

# Administration of Radioactive Substances Advisory Committee

**Minutes of the 88th meeting, held on 15 May 2025 at the Wesley Hotel, London**

**Present:**

Chairman: Professor K Bradley

**Members:**

Ms K Adamson

Ms S Aldridge

Dr K Dixon

Mr D Graham

Dr A Henry

Dr P Julyan

Dr G Petrides

Dr N Reed

Dr N Singh

Dr T Szyszko

Dr S Wan

Prof R Graham

Dr T Westwood

Prof Dickson

Mrs C Moody

Dr A Parthipun

Prof J Wadsley

**Observers:**

Ms C Boccia (DHSC)

**Secretariat:**

Mrs L Fraser (UKHSA)

Mr M Richardson (UKHSA)

Dr A Powell (UKHSA)

Miss L Burns (UKHSA)

## **Item 1 Welcome and apologies for absence**

- 1.1 The Chairman welcomed members to the 88<sup>th</sup> meeting.
- 1.2 Apologies have been received from Dr Clare Beadsmoore, Dr Allison Craig, Prof Neil Hartman, Dr Nabil Hujairi, Dr Shahid Rasul, Ms Nasreen Parkar (UKHSA), Ms Priya Iype (DHSC) and Ms Anncris Roberts (Scottish Gov).
- 1.3 The Chairman welcomed Professor Richard Graham to his first meeting and Ms Cass Boccia from DHSC.
- 1.4 The Chairman thanked the following members ahead of their term's ending:
  - Mr David Graham, concluding his third term at the end of August this year.
  - Ms Sarah Aldridge, concluding her second term at the end of July this year.
  - Dr Teresa Szyszko, concluding her first term in June this year.
- 1.5 The secretariat informed members that DHSC have very recently gained approval to recruit up to 6 new members. DHSC has also secured approval to reappoint Dr Peter Julyan for a third term and Dr Simon Wan and Dr Tom Westwood for second terms. DHSC will begin working with the appointments team to start the appointment and reappointment process with support from the secretariat.

[ACTION: Secretariat]

## **Item 2 Declarations of members interests**

- 2.1 The Chairman reminded members that their declaration of interests must be updated annually.
- 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.

[ACTION: Secretariat]

## **Item 3 Minutes and notes 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 previous meeting and will be published on the ARSAC website.

[ACTION: Secretariat]

## **Item 4 Matters arising**

**a) MRT Letter to NHSE**

- 4.1 Following the discussion at the previous meeting regarding the need for MRT dosimetry, a letter was sent to the senior commissioning contacts within NHSE and radiotherapy leads within the devolved nations.
- 4.2 The secretariat would share a copy of the letter with members and DHSC policy colleagues for information.

[ACTION: Secretariat]

**b) Items for ARSAC Notes for Guidance (NfG)**

- 4.3 The Chairman noted the relatively minor updates which were made to the NfG and published in February and March this year.
- 4.4 Feedback from IPEM was acknowledged, requesting that ARSAC include more detail in the summary of updates at the introduction to the guidance. It was suggested ARSAC could refer readers to the published committee meeting minutes for the rationale to changes within the NfG.
- 4.5 Members were asked for further amendments to NfG for publication in 2026. The secretariat will review the NfG and circulate a draft for comment and discussion at the next full committee meeting.

[ACTION: All]

**Item 5 Recommendations following the SimpleRad report**

- 5.1 The Chairman acknowledged the high standard of the SimpleRad report which has been published by the European Commission. The report includes recommendations on the implementation of different medicines and radiation protection legislation in relation to molecular radiotherapy.
- 5.2 The Secretariat confirmed that the findings of the report have been raised with DHSC, who subsequently informed the MHRA. The MHRA are maintaining a watching brief on the subject.
- 5.3 The Secretariat noted there are findings within this paper that tie in with the letter from ARSAC on MRT dosimetry discussed under Matters arising.
- 5.4 The Committee discussed the growing number of research studies involving MRT and the importance of encouraging appropriate dosimetry and verification as part of the study design, particularly through engagement with the MHRA clinical trials teams.
- 5.5 The secretariat will find relevant contacts within the MHRA and discuss whether any support is needed from ARSAC.

[ACTION: Secretariat]

**Item 6 Cardiac amyloid imaging (<sup>99m</sup>Tc-HMDP as an alternative to <sup>99m</sup>Tc-DPD)**

- 6.1 The Chairman reaffirmed the Committee's well-established position on appropriate radiopharmaceuticals for cardiac amyloid imaging.
- 6.2 Following updates to the BNMS guidelines and prior Committee discussions, further advice was sought from the National Amyloid Centre (NAC) regarding the use of alternative radiopharmaceuticals to <sup>99m</sup>Tc-DPD.
- 6.3 Members were invited to review the latest NAC advice and to discuss whether alternative radiopharmaceuticals can be approved on employer and practitioner licences for this clinical indication.

