Department of Health

Triennial Review of the Administration of Radioactive Substances Advisory Committee (ARSAC)

Review Report

March 2015

Title: Triennial Review of the Administration of Radioactive Substances Advisory Committee (ARSAC); Review Report
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Document Purpose: Corporate Report
Publication date: 26 March 2015
Target audience: Civil Society, Clinicians, Managers, Commissioners, Pharmacists, Doctors, Healthcare Scientists, Dentists, Diagnostic Radiographers, Therapeutic Radiographers, Allied Health Professionals, PCTs, Foundation Trusts, Clinical Commissioning Groups, Regulatory Body, Academic/Professional Institutions, Employer Representatives, Employee Representatives, Royal Colleges, Clinical Physicists.
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Published to gov.uk, in PDF format only.

www.gov.uk/dh

Triennial Review of the Administration of Radioactive Substances Advisory Committee (ARSAC)

Prepared by Lead Reviewer, ARSAC

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Executive summary

The Administration of Radioactive Substances Advisory Committee (ARSAC) is an Advisory Non-Departmental Public Body (ANDPB) of the Department of Health (DH). ARSAC advises DH Ministers on the certification of doctors and dentists using radioactive medicinal products (RMPs), and publishes associated guidance on the use of RMPs.

The DH's Triennial Review (the review) of ARSAC was conducted to provide assurance to DH and the public of: the ongoing need for the functions currently performed by ARSAC; and the efficiency of the administration of these functions. This review forms one of a series of reviews being conducted by DH between 2014-15 and 2016-17 of all the DH arm's length bodies.

The review of ARSAC was a 'light touch' review, which reflects the range of functions of the Committee and its relatively low cost. The evidence collected by the review team recognised the expertise and professionalism ARSAC brought to their role in ensuring patient and staff safety in the use of RMPs.

Based on the evidence, the review team concluded that ARSAC should continue as an ANDPB, with its current range of functions. In respect of the administration of functions, the report contains an additional seven recommendations, which are summarised on the next page. The recommendations are based on a number of interconnected themes which emerged during the review:

A: Needs of service users: while the current legislative framework requires certificates to be held by individuals, certificate holders are supported by a team of experts and specialists. ARSAC needs to ensure that this wider group is considered in the administration of its functions. ARSAC also needs to ensure its role is understood in the context of the health and care system, and not in isolation. In particular, certificates related to research projects are one component of a wider set of processes and requirements.

B: Digitisation: both for service users and the efficiency of the Committee's internal processes, further work should be done to introduce a web-based application and electronic processing system. While ARSAC's processes and systems remain largely paper based, it will be difficult to achieve any significant efficiencies in the applications process or to fully exploit links with other organisations in the health and care system.

C: The revision of the regulatory framework: while specific recommendations on the planned revision of the regulatory framework in 2018 were beyond the scope of the review, it is clear that this offers the opportunity to improve processes and customer experience. Any evidence submitted on the regulatory change has been shared with the relevant DH policy team, so it can be included in the development of the revised regulatory framework.

1. Summary of Recommendations

ARSAC – Function and delivery model

Recommendation 1: The main functions identified in this review should continue to be delivered by ARSAC, in its current form as an ANDPB. Pages 9-13.

Recommendation 2: ARSAC should re-iterate the responsibilities of individual certificate holders and those co-signing applications. They, and other members of the nuclear medicine community, should be reminded of their obligation to raise concerns where they have evidence of poor practice by certificate holders. ARSAC should publish clear guidance on the mechanism to do so. Pages 9 and 13. ***Action owner: ARSAC***

ARSAC – Governance and relationships

Recommendation 3: Appropriately redacted minutes and a short annual report should be published. The key channels for publication should be either the ARSAC website (not with-standing transitional issues to gov.uk) or regular circulation through the newsletter. Page 15 and 21. ***Action owner: ARSAC***

Recommendation 4: ARSAC should ensure that there is clear guidance in place to ensure that Committee members understand their obligations under the Equality Act 2010 specifically in relation to their work in ARSAC. Pages 15 and 21. ***Action owner: ARSAC***

Recommendation 5: ARSAC should engage with the Health Research Authority (HRA) to ensure that there is an agreed division of responsibilities on the assessment of nuclear medicine research proposals. This agreement should then be articulated clearly in the context of the entire process for research project approvals. Pages 16 and 21. ***Action owner: ARSAC***

Recommendation 6: ARSAC should consider how to ensure that the users of their guidance are confident they are up to date with the latest developments. Pages 16 and 21. ***Action owner: ARSAC***

ARSAC – Efficiency

Recommendation 7: a more sophisticated range of KPIs should be agreed between ARSAC and DH, which can be used to help service users anticipate the length of time they should allow for applications, and for DH to hold ARSAC to account. Page 18 and 21. ***Joint action owners: ARSAC and DH***

Recommendation 8: DH should explore an electronic web-based application and electronic processing system. Page 20 and 21. ***Action owners: DH sponsor team and the Digital, Channel Strategy and Publishing team.***

DH is responsible for assuring that appropriate actions are undertaken through their sponsorship of ARSAC.

2. Introduction and background

Public Bodies Reform

1. Public bodies need to be responsive to an ever changing landscape. They need to be efficient, effective, and accountable. Any duplication of activity needs to be cut and activities and functions no longer needed should be stopped. For functions which remain, the public have a right to be assured that they are as effective, efficient and as well governed as they can be. Regular challenge and review provides this assurance and so is central to the reform agenda.

2. Triennial Reviews (TRs) provide a systematic approach for the regular review of public bodies operating at arm's length to Government Departments. TRs have two main stages:

- **Stage one:** tests the continuing need for the body, both in terms of the functions it performs and the model and approach through which they are delivered
- **Stage two:** considers the body's governance, performance and capability as well as exploring opportunities for efficiencies.

3. The health and social care system reforms, set out in the Health and Social Care Act 2012 and the Care Act 2014, resulted in the devolution of functions and powers away from the DH to arm's length bodies and local health and care organisations. As steward of this evolving system, the DH is using Triennial Reviews to provide assurance that the system, and the new and reformed bodies within it, are fit for purpose.

4. To help DH effectively deliver its stewardship function, DH's programme of TRs extends to all Executive Non-Departmental Public Bodies (ENDPBs), Advisory Non-Departmental Public Bodies (ANDPBs), Executive Agencies and Special Health Authorities (SpHAs).

ARSAC Triennial Review

5. The review was conducted by a Department of Health lead reviewer assisted by a multi-disciplinary team drawn from across DH and Cabinet Office working under the direction of an impartial senior review sponsor (SRS). The members of the core team can be found in Annex A.

6. In accordance with Cabinet Office guidance that Triennial Reviews should be proportionate to the size of the body under review, the ARSAC triennial review was 'light touch' with the two main stages of the review undertaken in parallel. In addition, the scope of the review was defined to: consider bodies within the existing health and care system (including DH) as alternative delivery models, but did not explore wider commercialisation options; and to exclude the consideration of underlying legislation.

