ADMINISTRATION OF RADIOACTIVE SUBSTANCES ADVISORY COMMITTEE

MINUTES OF THE 74TH MEETING, HELD ON 3RD MAY 2018 AT GRANGE WHITE HALL HOTEL, LONDON

Present:	*Chairman:*	Dr J Rees	
	Members:	Professor S Barrington	
		Dr K Bradley	
		Dr C Coyle	
		Dr S Dizdarevic	
		Mr R Fernandez	
		Mr D Graham	
		Dr T Grüning	
		Dr A Hall	
		Dr N Hartman	
		Dr N Hujairi	
		Dr D Levine	
		Professor I Lyburn	
		Mr D McCool	
		Mrs C Moody	
		Professor S Vinjamuri	
	Observers:	Mr Joe Magee	(DH Northern Ireland)
	Secretariat:	Mrs L Fraser	(PHE)
		Miss N Parkar	(PHE)
		Miss K Stonell	(PHE)

ITEM 1 Welcome and apologies for absence

1.1 The Chairman welcomed members to the 74th meeting.

1.2 Apologies have been received from Dr Manoharan, Dr Fowler, Philippa Hunnisett (DHSC), Trudy Netherwood (DHSC), Ms McNicholas (HSE)

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 19th October 2017

3.1 The Chairman asked members for any corrections to ARSAC 01A-18. The minutes were accepted without amendment.

ITEM 4 Matters arising

a) ARSAC guide for applications

4.1 The Chairman drew members' attention to ARSAC 02-18 which has been updated following a review by the committee at the previous meeting.

4.2 Members felt it would be appropriate to discuss this further under agenda item 5.

b) HRA update and changes to the IRAS form

4.3 The Chairman advised members that NP and LF have monthly meetings with HRA and was pleased about the good links that have been forged.

4.4 Miss Parkar advised members that they attend two meetings relating to research - the HRA 4 Nations Radiation Assurance meetings and the IRAS Partners Board.

4.5 4 Nations meeting: this forum finalised guidelines and standards for the Radiation Assurance process which is now live for NHS oncology studies

4.6 Partners Board: there are some changes potentially with regard to the clinical trials regulations which may also be affected by Brexit. ARSAC's requirements were discussed at a previous Committee meeting and relayed to the HRA.

4.7 Members commented that there was frustration expressed by lay members of the REC about the lack of consistency on radiation risk, particularly relating to lifetime risk. Attempts are being made to seek clarity through the HRA but members asked if the Secretariat could also raise this.

4.8 Members also noted that, where risk is given as a percentage, whilst the physics are sound, they were unsure how a candidate on more than one trial might judge the difference in the radiation burden.

4.9 The Secretariat will convey members' comments to the HRA.

[ACTION: Secretariat]

c) ARSAC terms of reference

4.10 The Chairman drew members' attention to ARSAC 03/18 and reminded members that the status of ARSAC has now changed from a NDPB to an expert committee of DHSC.

4.11 Miss Parkar reminded members that the change in status of the committee was discussed in more depth at the January BSSD meeting where members suggested that the terms of reference are amended.

4.12 Members offered comments for inclusion to the terms of reference:

[ACTION: Secretariat]

d) RCR response to ARSAC letter on disbanding of RNR sub-committee

4.13 The Chairman drew member's attention to ARSAC 04/18. Members will recall that the Chairman agreed to write to the RCR on behalf of ARSAC, expressing its concerns about the disbanding of the RNR sub-committee (Annex A). A response from the Vice President at the RCR has been received (Annex B) and has been circulated to members for information.

e) Therapy working group

4.14 The Chairman advised members that the group met in December 2017.

4.15 Mr McCool advised members that the application forms were updated to reflect the views of the group. Once a number of applications have been received that provide a body of work, this can be reviewed further.

ITEM 5 Trends/issues on application

5.1 The Chairman thanked members for their comments prior to the meeting which will be taken under a, b and c below.

5.2 Members discussed concerns about the expectation of them under the new system of review. The Chairman clarified that members were not expected to work beyond their area of expertise. Members suggested additional guidance in the 'ARSAC guide for applications'.

5.3 The Chairman suggested it would be useful for each member to know who else the application is being sent to. Members also requested that a list of category members is circulated.

