



Department
of Health

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

Call for Evidence

November 2014

Title: Triennial Review of the Administration of Radioactive Substances Advisory Committee -
Call for Evidence

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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.

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Introduction

In recent years, the health and social care system in England has undergone substantial change. The Health and Social Care Act 2012 and the Care Act 2014 have devolved functions and powers away from the Department of Health to local and Arm's Length Bodies.

In this new system, the Department has the key stewardship and assurance function designed to ensure that the new system and the multiple new and reformed bodies within it, have the appropriate functions and are performing to a high standard.

To perform this stewardship function, the Department is putting in place Triennial Reviews of all its Arm's Length Bodies. This includes all Executive Non-Departmental Public Bodies (ENDPBs), Advisory Non-Departmental Bodies (ANDPBs), Executive Agencies (EA) and Special Health Authorities (SpHA). As an ANDPB, the Administration of Radioactive Substances Advisory Committee is subject to review in 2014-15.

The programme of reviews builds on the approach developed by the Cabinet Office as part of their work on Public Bodies Reform.

Purpose of the Review

This review is part of a wider programme the Department of Health has developed in support of its stewardship and assurance function. The review has two main aims which will be undertaken simultaneously:

- The first is to provide a robust challenge of the continuing need for the Administration of Radioactive Substances Advisory Committee (ARSAC), both in terms of the functions it performs and the model and approach in which these are delivered.
- The second will be consideration of ARSAC's governance, performance and capability as well as exploring opportunities for efficiencies.

This Call for Evidence seeks views from respondents to assist its consideration of both of the above stages.

Timeline

The Triennial Review of ARSAC has commenced and will be completed by the end of December 2014. The conclusions of the review will be announced in both Houses of Parliament and a copy of the final report will be published on the Department of Health website in early 2015.

Responding to this Review

In order to conduct the review in an open and transparent manner and ensure that the findings are rigorous and evidence-based, the review team is seeking the views of a wide range of stakeholders.

We are interested in the views of individuals and organisations that engage with the Administration of Radioactive Substances Advisory Committee or have a wider interest in its operations. The key areas of enquiry, based on the five standard areas that apply to all Triennial Reviews are set out below. In particular, the review team will focus on ARSAC's certification of doctors and dentists who want to use radioactive medicinal products on people.

Submissions should be uploaded at <http://consultations.dh.gov.uk/>. The site is accessible, but alternatively responses can be sent to: TR-ARSAC@dh.gsi.gov.uk.

Email submissions should clearly state interest and interaction with ARSAC whether a member or other stakeholder.

Interested stakeholders are also invited to attend a workshop to share their views on this Call for Evidence:

25 November 2014 11:00-13:00 hours London

To register please click on the link below:

<https://www.eventbrite.co.uk/e/arsac-triennial-review-workshop-tickets-14189121043>

Please note:

Places are limited and will be allocated on a 'first come first served' basis.

Only information directly relevant to the areas of investigation will be considered. Information where relevance is not demonstrable will not be taken as evidence. The review team is unable to respond to individual cases or consider complaints about ARSAC's certification function. Complaints should be directed to ARSAC at arsac@phe.gov.uk Patient Identifiable information should be avoided.

All submissions must be received by 18:00 hours on **Friday 5 December 2014**

Confidentiality

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 1998 (DPA).

If you want the information that you provide to be treated as confidential, please be aware that under the FOIA, there is a statutory Code of Practice with which public

authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department of Health and a Ministry of State.

The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Useful Links

Below are a few links that are being used by the review team as part of the review. These are not necessarily recommended reading but some respondents may find them of use.

- Administration of Radioactive Substances Advisory Committee:
<https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee/about>
- Department of Health website:
<https://www.gov.uk/government/organisations/department-of-health>
- Cabinet Office Triennial Review guidance:
<https://www.gov.uk/government/publications/triennial-reviews-guidance-and-schedule>

About the Administration of Radioactive Substances Advisory Committee (ARSAC)

The Administration of Radioactive Substances Advisory Committee (ARSAC), originally established in 1978, is an Advisory Non-Departmental Public Body (ANDPB) of the Department of Health (DH).

ARSAC advises government on the certification of doctors and dentists who want to use radioactive medicinal products on people. Doctors and dentists who use radioactive medicinal products (radiopharmaceuticals) 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. This certificate allows them to use radioactive medicinal products in diagnosis, therapy and research.

ARSAC also provides general advice to DH ministers in connection with the system of prior authorisation required by Article 5(a) of Council Directive 76/579/Euratom.

ARSAC currently comprises a Chair, Dr John Rees (Consultant Radiologist at University Hospital, Wales), 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. The committee comments on applications in confidence to the ARSAC Support Unit which is provided by Public Health England. 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

An official from the Department of Health authorises successful applications for a certificate on behalf of the Secretary of State for Health.

Introduction to the Questions

Triennial Reviews are usually carried out in two distinct phases. However, this review will consider the questions from both of these simultaneously. This recognises the nature and scale of ARSAC's work.

The review team are particularly interested in evidence in support of responses to the 12 questions set out in this Call for Evidence. Wherever possible, please provide evidence in support of your response.

The Review will be receiving a mixture of written evidence through this Call for Evidence as well as verbal submissions and testing through interview and a workshop.

The Review is considering evidence of stage one and two together. Stage one focuses on the ARSAC functions and how they are delivered. Stage two considers the ARSAC performance and capability, opportunities for efficiency, and the governance arrangements.

The questions below invite interested stakeholders to consider both together and feed in where they feel appropriate.

*** Please respond to **one or more** of the following 12 questions, in particular the Review is looking for evidence to inform considerations. ***

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?**

Yes/No

Please give reason for your answer.

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

Yes/No

Please give reasons for your answer.

- 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?**

Yes/No

Please give reasons for your answer.

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

Yes/No

Please give reasons for your answer.

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

Yes/No

Please give reasons for your answer.

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

Yes/No

Please give reasons for your answer.

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

Yes/No

Please give reasons for your answer.

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

Yes/No

Please give reasons for your answer.

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

Yes/No

Please reasons for your answer.

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

Yes/No

Please give reasons for your answer.

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?

Yes/No

Please give reasons for your answer.

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

Yes/No

Please give reasons for your answer.

If there is other evidence on ARSAC's role, functions, performance, efficiency or governance that you would like to submit as part of this Call for Evidence please attach it and state what it relates to.

***** END *****