ADMINISTRATION OF RADIOACTIVE SUBSTANCES ADVISORY COMMITTEE

MINUTES OF THE 70TH MEETING, HELD ON 12TH MAY 2016AT SKIPTON HOUSE, DEPARTMENT OF HEALTH, LONDON

Present:	*Chairman:*	Dr J Rees	
	Members:	Dr S Barrington	
		Dr K Bradley	
		Dr C Coyle	
		Dr S Dizdarevic	
		Mr R Fernandez	
		Dr C Fowler (by teleconference)	
		Dr A Hall	
		Mr D Jones	
		Dr D Levine	
		Prof I Lyburn	
		Dr J MacDonald	
		Dr P Manoharan	
		Mr D McCool	
		Dr A Quigley	
		Professor S Vinjamuri	
		Ms W Waddington	
	Observers:	Mr I Chell	(Department of Health)
		Dr A Wight	(Department of Health)
	Secretariat:	Mr A Bexon	(PHE)
		Mrs L Fraser	(PHE)
		Miss N Parkar	(PHE)
		Miss K Stonell	(PHE)

ITEM 1 Welcome and apologies for absence

The Chairman welcomed members to the 70th meeting and noted that Dr Daniel Levine was attending his first meeting. The Chairman also welcomed Mr Antony Bexon to the secretariat and advised of Mr Ebdon-Jackson's departure from the secretariat to focus on implementation of the Basic Safety Standard Directive (BSSD). The Chairman also welcomed Dr Ailsa Wight from the Department of Health (DH). Apologies were received.

The Chairman thanked Dr Ballinger for his significant contribution to the work of the committee after serving for 10 years.

ITEM 2 Declaration of interests

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

ITEM 3 Minutes and notes of meeting held on 1st October 2015

The Chairman asked members for any corrections to the minutes of the last meeting. The minutes were accepted as an accurate record.

ITEM 4 Matters arising

a) Paediatric administered activity

Mrs Fraser provided members with an update regarding the work being funded by the European Commission to establish DRL's for paediatric patients. Mrs Fraser also updated members on the progress of the IPEM working group on paediatric DRLs. Mrs Fraser would provide further feedback to members from both working groups when available.

[ACTION: Mrs Fraser]

b) ARSAC applicant survey

Members reviewed a draft survey for ARSAC applicants and offered comments to improve this further. It was proposed that the survey is managed electronically using PHE secure survey software.

[ACTION: Secretariat]

Members queried whether it was possible to have some kind of patient engagement or representation at ARSAC meetings. DH was fully supportive of this suggestion and the Chairman suggested that a patient representative would satisfy this requirement.

[ACTION: Secretariat]

c) Appraisal and revalidation: proposals for renewals

The Chairman advised members that a draft letter to Responsible Officers (RO's) has recently been sent to DH for approval prior to circulation. Certificate holders will be advised that their ARSAC certification should be discussed locally at their appraisal each year.

Members discussed an alternative proposal that a letter could be sent to the certificate holder a year before their certificate renewal is due, advising that a portfolio of evidence for the certificate they wish to renew is required as part of their appraisal and revalidation. Dr Bradley added that there are four individuals in the UK who act as RO to the ROs, and suggested their views should be sought. Dr Bradley would provide the names to the secretariat.

[ACTION: Dr Bradley]

d) Routine use of 177Lu-PSMA

The Chairman reminded members that only two therapy applications for ^{177}Lu-PSMA have been received. At the time of the last application, insufficient evidence was supplied to support routine use. Members commented that further work has been published in this area and agreed that the evidence base should be re-assessed when the next application is received.

The Chairman advised members that Particular Patient Request (PPR) applications should not be approved for ^{177}Lu-PSMA at the current time. PPR should not to be used for serials that are not used routinely elsewhere.

e) Triennial review

Members reviewed the ARSAC Annual Report for 2015/16. The report was agreed for publication on the ARSAC website to satisfy Recommendation 3 of the Triennial Review.