[ACTION: Secretariat]

5.4 Mrs Fraser advised members that most applications are being sent out to members by email. However, the Secretariat will ensure that, going forward, the Support Unit provides a note on postal applications of who else it has been sent to.

[ACTION: Secretariat]

a) Introduction of licensing

5.5 Dr Bradley raised concerns regarding SLNB melanoma. In particular, how information requested historically, now being split across the practitioner and the employer applications may result in gaps.

5.6 Miss Parkar commented that the intention of the split was to ensure that areas of responsibility were not duplicated.

5.7 The Chairman agreed that applications for new serials should demonstrate a safe service and therefore the employer application form should be enhanced. Members also suggested that there is an explanation in the newsletter that new employer applications for a sentinel node service will need to provide evidence of the whole team by way of a covering letter or additional information on the form.

[ACTION: Secretariat]

5.8 Members agreed that the committee should continue to challenge applications and will need to be vigilant of mismatches.

5.9 Members also discussed a practitioner's duty of care, for remote support, to educate the employer on the regulatory requirements to ensure the quality of service. The Secretariat will include this in the newsletter. Miss Parkar highlighted the section in the NfG with regard to providing remote cover, and this relates to checking the employer licence.

[ACTION: Secretariat]

5.10 Members also suggested that the employer application form includes a statement that, in signing the application form, they are mindful of their duty of care for the service as a whole which might also include teams outside of NM that NM interact with. The secretariat will include the employers' responsibilities under IR(ME)R up front.

[ACTION: Secretariat]

b) Email etiquette for responding to the SU

5.11 Members questioned whether it was appropriate to 'Reply All' when responding to the Support Unit with a response on an application. Under the previous review system, it was completely independent and therefore not unduly influenced.

5.12 It was highlighted that, under GDPR you cannot 'Reply All' to personal emails unless you have express permission that you can share their personal email address. The Secretariat will check the detail of GDPR.

[ACTION: Secretariat]

5.13 The Chairman accepted that there were advantages and disadvantages to this, but he agreed that sharing of the initial responses should be discouraged. A group discussion could follow if necessary.

5.14 Members also raised issues with NHS email inboxes. It was noted by some members that a larger NHS email inbox size can be requested. The Secretariat will pursue the use of alternative means.

[ACTION: Secretariat]

c) Reports on certification

5.15 The Chairman drew members' attention to the papers tabled by the Secretariat. Members noted the content of the reports.

5.16 The Chairman added that the current interim database is unable to do functional groups. Miss Parkar reminded members that the new database was created when licensing was introduced.

5.17 Members discussed whether holding a substantive consultant post is a requirement in order to apply for a licence. There may be instances where those not in a substantive consultant post may appropriately hold a licence. Members also discussed the potential fragmenting of a speciality. In any case, applicants must be able to demonstrate sufficient training.

ITEM 6 Application forms for Employer licences

6.1 The Chairman advised members that the radiopharmacists on the committee raised concerns that they were not always receiving the information needed to review an application.

6.2 Miss Parkar drew members' attention to ARSAC 05-18 which has been updated following discussions with Dr Hartman, Dr Hall and Dr Graham, to improve the radiopharmacy service provision questions. Members are asked to consider whether any further changes are required to the application form.

6.5 Members discussed local issues surrounding the terminology in the application forms, particularly in the case of universities who do not have a Medical Director or a Chief Pharmacist. Universities often work closely with the NHS and the lines of responsibility may be blurred.

6.6 Dr Hartman advised that considerable time had been spent discussing this. The main premise of the questions are based on what MHRA and NHS expectations are of the Chief Pharmacist who, for administration in the NHS, is still responsible by law for the procurement of all medicines.

6.7 Members also highlighted the terminology in question 42 and questioned whether both individuals should sign.

6.8 After further discussion, changes to the form were agreed:

[ACTION: Secretariat]

6.9 Mrs Fraser advised that queries have been received about multiple employers. There are many different models and the form is attempting to capture the information needed in a complex area.

ITEM 7 IT system

7.1 Mrs Fraser advised members that the project is progressing. In order to progress to the next phase, Alpha, an assessment of the Discovery outputs by DHSC is required. This has been arranged for 16th May. It is expected that this phase will take approximately 10 weeks, followed by another assessment.

