

ADMINISTRATION OF RADIOACTIVE SUBSTANCES ADVISORY COMMITTEE

MINUTES OF THE 73RD MEETING, HELD ON 19TH OCTOBER 2017 AT SKIPTON HOUSE, DEPARTMENT OF HEALTH, LONDON

Present:

<i>Chairman:</i>	Dr J Rees	
<i>Members:</i>	Professor S Barrington	
	Dr K Bradley	
	Mr R Fernandez	
	Dr C Fowler	
	Mr D Graham	
	Dr T Grüning	
	Dr N Hujairi	
	Dr D Levine	
	Professor I Lyburn	
	Dr J MacDonald	
	Mr D McCool	
	Mrs C Moody	
<i>Observers:</i>	Ms P Hunnisett (DH)	
<i>Secretariat:</i>	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 73rd meeting.
- 1.2 The Chairman advised members that this would be the last meeting for Dr Ann-Marie Quigley and Dr Julian MacDonald, both have served two 4-year terms. Ms Wendy Waddington will also be retiring from the Committee at the end of the year having served for 6 years. The Chairman thanked them for their contribution to the work of the committee.
- 1.3 Apologies have been received from Dr Coyle, Dr Dizdarevic, Dr Fowler, Dr Hartman, Dr Quigley, Dr Hall, Dr Manoharan, Professor Vinjamuri, Ms Waddington, Mr Bexon (PHE), Trudy Netherwood (DH), Ms McNicholas (HSE), Joe Magee DH(NI).

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 11th May 2017

- 3.1 The Chairman asked members for any corrections to ARSAC 07/17. The minutes were accepted with the minor amendments:

[ACTION: Secretariat]
- 3.2 The minutes will be published on the ARSAC website.

ITEM 4 Matters arising

a) Training course for H&N SLB/general criteria for assessment of applications

- 4.1 Mrs Fraser drew members' attention to ARSAC 08/17 and reminded members of discussions at the last meeting about criteria for head and neck SLNB following the introduction of the HeadStart training course. A number of high standard applications for diagnostic ARSAC certificates including this serial have been received and approved by the Committee.
- 4.2 The Secretariat has drafted assessment criteria for head and neck SLNB procedures and combined this with other guidance for the assessment of applications established at previous ARSAC meetings. Mrs Fraser emphasised that the intention is to improve the quality of information received so it is easier to assess applications on first submission, reducing the need to seek further information.
- 4.3 Members provided comments on Annex A, to be updated by the Secretariat.

[ACTION: Secretariat]
- 4.4 Members also questioned whether this document should be available to the site *and* practitioners, and whether a checklist that confirms the criteria set out in this document is published. Members agreed that this document will remain for internal use only at this stage.
- 4.5 Members are asked to send any further comments to the secretariat.

[ACTION: All]
- 4.6 Miss Parkar noted that the perception is that ARSAC does not approve applications when more information is requested, but in reality it is because applicants do not respond with the information requested.

b) Appraisal and revalidation

- 4.7 The Chairman noted that this has been an agenda item for some time and, in light of the change in regulations, suggested that this item is parked pending introduction of the new licensing system.
- 4.8 Dr Bradley advised members that little progress had been made since the last meeting in any case and agreed with the Chairman's stance, but re-iterated his views that the requirement needs to be more explicit and linked to revalidation.
- 4.9 The Chairman reminded members that the application form has been partially changed to now include self-declaration.

c) Therapy working group

- 4.10 The Chairman reminded members that Mr McCool agreed to Chair a task and finish group to explore changes required to capture greater information regarding therapeutic applications. Mr McCool advised that membership of the group has been finalised and a date is being arranged for the first meeting, hopefully early November 2017.

