Administration of Radioactive Substances Advisory Committee
Notes of the 89th meeting, held on 6th November 2025 at The Wesley Hotel, London

Present:

Chairman:
Prof K Bradley

Members:
Ms K Adamson
Dr C Beadsmoore
Dr A Craig
Mr R Cole
Prof J Dickson
Dr K Dixon
Dr A Eccles
Prof R Graham
Prof A Henry
Mr S Howell
Dr N Hujairi
Dr P Julyan
Mr C Lee
Mrs C Moody
Mr D Osowski
Dr A Parthipun
Prof V Prakash
Dr G Petrides
Prof N Reed
Dr N Singh
Dr S Wan
Prof J Wadsley
Dr T Westwood

Observers:
Ms C Boccia (DHSC)

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

Item 1 Welcome and apologies for absence

1.1 The Chairman welcomed members to the 89th meeting.

1.2 Apologies have been received from Dr Amar Challapalli, Prof Neil Hartman, Dr Shahid Rasul and Ms Nasreen Parkar (maternity leave), Ms Laura Burns (Secretariat), Dr Amina Powell (Secretariat).

1.3 The Chairman welcomed to the following new members who joined the Committee on 30 October 2025:

- Dr Amy Eccles
- Mr Chris Lee
- Mr Dariusz Osowski
- Prof Vineet Prakash
- Mr Richard Cole
- Mr Stephen Howell
- Dr Amar Challapalli (sent apologies)

Item 2 Declarations of members' interests

2.1 The Chairman reminded members that their declaration of interests must be updated annually. This is published on the members page of the ARSAC website.

2.2 Members should be asked to declare any changes to their declarations since the last meeting. A declaration may be made now or at the start of any relevant item or by email to the Secretariat as relevant.

2.3 Any declarations for new members will be recorded as part of their inductions which will be scheduled shortly.

Item 3 Minutes and notes of previous meeting

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

3.2 The Chairman noted two typographical errors in section 6.3, these would be corrected by the Secretariat.

3.3 The remainder of the minutes were accepted as an accurate record of the previous meeting and the corrected version will be published on the ARSAC website.

[ACTION: Secretariat]

Item 4 Matters arising

a) Committee appointments and appraisals

4.1 As noted in the welcome above, seven new members have been appointed to ARSAC from 30 October 2025. The Secretariat will set up inductions for new members after which they will start to be sent applications for assessment.

4.2 Appraisals for existing members for 2024-25 will be carried out shortly and members will receive a letter of thanks from the Chair and a separate letter to send to their employer. This has been delayed as there were issues getting the required data from Jira after the cloud migration, but the Secretariat now have this in hand. Members were reminded that time spent on ARSAC duties can contribute to CME/CPD.

b) 225-Actinium contamination

4.3 Members were reminded that this topic was first brought up by the Secretariat at the last meeting. 225Ac as an alpha emitter has promise for therapeutic applications. 225Ac has a half-life of 10 days, but it can be contaminated by 227Ac which has a half-life of 22 years. Concerns have been raised about these impurities and the impact on patient dose and waste management.

4.4 Members noted feedback supplied in one research application, where the sponsor had described a production process which eliminates contamination from 227Ac. The method of production will influence the potential level of contamination, and this is unlikely to be included in the information supplied to ARSAC, but the sponsor could be asked to clarify this as part of an application assessment.

4.5 At present, most trials using 225Ac labelled radiopharmaceutical are at a palliative stage, but this may not be the case in future, so it is important to consider potential contaminants and the impact on patient dose and waste.

4.6 Manufacturers' responses:

- Novartis reported contamination at 0.001%.
- Bayer described contamination as "minimal" but did not provide figures.

4.7 It was suggested that a discussion is needed with the Environmental Agency (EA) and noted that the EA have raised their own concerns and are in talks with other manufactures regarding disposal of waste with such long half-lives.

4.8 The Committee noted that the MHRA should provide clearer guidance. The Secretariat have not yet been able to raise this with an appropriate contact at the MHRA to question whether this is included in their assessment of

research trials. The Secretariat will continue to try to find an appropriate contact and can feedback to ARSAC at the next meeting.

