

Radiation Epidemiology and Radiobiology Research

Credible Options (Gate A) – Issue 1

October 2013

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Executive Summary

Background

Significant epidemiological and radiobiological research involving nuclear industry workers was previously sponsored by parts of the UK nuclear industry (e.g. British Nuclear Fuels Ltd and United Kingdom Atomic Energy Authority). This work generated important research assets which are now owned by the Nuclear Decommissioning Authority (NDA). NDA has continued to manage these assets and support research in these areas as it has a potential impact on the safety, cost, management, delivery and public acceptability of our decommissioning mission.

The objective of NDA's Radiation Epidemiology and Radiobiology Research Strategy is to ensure that our assets are appropriately managed and that research relevant to our mission is carried out.

Approach

Following internal review and discussion with our independently chaired Radiation Epidemiology Governance Group we identified a number of Credible Options for managing epidemiology and radiobiology research and associated research assets within the context of our current overall strategy for Research and Development (R&D).

The options for managing our research programme considered were:

- **Option 1:** Close the programme and withdraw from these areas
- **Option 2:** Close the programme but maintain a watching brief for relevant research
- **Option 3:** Compete the programme through open tender with NDA maintaining overall management responsibility
- **Option 4:** Transfer responsibility for management of the programme to one of our SLCs
- **Option 5:** Further develop a strategic relationship with PHE (formerly the HPA) with the long-term aim of restructuring the ownership and management of the assets

These options have been reviewed against a number of criteria and the results of our initial assessment are presented within this Credible Options (Gate A) paper.

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Way Forward

NDA will continue our work to evaluate and underpin our strategic position on Radiation Epidemiology and Radiobiology Research. A key part of this will be to understand the views of stakeholders.

We expect to have underpinned our strategic position on Radiation Epidemiology and Radiobiology Research by the end of 2013 when our Preferred Option will then be confirmed as our strategy. We are therefore interested in receiving views on the identified options, the criteria for selecting between them and the results of our initial assessment. Please email your comments to strategy@nda.gov.uk by 15/11/2013.

Document Revision Record

Version	Stage	Record of Change	Date
Draft 0.1	A	N/A	12 June 2013
Draft 0.2	A	Update following Epidemiology Governance Group	26 June 2013
Draft 0.3	A	Update following Strategy Development & Implementation Group	20 August 2013
Issue 1	A	Update following Executive Team Meeting - Strategy & Planning	3 October 2013

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Glossary

BNFL	British Nuclear Fuels Ltd.
DH	Department of Health
Data Custodian	The individual responsible for safeguarding data and assuring appropriate use (not to be confused with Data Owner, Data Controller or Data Processor, as defined under the Data Protection Act)
Epidemiology	The study of the patterns, causes, and effects of health and disease outcomes within populations
HPA	Health Protection Agency (now part of PHE)
HTA	Human Tissues Act
NDA	Nuclear Decommissioning Authority
NRRW	National Registry for Radiation Workers
PHE	Public Health England (formed on 01 April 2013)
Radiobiology	The study of the action of radiation on biological systems
SLC	Site License Company
UKAEA	United Kingdom Atomic Energy Authority
WSC	Westlakes Scientific Consulting

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1 Strategic Case

1.1 Topic Background and Context

Radiation epidemiology and radiobiology provide evidence in relation to the possible health risks of exposure to ionising radiation. Such evidence helps to develop areas of knowledge that can have an impact on the safety, cost, management, delivery and public acceptability of decommissioning activities. As outlined in our strategy for Research and Development (R&D), under the Energy Act 2004, NDA is required to promote and, where necessary, carry out research in relation to its prime function of decommissioning and clean-up.

The Radiation Epidemiology and Radiobiology Research Strategy will outline the NDA's approach to this topic area. The objective of our strategy is to ensure that our assets are appropriately managed and that research relevant to our mission is carried out.

1.1.1 Research

Within this topic there are two distinct areas of research to be considered and for the purposes of this strategy the technical scope of these areas can be defined as follows:

- Radiation Epidemiology - using exposure (primarily radiation dose) and health (primarily cancer registration and cause of death) information collected for a nuclear worker population with statistical analysis to study the patterns, causes, and effects of health and disease outcomes within that population.
- Radiobiology - using biological samples from nuclear workers, with dosimetry information and laboratory techniques, to directly study the action of radiation on biological systems.

The knowledge gained from these areas can have an impact on NDA's decommissioning mission (e.g. compliance with dose limits - or duty of care to assure compliance with best knowledge - may impact on working practices and/or staffing levels for workers within the decommissioning sector).