ITEM 8 ARSAC Notes for Guidance

8.1 The Chairman reminded members that the NfG has been revised twice this year. In order to ensure the NfG remains relevant, the Secretariat is now looking at changes required for the 2019 edition.

8.2 Miss Parkar drew members' attention to ARSAC 07-18 highlighting areas for agreement that were identified previously by the committee. Members agreed to the changes.

[ACTION: Secretariat]

8.3 Members also agreed that a statement should be included on the new application form about applications only needing to be made if exposure is greater than 1microSv.

[ACTION: Secretariat]

8.4 The Secretariat is proposing to create new HTML pages to cover the guidance on how to apply for Employer, Practitioner and Research licences, and Research approvals alongside the pdf copy of the full notes. Members agreed to this.

[ACTION: Secretariat]

ITEM 9 ARSAC approval of research studies with SOC exposures

9.1 The Chairman advised members that this has not formed an agenda item previously. Miss Parkar drew members' attention to ARSAC 08-18.

9.2 Miss Parkar added HRA guidance is currently based on ARSAC guidance; however the HRA will be reviewing this next week.

9.3 There is some confusion in the community as to whether research trials where imaging is listed in the protocol 'as clinically indicated' or 'standard of care' requires ARSAC approval.

9.4 Members agreed that the guidance is well written, however it was noted that established guidance is still being misinterpreted.

9.5 Members suggested amendments to the guidance. Mrs Fraser added that the secretariat needs to work with IRAS so it is a statement on display in the new system.

[ACTION: Secretariat]

ITEM 10 Shortages in supplies of radionuclides and the effect on the UK

10.1 The Chairman reminded members that the committee published a report in 2010 in response to the global shortages of ^{99}Mo.

10.2 Mrs Fraser drew members' attention to ARSAC 09-18.

10.3 Mrs Fraser reminded members a pharmacist from the Medicine Supply team, within the Medicines and Pharmacy Directorate at DHSC was keen to work with ARSAC. Her team are working with BEIS to ensure that medical radioisotopes continue to be available for the UK.

10.4 A stakeholder meeting took place last Friday to reassure concerned stakeholders about the issue of supplies of medical radioisotopes post Brexit. Dr Hartman offered feedback/comments from the meeting

10.5 Mrs Fraser noted there was willingness from the UK to do what needs to be done. It is dependent on the negotiations.

10.6 Mrs Fraser added that an Ernst & Young study is looking at suppliers of all medicines. They have talked to industry to look at contingency plans if any are in place, and they can then consider the impact of those plans.

10.7 Dr Hartman added that Euratom is discussed at these meetings but Euratom only applies to fissile materials. Miss Parkar added that the vast majority of NM products would not fall into the categories in Euratom. However, there was some question about brachytherapy sources which was going to be considered.

10.8 Mrs Fraser commented that, given the numbers of uncertainties, there is little the committee can do in terms of providing guidance but a watching brief should be maintained. The Chairman suggested that the majority of the recommendations of the report had not changed.

10.9 Mrs Fraser also added that, regardless of Brexit, there are still some issues with the supply chain. Information is being provided for an OECD survey, and there is an UNSCEAR survey underway.

ITEM 11 PHE update

11.1 The Chairman drew members' attention to ARSAC 10-18 and thanked the committee for its input, particularly in light of nearly double the number of applications being received in the final quarter of 2017.

11.2 Between 6th February and 31st March 2018, 60 licence applications under IR(ME)R were received, 28 of which were employer licences and 32 were practitioner licences. During the same period, 73 sponsor applications for research trials were received.

11.3 Mrs Fraser drew members' attention to Annex A which provides performance data for the last 3 years, and Annex B which sets out the communication plan.

11.4 Mrs Fraser also drew members' attention to the Annual Report in Annex C. Members agreed that this could be published once a minor change was made.