[ACTION: Secretariat]

4.9 Members discussed detection methods, regulatory oversight, and pharmacopoeia standards for impurities. Whilst ARSAC should remain alert, questions need to be raised with regulators and continue monitoring manufacturer assurances.

c) NDRLs for CT as part of hybrid imaging

4.10 Review of the CT DRLs for PET/CT and SPECT/CT is overdue. This was last published in 2014.

4.11 Members volunteered to contribute to UKHSA led review. It was noted that IPEM may be stepping back from leading these types of review.

4.12 The importance of including CT physicists and ensuring governance was emphasised.

[ACTION: LF to feedback UKHSA's work surrounding this]

Item 5 ARSAC Notes for Guidance – 2026 draft ARSAC 10-25 & Annex A

5.1 The cover paper 10-25 is provided with a tracked changes version of the ARSAC Notes for Guidance (NfG) at Annex A.

5.2 The updates this year are relatively minor and are included in the paper.

5.3 Following the update to the document, the introduction will be updated with the key changes and the numbering and formatting will be reviewed prior to publication.

5.4 Members were asked to agree or comment on the proposed changes and suggest any further changes.

IR(ME)R regulations

- New IR(ME)R amendments (2024) include software influencing exposures or assisting clinical evaluation.
- The language should be consistent with IR(ME)R terminology (e.g. "equipment" rather than "medical devices").

Software

- Section 2.7 to be updated to cover commissioning and QA of software.
- Both equipment and software to be considered medical devices and the QA schedules must apply equally to both.

Terminology updates suggested

- Section 2.5: Employers must cooperate to ensure safety and minimise risks.
  - Wording adjusted for multi-employer services (e.g. “Where there are multiple employers involved...”)
  - Sections 2.19 – 2.22: Replace “third party providers” with “cooperation between employers”.

Technical updates

- DRL updates in tables 5.1 and 5.2.
- GFR measurement with chromium EDTA to be removed.
- Sentinel Lymph Node biopsy administered activity to be updated (from 40 to 80 MBq).
- NDRL for Cardiac mIBG imaging varies within the UK (370MBq) compared to within the EU (185MBq) this would be reviewed for a future edition.
- Section 7.4 – Pregnancy procedures – Thresholds to be clarified.
- Employers should audit written procedures regularly.
- Breastfeeding interruption guidance – table 7.4 – effective half-lives under review, ICRP task group updating dosimetry.

[ACTION: Dr Petrides to share data on Cardiac mIBG administered activity to be reviewed]
[ACTION: ALL to reassess pregnancy and breastfeeding guidance for consistency with other regulatory bodies]
[ACTION: Secretariat to publish updated NfG in the new year to reflect IR(ME)R amendments]

Item 6 Employer licence application form update ARSAC 11-25 & Annex A

6.1 Following discussion at the last ARSAC meeting on the changes in the IR(ME)R Amendment Regulations, updates to the employer licence application form have been developed and are presented in Annex A. With an additional question on MPE support from another employer also included in Annex A.

6.2 Members were invited to review the proposed changes and agree revisions to the forms. With the view for any updates to be copied to the employer licence amendment and renewal forms.

Q19 (MPE Support)

- This section has been expanded to include remote/outsourced arrangements.
- Employers must now specify cooperation agreements (e.g. SLA) if services are outsourced.
- A concern was raised regarding double counting MPEs across sites as cover can be thin on the ground.

Conclusion – The proposed Q19A should be removed and existing Q19(B in the paper) should be extended to include additional details (include other employers name, governance arrangements).

Q20

- This will capture scientific support not provided by accredited MPEs.

Q26 (Software)

- This covers assessment, selection, introduction, QA and onward management.
- Employers are responsible for licensing and compliance.
- Categories include resolution recovery, dose modulation, reporting and AI.
- Both certified and home- developed software must meet safety standards.

Conclusion – To merge Q26 and Q26.2, focussing on QA schedules (including commissioning).