7. It was also out of scope of the review to make specific recommendations related to the future simplification of the regulations underpinning ARSAC's work. There is a separate programme of work which will be delivered in 2018 following a revision of the overarching EU legislation. This timeline reflects the transposition date of the EU legislation to UK law. However, the review team has noted issues uncovered by this report which could potentially be addressed by regulatory change. All

evidence submitted during this review releating to the regulatory change has been passed to the relevant policy officials in DH.

8. In addition to the independent SRS, the review was overseen and challenged by a small project board. Project board meetings were chaired by the SRS, and attended by: ARSAC's Chair; a representative from the DH sponsor team; and the review lead. The review was subject to the wider scrutiny of the DH Triennial Review Steering Group, and Ministerial clearance has been given by Department of Health and Cabinet Office Ministers.

9. Evidence was gathered through a variety of means, including desk based review, submitted evidence, a stakeholder workshop and interviews with the ARSAC Chair, ARSAC support unit, and DH sponsor team officials. A public 'Call for Evidence' was run between 14 November and 5 December 2014 (see Annex B).

Background on ARSAC

Legal and policy framework

10. ARSAC was established in 1978, as an ANDPB of DH. ARSAC has a support unit in Public Health England (PHE), which is staffed by PHE civil servants.

11. Doctors and dentists who use radioactive medicinal products (RMPs) on people are required under the Medicines (Administration of Radioactive Substances) Regulations (MARS) 1978, as amended by the MARS 1995, to obtain a certificate from DH Ministers. Certificates are a pre-requisite for them to use RMPs in diagnosis, therapy and research. ARSAC advises the government on this certification.

12. The MARS regulations also serve the function of ensuring the UK is compliant with Article 5(A) of the European Council Directive 76/579/Euratom, which required member states to have a system of prior authorisation in relation to the use of RMPs. In this context, ARSAC also provides general advice to DH ministers in connection with the system of prior authorisation required under the article.

ARSAC's Functions

13. ARSAC has two broad functions:
    - advice to the Secretary of State on the certification of individual doctors and dentists who wish to use RMPs. In practice the support unit (staffed by civil servants) are authorised to issue certificates; and
    - guidance related to the use of RMPs.

14. The certification process requires individuals to apply to ARSAC, supported by a range of key stakeholders from the institution where the medical procedures will take place. These stakeholders are required to sign the application form as well as support certificate holders in the clinical environment. Applications can be for routine diagnostic procedures or therapeutic procedures or research: currently certificates cannot cover both. Certificates can also be renewals or new applications. Applications are reviewed by the support unit or by 'sub-groups' of Committee members.

15. ARSAC guidance has three components: specific notes on completing application forms, which are essentially supporting material for the certification process; clinical good practice; and matters related

more widely to the use of RMPs. An example of the latter is advice for patients and doctors on radiation detectors at the London Olympics 2012. Practical advice on completing applications, together with good practice guidance, is contained in the "Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources". Guidance is also published through ARSAC newsletters and updates. Advice is developed through 'task and finish' sub-groups comprising committee members drawn from across the UK. Both the main committee and these sub-groups are supported by administrative and scientific staff from the ARSAC support unit, provided by Public Health England (PHE).

Stage One Report

3. Function

16. This section of the review focuses on whether the functions currently undertaken by ARSAC should continue based on their contribution to the core business of government and the health and care system. Proposed improvements to how the functions are delivered are in the stage two report.

Certification

17. The existing EU and UK legislative frameworks, designed to ensure patient and practitioner safety in the use of nuclear medicine, prescribes the need for a prior-authorisation function. Within this, the UK legislation requires prior-authorisation to take the form of certificates issued to individual doctors and dentists. This function applies to the administration of radioactive substances for the purposes of diagnosis, treatment, or research. Prior authorisation is common practice in the EU, it is recognised as an effective component of ensuring patient safety in the field of nuclear medicines, and fundamental legislative change is beyond the scope of this review, **the review team is content that the system of prior-authorisation in place in the UK should continue [Recommendation 1]**. The UK specific legislation, which is the basis of individual certification, will be subject to revision in 2018 following its own consultation process. As such the review team believes that **individual certification should also continue, until at least the revision of the regulatory framework [Recommendation 1].**

18. The proper use of certificates, once issued, is dependent on self-regulation within institutions and the nuclear medicine community. There is a risk that the process could be abused by an individual undertaking specific procedures not included on their certificate, or without the required support. The small size of the nuclear medicine community, and the range of signatures required on the application form, means that personal and institutional credibility and reputation are closely linked to high standards of compliance. There is some evidence that this environment creates effective self-regulation, and while this form of regulation may be sufficient, there is little evidence on which to judge whether it is proportionate to the risk. To strengthen this self-regulation, **the review team recommends ARSAC should re-iterate the responsibilities of individual certificate holders and those co-signing applications. They, and other members of the nuclear medicine community, should be reminded of their obligation to raise concerns where they have evidence of poor practice by certificate holders. ARSAC should publish clear guidance on the mechanism to do so. [Recommendation 2]**.

19. The review team notes that the regulatory reform in 2018 could offer the opportunity to create a more joined up and proportionate regulatory process with the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER), perhaps by incorporating formal review of ARSAC certificates into a joint inspection remit. IRMER is being revised as part of the same exercise as the MARS regulations.

Guidance

20. The evidence submitted to the review team suggested that the ARSAC guidance, especially in relation to administered activities, is widely used by clinicians as well as others involved in the administration of RMPs, for example nuclear medicine and medical physicists. In addition, some RMPs are not licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA) or National Institute for Health and Care Excellence (NICE), especially where they pre-date these regulatory regimes and have comparatively low usage. Advice on good practice is particularly valuable in these circumstances.

21. Responses to the call for evidence also suggested that the expert and impartial nature of the Committee significantly contributes to the credibility of the guidance as a nationally accepted set of standards. **The review team recommends that there is value in the ongoing provision of guidance on clinical good practice in this field [Recommendation 1].**

4. Delivery model

22. This section of the report focuses on whether ARSAC, in its current form as an Advisory Non-Departmental Public Body (ANDPB), is the most effective delivery model for the function described in the 'Function' section above. Specific proposals for improvements to the existing model are contained in the stage two report.

23. It is Government policy that NDPBs should only be set up, or remain, in existence where the NDPB model can be clearly evidenced as the most appropriate and cost-effective model for delivering the function in question. Cabinet Office guidance has a checklist of delivery options reproduced in the table below. Some of the options were rejected early as being inappropriate. For those which remained, the review team gathered further evidence to analyse each option.