[ACTION:Secretariat]

The Chairman advised members that an equality statement has been included in appraisal and induction documents to satisfy Recommendation 4 of the Triennial Review.

The secretariat advised members that work had commenced on a high level design specification for a new IT system for submitting and processing ARSAC applications. The new IT system needs to be functional prior to the implementation of the BSSD. Input will be required from the committee at a later stage.

[ACTION: Secretariat]

ITEM 5 Trends/issues on applications

a) ARSAC application forms for radionuclide therapy

Mr McCool set out a proposal for changes to the application forms for radionuclide therapy following discussions at the previous meeting. Members discussed the level of evidence that is required from applicants and the different types of therapies. Mr McCool agreed to revise the proposal in light of members' comments.

[ACTION: Mr McCool]

b) Training for FG's and non-imaging serials

Members discussed the training requirements for applications where all functional groups have been selected. Some serials within the same functional group have very different applications and applicants may not have training in all serials. The Chairman suggested that in future a guide for applicants could be included in a newsletter or guidance incorporated into the new IT system

Members noted the different approach used for diagnostic and sealed source therapy serials with regard to the clinical indication specified in the Notes for Guidance (NfG). Mrs Fraser added that consideration could be given to specifying the intended use within the clinical indications for sealed sources. Members agreed that this should be investigated.

[ACTION: Secretariat]

Members discussed concerns regarding applications for non-imaging serials from applicants who have not completed a formal training programme. The committee looks at applications on a case by case basis and will consider other avenues of training.

c) RMP list

A full Radioactive Medicinal Products (RMP) list is normally issued to members every April. The secretariat has reviewed the list to only include serials that are currently certificated. The secretariat will circulate the list to members for verification and keep it more up to date in future.

[ACTION: Secretariat]

d) Bone scan – flare response

Members discussed concerns regarding flare phenomenon and the potential for patients to be withdrawn from a study inappropriately on the basis of a misinterpreted bone scan. Members felt that the community had sufficient experience. The oncology community is very well versed with the flare phenomenon and use bone scans as part of a wide range of information before making a clinical decision to remove a patient from a study. There was some concern that this would still be an issue when research was undertaken in small departments.

e) Rationale for non-standard tracers in research applications

Members discussed the information provided on research applications to justify the use of novel tracers. Mrs Fraser would discuss with the HRA whether it was possible to include additional information within the IRAS form or the guidance for applicants.

[ACTION: Secretariat]

f) Healthy volunteers in research receiving >10mSv

The Chairman highlighted a recent increase in research applications including healthy volunteers receiving greater than 10mSv per annum. The ARSAC NfG also discourages participants less than 50 years of age due to the increased risk. Members should request specific justification to include participants below 50 if not provided by the study sponsor.

g) Vulval Sentinel Lymph Node Biopsy (SNLB)

The Chairman advised members that two incidents have come to the attention of the secretariat recently with regard to certification for Vulva SLNB. Members discussed the number of cases per year required to maintain competence. The incidence of Breast cancer is different to vulva and penile cancer and the same numbers cannot be applied. Members agreed that Vulva SNLB should also only be managed in specialised centres or at smaller centres linked to established centres within a cancer network.

h) Tc-99m-Tektrotyd-somastostatin receptor imaging

The Chairman advised members of enquiries regarding the certification for ^{99m}Tc-Tektrotyd which is now available as an alternative to ^{111}In-Octreotide. Members commented that training requirements were broadly similar however any applications will still be assessed on a case by case basis by the diagnostic subgroup.