Item 7 Employer renewals – proposed updates to process (repeat amenders) ARSAC 12-25

7.1 Issues surrounding repeat amenders (since 2018, 590 amendments have been received from 266 sites). Some sites submit numerous amendments (up to 20), this is delaying full 5-year scrutiny as amendments are allowing extended operation without full-service reviews. 47% of sites have submitted a single amendment application, these can be assumed to have received the full renewal scrutiny. It was agreed by the committee to hold expiry dates at a fixed 5 years from original issue, regardless of amendments.

7.2 The above agreed changes are to be reflected in the Notes for Guidance and a newsletter will be circulated to all sites.

7.3 Reminders will be sent at 6-months pre-expiry, in addition to the current reminders sent at 14 weeks pre-expiry. This will hopefully prompt full renewals if amendments are in the pipeline within that time.

Item 8 HRA radiation question set ARSAC 13-25 & Annex A

8.1 ARSAC 13-25 includes background information describing the work that ARSAC has previously done with the Health Research Authority (HRA).

8.2 The HRA are now developing a new system to replace both IRAS systems which are currently in use. This will include a new ionising radiation question set that will replace the current PRA form. Annex A includes the proposed question set for review by ARSAC. This incorporates previous feedback from ARSAC in 2021.

8.3 The Committee have been asked to review the proposed question set including specific questions for ARSAC from the HRA. There is no fixed deadline from HRA to provide feedback on this question set. The functionality related to ionising radiation will be introduced slightly later in the HRA programme.

8.4 The Committee reviewed ARSAC 13-25 Annex A, with reassurance that the ordering and presentation of the document will be improved.

- Page 3 Status of sponsor
  - Concern around the tone of this question were discussed.
  - Committee agreed that it is important to know whether the research application is commercial or non-commercial, this helps with contextual understanding of the study and is an easy piece of information to provide.
  - Knowing the sponsor type helps the Committee to understand the study's design and might change the feedback provided.
  - There is no implication of bias against either commercial or non-commercial groups.

- Page 4
  - The Committee agreed that it in order to assess the appropriateness of using the study, they need to understand what is happening throughout the study to provide a clinical evaluation.

- Page 5
  - Number of patient participants needed in the UK and globally This information is useful due to different parameters internationally.

- Page 7
  - ARSAC needs to be aware of other ionising exposures to put these into context with the NM investigations.
  - It would be beneficial to also include other imaging with non-ionising radiation – US or MRI.
  - ARSAC need to know what is considered Standard of Care.
  - The Committee requested reassurance that the lowest burden investigations will be used, especially for children (e.g., echo instead of MUGA).
  - Queries were raised regarding IMPs as these were not included in this form. Is there an MHRA overlap? When talking about the impurities and products that would have an impact on the dose but may not be necessarily highlighted by the sponsor.
  - ARSAC need to see the output document and have time to review this.

- Page 10
  - Can be removed.

- Page 11
  - No, it is not possible to simplify the language in these tables.
  - and/or target tissue dose per participant – to remove from healthy volunteer section – no therapy for HV – will still need total dose.

- Q12
  - Lack of inclusive language in sex – only Male/female at present.

8.5 The secretariat would collate members' comments and feedback to the HRA.

[ACTION: Secretariat]

Item 9 131I-mIBG supply issues

9.1 At the November 2024 meeting, following a request from DHSC, ARSAC developed and agreed an assessment of the impact of 131I-mIBG supply issues in the UK. Following the meeting, the impact assessment was sent to the IR(ME)R policy lead and the medicines supply team at DHSC.

9.2 A new European supplier (Polatom) was identified, but UK departments experienced significant problems with Polatom's supply chain over the summer. UK sites were informed that there would be no production of 131I-mIBG during October 2025 whilst Polatom continued with QC investigations.

9.3 The Secretariat notified the DHSC medicines supply team of these new issues and an alternative supplier in Hungary (Izotop) was identified and confirmed. DHSC supported with MHRA approvals, and this should improve the overall resilience going forward.

