

Administration of Radioactive Substances Advisory Committee

Minutes of the 84th meeting, held on 11 May 2023 at the Wesley London Euston Hotel, London

Present:

Chairman: Professor K Bradley

Members:

Ms K Adamson
Ms S Aldridge
Dr C Beadsmoore
Dr M Cooper
Dr A Craig
Mr D Graham
Dr J Dickson
Dr K Dixon
Dr N Hujairi
Dr P Julyan
Mrs C Moody
Dr G Petrides
Dr N Singh
Dr T Szyszko
Professor S Vinjamuri
Professor J Wadsley
Dr S Wan
Dr T Westwood

Secretariat:

Mrs L Fraser (UKHSA)
Miss K Stonell (UKHSA)

Item 1: Welcome and apologies for absence

- 1.1 The Chairman welcomed members to the 84th meeting.
- 1.2 Apologies have been received from Dr Mark Gaze, Prof Ian Lyburn, Dr Neil Hartman, Dr Shahid Rasul, Ms Priya Iype, Ms Anncris Roberts , Dr Amina Powell and Mrs Nasreen Parkar.
- 1.3 DHSC is finalising clearance to re-advertise the Consultant Oncologist vacancy. Members were asked to discuss the vacancy with any colleagues that have an interest in Brachytherapy.

[Action: All]

- 1.4 The Chairman advised members that Dr Clare Beadsmoore, Dr George Petrides, Dr John Dickson, Prof Jonathan Wadsley and Dr Nitasha Singh will be re-appointed for second terms in September 2023.

Item 2: Declarations of members interests

- 2.1 The Chairman advised that members interests are 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. Members should inform the ARSAC secretariat of any changes between meetings.
- 2.3 The Secretariat will ensure the members page on the ARSAC website is up to date.

[Action: Secretariat]

Item 3: Minutes and notes of previous meeting

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

Item 4: Matters arising

a) HRA update

- 4.1 Mrs Fraser drew members' attention to the update provided by the HRA.
- 4.2 Members offered feedback regarding the following areas, which will be passed on to the HRA by the Secretariat:
 - Funding mechanisms

- Duplication of effort with applications being reviewed through the central review process and then reviewed again at site for all research studies
- Applications identified with errors following local review, which require amendment to ARSAC
- Some CRO's lack the appropriate expertise or skillset to support complex trials

[Action: Secretariat]

b) ARSAC Notes for Guidance

- 4.3 Mrs Fraser reminded members that updated NfG were published in February 2023. Members are asked to send any further updates to the Secretariat to review at the November 2023 meeting, for publication early 2024.

[Action: All]

c) Feedback from SAUE incident

- 4.4 Mrs Fraser advised members that the service which had their employer licence revoked remains suspended. The Secretariat will provide an update in due course.

[Action: Secretariat]

Item 5: ARSAC requirements for practitioner licences

- 5.1 The Chairman drew members' attention to ARSAC 03-23 which includes correspondence with the RCR.
- 5.2 Members discussed this at length. Of particular note:
- The role of operators and practitioners in oncology is well understood. Multiple applications may be the result of succession planning and ensuring resilience
 - Within some services there is only one practitioner in the hospital so by default that individual must hold a licence. The application form does not allow for circumstances surrounding the application to be included
 - It is important to recognise that a practitioner licence is not a qualification but a legal obligation
 - Applications are welcome from oncologists, but the role of nuclear medicine physicians should not be overlooked. There is no mention of this role in any of the correspondence although it is acknowledged that it does not exist in all Trusts.
 - There is an increase in training numbers in clinical oncology and this may be driven further when Lutetium PSMA is approved.
 - Some locums can be very integrated for many years and be senior members of the team
- 5.3 The Chairman commented on examples of where applications are considered on a case-by-case basis for locums and exceptions are made.

5.4 Prof Vinjamuri advised members that the GMC consultation to all College specialities is for a new system, moving away from the historical curriculum and defining their own knowledge/experience skills.

5.5 The Chairman will respond to the RCR to summarise the Committee discussions.

[Action: Chairman]

5.6 Mrs Fraser drew member's attention to the improvement notice issued to an employer by the CQC following inspection of a brachytherapy service. Members suggested that guidance on the process for delegation and the use of authorisation guidelines could be included in the NfG.

[Action: Secretariat]

5.7 Members praised the efforts of the Secretariat and Support Unit with the application process.

Item 6: Process for establishing ARSAC Diagnostic Reference Levels

6.1 The Chairman drew member's attention to ARSAC 04-23 with suggestions for the process of establishing adult ARSAC DRLs

6.2 Members discussed the suggestions in ARSAC 04-23. Of particular note:

- DRL is not an absolute maximum, it is guidance for departments to set their own local DRL's against and can shift depending on what departments can achieve
- A descriptor referring to optimisations may be more useful at this time
- A survey would be beneficial with a commentary published in NM Communications which could be referenced in the ARSAC NfG.

6.3 Mrs Fraser suggested that the process outlined is piloted for FDG whole body tumour imaging.

6.4 The Chairman also asked members to consider whether ARSAC should provide further guidance updates in relation to paediatric DRLs. Members suggested that the commentary refers to review at a later date.

Item 7: ARSAC members guide for assessing applications

7.1 The Chairman drew member's attention to ARSAC 05-23.

7.2 The Chairman reflected on discussions at the last meeting and ARSAC continuing to act in the best interests of the patient and challenge concerns. The Secretariat will include some text in the guide.