Some points raised in this discussion included:

- The Perugini grading system was developed for DPD and cannot be applied in the same way to scans with HMDP
- Significant comparative work between PYP and DPD has been undertaken in the United States. Some international guidance supports the acceptability of HMPD as an alternative to DPD
- The rationale for employers considering HMDP was explored. Cost, accessibility, and ease of use were all cited as motivating factors.
- It was queried whether access to HMDP might be in the patient's best interest, and the importance of patient-centred considerations was acknowledged.

Conclusion – ARSAC should maintain the position that DPD is the preferred radiopharmaceutical. However, it would be acceptable to issue licences for HMDP for cardiac amyloid imaging.

- 6.4 Members agreed to change the procedure code for DPD to include HMDP. The Secretariat would send a newsletter detailing the change and informing licence holders that if they already hold the procedure code for DPD on their licence, it will now include HMDP. Any future applications will automatically receive the updated procedure code.

[ACTION: Secretariat]

**Item 7 Employer application forms: inclusion of therapy dosimetry software/equipment**

- 7.1 IR(ME)R amendment regulations came into force in England, Scotland and Wales in October 2024 and expand the definition of equipment to include software.
- 7.2 The paper ARSAC 05-25 was introduced, summarising:
- The new definition of equipment.

- A joint interpretation statement issued by UK regulators
- A request for the Committee to consider whether the employer licence application forms should be amended to include information about software used in the administration of radioactive substances.

- 7.3 The Committee reviewed Part C of the equipment definition, where Artificial Intelligence (AI) may directly assist an operator in carrying out a clinical evaluation.
- 7.4 The Committee acknowledged that while AI and software use is increasing, ARSAC is not the governing body to decide the appropriateness of specific software packages. Nonetheless, the governance of such equipment (including software) falls under IR(ME)R and these obligations and should be reflected in the licensing process.
- 7.5 The secretariat will draft an update to the employer licence application forms to include questions on governance around introduction of software for review at the next meeting.

[ACTION: Secretariat]

#### **Item 8 ARSAC Members guide for assessing applications**

- 8.1 The Secretariat presented the most recent version of the ARSAC members guide for assessing applications. Members were invited to review and provide comments on the revised document.
- 8.2 No comments or objections were raised by the Committee. The secretariat will accept the changes and use the next version for the induction of new members later in 2025.

[ACTION: Secretariat]

#### **Item 9 Trends and issues on applications**

- 9.1 The Secretariat introduced paper ARSAC 07-25, which summarises a number of recent issues for discussion relating to licence applications.

##### **a) Applicant for PET without NM experience**

- 9.2 The application was not supported due to insufficient evidence of broader nuclear medicine training and experience necessary for a comprehensive practitioner licence.
- 9.3 The Chairman asked members to confirm whether the current approach remains appropriate – i.e. that a licence should not be granted for PET procedures alone without sufficient nuclear medicine experience, especially in the absence of comprehensive training

- 9.4 Members raised concerns around practitioner shortages and restricting licences might be problematic if the requirements are interpreted too strictly. The Chairman clarified that ARSAC looks for skills beyond reporting, including troubleshooting, understanding the full nuclear medicine process, and broader clinical judgement.
- 9.5 The Committee agreed that the current approach remains appropriate but should remain flexible for exceptional cases where substantial experience can be clearly demonstrated and there is no alternative licence holder available.

**b) Endocrinologist application for  $^{177}\text{Lu}$  Dota for neuroendocrine malignancy**

- 9.6 The Committee considered a practitioner licence amendment application from an endocrinologist requesting a licence to administer  $^{177}\text{Lu}$ -DOTATATE for the treatment of neuroendocrine malignancies.
- 9.7 The Chairman brought this to member's attention and to seek the Committees view on the appropriateness of supporting similar applications under the current circumstances.
- 9.8 The Committee agreed that each application must be reviewed on its own merits, but there should be no automatic exclusion based on specialty alone. However, a clear demonstration of appropriate training and site suitability is required.

**c) Use of cyclotron produced  $^{225}\text{Ac}$  (with  $^{227}\text{Ac}$  impurities)**

- 9.9 The Committee considered a query received by the Secretariat regarding the use of cyclotron produced  $^{225}\text{Ac}$  which may contain up to 5%  $^{227}\text{Ac}$  as a long-lived contaminant. Concerns were raised regarding:
- The potential for increased patient radiation dose
  - The creation of long-lived radioactive waste
  - Systemic uptake and retention in the body
- 9.10 The Chairman noted that information on radiochemical impurities is not routinely supplied in applications to ARSAC.
- 9.11 The secretariat will contact MHRA to ask if they are aware of the use and approval status of  $^{225}\text{Ac}$  with  $^{227}\text{Ac}$  impurities and if this is already being addressed via product licensing or clinical trials assessments.