Delivery option	**Initial Assessment**
Abolish	Consider – the review team considered whether ARSAC's functions were required
Move out of central government	Consider – the review team considered whether other organisations in the health and care system offered appropriate delivery models.
Commercial model	Reject – the nature and scale of ARSAC's current functions did not justify in depth consideration of commercial models.
Bring-in house	Consider – the review team considered DH as an alternative delivery body.
Merger with another body	Consider – the review team gathered evidence on synergies with other organisations in the health and care system

Less formal structure	Reject – the Cabinet Office Categories of Public Bodies list a number of options for less formal advisory bodies: Temporary Advisory Bodies, Task Forces and Reviews, Stakeholder Groups/Forums, Public Sector Working Groups and Internal Advisory Committees. All were rejected as the functions require long-term, specialist, impartial and consistent advice.
Delivery by a new Executive Agency	Reject – the function provided by ARSAC is non-executive.
Continued delivery by an NDPB.	Consider – the review team considered whether the IRP met one or more of the 'three tests'.

Certification

24. The review team considered whether other delivery models could be more efficient or effective in providing advice to ministers in relation to certification and guidance. Due to the size and specific nature of the Committee's function the review team only considered whether other existing organisations within the health and care system could deliver the function. The criteria the review team considered are listed below. These are based on the Cabinet office guidance on: the 'three test' for NDPBs status[1]; and 'Triennial Reviews: Guidance on Reviews of non-Departmental Public Bodies'.

    - Quality of advice: the vast majority of respondents to the call for evidence recognised the importance of having practising nuclear medicine experts considering applications for certificates. The Committee is supported by a support unit with relevant scientific knowledge and a working knowledge of the equipment required for specific medical procedures. Other than the clerical staff, the rest of the support unit has wider scientific functions in PHE, which has the advantage of ensuring they have up to date scientific knowledge. In respect of the 'three tests' this criterion reflects the requirement for technical advice, requiring external expertise.

    - Independence of advice: while ARSAC is specifically named in the MARS regulations, it could be incorporated into other organisations. Suggestions included one of the Royal Colleges and the British Nuclear Medicine Society. The counter argument emerging from the evidence is that it is important to ensure advice on certification is impartial, which could be compromised if the function was to be undertaken by a self-regulating body whose members are potential applicants for certificates. This criterion links to the second and third of the 'three tests' relating to impartiality and the establishment of fact independently from ministers. HRA was also proposed as an alternative provider of research certificates, this is considered at paragraph 26.

    - The cost of the Committee: the non-staff costs associated with ARSAC, including staging committee meetings and associated committee member expenses do not exceed £15K per annum. Committee members are not paid for the time spent on ARSAC work; only for reasonable travel and expenses associated with attending committee meetings. The chair

[1] The "three tests" are: is this a technical function (which needs external expertise to deliver); is this a function which needs to be, and be seen to be, delivered with absolute political impartiality (such as certain regulatory or funding functions); and, is this a function which needs to be delivered independently of Ministers to establish facts and/or figures with integrity.

spends an average of five to six hours each week, and the members spend an average of two or three hours a week on ARSAC related work. This time is un-remunerated.

- The cost of the support unit: the support unit has just over 3 full time equivalents, across five members of staff. The support unit is paid for from PHE's general funding allocation from DH. The total salary cost of the support unit is just over £125,000, which includes £8,000 per annum from DH specifically for scientific advice on Nuclear Medicine to support ARSAC.

- ARSAC has a UK wide remit, so any delivery model should ensure that it is able to operate with independence and impartiality across the whole of the country.

25. Based on these criteria, **the review team concluded that an ANDPB continues to be the most appropriate delivery model for the certification functions [Recommendation 1]**. The particular features that ANDPB status maintains are independence from DH and other public and private bodies organisations related to the health and care system, and credibility as a UK-wide expert Committee.

26. The review team recognised that moving the research certificate function to HRA could potentially streamline the overall research process, although losing the link between research and other certificates. The key factor in making this decision would be whether the benefits would be sufficient to justify re-creating the certification process in the ethics committee element of the HRA research approvals regime. The relationship between ARSAC and HRA is explored in more detail in the stage two report under 'ARSAC relationships with the wider health and care system', with a recommendation (see recommendation 4) to evaluate this relationship further.

Guidance

27. For the period 1 November 2014 to 31 January 2015 there were 4153 page views of the ARSAC pages of the gov.uk website. While there isn't time series data on the gov.uk website, as the pages transitioned during summer 2014, the review team believes the level of usage outlined above indicates the value of the guidance to the nuclear medicine community. This is supported by the call for evidence, in which a number of respondents cite aspects of the ARSAC guidance as the definitive guidance in the UK. While there are other bodies, such as HRA, who could provide guidance, the independence of ARSAC was regarded as a significant benefit by the vast majority of respondents.

28. ARSAC newsletters and updates are also generally well received by respondents and are seen as helping to ensure that there are national standards of best practice. The newsletters are also a useful tool for continuing professional development. As such, the **review team is not recommending any fundamental changes to the current delivery model [Recommendation 1]**.

Stage One Conclusion

29. Stage one of the ARSAC TR identified two functions currently undertaken by the Committee, and considered the ongoing need for these functions. Based on consideration of the existing legislative background, and the value of the guidance apparent in the call for evidence, the review team reached the conclusion in recommendation 1, that both functions should continue.

30. The key recommendation in the stage one report that requires action is recommendation 2. This proposes ARSAC should reinforce key messages relating to the self-regulation of practice by certificate holders by the nuclear medicine community.

Recommendation 1: The main functions identified in this review should continue to be delivered by ARSAC, in its current form as an ANDPB.

Recommendation 2: ARSAC should re-iterate the responsibilities of individual certificate holders and those co-signing applications. They, and also other members of the nuclear medicine community, should be reminded of their obligation to raise concerns where they have evidence of poor practice by certificate holders. ARSAC should publish clear guidance on the mechanism to do so.

Stage Two Report

31. The stage two report explores whether ARSAC adheres to principles of good governance, and any potential improvements in performance or efficiencies.

5. Governance and relationships

Governance of ARSAC

32. Good corporate governance is central to the effective and efficient running of all public bodies. ARSAC complies with the requirements of good governance set out in *Managing Public Money*. A full 'comply or explain' analysis against these principles of good corporate governance is provided at Annex F.

33. ARSAC has an independent Chair, Dr John Rees (Consultant Radiologist at the University Hospital of Wales, Cardiff), and 21 members. The majority of ARSAC's members are medical doctors who are appointed to the Committee as independent experts in their field, for example, nuclear medicine.

34. In most cases, advice to Health Ministers to issue a certificate is not provided by a single committee member. Exceptions include circumstances of urgent clinical need. Such authorisations are carried out under a strict procedure and involve a senior scientific member of the ARSAC support unit.

