

ADMINISTRATION OF RADIOACTIVE SUBSTANCES ADVISORY COMMITTEE

MINUTES OF THE 77TH MEETING, HELD ON 28TH NOVEMBER 2019 AT SKIPTON HOUSE, DEPARTMENT OF HEALTH AND SOCIAL CARE, LONDON

Present:

Chairman: Dr K Bradley

Members: Ms K Adamson
Ms S Aldridge
Dr C Coyle
Dr S Dizdarevic
Mr R Fernandez
Dr M Gaze
Mr D Graham
Dr A Hall
Dr N Hartman
Dr N Hujairi
Dr P Julyan
Professor I Lyburn
Mr D McCool
Mrs C Moody
Dr S Rasul

Observers: Mr M Ager (Welsh Government)
Miss S Peters (DHSC)

Secretariat: Mrs L Fraser (PHE)
Miss N Parkar (PHE)
Miss K Stonell (PHE)

ITEM 1 Welcome and apologies

- 1.1 The Chairman welcomed members to the 77th meeting.
- 1.2 The Chairman welcomed new observers from DHSC and Welsh Government (WG) to the meeting and advised members that this will be the last meeting for Mr McCool, Dr Grüning, Dr Dizdarevic and Dr Hall.
- 1.3 Apologies have been received from Dr Grüning, Dr Levine, Dr Dixon, Professor Vinjamuri, Dr Redman and Dr Orford (WG).

ITEM 2 Declaration of interests

- 2.1 Members were asked to declare any relevant interests, either now, or before the items concerned.

ITEM 3 Minutes and notes of meeting held on 16th May 2019

- 3.1 The Chairman asked members for corrections to ARSAC 09-19A.
- 3.2 The minutes were accepted without amendment.

ITEM 4 Matters arising

a) ARSAC guide for assessing applications

- 4.1 Miss Parkar drew members' attention to ARSAC 10-19. The ARSAC guide for assessment of applications was reviewed at the last meeting and the guide has been updated for use going forward.

b) Adequate MPE support for remote services

- 4.2 The Chairman reminded members of the discussions at the previous meeting regarding MPE support. Miss Parkar advised members that the IPEM Nuclear Medicine Special Interest Group (NMSIG) are looking to develop guidance through a working party and have requested two members from ARSAC to join the working party. Guidance would be helpful to clarify MPE support and to distinguish this from routine physics support. Dr Julyan and Ms Adamson volunteered to sit on the working party.

c) HRA update

- 4.3 Miss Parkar reminded members of the revised IRAS question set discussed at last meeting. Comments from the committee were provided to the HRA. The radiation module questions are still being finalised with the 4-Nations Radiation Assurance Group and the HRA hope to have a final draft in January/February 2020.
- 4.4 Mrs Fraser has been in discussion with the HRA regarding ARSAC processing times. Within the Support Unit, processes have changed, reducing the average processing time by about 20 days. The HRA recognises that ARSAC members are all volunteers and there are significant pressures on their time. Members may recall discussions previously in 2012 regarding a letter from the Chief Medical Officer encouraging Trusts to release staff to join committees. The HRA is looking to see if something similar can be issued again to Chief Executives to encourage the release of staff for committees and wider work.

ITEM 5 Trends and issues on applications

- 5.1 Members questioned whether it was acceptable to contact other members to discuss an application. The Chairman stated that, in general, ARSAC would like independent assessments however, it is acknowledged that there may be occasions when members wish to gain an extra understanding from others in order to save time.
- 5.2 Members noted a number of PET only applications had recently been received. The Chairman highlighted that ARSAC guidance states that PET only practitioner licences will generally only be considered for someone who holds, or is eligible to hold, a large general range of NM procedure codes.
- 5.3 Members commented that the phrase 'practitioner' in IR(ME)R adds confusion as there are many roles in healthcare with 'practitioner' in their title. Members suggested that "IR(ME)R practitioner" should be used for clarity.
- 5.4 Members discussed the requirement for audit and whether ARSAC should insist that IR(ME)R practitioners and employers agree to audit the clinical scenario and outcomes for radionuclide therapies. Members suggested that it may be beneficial for new practices and historical practices to be audited. This would not be for ARSAC to lead, but to recommend it as good practice through the RCR and RCP. The BNMS may also be an appropriate forum to include physics and pharmacy input.
- 5.5 Members went on to discuss methods of dose estimation and suggested a further paragraph should be included in section 5 of the guidance notes about personalised dosimetry for therapy. Miss Parkar advised that the revised NfG will hopefully be published in January. Dr Gaze agreed to draft a paragraph for inclusion in the NfG in the next 2-3 weeks.

[ACTION: Dr Gaze]

- 5.6 Members suggested adding a further question in the application form for therapeutic procedures. The Secretariat would review the wording to determine where this would be best suited.

