to provide comments and feedback prior to responding formally to DHSC.

8.2 It was concluded that the paper had answered the questions posed by DHSC with no further amendments required. The secretariat will include a cover letter to DHSC offering recommendations if required.

[ACTION: Secretariat]

Item 9 ECMC report - Imaging reviews for setting up Early-Phase Oncology Trials

9.1 The Chairman drew members attention to ARSAC 15-24. This document describes 6 challenges and recommendations which are listed in the cover paper, these question the suitability of IR(ME)R when applied to early phase trials and the burden of approvals processes.

9.2 It was discussed amongst the committee the issues with the approvals process

Item 10 Research Update

a) Inappropriate CRE reviewers for research studies

10.1 At the last meeting, concerns were raised regarding the appropriateness of some CRE reviewers for nuclear medicine research applications. The Secretariat have liaised with the HRA and discussed the processes for Radiation Assurance and non-Radiation Assurance studies. The guidance is clear on where a licensed practitioner is recommended for research studies and when a CRE who is not a licensed practitioner can complete the assessment. For therapy research studies the ARSAC Support Unit will now specify for members whether the CRE is a licenced practitioner.

b) Update to IRAS

10.2 ARSAC last reviewed the radiation question set used for research studies in 2019 and gave feedback on this as part of the proposed update to IRAS. A new project has started to update IRAS and the question set will be revisited as part of this work.

Item 11 Trends and issues on applications

a) Short employer licences

11.1 The Secretariat provided an update on short licences. It was noted that a 2-year licence is often seen to be of benefit, leading to improved services.

11.2 The Committee raised concerns with the number of short licences that have been issued due to low levels of MPE support. The Committee discussed MPE training pathways, and the obstacles faced when applying to become an MPE. The Secretariat agreed to carry out further analysis on the number of applications with low levels MPE support.

[Action: Secretariat]

11.3 Members discussed and agreed a process for informing the relevant IR(ME)R regulator if the same issues are identified again at the 2-year renewal stage. The Secretariat would update the process for dealing with short licences to reflect the decisions of the Committee.

[Action: Secretariat]

b) Applicants in Locum appointments

11.4 The Committee discussed the appropriateness of the current expectation that applicants for practitioner licences should be on the specialist register and in a substantive post. There was consideration of whether this policy might exclude experienced individuals and thus potentially jeopardise clinical services. It was discussed if the requirement is still necessary or if flexibility can be introduced in specific circumstances. Members noted that it is particularly difficult to gain CESR within nuclear medicine physician roles, while oncologist roles appear to have an evidence requirement to support the CESR application process and specialist register requirements that is more likely to be satisfied.

11.5 The Committee agreed that the policy remains adequate in circumstances where there is already a practitioner licence holder in a substantive post and the service will not be impacted by the rejection of a practitioner licence application. Regarding those applicants who are not on the specialist register, it was agreed that an exceptional case of need should be made to permit the issue of a licence. It was noted that whilst the current approach may be sound, there is a concern that as experienced practitioners retire, there may not be enough new practitioners to replace them, leading to shortages.

c) How to see Chair's feedback in Jira

11.6 The secretariat described the new process that would enable Committee members to view the outcome of an application they have reviewed if it required chair review.

[ACTION: Secretariat]

d) Research applications which are supportable in principle with errors on

documentation, for example SOC exposures

11.7 It was noted that some research applications are supportable in principle but contain errors in documentation, such as discrepancies in the numbers or types of standard of care exposures. The Committee discussed the importance of informing the HRA when they are provided with incorrect information that was previously signed off by the ethics committee. Members should continue to flag any concerns they have about individual applications.

Item 12 UKHSA update

a) ARSAC application processing timescales

12.1 The secretariat provided an update on the numbers of applications being received and the average processing times. It was noted that the average processing times for applications remains consistent.

Item 13 Nuclear medicine items from other committees/meetings

a) RCR

13.1 no representative present

b) RCP

13.2 no update provided.

c) ICSC

13.3 no update provided.

d) UKRG

13.4 No update from the most recent meeting, however the recent Molybdenum generator shortages were highlighted. It was suggested that Jilly Croasdale (BNMS President) and Clint Waight (UKRG Chair) should be commended for their communication and proactiveness in addressing this issue.

[ACTION: Chair and secretariat]

e) BNMS

13.5 Dr Szyszko noted that the next BNMS MRT consortium meeting will be held in January 2025. A parliamentary round table event would be held in December 2024 to raise awareness of issues affecting MRT services.

f) SCoR

13.6 no representative present

g) EANM physics committee

13.7 Prof Dickson noted he has served his term on this committee and will not be able to report going forward.

Item 14 Date of next meeting

14.1 The next Committee meeting is already scheduled for Thursday 15 May 2025**.**

Item 15 Any other business

15.1 No items were raised.