35. The composition of the Committee was broadly felt to reflect the functions it performs. While there were no overarching themes arising from the Call for Evidence about composition, there was a concern that emerged from nuclear medicine professionals, other than clinicians, about whether the Committee has the appropriate level of engagement. The certification is based on a series of technical decisions and each application is supported by a whole team, represented at least in part by the range of signatories on the application form. From this perspective, wider engagement may be helpful in supporting process redesign, making applications under the current, or any future regime, more efficient. In respect of guidance and certification in relation to new medicines or developments, ARSAC must ensure it has engaged appropriate scientific support to ensure the wider implications are fully understood.

Principles of Good Corporate Governance

Good corporate governance is central to the effective operation of all public bodies. As part of the review process, therefore, as an Arm's Length Body of Department of Health, the governance arrangements in place in ARSAC should be reviewed. As a minimum, the controls, processes and safeguards in place in the ALB should be assessed against the principles and policies set out in this guidance. These reflect best practice in the public and private sectors and, in particular, draw from the principles and approach set out in the ***Corporate Governance in Central Government Departments: Code of Good Practice***.

36. ARSAC meets in full twice a year. The minutes of the meetings are not currently published. ARSAC also has a mechanism to provide a short annual report to DH, which covers the activities undertaken by ARSAC during the year. While the review team recognises that there are concerns with publishing

data relating to specific applications, **the team recommends that redacted minutes and a short annual report are published. The key channels for publication should be either the ARSAC website (not with-standing transitional issues to gov.uk) or regular circulation through the newsletter [Recommendation 3].** This would aid transparency in the way the Committee operates.

37. In addition to the principle of good governance, the Committee also has a duty to comply with the Equality Act 2010 ('the 2010 Act'). All committee members are appointed in line with best practice on public appointment, which takes the 2010 Act into consideration. There is another aspect, however, to this duty, which in the context of ARSAC is to ensure that the consideration of certificate applications is not subject to direct or indirect discrimination. While there is no evidence that this has been an issue for ARSAC, and individual members of the Committee have undertaken standard NHS equalities training as part of their continuous professional development, the Committee does not have a clearly articulated policy. **The review team recommends that ARSAC should have a clear policy which puts the obligations under the 2010 Act in the context of ARSAC's work [Recommendation 4].** This would ensure that committee members had clear guide lines while considering applications.

Relationship with Department of Health

38. DH is the steward of the system and acts as sponsor for all its arm's length bodies. ARSAC has a Senior Departmental Sponsor who leads the overall Departmental sponsor function with a senior civil servant led team providing day to day sponsorship. Sponsors are supported by sponsorship standards and a sponsor guide and all sponsors receive an induction. The ARSAC-DH working relationship is centred on these sponsorship arrangements.

39. The review team found evidence of open channels of communication between DH and ARSAC, which both the Committee support unit and the sponsor team regarded as effective and appropriate. There was also evidence of open and collaborative dialogue when issues arise, for example in relation to the poor performance of a committee member. There were examples where Departmental policies, some of which are based on government wide policy, were perceived to be problematic by the Committee. One example was the new 'presumption against re-appointment' policy for arm's length bodies. The Committee considered that there should be a presumption each member should serve two terms to exploit their experience and because there are a limited number of experts in the field. While such issues were not always fully resolved, the sponsor team did champion ARSAC within DH to ensure they were escalated to the appropriate level.

40. The review team did highlight two areas that DH and ARSAC need to ensure are managed effectively in future.
    - DH needs to ensure that the annual appraisal process for the Committee Chair is consistent with the process the chair has in place for committee members. This requires an appropriate level of senior engagement between the Committee chair and senior departmental sponsors, and written records kept.
    - Additionally, the well established existing KPI for ARSAC's certification processing has limited use in measuring the Committee's performance and needs to be revised; this is addressed in more detail in the section on "Efficiency" below. See recommendation 8.

Relationship with others in the health and care system

41. ARSAC demonstrated good levels of engagement with organisations like the Royal Colleges and the British Nuclear Medicine Society (BNMS), which represent the interests of individuals likely to apply for ARSAC certificates. This was borne out in the evidence submitted by these organisations. But the review team believes that there would be benefit in ARSAC ensuring that its role in the wider health and care system, and its relationship with other organisations, is clear and well communicated, in particular in relation to the research certification function.

42. In the call for evidence, there was a perception across respondents who commented on research related matters that information required for research certification duplicated information also considered by the HRA and its ethics committees. New nuclear medicine products being used in research projects are usually unlicensed as the research process is part of establishing whether they are effective in terms of patient health outcomes; safety of medical staff; and commercial viability.

43. In the context of the wider research process, ARSAC considers the research methodology as part of the research certification approval process, with the specific purpose of ensuring compliance with the MARS regulations. This does mean ARSAC requires information that is also included in applications to ethics committees, but it is used for specific purposes not covered by the HRA. The introduction of the Preliminary Research Form in the Integrated Research Application System (IRAS) reduces duplication in the end to end process, as the same information in the same format can be used for both ethics committee and ARSAC approval. This could be further streamlined by the introduction of a digital application system (see section "Web-based application and electronic processing system" below). Also, at the time of the review, ARSAC was considering dual certificates which would allow individuals to apply to hold a single certificate (obtained through a single application) for both diagnostic / therapeutic purposes and for research. HRA have been engaged in these discussions.

44. While ARSAC continues to work to streamline the process, the evidence still suggested that service users perceive there to be a lack of clarity around who is responsible for evaluating the scientific merit of a research proposal i.e. confusion around how ARSAC and the ethics committee in HRA fit together. While continuing improvements to the certification process will go some way to address this perception, **the review team recommends that ARSAC should engage with the HRA to ensure there is an agreed division of responsibilities on the assessment of nuclear medicine research proposals. This agreement should then be articulated clearly in the context of the entire process for research project approvals [Recommendation 5].**

45. While the ARSAC guidance is well regarded, a criticism that did emerge in the call for evidence was the profile of the guidance and communication, including confusion around version control. On the latter, confusion centred on inconsistency between the publication dates on the cover page and the version history on the next page. ARSAC newsletters were similarly well regarded, but there was a theme in the evidence that regular, rather than ad hoc, publication would be beneficial. The review team believe that the root cause of this concern was that individuals were not confident that they would see important updates or guidance as they were published, not helped by the version control issue. At the time of the TR this was compounded by transitional issues around the ARSAC website being migrated to gov.uk.

46. Regular newsletters would address this concern, but it could also be tackled by adopting a different approach to communications. For example, allowing people to sign up to have newsletters or guidance updates e-mailed to them so they could be sure they are up to date. **The review team**

recommends that ARSAC consider how to ensure that the users of their guidance are confident they are up to date with the latest developments [Recommendation 6]. This group is wider than certificate holders, as the point was raised by those involved in the wider administration of RMPs in hospitals.

47. The review team also notes that the upcoming regulatory reform is an opportunity for ARSAC to think about its place within the wider family of scientific and health ANDPB and expert committees. The Committee draws its membership from a small community of experts, which brings risks in terms of long term sustainability. While other committees will have discrete functions, the review team would encourage ARSAC and DH to consider if drawing together these functions may create a more sustainable mechanism for ensuring the necessary skills and expertise are available in the forthcoming new regulatory framework.