d) HRA update and changes to the IRAS form

- 4.11 Miss Parker drew members' attention to ARSAC 09/17. The roll out of Radiation Assurance is currently on hold while a process for the implementation across all 4 Nations is discussed. The ARSAC secretariat attends the 4-Nations meetings.
- 4.12 The process for the recruitment and training for MPE and CRE reviewers to provide more consistent and standardised reviews for centres who have difficulty getting reviewers is still being discussed. Regardless of the roll out, studies can continue to recruit their own MPE's and CRE's.
- 4.13 Standardised Radiation Risk statements were published on the HRA website for consultation for which the response was poor initially, so the deadline was extended to the end of September 2017. The HRA is currently reviewing the responses and will amend the guidance as required. One of the main concerns echoed by the community was about statements being adapted locally by MPE's/CRE's.
- 4.14 ARSAC remains one of the IRAS partners and the secretariat attends monthly meetings. Members have been asked previously to comment on any potential changes that would be required to the IRAS form following implementation of the new licensing system.
- 4.15 Miss Parker drew members' attention to Dr Fowler's comments on proposed changes to IRAS. Members discussed these changes and The Chairman will advise Dr Fowler of the committee's decisions.

[ACTION: The Chairman]

- 4.16 Members are asked to provide any further comments on changes required to IRAS to the secretariat.

[ACTION: All]

ITEM 5 Licensing under IR(ME)R 2018

- 5.1 The Chairman noted the progress made following two meetings of the committee to specifically discuss BSSD. Members will recall that during the last meeting in July, a period of consultation for the Regulations was underway.

a) Update on the implementation of the Basic Safety Standards Directive

- 5.2 Mrs Fraser drew members' attention to ARSAC 10/17. The secretariat submitted a response to the consultation on behalf of the committee. DH received a good response and the draft regulations have been revised in light of some of the consultation comments. DH will be publishing a response to the consultation in due course but a date for this has not yet been agreed.
- 5.3 The timetable to lay IR(ME)R 2018 before parliament is fluid but the deadline for them to be enforced remains 6th February 2018. Separate IR(ME)R will be made in Northern Ireland and these are also expected to come into force on 6th February 2018.
- 5.4 Mr Ebdon-Jackson is producing non-statutory guidance to accompany the regulations. The guidance will be comprehensive in scope but not in detail. However, they will reference the ARSAC NfG. The secretariat is liaising with Mr Ebdon-Jackson to ensure the approach in the non-statutory guidance is consistent with any ARSAC guidance. The date for publication of the guidance has not been determined by Mr Ebdon-Jackson.
- 5.5 Members were keen to see guidance, particularly relating to employers, as soon as possible. The Chairman requested that the secretariat liaise with Mr Ebdon-Jackson to determine the timescale.

[ACTION: Secretariat]

- 5.6 The Chairman suggested a further meeting of the committee on 18th January 2018 specifically relating to the BSSD. Details will be finalised by the secretariat in due course.

[ACTION: Secretariat]

b) Application forms and revised review process

- 5.7 The Chairman reminded members that, at the meeting on 11th May 2017, draft application questions were circulated to members for comment.
- 5.8 Miss Parkar drew members' attention to ARSAC 11/17. The questions have been updated to take account of members' comments from the meeting and members were asked to consider the latest drafts at Annex A and B. The expectation is that, when the system moves fully electronic, as the validation criteria are improved, incomplete applications cannot be submitted.
- 5.9 Members offered the comments on the Annex to be updated by the Secretariat:

[ACTION: Secretariat]

Mr Graham would seek views from Dr Hartman and Dr Hall and submit a proposal expanding questions relating to radiopharmacy provision.

[ACTION: Mr Graham]

- 5.10 Miss Parkar drew members' attention to Annex C which detailed an alternative proposal for the review of new applications. Future recruitment of physicists to the committee should consider separate areas of expertise in therapy and diagnostic. The Chairman noted this for the upcoming advertisements for 4 vacancies to allow for the assessment of new types of applications.

- 5.11 The Chairman asked members to send any other comments to the secretariat as soon as possible in order that a revised document can be circulated.

[ACTION: All]

c) IT system

- 5.12 Mrs Fraser advised members that the capital business case has been approved. The digital development process is split into 3 separate phases – Discovery, Alpha and Beta. DH has given approval for the Discovery phase.