9.4 Recent communication with NHSE suggest that there is a disconnect between NHSE and DHSC regarding supply issues and alternative treatment options. Prof Jon Wadsley has submitted a NHSE policy proposal which is making progress through the full evidence review but at present, 177Lu-DOTATATE is not commissioned where it could be an appropriate alternative to 131I-mIBG.

9.5 Members were asked to note the continued issues and suggest any further action for ARSAC.

9.6 The UK does need a supply of 131I-mIBG because there are some people that need it. For a few patients, 177Lu-DOTATATE would be more cost effective and better patient experience as there is less need for prolonged in-patient stays.

9.7 Concerns were raised that DHSC don't seem to be aware of current 131I-mIBG issues.

9.8 Members noted that departments using 131I-mIBG from Izotop should review their protocols as the SmPC is very different. The giving set is no longer supplied.

9.9 Members concluded that two main issues remain:
- A reliable and stable UK supply of 131I-mIBG is needed.
- Alternative radiopharmaceuticals need to be commissioned.

[ACTION: Secretariat to highlight the above with DHSC]

Item 10 Trends and issues on applications ARSAC 14-25

10.1 The paper ARSAC 14-25 summarises several recent issues which have been proposed by the Secretariat for discussion. Members were also invited to also raise issues for discussion under this agenda item.

a) Short employer licences

10.2 Further data on short licences was supplied in the paper ARSAC 14-25. The CQC have been formally notified of three repeat short licences.

10.3 As with other recent short licence reviews there was a broadly equal split between concerns over the age of imaging equipment and the level of MPE support.

b) NELMAS trial

10.3 Members were made aware of issues identified with the NELMAS trial which was first reviewed by ARSAC in 2023. This is a multi-centre study involving some patients receiving ^{177}Lu-DOTATATE therapy. The original ARSAC application did not include dosimetry or verification imaging, but these were later added and ARSAC approval was granted on this basis.

10.4 One of the UK participating sites raised an issue regarding post treatment verification imaging with the Secretariat as they had been advised that this was not necessary. ARSAC sought further clarification from the Chief Investigator (CI) who stated that the discrepancy was caused by the contradictory opinions of several experts involved in discussions about the requirement for post-therapy imaging in the adjuvant setting, and internal miscommunication. The CI then confirmed that the NELMAS trial had been terminated due to the funder's withdrawal but stated that this was entirely unrelated to the scientific context of the trial protocol.

10.5 Members discussed their involvement in this trial and noted that multiple departments were advised that imaging wasn't needed. However, adjuvant studies require biodistribution checks, which can affect prognosis and clinical management.

10.6 Members noted that the original protocol design for this trial dates to 2019, but practice has evolved since then, creating inconsistencies.

10.7 Probity concerns can arise when changes occur without formal protocol amendment. Documentation should be updated and reflected in patient information.

10.8 Members suggested that if similar concerns are raised in future, ARSAC should request protocol amendments for any changes. This would ensure consistency across sites. ARSAC could inform the ethics committee of significant changes and consider notifying the Medical Director for the CI.

10.9 Members agreed that the Chair should write to the Medical Director for the NELMAS trial CI. The secretariat would provide support for this.

[ACTION: Secretariat and Chair]

c) Ageing equipment

10.10 A short employer licence may be issued where there are concerns relating to the age of gamma cameras or PET scanners. ARSAC uses a 2014 statement from the European Society of Radiology (Renewal of radiological equipment) when considering applications with ageing equipment. Life expectancy guidance for all nuclear imaging modality devices is given as 8, 10 and 12 years based on their utilisation (quantified as 750, 500 and 250 8-hour shifts/year respectively).

10.11 Members were asked to consider the licensing matters surrounding ageing equipment, agree criteria for a range of equipment and how they should be applied to ensure consistency.

10.12 Currently stand-alone gamma cameras are assessed around the 10-year mark, with concerns arising at 20 years. High end equipment with diagnostic CT is assessed on a 7-year cycle, with concern at 14 years (double expectation).

10.13 Installation dates can be misleading, especially with second hand equipment. It is important to know the year of manufacture.

10.14 It was highlighted that there is a need for consistency in the short licence approach, but also a requirement for flexibility and judgement. The current system is considered to be working well, with discussions and opportunities for employers to state their case for ageing equipment.