6. Performance and capability

Operational performance

48. ARSAC's certification work is demand led, with between 1200 to 1400 applications per year. In both the years June 2011 to July 2012, and June 2012 to July 2013, approximately:

- 20% of applications were renewals (i.e. doctors and dentists applying for a certificate to continue undertaking procedures they were already conducting);
- 65% of applications were related to research; and
- 15% were for new diagnostic and therapeutic certificates.

49. In the same time periods, approximately 74% of applications each year were dealt with by the support unit and 26% of applications were referred to the Committee. The average turnaround time for approvals in both years, per quarter, was consistently 36 days. Where certificates took longer, the primary cause was ongoing correspondence with the applicant where queries arose relating to the original form (although the ARSAC data base does not support a more sophisticated analysis of the data). Further details are contained in Tables 1 and 2 at Annex C.

50. The support unit use agreed risk criteria to assess which applications should be seen by the Committee. Up to 95% of renewals are managed by the support unit. Also, while all research certificate applications for original and novel research proposals go to the Committee, applications for additional clinicians associated with a research project that already has an ARSAC certificate holder are handled by the support unit. All new diagnostic/therapeutic certificate applications are considered by the Committee. The balance of certificates seen by the Committee is kept under review. For example, at the time of the TR the Committee was considering the value of assessing a larger proportion of renewals in order to achieve greater assurance that applicants in this category had undertaken appropriate continued professional development. The review team believes that keeping risk criteria under review is best practice, and would encourage the Committee to continue to keep assuring itself that they are considering the highest risk applications.

51. To support this system of prioritising which applications are seen by the Committee, it is essential that the support unit has appropriate knowledge of both the relevant areas of science and the clinical environment. Conscious of this, the composition of the support unit, and a programme by which members of that team spend a month each year undertaking relevant clinical work, are designed to ensure such knowledge is developed, maintained, and kept up to date.

52. For the purpose of considering applications, the Committee is split into 6 subgroups, which ensure that applications are seen by a group of specialists who have relevant experience and expertise. Having applications reviewed in this way is intended to ensure that standards are consistently applied, and also prevents all committee members having to review all applications. Where there is disagreement within a subgroup, or a particularly contentious issue arises, the application is referred to the Committee chair. Only a small proportion of respondents to the call for evidence questioned the value of a committee structure and associated sub-groups, and there was no clear theme in respect of alternatives. A far larger proportion cited the breadth of experience on the Committee as a benefit.

53. In addition to the standard certification process, ARSAC offers an additional process where a clinician believes they need to urgently undertake a procedure not covered by their certificate, called "Particular Patient Requests" (PPRs). There is a clearly defined process behind PPRs, which received virtually no criticism in evidence collected by the review team. Rather, it was a well understood and respected process, with respondents confident that ARSAC responds in a timely and appropriate way to PPRs.

54. In relation to the diagnostic and therapeutic certificates, the turnaround times were not cited as problematic in the call for evidence. The relationship with research is more complex as the certificates are one part of a wider process; this has been explored in more depth in the section "relationship with others in the health and care system", so is not repeated here.

55. It is the review team's view that this process for managing applications provides an effective screening mechanism ensuring that the Committee focuses on the most contentious applications. While the process for diagnostic and therapeutic certificates could be improved, which is explored in more detail in the section below on a web-based application process, the current performance of the Committee is not a significant issue for those applying for certificates.

7. Efficiency

KPI and benchmarking performance

56. At the time of the TR, ARSAC had one key performance indicator (KPI), which was a mean turnaround time of 60 days for 90% of applications. Between July 2012 and June 2013, this target had not been missed; in fact the average number of cases turned around in 60 days had not dipped below 98%. Historically, compliance with this KPI is published in newsletters when they are issued, although where there are long gaps between publications the targets are not published elsewhere.

57. The review team believe this KPI does not reflect either the time it takes to process different types of applications, for example renewals or new applications, or support the identification of any inefficiency in the process. As such, the review team believes that the existing KPI does not enable customers to anticipate how long their application will take or their contribution to the process. It also does not significantly add to DH's ability to hold ARSAC to account. **The review team recommends that a more sophisticated range of KPIs is agreed between ARSAC and DH, which can be used to help service users anticipate the length of time they should allow for applications, and for DH to hold ARSAC to account [Recommendation 7].**

58. The review team recognises, in making recommendation 7, that the process for managing applications is largely paper based. While ARSAC has a basic data base, the data it holds cannot be

easily manipulated either for cross-referencing information or for break downs of the process or application types. This means that any further break down of KPIs is hindered by the paper based systems. Because of this, any changes should be proportionate in terms of the work they create for the support unit and the Committee, but should be reviewed again at such time as an electronic processing system is implemented. This is considered in recommendation 8.

59. Neither the review team's research nor the call for evidence highlighted any organisations which have a set of KPIs that could be directly applied to ARSAC in respect to benchmarking. The call for evidence did highlight some areas for ARSAC and DH to consider when reviewing the existing KPI: these should be seen as examples, to support the development of the process for applications for research certificates in the context of the wider process of research project approval.

- Research ethics committees (RECs): HRA states that on average, RECs give an opinion on research applications in less than 40 days, with a maximum allowance of 60 days. HRA also distinguishes between 'proportionate' and 'full' reviews, seeking to have a significantly lower turnaround time for the former.
- MHRA: has a range of KPIs, including the assessment of applications for clinical trials of medicines in the UK, with a 98% in 30 days (all trial phases) target.

60. Should individual-based certification be replaced by institution-based certification in the 2018 regulatory reform, ARSAC should revisit whether there are any European bodies providing prior authorisation which could provide a useful bench mark.

61. ARSAC does exploit scientific journals when developing guidance. For example, ARSAC was considering guidance on PET/CT scanning to facilitate more tailored dosage arrangements, which the support unit intended to publish through this channel. The use of journals provides a mechanism to have the science peer reviewed, which adds to the credibility of ARSAC guidance.

Fees and charging

62. The call for evidence suggested that there was opposition to the introduction of an application fee. The primary reasons cited were: it is unreasonable to charge an individual to pay for a certificate which is required for them to undertake their jobs; and a desire to not add any additional complications to the process. As the cost of running the Committee is comparatively low, there is also a risk that the additional bureaucracy in recovering costs would be disproportionate to the amount of revenue generated. Further detailed work would be required to establish the administrative costs of a fee collection system and an appropriate level of fees.

63. There were two exceptions that emerged in the call for evidence in relation to applications fees. The first was that there was some acceptance that the development of a more comprehensive audit or regulatory regime could justify an application fee, provided fee income was used to fund and sustain such a regime. Although this was not a universally expressed view, the workshop conducted by the review team considered that the introduction of a more demonstrable accreditation or audit function would have benefits for hospitals, and provide an additional safeguard for patient safety. The second was that large private organisations funding research would be able to absorb the costs.