- 5.13 It is anticipated that the Discovery phase will commence on 13th November and will take 4-6 weeks to complete. As the digital process progresses, timescales will become clearer. A new IT system will not be fully operational for 6th February 2018. PHE is also working on contingency plans for licence applications from 6th February 2018.

- 5.14 As part of Discovery, user needs will be identified and this may involve input from committee members.

- 5.15 Mrs Fraser advised members that KPI's will be reviewed when the new system is operational. The Support Unit will be undertaking the function of issuing licences on behalf of a number of licensing authorities and processing targets will need to be agreed.

- 5.16 Mrs Fraser also advised members that DH lawyers have confirmed that electronic submission of applications is acceptable.

d) Communications plan

- 5.17 Mrs Fraser drew members' attention to ARSAC 12/17. The introduction of licensing is a major change that needs to be communicated to as many applicants as possible. The email bulletin currently has 2400 subscribers which will be a key tool in communicating during the period of change. Emails sent to the ARSAC mailbox will receive an automatic reply including a link to subscribe to the email bulletin. However, difficulties are still envisaged in getting the message to certain groups e.g. sponsor companies, and PHE is working with HRA to try to address this. Members are asked to consider the draft communications plan at Annex A and provide any additional suggestions to secretariat. The secretariat is also considering a video communication on the website.

[ACTION: All]

- 5.18 The Chairman was concerned that some applicants are actively selecting not to subscribe to the email bulletin. Members suggested that RPA2000 was contacted for a list of all MPE's.

[ACTION: Secretariat]

- 5.19 Annex B provides a summary of the changes which will be published on the website as soon as possible.

ITEM 6 Status of ARSAC

- 6.1 The Chairman noted that ARSAC is not specifically mentioned in the new regulations - they instead refer to an expert committee.

- 6.2 Mrs Fraser reminded members that ARSAC was established under the MARS regulations, whose status is an advisory non-departmental public body (aNDPB). When the MARS Regulations are revoked and IR(ME)R 2018 comes into force, this will change. However, there is still a requirement for ARSAC to exist to advise on licence applications and to assess research involving radioactive

substances. Discussions are currently taking place with DH to determine whether the committee will remain as an aNDBP or be reclassified as an Expert Committee of the Department of Health. Any change in status will have very little impact on the committee operationally, and some processes will be simpler.

- 6.3 The secretariat will be reviewing the current terms of reference for consideration at the next committee meeting.

[ACTION: Secretariat]

ITEM 7 Revision of ARSAC Notes for Guidance 2018

- 7.1 The Chairman drew members' attention ARSAC 14/17, noting that a considerable amount of work has been undertaken by the secretariat since the last meeting. The Secretariat hope to get the NfG published on the website in late January or early February 2018 dependant on the webpublishing approval process.
- 7.2 Miss Parkar commented that the paper includes a preliminary draft with a number of sections highlighted which still require updating, and there may be further changes required following discussions today.
- 7.3 The Chairman suggested that the revised format overall was acceptable. Members are asked to send any further comments to the secretariat as soon as possible.

[ACTION: All]

ITEM 8 ARSAC Authorised Procedure list

- 8.1 The Chairman drew members' attention to ARSAC 15/17. Members will recall that an in depth review of the list was taken by the secretariat together with Dr Grüning and Dr Hartman in order to reduce inconsistencies, and introduce a new numbering system based on the isotope, pharmaceutical and the indication.
- 8.2 Miss Parkar drew members attention to the revised list circulated in August 2017. Members were asked to confirm that the list is suitable for use for authorisations under the licensing system.
- 8.3 The committee discussed the list the Secretariat will update the procedure list accordingly:
- 8.4 Miss Parkar explained how the new procedure code is derived. This will be set out in writing in due course. During the transition it will be easier for applicants to apply using old serial numbers and the secretariat will convert it to the new procedure codes prior to issuing the licence. The updated NfG will include the new procedures codes alongside the old serial numbers.
- 8.5 Miss Parkar added that, with respect to the employer aspect for PPR's the DH legal team has confirmed that a single person can apply on behalf of the employer and themselves.
- 8.6 Miss Parkar drew members' attention to Annex B (Part B – PET) and reminded members that, at the last BSSD meeting, Mr Graham agreed to investigate the activities listed against the SmPC's. The list at Annex B is an attempt to rationalise administered activities into SI units.
- 8.7 Members briefly discussed whether a weight based system should be included for all the serials. Members were agreeable to a 'recommended weight based' column where appropriate. Brain imaging procedures should remain as DRL's only. Members confirmed that a weight based system could be applied to some procedures and are asked to confirm appropriate values to quote in the NfG:

[ACTION: All]

8.7 Professor Barrington will provide further information on appropriate activities for some procedures.
[ACTION: Professor Barrington]

8.8 Members also suggested that the EANM guidelines are referenced.
[ACTION: Secretariat]

ITEM 9 Trends/issues on applications

9.1 The Chairman noted that this was a standing agenda item for members to raise any particular areas of concern that arise between meetings. Members did not raise any issues for discussion.

ITEM 10 PHE update

a) ARSAC Support Unit performance

10.1 The Chairman drew members' attention to ARSAC 16/17, noting a good performance. The Chairman also noted that KPI's will be changed when the new system is operational.

b) Renewals of certificates that expire in Feb-May 2018

10.2 Miss Parkar advised members that the Support Unit is being pro-active for the transition to the new licensing arrangements. Those practitioners whose certificates expire in the months' immediately following implementation have been invited to renew them early.

10.3 The Support Unit has also determined cut-off dates as follows in order to allow for the completion of processing of applications for certificates prior to the implementation date.

- New and additions, diagnostic and therapy applications: 20th December 2017
- Renewals: 16th January 2018
- New research certificate applications: 16th January 2018
- Research sponsor applications can continue as normal but from the 6th February 2018, applications will be subject to a fee.

10.4 From 6th February 2018, members may start seeing different types of applications. However, it is expected that the work commitment will be equivalent. Discussions are underway with the community to deter people from applying immediately where unnecessary.

ITEM 11 Nuclear medicine items from other committees/meetings

a) RCR

i) Clinical Radiology (C Fowler/L Fraser)

11.1 The Chairman advised members that the Radionuclide Radiology sub-committee will no longer continue as a standing committee of the College. The RCR will appoint an RCR Adviser in Radionuclide Radiology to lead on this area and provide advice, input and expertise as necessary. Clare Beadsmore will attend the next ICSC in NM on 7th November 2017. Thereafter the RCR Adviser will attend. Members briefly discussed the implications of this action and agreed that the Chairman should write to the college to express the committee's concerns.

[ACTION: The Chairman]

ii) Clinical Oncology (C Coyle)

11.3 No-one present to report.

b) RCP (S Dizdarevic/L Fraser)

11.4 Mrs Fraser noted mention of Phase 2 of the PET CT contract. There was also discussion about Brexit and the effect on supply of radioisotopes.

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

11.5 Nothing additional to discussions at RCP.

d) UKRG

11.6 Nothing of note to report

e) BNMS

11.7 No-one present to report.

ITEM 12 Any other business

12.1 No further business was brought to the attention of The Chairman.

ITEM 13 Date of next meeting

13.1 The Chairman reminded members that the next full meeting will take place on 3rd May 2018.

13.2 A Doodlepoll for two suggested dates in September (20th or 27th) will be set up by the Secretariat.
[ACTION: Secretariat]

13.3 A further BSSD meeting will be provisionally arranged on 18th January 2018 which will provide an opportunity for the Committee to receive further guidance on the new application process.

[ACTION: Secretariat]

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 Biopsy
SIRT	Selective Internal Radiation Therapy
UCLH	University College London Hospitals (NHS Trust)
UK	United Kingdom
UKRG	United Kingdom Radiopharmacy Group