[Action: Secretariat]

7.3 Members agreed that this remained a helpful guide but they would benefit from additional instructions for using Jira. The Secretariat will arrange MS Teams calls for Jira training.

[Action: Secretariat]

- 7.5 Mrs Fraser highlighted a current known issue with emails which were being blocked by Trust firewalls. The Secretariat will confirm when this has been resolved.

[Action: Secretariat]

Item 8: Review of the Ionising Radiation (Medical Exposure) Regulations 2017

- 8.1 Mrs Fraser drew members' attention to ARSAC 06-23 which provides a brief summary of proposed changes to IR(ME)R. Regulation 22 required the Secretary of State to carry out a review five years from implementation.
- 8.2 Mrs Fraser noted the announcement yesterday about retained EU law. The Secretariat will provide an update in due course.

[Action: Secretariat]

- 8.3 Members expressed objection to how fees are charged and asked the Secretariat to consider alternative charging models, such as a subscription, or tiered charging.

[Action: Secretariat]

Item 9: Research questions for therapy trials

- 9.1 The Chairman drew members' attention to ARSAC 07-23.
- 9.2 Members discussed the requirement for dosimetry, of particular note:
- There are resource implications for the clinical community carrying out dosimetry
 - There is significant variability between patients and different cycles of the same treatment and some novel therapies have to be personalised. Therefore, a 'one size fits all' approach is not necessarily appropriate
 - EANM guidelines take a pragmatic approach that if it is established and dose models are understood, dosimetry could be forfeited
 - Some new therapy products are going to get held up due to lack of capacity in the radiopharmacy workforce
 - The research protocol should justify whether dosimetry is required.
 - NIHR is holding a meeting the day before the Autumn BNMS meeting for all stakeholders to discuss MRT research delivery in the UK. NHSE is currently consulting on MRT
- 9.3 The Chairman commented that at the point ARSAC receives a research application it is often too late for change. It is a complex field, but some general principles could be established. The Secretariat will develop some broad application advice in the first instance.

[Action: Secretariat]

Item 10: Trends and issues on applications

a) Radiation risk statements in participant information sheets

- 10.1 Mrs Fraser drew members attention to ARSAC 08-23 and clarified that the Clinical Radiation Expert (CRE) should include a statement on the clinical prognosis of the participants in the study. If this information is missing or unclear, members can query this, and the Secretariat will relay this to the study sponsor.

b) Renewal applications – secretariat assessments

- 10.2 Mrs Fraser reminded members of the agreed process for the assessment of renewal applications. Some renewals for short licences have been received. The Chairman reflected on the letter that is sent to the senior responsible officer that accompanies the short licence. There have been service improvements such as investment in gamma cameras because of this letter.
- 10.3 Members discussed action to be taken where the renewal application of the short licence does not demonstrate any progress. Mrs Fraser advised members that this could be discussed with CQC in the first instance, before approaching inspectorates in the devolved nations.

[Action: Secretariat]

- 10.4 The Secretariat will also update the application form relating to training and experience so that it is clear that if applying for new procedures, training related to new procedures is required, not all training.

[Action: Secretariat]

Item 11: UKHSA update

- 11.1 Mrs Fraser drew members' attention to ARSAC 09-23.

a) Annual report

- 11.2 This will be published on the ARSAC website.

[Action: Secretariat]

b) Clinical imaging and nuclear medicine errors

- 11.3 The Working Party continues to progress this. All NM will be included under one clinical imaging taxonomy.

c) BNMS conference

- 11.4 The ARSAC Secretariat and Support Unit is hosting a stand at the BNMS conference in Harrogate from 22nd–24th May 2023.

d) JIRA applications

11.5 The online portal was updated in February to allow notifications to be submitted. The only applications now being submitted by email are particular patient licences (PPL).

e) ARSAC application processing timescales

11.6 The output from JIRA includes number of applications, processing times and average resolution time.

Item 12: Nuclear medicine items from other committees/meetings

a) RCR

12.1 Nothing of relevance to NM to report.

i. Clinical Oncology

12.2 Prof Wadsley advised members that he sits on the RT board and there is a MRT update at the next meeting.

b) RCP

12.3 Nothing of relevance to NM to report.

c) ICSC

12.4 Mrs Fraser advised members that there was a lot of discussion at the meeting last week about training. Dr Beadsmoore noted that the correspondence between ARSAC and the RCR on practitioner licence requirements for locums was discussed.

d) UKRG

12.5 Nothing of relevance to NM to report.

e) BNMS

12.6 The Chairman advised members that a document aimed at commissioning new PET tracers is being prepared and sent this week for comment. This will be published in Nuclear Medicine Communications.

12.7 Dr Szyszko advised members that BNMS will be tailoring specific training needs.

f) SCoR

12.8 Nothing of relevance to NM to report.

g) EANM physics committee

- 12.9 Dr Dickson advised members that that EANM is redefining the syllabus for medical physics experts with AI at European level. SIMPLERAD: there are discrepancies between pharmacy SmPC's and the need to have personalised treatments under Euratom.

Item 13: Date of next meeting

- 13.1 The next meeting will take place in November 2023. Members agreed that face to face meetings provided for better engagement and focus. The Secretariat will issue a Doodle poll for meeting format options.

[Action: Secretariat]

Item 14: Any other business

- 14.1 Mrs Fraser advised members that the IAEA will be returning to the UK in January 2024 to follow up the recommendations and suggestions from the IRRS mission in 2019. The Secretariat will provide feedback in due course.

[Action: Secretariat]