10.15 Members noted that it would be helpful to include a statement about ageing equipment in the NfG.

[ACTION: Secretariat]

d) MPE support

10.16 There are a variety of models for the provision of MPE support to radionuclide services. An example of complex support arrangements is given in the paper 14-25 and contrasted with a more secure “hub and spoke” model. Current guidance from IPEM only stipulates whole-time equivalent MPE support and neither example provided may meet the guidance recommendations.

10.17 Members were asked to consider the matters surrounding the different methods for the provision of MPE support.

10.18 Concerns were raised about the fragmentation of MPE support, and the complex contract and sub-contracting arrangements described in the paper. Members also noted that the quality of the applications differs between hub

and spoke centres and those where support is more fragmented. Members were encouraged to review each application on its own merit and raise concerns or questions to clarify that the support arrangements are safe.

e) SLNB only services without a calibrator

10.19 ARSAC have received several employer applications from sites who undertake Sentinel Lymph Node Biopsies only. In some cases, a radionuclide calibrator is available on site, but where this is not available, individual patient dose-syringes are supplied from another site, with the activity specified and assayed before despatch.

10.20 In all cases, Committee requested further information regarding the control-methods used to assure that the activity at time-of-injection is as intended. Committee recommended the regular auditing of actual time-of-injection versus intended time, and the assay of injection-residue activities (after return to the primary site) to mitigate against the potential for systematic under-dosing.

10.21 Members noted that some applications have been very detailed, explaining how their system works without an onsite calibrator. Other applications have not been as detailed, resulting in repeated questions to gain understanding.

10.22 There have been complaints from sites with calibrators about insufficient activity in the syringe. However, if there is no calibrator, it is impossible to find out if there was something wrong with the dose.

10.23 It was concluded this cannot be a one size fits all approach and more detail is required for complex administrations or setups.

Item 11 UKHSA update ARSAC 15-25

a) Staffing update

11.1 Tracey Griffin joined the ARSAC Support Unit in October 2025. Mark Richardson will continue to work as a Scientific Advisor to ARSAC and is covering part of Nasreen Parker’s maternity leave.

b) Processing data timelines report

11.2 Application processing times are shown in the paper ARSAC 15-25. Members were asked to note the latest data.

11.3 Most applications are resolved in 60 days.

11.4 It was noted from the committee that there are still some issues with accessing Jira. From receiving login code, emails being redirected to spam or not being received at all and issues with the authenticator app. Members

are encouraged to contact ARSAC with any issues so these can be escalated and resolved.

Item 12 Nuclear medicine items from other committees/meetings

12.1 The Chair asked members to provide an update from any committee they attend.

a) RCR

12.2 Prof Wadsley attends the Radiotherapy Board and reported on a policy paper published ahead of the cancer plan, focusing on novel cancer therapies with MRT as a case study, advocating for proper funding of services like dosimetry. The Secretariat would share this with members for information.

[ACTION: Secretariat]

b) RCP

12.3 Nothing to report

c) ICSC

12.4 Nothing to report

d) UKRG

12.5 Nothing to report

e) BNMS

12.6 Dr Eccles is now secretary for BNMS, the society's 60th anniversary will be celebrated in Manchester next year.

f) SCoR

12.7 Praise given for the ARSAC secretariat.

g) Head of NM physics group

12.8 This group ran a survey on administered activity for bone scans. This showed little deviation in administered activity but lots of variation in acquisition protocols. A paper summarising the results is expected at the end of this financial year.

h) NIHR research review

12.9 Recognising the growth in MRT research studies and challenges in delivering them, the NIHR IDNs commissioned a review to look at horizon scanning, trials in pipeline and barriers to start up. This is part of the government life

sciences strategy. Hoping to have a report by February 2026. This will link into 10-year plan.

Item 13 Date of next meeting

13.1 Date of the May 2026 meeting: 14th May 2026.

Item 14 Any other business

14.1 It was noted from members that the website could be more user friendly to the general public regarding radiation diagnosis and treatment.