[ACTION: Secretariat]

a) Safe service supervision – remote practitioners

- 5.7 The Chairman drew members attention to ARSAC 11-19. There have been a number of applications for employer licences where there is no permanent IR(ME)R practitioner on site. Members were asked to consider what is an adequate level of support, and whether the current guidance in the NfG should be strengthened.
- 5.8 Members offered the following comments:
- It is very beneficial to spend time on the remote site and for the IR(ME)R practitioner to have input
 - An IR(ME)R practitioner needs to be on site for full time PET service
 - Whether it is a new service, or private services, the assessment should be consistent
 - Throughput is now faster and more complicated; therefore input is needed directly by way of on-site presence on a regular basis
- 5.9 The Chairman highlighted a recent therapy employer licence application requesting a change to their licence to allow remote practitioner supervision. This request was rejected as it was deemed that the practitioner should be on site for the therapy administration.
- 5.10 Members questioned whether ARSAC could review CQC incident reports. Regular liaison meetings take place between the secretariat and CQC to discuss feedback from licensing and incidents. The

secretariat could determine whether there is any possibility of obtaining more detailed information about NM incidents from CQC in future.

[ACTION: Secretariat]

5.11 Mrs Fraser advised members that the CQC is the enforcing authority for England only. It may also be possible to liaise with the IR(ME)R enforcement authorities in the devolved administrations who may share the number of incidents. Miss Parkar added that feedback on licensing is provided to all enforcement authorities to inform their inspection programmes.

5.12 Members agreed that the guidance notes should include a statement that the facilities and the practice should meet the recommendations of the good practice guide.

[ACTION: Secretariat]

5.13 The Chairman acknowledged a strong and consistent steer from the committee that practitioners need to face all responsibilities and be physically present. How that is communicated needs to be considered and guidance needs to be extremely clear.

ITEM 6 New Practitioner Application form

6.1 The Chairman drew members' attention to ARSAC 12-19 and Annex A.

6.2 Miss Parkar reminded members that a Therapy Task and Finish group was set up to review the type of questions that were going to be asked on the practitioner licence application form. The application form has been updated further following discussions by the working group.

6.3 Members suggested a number of amendments to the application form. The Secretariat will update the application form accordingly.

[ACTION: Secretariat]

ITEM 7 Licence renewals

a) Employer licences

7.1 Mrs Fraser drew members attention to ARSAC 13-19 and reminded members of discussions at previous meetings regarding shorter duration licences. Members were asked to consider what information will be required within a renewal form, whether the existing application form should be used, and how the application should be assessed and reviewed.

7.2 Members discussed the basis for the renewal and that applicants must be able to demonstrate that they have addressed the issues set out in the letter accompanying the shorter licence.

7.3 Miss Parkar highlighted the suggestion at the previous meeting about sending a notice reminding applicants of the rectifications required, 6-months before expiry. Members agreed to the Secretariat instigating a notice period.

[ACTION: Secretariat]

7.4 Members also agreed that the existing application form should be used rather than designing a renewal form.

b) Practitioner licences

7.5 Mrs Fraser drew members' attention to ARSAC 13-19. Members were asked to consider whether the same form should be used for licence renewals and what other information is required.

7.6 Members discussed whether ARSAC should verify/measure Continuous Professional Development (CPD) but agreed that this was not ARSAC's remit and it is the duty and responsibility of the practitioner/doctor. Members agreed that a declaration should be added to the existing application form.

[ACTION: Secretariat]

ITEM 8 Revision of the ARSAC Guidance

8.1 Miss Parkar drew members' attention to ARSAC 14-19 and Annex A.

8.2 Minor updates have been made throughout the document. Of particular note:

- Removal of duplicated text and text intended for the initial year of licencing that is no longer relevant.
- Clarification of MPE support requirements.
- Inclusion of text relating to requirements for cerebral amyloid procedures as per the current website guidance.

8.3 The Secretariat will also consider the changes highlighted today and update the guidance accordingly.

[ACTION: Secretariat]

8.4 Dr Julyan will provide some updated text for the paediatric PET section and this will be included with Chair's approval prior to publication.

[ACTION: Dr Julyan]

8.5 It is hoped the revised guidance will be published early in the New Year. Members are asked to advise the Secretariat of any other changes required/comments on text etc.

[ACTION: All]

8.6 Members queried the procedures codes that were listed in the notes. Miss Parkar added that the procedure codes are listed in the order that they appear on a licence, and not numerical order.

ITEM 9 IT system for applications

9.1 Mrs Fraser drew members' attention to ARSAC 15-19 and provided an update on the work to develop an application system to allow people to submit applications to the Support Unit online. There will be a pilot of research applications around February 2020.

ITEM 10 RCR proposed guidance

10.1 The Chairman drew members' attention to ARSAC 16-19 setting out proposed guidance by the RCR of a pathway for existing radiologists to obtain a practitioner licence.