64. As the current system is based on awarding certificates to individuals, rather than institutions or research funding bodies, the review team does not recommend that an application fee is introduced at this time. However, this is an issue that ARSAC should return to if the regulatory reform in 2018 results in a departure from the current principle of prior authority being granted to individuals, or the introduction of a more comprehensive audit or regulatory service.

Web-based application and electronic processing system

65. One of the strongest themes that came through in the research undertaken by the review team was the benefits of developing a web-based application and electronic processing system.

66. From a service user perspective, the application process could be made significantly easier if it were electronic. Examples provided indicated: a correctly designed electronic application would make the collection of signatures significantly easier; communications between the support unit, committee, and applicants could also be improved (at least 12 days in the current processes is allowed for paper-based information exchange by post); and the links to the HRA IRAS system could be automated.

67. An electronic processing system would enable the more effective manipulation of data, which would facilitate the development of more sophisticated KPIs and improve the robustness of the checks the support unit undertakes in relation to previous applications and equipment held at specific institutions.

68. At present paper copies of an individual's certificate are issued to an employer. Communications within and across sites (where a single institution has multiple sites) is currently at the discretion of local administrators. An electronic system would also facilitate wider direct cross-communication with site administration and research personnel.

69. While it was beyond the scope of the review to provide a specific IT solution, and consequently to put a specific figure on the potential benefits, the review team recognises that there is a strong demand for change from the service users and the teams that support them in their applications. Furthermore, the potential improvements outlined above are unlikely to be realised without the ability to have a more sophisticated interaction with service users and better capability to interrogate data. As such, this is an area that **the review team strongly recommends is explored further by the DH sponsor team and the Digital, Channel Strategy and Publishing team, with the latter utilising well established digital advice networks across government to identify an appropriate and cost effective way forward [Recommendation 8].**

Stage two conclusions

70. Stage two of the ARSAC TR considered potential improvements in the operation of the Committee. The recommendations cover three areas, which emerge from the review.

- Governance: these recommendations (3 and 4) are intended to enable ARSAC to demonstrate that it is operating under the principles of good governance and to improve transparency.
- Service users: these recommendations (5, 6, 7, and 8) are intended to clarify what expectations those using the services ARSAC provides should have about turn-around times, and ARSAC's interactions with other bodies in the wider health and care system. They also reflect the fact that ARSAC's work affected individuals and teams who are not certificate holders.
- Digitisation: recommendation 8 recognises that ARSAC has largely paper based systems, which create constraints on the operation of the Committee, and on the level of service for applicants.

Recommendation 3: Appropriately redacted minutes and a short annual report should be published. The key channels for publication should be either the ARSAC website (not with-standing transitional issues to gov.uk) or regular circulation through the newsletter.

Recommendation 4: ARSAC should ensure that there is clear guidance in place to ensure that Committee members understand their obligations under the Equality Act 2010 specifically in relation to their work in ARSAC.

Recommendation 5: ARSAC should engage with the HRA to ensure that there is a clear and agreed division of responsibilities on the assessment of nuclear medicine research proposals. This agreement should then be articulated clearly in the context of the entire process for research project approvals.

Recommendation 6: ARSAC should consider how to ensure that the users of their guidance are confident they are up to date with the latest developments

Recommendation 7: a more sophisticated range of KPIs should be agreed between ARSAC and DH, which can be used to help service users anticipate the length of time they should allow for applications, and for DH to hold ARSAC to account.

Recommendation 8: DH, PHE, and ARSAC should explore an electronic web-based application and electronic processing system as a priority.

Annexes

Annex A: Review team, project board membership, and review cost

Review team

Role	Name
Senior Review Sponsor	Professor Alex Elliott
Lead Reviewer	Adam McMordie
Assistant Reviewer	Paul McCormack

Project Board

Role	Name
Chair	Professor Alex Elliott
Member: ARSAC Chair	Dr John Rees
Member: TR review team	Adam McMordie
Member: DH Sponsor team	Stuart Conney
Attendee: DH Sponsor team	Ian Chell
Secretary	Paul McCormack

Review Costs

The direct cost of the review is estimated to be £11,200. This comprises the DH resources (total salary costs for review team members), and travel and subsistence for the SRS and review team.

No additional fees were paid to members of ARSAC, the ARSAC support unit, or the SRS.

The indirect costs of the Committee Chair and ARSAC support unit's time are not included in this calculation.

Annex B: call for evidence questions

1. Do you believe there is a more effective or efficient way for DH to comply with the statutory requirements under the Medicines (Administration of Radioactive Substances) Regulations (MARS) 1978, as amended by the MARS 1995, that ARSAC currently fulfils?

2. Is the guidance provided by ARSAC in respect of its certification function under MARS necessary for the effective management of radioactive substances?

3. Are the guidance, reports and newsletters provided by ARSAC in respect of its general advice function necessary and useful for the effective management of radioactive substances?

4. Are there other bodies who could more efficiently fulfil the functions currently undertaken by ARSAC?

5. Does ARSAC have the right level of independence to ensure its advice is professional and impartial?

6. Does the current composition of the Committee's membership best support the functions you believe are necessary?

7. Do you consider a web-based application and electronic processing system might improve the efficiency of ARSAC?

8. Should the Committee cover its costs by charging an administration fee for applications?

9. Are there other organisations which could be used as a benchmark for the performance of ARSAC?

10. Does the Committee ensure that advice on the provision of certificates in respect of routine requests is provided in a timely manner?

11. Does the Committee ensure that advice on the provision of certificates in respect of 'particular patient requests' (PPR) is provided in a timely manner?

12. Are there ways in which the Committee could be performing more effectively?

Annex C table 1: ARSAC Certificate Applications – Summary 2011-12 to 2013-14

Date		Applications received					Applications processed		
		Renewals	Research	Diagnostic/ Therapeutic	Total		Refused*	Sent to Committee	Actioned by Support unit
1 July 2011 to 30 June 2012		246	832	181	1259		1	320	939
1 July 2012 To 30 June 2013		293	885	196	1374		1	357	1017
1 July 2013 to 30 June 2014		268	1068	225	1561		7	426	1135

*The low number of cases rejected does not reflect the number of applications modified during the application process by the Committee. Modifications include the withdrawal of applications while further training is completed or a reduction in the number of procedures being sought. Of the Diagnostic and therapeutic certificates the Committee considered, approximately 50% generated requests for clarification with approximately 10% resulting in modified applications. For research certificates considered by the Committee, further clarification was sought on approximately 45% and 25% were modified as a consequence of the Committee's input.