ITEM 6 PHE update

a) Changes to Secretariat/Leinster Review

Mr Bexon drew members' attention to the outcome of the review undertaken by Paul Leinster last year to look at the role of PHE's Centre for Radiation, Chemical and Environmental Hazards (CRCE). One of the main recommendations of the review was that PHE should develop an overarching environmental strategy. It was also clear from the review that the full range of activities that CRCE currently undertakes should continue. The Chairman is an invited member of the Public Health Oversight Group which will meet in June to draft a strategy for the next 5-10 years. The Implementation Group will then take this forward.

b) ARSAC Support Unit Performance

The Chairman advised members that the Support Unit has experienced a high workload in the previous quarter. The Quarterly Report is automatically generated from the database. The secretariat informed members that the figures presented in the report were not representative of the actual performance of the Support Unit, due to the way the report selects records included in the statistics. More representative figures have been generated which

show that for the last three years the Committee and Support Unit have met the Key Performance Indicators (KPI) set by the Department of Health. Further refinement of the KPI data will be built into the new IT system.

The Chairman informed members that he had recently presented similar information at an RCR study day. Video was available online and members suggested this could be added to the ARSAC website.

[ACTION: Secretariat]

ITEM 7 Revision of ARSAC Notes for Guidance (NfG)

a) Annual review of NfG

The Chairman advised members that as the NfG is now a live document online, it will be updated on an annual basis. It is intended that proposed revisions will be discussed at the May meetings, approved at the October meetings and published in the following January.

b) Thyroid Blocking

Mrs Fraser advised members that the policy on thyroid blocking has not been reviewed for some time. The SPC for Potassium Iodide includes a contraindication for patients aged over 45 years which is not mentioned in the notes. The Chairman would seek input from Dr Grüning.

[ACTION: The Chairman]

c) Radioiodine in breast feeding women

Mrs Fraser advised members that the draft statement produced by Mr Fernandez will be included in the next edition. Mr Fernandez suggested it was an unlikely scenario but attention ought to be drawn to the possibility.

[ACTION: Secretariat]

d) DRL for MAA SIRT workup

Mrs Fraser noted several queries regarding the DRL for ^{99m}Tc-MAA SIRT studies. Initial research studies used an activity of 150MBq however, the current DRL is 100MBq. Members agreed that the DRL should be increased to 150MBq.

[ACTION: Secretariat]

e) PET serials listed in Appendix I Part B

Members were asked to consider whether additional PET serials should be added to the NfG in line with the 'Evidence based guidelines for PET' published jointly by the RCR and RCP recently. Members agreed that the NfG should be consistent with UK evidence based indications and agreed to review proposals for inclusion in the Notes.

[ACTION: Secretariat/All]

f) CT DRL's for hybrid imaging

Mrs Fraser advised members that the IPEM Working Group plan to publish a paper on a survey of CT DRL's in hybrid imaging. Members suggested that this was not within ARSAC's remit but a 'signpost' should be provided that this is good practice.

[ACTION: Secretariat]

ITEM 8 PPR applications

Members discussed the formalisation of the PPR process; minor corrections would be made by the secretariat. The Chairman recapped on his earlier comment that a PPR should only be used for a serial that has an

established use and is required in an emergency urgent setting for a certificate holder that does not have the serial on their certificate. It is not to be used for serials that are not used routinely.

[ACTION: Secretariat]

ITEM 9 HRA updates

The Chairman welcomed Dr Janet Messer and Mr Chris Cannaby from the HRA who were attending to discuss research issues raised by ARSAC and potential solutions within the HRA Approval and Radiation Assurance processes.

Mr Cannaby provided members with a brief history surrounding the HRA Approval process and the Radiation Assurance process proposed to make the initial review of the radiation aspects of the study simpler and more consistent. As part of the Radiation Assurance process standardised risk statements were created together with a suite of documentation to try and standardise what goes into a review of the radiation aspects of a study. A pilot has been completed and evaluated. The process has been continually refined during the pilot.