10.2 Members offered comments on the draft guidance which will be fed back to the RCR by the Chairman.

[ACTION: The Chairman]

ITEM 11 Integrated Regulatory Review Service (IRRS) Mission

11.1 Mrs Fraser provided a brief to members.

- 11.2 Between 14-25th October 2019, a team of 18 inspectors from the IAEA carried out a review of the UK's regulatory safety framework. The IAEA team assessed the UK's compliance against the IAEA Safety Standards. During the review, IAEA inspectors observed inspections within a nuclear power plant, an industrial radiography facility, a hospital and a waste management facility.
- 11.3 PHE and DHSC provided input to the review regarding employer and practitioner licences issued under IR(ME)R and the assessment of licence applications by ARSAC. Written information was provided in advance of the review and the secretariat attended IAEA interviews in October.
- 11.4 The IAEA team identified strengths and good practice in the UK's regulatory authorities including staff competence and extensive guidance. The report is expected to be published by the UK in early 2020.

ITEM 12 PHE Update

- 12.1 Miss Parkar advised members that Maryanne Dodd has joined the Support Unit as an administrator.
- 12.2 Miss Parkar drew members attention to ARSAC 17-19. There has been a general shift in workload now from new applications to amendments. The average processing time is approximately 6 weeks.
- 12.3 Miss Parkar thanked members for providing the time taken for reviews. The average time is 1.5 to 2 hours per week. The Secretariat will continue to monitor this in future.

ITEM 13 Nuclear medicine items from other committees/meetings

a) RCR

i. Clinical Oncology (Catherine Coyle)

- 13.1 The new IR(ME)R guidance document came out for consultation in September.
- 13.2 The change in delivery route to fly generators into Birmingham discussed as the last ARSAC meeting, was discussed.

b) RCP (Sabina Dizdarevic/Louise Fraser)

- 13.3 The Joint Standing Committee (JSC) met last week. NICE guidelines for benign disorders has been published. There is a task and finish group for Lutetium PSMA and also for non-FDG tracers. Huge improvements have been made with commissioners attending meetings. PSMA has been approved for a limited period.

c) Inter-Collegiate Standing Committee (ICSC) (Sabina Dizdarevic/Louise Fraser)

- 13.4 The ICSC also met last week and discussed similar matters to the JSC NM.

- 13.5 Dr Gaze advised members that Dr Dizdarevic will be the new Chair.

d) United Kingdom Radiopharmacy Group (UKRG) (Neil Hartman/David Graham/Adrian Hall)

- 13.6 No committee members attended the last meeting.

e) BNMS (Sobhan Vinjamuri)

- 13.7 The annual meeting is taking place on 18th - 20th May 2020. The programme is well established and ARSAC will likely have a stand again.
- 13.8 BNMS is going to publish its achievements from last year. A Fellowship programme will be advertised imminently.
- 13.9 John Buscombe has written to the presidents of IPEM, RCR and RCP to suggest a task and finish group is established to investigate variable access to MRT for patients across the UK. BNMS are proposing a strategy which will incorporate a national hub and spoke model for support.

f) Society and College of Radiographers (SCoR) (Clare Moody)

- 13.10 Pause and check posters have been produced for nuclear medicine for imaging in the scan room and administration of radio-isotopes for molecular imaging procedures.
- 13.11 Work continues on standardisation of the PET advice document.
- 13.12 Administration of contrast needs to be specified for each individual through a patient group direction (PGD). This only applies to registered staff groups, and ways of getting clinical technologists to give contrast are being considered, possibly by 'buddying up'. Mrs Fraser commented that this can be done under an exemption in the Human Medicines Regulations 2012 rather than a PGD. Mrs Fraser will send a summary of requirements to Ms Moody.

[ACTION: Secretariat]

g) IR(ME)R Guidance Working parties (Louise Fraser)

- 13.13 IR(ME)R guidance documents for therapy and diagnostics are in the final draft stages. Nuclear Medicine has been included in both documents. PHE is reviewing consultation responses which will hopefully be agreed next week and sent to the RCR for publication early next year. Mrs Fraser will share the link when it is available.

[ACTION: Secretariat]

ITEM 14 Date of next meetings

- 14.1 The Secretariat will issue a Doodle poll for meetings in 2020. Members are asked to inform the Secretariat of any specific preferences for days of the week.

[ACTION: Secretariat/All]

ITEM 15 Any other business

- 15.1 The Chairman thanked those members who are leaving for their contribution to the work of the committee.

ABBREVIATIONS

ARSAC	Administration of Radioactive Substances Advisory Committee
BNMS	British Nuclear Medicine Society
CQC	Care Quality Commission
DHSC	Department of Health and Social Care
HRA	Health Research Authority
IAEA	International Atomic Energy Agency
IPEM	Institute of Physics and Engineering in Medicine
IRAS	Integrated Research Application System
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations
MHRA	Medicines and Healthcare Products Regulatory Agency
MPE	Medical Physics Expert
NM	Nuclear Medicine
NfG	Notes for Guidance
PET	Positron Emission Tomography
PHE	Public Health England
PRA	Preliminary Research Assessment
RCP	Royal College of Physicians
RCR	Royal College of Radiologists