Annex C table 2: ARSAC Certificate Application – Processing 2011-12 to 2013-14

	1 July 2011 – 30 June 2012				1 July 2012 – 30 Jun3 2013				1 July 2013 – 30 June 2014			
	Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Mean time (days) for processing each application (agreed KPI is <36 days)	20.1	14.8	22.1	20.8	21.9	17.9	19.5	23.6	20.1	16.8	16.9	17.6
Percentage completed within 60 calendar days (agreed KPI is >90%)	99.2%	98.6%	97.4%	99.6%	99.2%	98.4%	100.0%	98.7%	97.9%	99.6%	98.9%	98.3%
Number of applications received	330	295	302	332	363	327	354	330	345	391	399	426
Number of applications processed (issued, refused or closed)	382	317	368	384	441	385	370	504	357	430	1017*	529
Notes: * = Includes one-off processing of archiving historic research files.												

Annex D: List of respondents to the call for evidence

Organisations
Wendy Fisher Consulting
University of Edinburgh
Radiation Physics Dept, Hull & East Yorkshire Hospitals
NHS Grampian
Norfolk and Norwich University Hospitals NHS Foundation Trust
Plymouth Hospitals
Abertawe Bro Morgannwg University Health Board
Poole Hospital NHS Foundation Trust[2]
Royal Liverpool & Broadgreen University Hospitals NHS Trust
Poole hospital NHS Foundation Trust
Central Manchester University Hospitals
Western Sussex Hospitals NHS FT
Royal Bournemouth and Christchurch Hospitals NHS FT
University Hospital Birmingham NHS Foundation Trust
Bradford Teaching Hospitals NHS Trust
Radiopharmacy, Guys and St Thomas Hospital
NHS Grampian
Anonymous
Poole NHS Foundation Trust
Christie Medical Physics and Engineering
BIR (N.B. this is the BIR response not a personal response)
Royal College of Radiologists
Royal College of Physicians
Regulatory & Quality Improvement Authority
Institute of Physics and Engineering in Medicine
BNMS
Poole Hospital NHS Foundation Trust

The review team also interviewed the ARSAC Chair and Support Unit.

[2] Four individual responses were received from Poole NHS Foundation Trust

Annex E Written Ministerial Statement of 30 October 2014

Written Ministerial Statement

DEPARTMENT OF HEALTH

Triennial reviews of non- Departmental public bodies

Thursday 30 October 2014

The Parliamentary Under Secretary of State, Department of Health (George Freeman): I am today announcing the start of the triennial reviews of the National Institute for Health and Care Excellence (NICE), the Medicines and Healthcare Products Regulatory Agency (MHRA), the British Pharmacopoeia Commission (BPC), the Commission on Human Medicines (CHM), the Administration of Radioactive Substances Advisory Committee (ARSAC) and the Independent Reconfiguration Panel (IRP).

All Government Departments are required to review their non-Departmental public bodies (NDPBs) at least once every three years. Due to the wide ranging reforms made by the Health and Social Care Act 2012, DH was exempt from the first round of reviews in 2011-14. In order to ensure that DH is an effective system steward and can be assured of all the bodies it is responsible for, we have extended the programme of reviews over the next three years to all of its arm's length bodies and executive agencies.

The reviews of the aforementioned bodies have been selected to commence during the first year of the programme (2014-15). The reviews will be conducted in two stages. The first stage will examine the continuing need for the function and whether the organisation's form, including operating at arm's length from government, remains appropriate. If the outcome of this stage is that delivery should continue, the second stage of the review will assess whether the bodies are operating efficiently and in line with the recognised principles of good corporate governance.

Annex F: ARSAC Compliance with the Principles of Good Corporate Governance

This annex lays outs ARSAC's compliance with the principles of good governance, including where the Department of Health has made arrangement which are proportionate to the scale and function of the Committee.

Principles of Good Corporate Governance		Findings of Review
Accountability	**Principle:** The minister is ultimately accountable to Parliament and the public for the overall performance, and continued existence, of the advisory NDPB.	ARSAC is mostly compliant overall.
	Provision 1 The minister and sponsoring department should exercise appropriate scrutiny and oversight of the advisory NDPB. This includes oversight of any public monies spent by, or on behalf of, the body.	ARSAC is compliant. The ARSAC Support Unit provides oversight of ARSAC's expenditure, and reports through standard Public Health England (PHE) processes. ARSAC is not a separate legal entity from DH. Associated costs are included within the Core Department account.
	Provision 2 Appointments to the advisory NDPB should be made in line with any statutory requirements and, where appropriate, with the Code of Practice issued by the Commissioner for Public Appointments.	ARSAC is compliant. All DH public appointments follow the Code.
	Provision 3 The minister will normally appoint the Chair and all board members of the advisory NDPB and be able to remove individuals whose performance or conduct is unsatisfactory.	ARSAC is compliant.
	Provision 4 The minister should meet the Chair on a regular basis.	ARSAC is partially compliant. The Chair meets with DH officials regularly, who are able to escalate any information to Ministers as required. This is proportionate to the scale and nature of the function.
	Provision 5 There should be a requirement to inform Parliament and the public of the work of the advisory NDPB in an annual report (or equivalent publication) proportionate to its role.	Improvement suggested. Recommendation 3 of the main report would improve compliance.
	Provision 6 The advisory NDPB must be compliant with Data Protection legislation.	ARSAC is compliant. The ARSAC Support Unit is responsible for compliance, using the PHE data protection policy.

	Provision 7 The advisory NDPB should be subject to the Public Records Acts 1958 and 1967.	ARSAC is compliant. The ARSAC Support Unit is responsible for compliance.

Role of the Sponsoring Department	**Principle**: The departmental board ensures that there are appropriate governance arrangements in place with the advisory NDPB. There is a sponsor team within the department that provides appropriate oversight and scrutiny of, and support and assistance to, the advisory NDPB.	ARSAC is mostly compliant overall.
	Provision 1 The departmental board's agenda should include scrutiny of the performance of the advisory NDPB proportionate to its size and role.	ARSAC is compliant. Scrutiny of the performance of ARSAC is overseen by the Senior Departmental Sponsor (at Director General level), who is responsible for escalating any issues to the Departmental Board. This is appropriate given the scale of ARSAC's current functions.
	Provision 2 There should be a document in place which sets out clearly the terms of reference of the advisory NDPB. It should be accessible and understood by the sponsoring department and by the Chair and members of the advisory NDPB. It should be regularly reviewed and updated.	ARSAC is compliant. "Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources" is available on the ARSAC pages on gov.uk, and outlines, amongst other things, the work of ARSAC. The current format of the guidance dates from March 2006. The guidance has been revised several times since then, most recently in 2014.
	Provision 3 There should be a dedicated sponsor team within the sponsor department. The role of the sponsor team should be clearly defined.	ARSAC is compliant.
	Provision 4 There should be regular and ongoing dialogue between the sponsoring department and the advisory NDPB.	ARSAC is compliant.
	Provision 5 There should be an annual evaluation of the performance of the advisory NDPB and any supporting committees – and of the Chair and individual members.	ARSAC is compliant.

