

ADMINISTRATION OF RADIOACTIVE SUBSTANCES ADVISORY COMMITTEE

MINUTES OF THE 81ST MEETING (BY TELECONFERENCE), HELD ON 11TH NOVEMBER 2021

Present:

Chairman: Professor K Bradley

Members: Ms K Adamson
Ms S Aldridge
Dr M Cooper
Dr C Coyle
Dr A Craig
Dr J Dickson
Dr K Dixon
Dr N Hartman
Dr P Julyan
Dr D Levine
Professor I Lyburn
Mrs C Moody
Dr G Petrides
Dr S Rasul
Dr N Singh
Dr T Szyszko
Professor S Vinjamuri
Professor J Wadsley

Observers: Mr J Capiron (Scottish Government)
Mr M Ager (Welsh Government)
Ms S Peters (DHSC)

Secretariat: Mrs L Fraser (UKHSA)
Miss N Parkar (UKHSA)
Dr A Powell (UKHSA)
Miss K Stonell (UKHSA)

ITEM 1 Welcome and apologies for absence

- 1.1 The Chairman welcomed members to the 81st meeting.
- 1.2 Apologies have been received from Dr Nabil Hujairi, Dr Mark Gaze and Dr Clare Beadsmoore.
- 1.3 The Chairman welcomed Dr Allison Craig, Dr Teresa Szyszko and Dr Maggie Cooper to their first meeting.
- 1.4 The Chairman advised members that this will be the last meeting for Dr Catherine Coyle and Dr Daniel Levine.

ITEM 2 Declarations of members interests

- 2.1 The Chairman advised that members interests are published on the membership page of the ARSAC website.
- 2.2 Members were asked to declare any changes to their interests since the last meeting (or since induction for the new members). A declaration may be made now or at the start of any relevant item.

ITEM 3 Minutes and notes of previous meeting

- 3.1 The Chairman asked members for corrections to the minutes from the previous meeting. The Chairman reminded members that the minutes are an abridged version of the full notes with any sensitive or identifiable information removed.
- 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) Practitioner training

- 4.1 The Chairman reminded members about the discussion at the last meeting. The ARSAC website has subsequently been updated with further guidance on demonstrating practitioner training and experience and includes a link to the nuclear medicine curriculum. The ARSAC Notes for Guidance have also been updated to reflect these changes.

b) HRA new research question set and guidance

- 4.2 The Chairman drew members' attention to the statement from the HRA on progress of the new radiation question set. The Secretariat will keep members up to date with progress of the migration.

[ACTION: Secretariat]

c) BNMS MRT report

- 4.3 The Chairman reminded members that following their review of the draft version of the BNMS MRT report, feedback was provided to the BNMS on the report in October. The BNMS responded to thank the Committee for their careful consideration but unfortunately, they were unable to update the report based on ARSAC's feedback. The Chairman thanked members for their contribution.

ITEM 5 Licence renewals

5.1 Mrs Fraser drew members' attention to ARSAC 07-21 which describes previous discussions relating to licence renewals and describes proposals for incorporating renewal applications within Jira.

5.2 Members were asked to review the draft application form and consider how practitioner and employer licence renewal applications should be assessed, either by Committee or Secretariat. Members were also asked to consider whether the practitioner amendment form should be updated to include renewals or whether a separate form should be developed.

5.3 Members offered comments on the process and forms which will be updated by the Secretariat and Chairman.

[ACTION: Secretariat/The Chairman]

5.4 The Chairman suggested that where nothing material has changed, renewal applications can be assessed by the Secretariat. However, where a short licence has been issued, the application should be reviewed by members. This is for a small minority of applications and was agreed by members.

5.5 Members discussed age of imaging equipment, but noted that some older gamma cameras used in a limited range of studies function perfectly well. Members suggested that it should be determined whether equipment is 'appropriate for use'. Miss Parkar suggested that the current QA questions within the application form could be split to include a question on clinical utility. The Secretariat will look to review the internal committee guidance on this.

[ACTION: Secretariat]

ITEM 6 Notes for Guidance

6.1 The Chairman drew members' attention to ARSAC 08-21 which highlights the most significant proposed changes to the ARSAC Notes for Guidance (NfG) 2022 version following discussions at previous meetings, or subsequent comments from members. Annex A is a copy of the NfG with tracked changes. Publication is currently planned for January 2022. Miss Parkar added that significant changes or updates will be summarised at the front of the NfG.

6.2 Miss Parkar took members through ARSAC 08-21, to discuss the proposed main changes to the ARSAC NfG. members provided feedback on the changes and these will be incorporated in the final version.

6.3 Members discussed whether a more generic radiopharmaceutical name can be used for licences for the chemical DOTATATE/DOTATOC/DOTANOC however members concluded that this should remain as it is for now.