Dr Messer added that one aspect being considered was the creation of panels of experts available for MPE and CRE review. Members raised a number of concerns and discussed at length the process by which MPE's and CRE's would be selected for the panel and registered with HRA:

- Business pressures could dictate that current CRE's and MPE's are unable to commit the time to sitting on the panel. How can individuals support their own research studies without taking on the onerous task of sitting on the panel? Can individuals act as CRE if they do not sit on the panel? A situation could arise where a single centre trial is going on in your site but the CRE and MPE are based elsewhere. The panel of MPE's and CRE's requires careful thought as it could easily exclude people performing these roles at present. Dr Messer advised that this needed to be assessed with other Devolved Administrations (DAs).
- In view of business pressures, the panel could be drawn from a very small pool. Dr Messer accepted that this was one of the risks identified and the incremental approach previously taken by the HRA reflects this.
- Currently this work is voluntary but, where Trusts consider this a formal role, a new consultant appointment could have CRE duties in the job description.
- Trusts could commit staff to the role without first ensuring that they have the capacity to do so. Dr Messer suggested that trusts should not sign individuals up without first engaging with the individuals.

Miss Parkar noted that the HRA Approval process is for the NHS in England and will be mandatory but understood that the Radiation Assurance process would not be mandatory. Dr Messer advised that this was yet to be discussed with DA's but the plan was to incorporate it within the approvals process.

Mr Cannaby added that roll-out of the panel would mirror the HRA Approval process in a phased approach. Reviewers would be provided with guidance to input to IRAS and PIS. An open call to the community will be used to advertise panel vacancies. Guardians have produced job descriptions for the role of reviewer which sets out expectations and experience. Appointment will not be by interview and it is expected to be a very flexible role on a rotational basis.

a) Section A2 guidance for IRAS PRA

Ms Waddington commented on her involvement in the development of guidance for MPE/CRE and the statements to go in the PIS. The final guidance will make the task of reviewing much simpler as it includes template statements for all levels of radiation risk arising in the context of different patient groups.

Dr Messer provided an update on the mechanism with which to contact the imaging departments in order to give them prior notification of research being conducted. HRA is proposing to email a central point at each site involved in a study when an IRAS form is submitted. This would require an element of local cascade at the site.

Members recapped on discussions from the meeting in May-15 where members accepted the need to make studies easier but felt that a single email notification was not acceptable. Members commented that this could easily result in NM practitioners carrying responsibility for research they didn't know about at the risk of unnecessary radiation exposure in patients. Dr Messer clarified that the HRA is happy to consider alternative suggestions.

The Chairman thanked Dr Messer and Mr Cannaby for attending the meeting and drew the discussion on this topic to a close.

ITEM 10 Nuclear medicine items from other committees/meetings

a) RCR

Dr Bradley announced that, following a joint application process for clinical radiology and NM, 7 NM training posts were offered and accepted. These will commence in August 2016.
Dr Bradley referred to the Hybrid Imaging reporting document and noted that the RCR was meeting in 2 weeks.

b) RCP

Nothing of note to report.

c) ICSC

The Chairman advised members that Dr Andy Scarsbrook is the new chair.

d) UKRG

Dr Hall advised members that Alliance Medical has claimed they may be in a position to supply cyclotron produced ^{99m}Tc by the end of 2017.

Dr Hall also drew members' attention to the commercial availability of two new ^{68}Ga kits. ^{68}Ga-dototate kits came to the market last week and a ^{68}Ga-PSMA kit is expected to be available from June 2016. The kits do not require automated synthesis systems and the cost is comparable with in-house production but without the need for the equipment and experience.

e) BNMS

Nothing of note to report. Professor Vinjamuri advised members that the scientific meeting is a route for communication with the Society from any avenue.

The Chairman noted that Mr Ebdon-Jackson has been awarded the Norman Veall Medal by the British Nuclear Medicine Society for services to NM.

f) BNCS

No-one present to report.

ITEM 11 Any other business

No further business was raised.

ITEM 12 Dates of next meetings: confirmed 29th September 2016

The Chairman advised members that the meetings for 2017 will take place on 11th May 2017 and 19th October 2017.