[ACTION: Secretariat]

11.5 The Chairman advised members that interviews for the vacancies will take place shortly.

ITEM 12 Nuclear medicine items from other committees/meetings

a) RCR

i) Clinical Radiology (C Fowler/L Fraser)

12.1 Richard Graham has been appointed as Radionuclide Radiology Adviser.

ii) Clinical Oncology (C Coyle)

12.2 The RCR has highlighted concerns about the supply of radioisotopes. The RT Board is planning to produce new guidance on IR(ME)R. There is currently a dip in the roll out of research trials; this has been attributed to the change from certification to licencing.

iii) RCP (S Dizdarevic/L Fraser)

12.3 Dr Dizdarevic advised members that a letter was sent on behalf of the President to PET CT commissioners raising concerns about delays in patient pathways, workforce, two tier path system. The service will start on 1st July 2018. A response has not been received. Both colleges support raising concerns together.

iv) Inter Collegiate Standing Committee (S Dizdarevic/L Fraser)

12.4 Mrs Fraser advised members that, at present there are 'Understanding IR(ME)R' guides for radiotherapy external beam, diagnostic imaging and interventional imaging but nothing for NM. Whether NM should be included in these documents or be a separate document is going to be discussed with BNMS.

v) UKRG (D Graham/A Hall/N Hartman)

12.5 Dr Hall advised members that there is a guidance document for chief pharmacists to try to make them aware of their responsibilities. It is due to be updated and they may be asked to sign licence applications.

vi) BNMS (S Vinjamuri/S Dizdarevic)

12.6 Professor Vinjamuri advised members that Dr John Buscombe is now President. BNMS has introduced a student membership category for online access to the journal. The other membership drive is targeted at the private sector without any representation.

12.7 Mrs Moody advised members that she has joined a NM advisory group with the SCoR. The group is planning on producing a PET MR advice document by December and is also looking at 'pause and check' in NM. A study date for current and future development is planned. The Secretariat will add the group to the standing agenda item.

[ACTION: Secretariat]

ITEM 13 Date of next meetings

13.1 The Chairman reminded members that the next meetings will take place on 15th November 2018 and 16th May 2019.

[ACTION: Secretariat]

ITEM 14 Any other business

14.1 Some members highlighted that support from Trusts for work that is not remunerated is diminishing and are taking the stance that such work must be done in the individuals' own time. The Chairman reminded members that a letter from the Chief Medical Officer was sent to all employers encouraging them to support staff on committees. Mrs Fraser will discuss the issue with DHSC.

[ACTION: Secretariat]

14.2 The Chairman advised members that they will each receive a letter as part of the appraisal process.

[ACTION: The Chairman]

ABBREVIATIONS

ARSAC	Administration of Radioactive Substances Advisory Committee
BEIS	Business, Energy and Industrial Strategy (Department for)
BIR	British Institute of Radiology
BSSD	Basic Safety Standard Directive
BNMS	British Nuclear Medicine Society
CMO	Chief Medical Officer
CPD	Continuous Professional Development
CRE	Clinical Radiation Expert
CT	Computed tomography
CTE	Chronic Traumatic Encephalopathy
DA	Devolved Administrations
DH	Department of Health
DPD	Dicarboxypropane Diphosphonate
DRL	Diagnostic Reference Level
EANM	European Association of Nuclear Medicine
EC	European Community
FRCR	Fellow of the Royal College of Radiologists
HARP	HRA Assessment Review Portal
HDP	Hydroxymethylene diphosphate
HRA	Health Research Authority
HSE	Health and Safety Executive
ICRP	International Commission on Radiological Protection
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
JCC	Joint Collegiate Council
KPI	Key Performance Indicators
MAA	Macroaggregated Albumin
MARS	Medicines Administration of Radioactive Substances Regulations
MDGN	Medical and Dental Guidance Notes
MEWG	Medical Exposure Working Group
MHRA	Medicines and Healthcare Products Regulatory Agency
MPE	Medical Physics Expert
NHS	National Health Service
NM	Nuclear Medicine
NfG	Notes for Guidance
PET	Positron Emission Tomography
PHE	Public Health England
PRA	Preliminary Research Assessment
PSMA	Prostate Specific Membrane Antigen
RCP	Royal College of Physicians
RCR	Royal College of Radiologists
R&D	Research and Development
RMP	Radioactive Medicinal Products
RO	Responsible Officer
SNLB	Sentinel Lymph Node Biospy
SIRT	Selective Internal Radiation Therapy
UCLH	University College London Hospitals (NHS Trust)
UK	United Kingdom
UKRG	United Kingdom Radiopharmacy Group