6.4 Members discussed whether for PSMA, the notes should specify the different radiopharmaceuticals this code would apply to. Miss Parkar advised that while the specific variations for each isotope could be included as a footnote to the table in the notes this has not been done for other codes before.

6.5 The Secretariat will update the Notes for Guidance based on the feedback from the Committee

[ACTION: Secretariat]

ITEM 7 Trends and issues on applications

7.1 The Chairman drew members' attention to ARSAC 09-21. Members were asked to raise any other trends or issues that they have noted on applications for discussion.

a) **Short licences (ageing equipment, UKRG guidance, formal review of a committee decision to issue a short employer licence)**

7.2 Short employer licences are issued where the Committee raises concerns during application assessment. The most common reasons are highlighted in ARSAC 09-21. Recently, several sites with ageing equipment have been issued with short (two year) licences and this trend seems to be increasing.

- 7.3 Mrs Fraser reflected on earlier discussions about processing renewals. The Secretariat would review the issues from the original application and flag these to the Committee.

Ageing equipment

- 7.4 Members discussed the issue of ageing equipment and The Secretariat will provide draft guidance for consideration for inclusion in the NfG in January 2022.

[ACTION: Secretariat]

Carrying out procedures without a valid certificate or licence

- 7.5 Mrs Fraser noted nine occasions where there was not an appropriate employer licence due to misconceptions about what the licence included.

Non Compliance with UKRG guidance for drawing up radiopharmaceuticals.

- 7.6 The Chairman drew members' attention to the UKRG guidance for drawing up radiopharmaceuticals. Short licences have been issued as a result of no action plan being in place, where the application is signed by a non-pharmacist or where novel radiopharmaceuticals are used.

- 7.7 Members reflected on the current policy that if UKRG drawing up guidance is not complied with, a risk assessment is required, with an added caveat that it should include an indication of by when compliance is anticipated.

- 7.8 Miss Parker added that the short licences that have been issued were for a lack of compliance with UKRG guidance in combination with other factors.

Low levels of MPE support

- 7.9 Members are keen to see publication of the IPEM guidance document on MPE support to nuclear medicine services. Members noted that this may cause an issue at centres with less support than the recommended level, but it will be helpful to be able to refer to guidance on what is considered appropriate.

- 7.10 Mrs Fraser suggested that the IPEM guidance may be applied on a case by case basis.

- 7.11 Members agreed that this should be added as an agenda item at the next meeting for consideration.

[ACTION: Secretariat]

- 7.12 For members information, ARSAC 09-21 also highlights the first formal request to review a Committee decision and the process followed by the Secretariat, Chairman and DHSC. The decision to issue a short licence was upheld.

b) Use of 99mTc pertechnetate for gastric emptying studies

- 7.13 Mrs Fraser drew members' attention to a licensing breach notified to the Secretariat, where the employer was not authorised for gastric emptying studies. The IR(ME)R regulator was also notified of the licensing breach and the investigation confirmed that the gastric emptying studies that had been carried out without authorisation had used 99mTc-pertechnetate as the radiolabel, rather than a non-absorbable compound. The investigation is still ongoing and as part of that, the regulator is writing to other centres in the region to determine use. The Chairman suggested that this was not the correct way to undertake gastric emptying studies.

- 7.14 There are three different procedure codes for oesophageal/gastric/intestinal motility studies and members were asked to consider whether this is appropriate and whether further guidance is required. There was insufficient time to conclude this discussion and the Secretariat will gain further advice from the Committee by email.

[ACTION: Secretariat]

c) Practitioner licences for 177Lu-PSMA

- 7.15 The Chairman drew members' attention to the anticipated increase in practitioner licence applications for 177Lu-PSMA in future. Members were asked to consider what guidance should be published for the experience and training required for ARSAC to support such applications. This is particularly relevant for clinical oncologists who may have a limited scope of molecular RT or none until they apply for this procedure.

- 7.16 Professor Wadsley reiterated a potential conflict of interest through provision of advice in a consultancy capacity for AAA.

- 7.17 Members agreed that there is likely to be a surge in this practise as this procedure will be applicable to a wide range of men, not just major cancer centres or NM centres and there is a need for guidance. Clinical oncologists are unlikely to have much molecular RT experience. In the current climate, it is still difficult to attend centres to observe administrations, so this may be done virtually. There is concern that a surgeon/urologist will send patients for this treatment inside or outside the NHS without following due process of a MDT.

- 7.18 Members noted that a previous successful model had been a training course developed by the drug company. ARSAC had reviewed the course content and could then support applications from individuals who had completed the training.