[ACTION: Secretariat]

**d) Inclusion of  $^{18}\text{F}$ -FDG-PET as alternative to bone scans**

- 9.12 The Committee discussed the recent increase in amendments to research applications where  $^{18}\text{F}$ -FDG-PET is being proposed as an alternative to  $^{99\text{m}}\text{Tc}$  bone scans, primarily in anticipation of potential radiopharmaceutical shortages.
- 9.13 Following discussion, the Committee agreed that  $^{18}\text{F}$ -FDG as a substitute for  $^{99\text{m}}\text{Tc}$  should not be accepted by default in research applications without robust

justification.

**e) Checks on employer application for repeat amenders (those who don't ever renew)**

- 9.14 The Committee reviewed the issue of employer licence holders submitting multiple amendments over several years without ever completing a full renewal form, meaning the service details are not comprehensively reviewed.
- 9.15 The Chairman proposed that, regardless of the number of amendments submitted, all employer licences should be fully reviewed at the 5-year mark.
- 9.16 The Committee agreed that the 5-year full renewal requirement is important for maintaining oversight of services.
- 9.17 The secretariat will identify how many employers may be affected by this policy change and draft a proposal for committee review at the next meeting.

[ACTION: Secretariat]

**f) Short licences**

- 9.18 The Committee reviewed updated information on short-term licences, and were asked to confirm whether the current approach remains suitable. Of the 36 short licences currently in place:
- 10 were issued to concerns solely around the level of MPE support
  - 8 were issued due to an MPE concern coupled with an additional governance concern
- 9.19 Where a second short licence is issued, the secretariat will now begin notifying the relevant IR(ME)R regulators at the same stage as notifying employers. The Committee agreed that this will increase transparency and help ensure timely resolution of issues.
- 9.20 The Committee confirmed the current process remains appropriate.

**Item 10 UKHSA update**

**a) ARSAC online portal**

- 10.1 The ARSAC online portal was migrated to the Jira cloud platform on 24 March 2025. The Secretariat have held some familiarisation sessions for committee members and have developed a dashboard for members to see applications that they have been asked to review.

**b) ARSAC annual report**

- 10.3 In keeping with previous years, an annual report has been drafted for the period of

1st April 2024 to 31st March 2025. The approved report will be published on the ARSAC website.

[ACTION: Secretariat]

**c) BNMS**

10.4 The Secretariat (Louise Fraser and Amina Powell) along with colleagues from the Support Unit (Kim Stonell and Laura Burns) will be attending the BNMS Spring Meeting 2025.

**d) National Incident Learning System**

10.5 Following on from the publication of the guidance and coding taxonomy for the [National incident learning in clinical imaging, MRI and nuclear medicine](#). The UKHSA Medical Exposure Group (MEG) have established a database to support the collation of national incident data for analysis. The published coding taxonomy will allow healthcare professionals to locally code radiation incidents and near misses, which will support the analysis of these events and identify trends at a national level.

10.6 The Committee welcomed the initiative and noted the positive early feedback. It was agreed this should remain a standing agenda item for updates and ongoing review.

**Item 11 Nuclear medicine items from other committees/meetings**

**a) RCR**

11.1 No representative to report

**b) RCP**

11.2 No representative to report

**c) ICSC**

11.3 Mrs Fraser attended the last meeting of this group in January.

**d) UKRG**

11.4 It was noted that there were previous HDP shortages which were managed by UKRG, BNMS and DHSC to minimise supply disruption across the UK.

11.5 Mr Graham noted he would not be able to attend the next UKRG meeting.

**e) BNMS**

11.6 Mr Graham will be presenting the Highlights selection

**f) SCoR**

11.7 No update to report

**g) EANM physics committee**

11.8 No update as Prof Dickson has left this committee.

**Item 12 Date of next meetings - 6th November 2025**

12.1 The next meeting is booked for 6<sup>th</sup> November 2025.

12.2 A doodle poll will be sent to members to set a date for the May 2026 meeting.

**Item 13 Any Other Business**

13.1 The Secretariat informed members of work beginning in UKHSA to update the CT NDRL's as part of SPECT-CT and PET-CT imaging. Dr Julyan offered to contribute as he was a member of the last Working Party which was led by IPEM, Prof Dickson also volunteered.

13.2 Following up on the report sent to DHSC regarding the impact of supply changes of <sup>131</sup>I-mIBG. Members noted that <sup>131</sup>I-mIBG is now supplied to the UK from Polatom. Some recent orders for Sheffield had been cancelled at short notice. Prof Wadsley noted that a policy proposal for the use of <sup>177</sup>Lu-DOTATATE had been submitted to NHSE. The secretariat will flag these issues with the DHSC medicines supply team.

[ACTION: Secretariat]

13.3 The supply issues with <sup>75</sup>Se-SeHCAT capsules have been resolved. GE sent a letter recently to confirm that Eckert & Ziegler will take on production of these capsules in future.