Role of the Chair	**Principle**: The Chair is responsible for leadership of the advisory NDPB and for ensuring its overall effectiveness.	ARSAC is fully compliant overall.
	Provision 1 The advisory NDPB should be led by a non-executive Chair.	ARSAC is compliant.
	Provision 2 There should be a formal, rigorous and transparent process for the appointment of the Chair. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments. The Chair should have a clearly defined role in the appointment of non-executive board members.	ARSAC is compliant. All DH public appointments follow the Code. The role of the Chair in the appointments process was made clear on appointment.
	Provision 3 The duties, role and responsibilities, terms of office and remuneration (if only expenses) of the Chair should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The responsibilities of the Chair will normally include: • representing the advisory NDPB in any discussions with ministers; • advising the sponsoring department and ministers about member appointments and the performance of members ; • ensuring that the members have a proper knowledge and understanding of their role and responsibilities. The Chair should ensure that new members undergo a proper induction process and is normally responsible for undertaking an annual assessment of non-executive board members' performance; • ensuring that the advisory NDPB, in reaching decisions, takes proper account of guidance provided by the sponsoring department or ministers; • ensuring that the advisory NDPB carries out its business efficiently and effectively; and • representing the views of the advisory NDPB to the general public, when required.	ARSAC is compliant. All public appointees have terms and conditions of appointment attached to their offer letter. The responsibility to abide with the Cabinet Office's Code of Conduct is made clear.

Role of other members	**Principle:** The members should provide independent, expert advice.	ARSAC is fully compliant overall.
	Provision 1 There should be a formal, rigorous and transparent process for the appointment of members to the advisory NDPB. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments.	ARSAC is compliant. All DH public appointments follow the Code.
	Provision 2 Members should be properly independent of the department and of any vested interest (unless serving in an ex-officio or representative capacity).	ARSAC is compliant. ARSAC members are by necessity drawn from the nuclear medicine community, and are permitted to hold interests. Members declare interests at meetings and complete an Annual Declaration of Interests. If an interest is declared at a meeting, the Chair will decide whether or not that member participates in the discussion. The interest declared at the meeting is recorded in the minutes and whether the member participated in the discussions is recorded.
	Provision 3 Members should be drawn from a wide range of diverse backgrounds, but should have knowledge and expertise in the field within which the body has been set up to advise ministers. The advisory NDPBs as a whole should have an appropriate balance of skills, experience, independence and knowledge.	ARSAC is compliant. Members are drawn from a range of relevant specialisms that reflect the nature of ARSAC's current functions.
	Provision 4 The duties, role and responsibilities, terms of office and remuneration of members should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements.	ARSAC is compliant. All public appointees have terms and conditions of appointment attached to their offer letter. The responsibility to abide with the Cabinet Office's Code of Conduct is made clear.

	Provision 5 All members must allocate sufficient time to the advisory NDPBs to discharge their responsibilities effectively.	ARSAC is compliant. Members respond in a timely and appropriate manner to requests for advice on certificate applications. Members attend meetings as required. These activities are assessed as part of the appraisal process. The ARSAC support unit has mechanism in place to assure duties are discharged in a timely fashion, and this forms part of committee members' annual appraisal.
	Provision 6 There should be a proper induction process for new members. This should be led by the Chair. There should be regular reviews by the Chair of individual members' training and development needs.	ARSAC is compliant. All new members attend an Induction Day and receive an Induction Pack from the ARSAC Support Unit. Additional, new members receive mentoring from established members, the chair, and the Support Unit. Members' training and development needs are discussed at their annual appraisal.
	Provision 7 All members should ensure that high standards of corporate governance are observed at all times. This should include ensuring that the advisory NDPB operates in an open, accountable and responsive way.	ARSAC is compliant. The report recommends openness could be more clearly demonstrated with the publication of further information. See recommendation 3.

Communications	**Principle**: The advisory NDPB should be open, transparent, accountable and responsive.	ARSAC is mostly compliant overall.
	Provision 1 The advisory NDPB should operate in line with the statutory requirements and spirit of the Freedom of Information Act 2000.	ARSAC is compliant.
	Provision 2 The advisory NDPB should make an explicit commitment to openness in all its activities. Where appropriate, it should establish clear and effective channels of communication with key stakeholders. It should engage and consult with the public on issues of real public interest or concern. This might include holding open meetings or annual public meetings. The results of reviews or inquiries should be published.	ARSAC is partially compliant. ARSAC guidance and newsletters are in the public domain and are generally well regarded by stakeholders. Recommendation 6 of the main report considers potential improvements in communications.
	Provision 3 The advisory NDPB should proactively publish agendas and minutes of its meetings.	Improvement suggested. See recommendation 3 of the main report.
	Provision 4 There should be robust and effective systems in place to ensure that the advisory NDPB is not, and is not perceived to be, engaging in political lobbying. There should also be restrictions on members attending Party Conferences in a professional capacity.	ARSAC is partially compliant. Committee members' terms of appointment include a requirement to comply with the Cabinet Office 'Code of Conduct' for board members of public bodies, which includes guidance on political activity. ARSAC does not have a rigorous enforcement system but given the nature of the current functions, and the requirement for specific expertise, this is proportionate and appropriate.

Conduct and Behaviour	**Principle**: Members should work to the highest personal and professional standards. They should promote the values of the advisory NDPB and of good governance through their conduct and behaviour.	ARSAC is mostly compliant overall.
	Provision 1 A Code of Conduct must be in place setting out the standards of personal and professional behaviour expected of all members. This should follow the Cabinet Office Code. All members should be aware of the Code. The Code should form part of the terms and conditions of appointment.	ARSAC is compliant. All public appointees have terms and conditions of appointment attached to their offer letter. The responsibility to abide with the Cabinet Office's Code of Conduct is set out.
	Provision 2 There are clear rules and procedures in place for managing conflicts of interest. There is a publicly available Register of Interests for members. This is regularly updated.	ARSAC is compliant. Conflicts of interest are discussed at committee meetings, and published.
	Provision 3 There must be clear rules in place governing the claiming of expenses. These should be published. Effective systems should be in place to ensure compliance with these rules.	ARSAC is compliant. There is a formal expenses policy in place.
	Provision 4 There are clear rules and guidelines in place on political activity for members and that there are effective systems in place to ensure compliance with any restrictions.	ARSAC is partially compliant. Committee members' terms of appointment include a requirement to comply with the Cabinet Office 'Code of Conduct' for board members of public bodies, which includes guidance on political activity. The Chair and Support Unit actively consider change of circumstances, which could affect an individuals' ability to perform the required functions of a committee members.
	Provision 5 There are rules in place for members on the acceptance of appointments or employment after resignation or retirement. These are enforced effectively.	ARSAC is partially compliant. ARSAC members are subject to the 'Code of Conduct' for board members of public bodies. Members of ARSAC are selected for their expertise, which require active or recent involvement in nuclear medicine community. As such there are no restrictions on appointments on resignation, which is appropriate given the need for expertise on the Committee.