- 7.19 The Chairman suggested that guidance is included in a newsletter initially, to be subsequently embedded in the NfG. The Secretariat will draft a newsletter setting out the expectation.

[ACTION: Secretariat]

- 7.20 Members suggested that representatives from each of the professional groups provides comment for the newsletter about requirements for such a service in terms of procurement, facilities, training etc.

d) Practitioner licence applications from locums

- 7.21 The Chairman noted that recently, there have been a number of applications from locums for practitioner licences who are not on the specialist register. The current NfG states that it is expected that practitioners are on the specialist register and are appointed in a substantive consultant post. Additional guidance has been proposed for inclusion in the 2022 NfG to clarify that individuals in locum posts who wish to apply for a licence should include specific justification in their application.

- 7.22 Members agreed that these applications should only be supported in exceptional circumstances.

ITEM 8 UKHSA update

a) Transition from PHE to UKHSA

- 8.1 Dr Powell advised members that, following the transition of PHE to the UKHSA on 1st October 2021, there has been no impact upon the work of the ARSAC Secretariat or Support Unit. The PHE domain will continue to be used for email addresses but will revert to the UKHSA domain in due course. The Secretariat will notify members when changes to email addresses are expected.

b) JIRA progress

8.2 Dr Powell reminded members that in September 2021, new and amendment practitioner licence applications were successfully launched on Jira. The next stage in development is employer licence applications and it is intended to ask applicants to complete a short form on Jira and attach an application form and any other relevant documentation. Testing is well underway and a launch is planned for early 2022.

8.3 Members are asked to continue to inform the Support Unit by email of any annual leave as out of office notifications are not received through Jira.

[ACTION: All]

c) Timescales report

8.4 Dr Powell drew members' attention to ARSAC 10-21. Members are asked to consider the data presented on times taken by ARSAC in the processing of applications and whether there is a need to establish a task and finish group to generate reports on processing times.

8.5 The Chairman suggested that the Secretariat draft a proposal for a timescales report for members to consider.

[ACTION: Secretariat]

ITEM 9 Nuclear medicine items from other committees/meetings

a) RCR

9.1 Mrs Fraser advised members that Dr Gaze met with Dr Dizdarevic and the RCR President to discuss supplies of medical radioisotopes.

i. Clinical Oncology

9.2 Nothing of relevance to NM to report.

b) RCP

9.3 Nothing of relevance to NM to report.

c) ICSC

9.4 Nothing of relevance to NM to report.

d) UKRG

9.5 Nothing of relevance to NM to report.

e) BNMS

9.6 The Chairman had received good feedback from the presentation at BNMS by Mrs Fraser.

9.7 Dr Szyszko informed the Committee that the BNMS is drafting a PET provision of service standard document covering standard mobile units for all four UK nations. The focus is on standard levels of support of MPE's and collaboration in mobile PET units. There is no timeline for publication.

9.8 Work is also being undertaken to support research and this includes several ARSAC members.

9.9 The next BNMS meeting is face to face in Glasgow in May 2022 and ARSAC has been offered a table exhibition place.

f) SCoR

9.10 Nothing of relevance to NM to report.

g) IPEM MPE working party

9.12 Nothing further of relevance to NM to report to that discussed earlier in the agenda.

h) EANM physics committee

9.13 A paper making recommendations for administered activity for large FOV PET is in publication. The physics committees are being restructured which will impact how they liaise with regulators and regulatory bodies. A meeting is taking place tomorrow and Dr Dickson will provide an update on any relevant items raised at the next meeting.

[ACTION: Dr Dickson]

ITEM 10 Date of next meetings

10.1 The Secretariat will issue a Doodle poll for the next meeting in May 2022. A decision on whether the meeting is held on MS Teams or face to face will be made nearer to the meeting date.

[ACTION: The Secretariat]

ITEM 11 Any other business

11.1 No further matters were raised by members.

ABBREVIATIONS

ARSAC	Administration of Radioactive Substances Advisory Committee
BNMS	British Nuclear Medicine Society
CT	Computed tomography
DHSC	Department of Health and Social Care
DRL	Diagnostic Reference Level
EANM	European Association of Nuclear Medicine
HRA	Health Research Authority
ICSC	Inter-Collegiate Standing Committee
IPEM	Institute of Physics and Engineering in Medicine
IRAS	Integrated Research Application System
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations
MPE	Medical Physics Expert
NHS	National Health Service
NM	Nuclear Medicine
NfG	Notes for Guidance
PET	Positron Emission Tomography
PSMA	Prostate Specific Membrane Antigen
RCP	Royal College of Physicians
RCR	Royal College of Radiologists
UKHSA	United Kingdom Health Security Agency
UKRG	United Kingdom Radiopharmacy Group