1.1.2 Research Assets

The primary asset required for enabling epidemiological research is relevant information stored in a database in a structured manner. Following its formation, NDA assumed ownership of two epidemiological databases via transfer schemes. The databases respectively contain information relating to workers employed at sites operated by the former British Nuclear Fuels Ltd (BNFL) and the former United Kingdom Atomic Energy Authority (UKAEA). These databases contain information on tens of thousands of workers spanning several decades, have taken many million pounds worth of effort to construct and are considered unique, irreplaceable and, in the context of such research, invaluable.

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Previous radiobiological research projects have resulted in a collection of biological materials, isolated from blood samples voluntarily donated by nuclear workers employed, at some time, at the Sellafield site. This also now falls within the NDA estate and is a potential asset to further research within this area.

The future of these research assets is a key consideration.

1.1.3 Other Considerations

Because some of this work involves personal/medical information and/or biological samples there are additional legal and ethical issues that must also be considered. In particular, the position of an individual or their representative(s), with regard to (data) asset ownership, irrespective of the ownership of the database, file or sample store in which such information is held, indicates that they too are important stakeholders with respect to any proposed strategy.

Research into the potential health effects of radiation exposure has also been conducted by other national and international bodies and it may be considered that a coordinated UK approach would ensure the most cost-effective use of public funds.

1.2 Current Situation

1.2.1 Pre-2010 Strategy Arrangements

The existing strategy for our radiation epidemiology and radiobiology dates back to our first Strategy^[1], which was produced in 2006 shortly after NDA assumed responsibility for oversight of this work. In the first Strategy, a commitment was made to continue to support the collection and management of epidemiological data (including dosimetry) and radiobiological samples, and also that the epidemiological and radiobiological research programmes would continue to be funded as part of our skills strategy.

Arrangements for delivery of the Strategy commitments were through two primary routes. Management of the research assets and the radiation epidemiology and radiobiology research programme for the former BNFL sites was through a contract with Westlakes Scientific Consulting (WSC), an organisation which had extensive previous experience in this role (this work having been outsourced to them by BNFL in 1994). The United Kingdom Atomic Energy Authority was contracted to continue to manage the 'UKAEA' epidemiological database and research programme and this was further largely subcontracted to Nuvia Limited, an organisation with staff with extensive relevant experience.

Subsequent events have made this strategy untenable:

- WSC went into administration in July 2010. This put the epidemiological database associated with research on the effects of radiation on the workforce at the former BNFL sites at risk of being lost or irretrievably damaged. Biological samples collected from workers at the former BNFL

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sites, for use in genetics research, were also held by WSC and were similarly put at risk.

- Following restructuring of their business the United Kingdom Atomic Energy Authority informed us, in 2010, that they no longer wished to provide management for the 'UKAEA' epidemiological project and database.

1.2.2 2010-2011 Recovery and Options Review

The collapse of WSC forced NDA to take immediate direct action to protect vulnerable research assets and an options review was subsequently undertaken within NDA and in consultation with the former NDA-WSC Epidemiology Governance Group.

NDA is a strategic body and delivers its mission through others, primarily our Site Licence Companies. Direct management of such assets would therefore be outside of our normal methods of operation.

Following a review of the available external options, we identified the Health Protection Agency (HPA) as being the organisation with the most extensive skills, knowledge and experience, in radiation epidemiological and radiobiological research involving nuclear workers – particularly through their ownership and management of the National Registry for Radiation Workers (NRRW). The HPA's national role as the advisory body on radiation protection, their overall expertise and experience within this area and the security of their position as a non-departmental public body also gave increased confidence as to the likely stability of a contractual arrangement with them.

The NDA Governance Group, led by an independent Chair and including representatives of the NDA, a Data Custodian and representatives of the staff and trades unions, was involved in reviewing options between 2010 and 2011 and was instrumental in endorsing the NDA approach involving contracting with the HPA and a longer term aim of bringing together the UK radiation worker epidemiology research assets. Accordingly, in December 2011, NDA placed contracts with the HPA to stabilise, manage and develop the NDA radiation epidemiology and radiobiology programmes and associated research assets.

The current arrangement continues to support the strategy to which we committed in 2006 in supporting the collection and management of data and assets in addition to research programmes.

1.2.3 2011-2013 Status

It is noted that, as of April 2013 (and as a result of the Health and Social Care Act 2012), the functions of the HPA were assumed by Public Health England (PHE), a new executive agency of the Department of Health (DH). This change was anticipated and, as staff and contracts transferred from HPA to PHE, has not caused any disruption to the arrangements put in place to manage this topic area.

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1.3 Case for Change

Although we undertook an options review with stakeholders within the NDA and the Governance Group prior to establishing the stabilisation stage, we consider it appropriate to ascertain wider review as we seek to confirm the NDA Strategy in this area and move to implement the next stages of the Strategy.

We seek, in particular, to consider the possibility for putting in place long-term national strategic arrangements that would allow NDA to realign its role within this area so that it is more in keeping with its mission.

1.4 Aspirational Outcomes

There are a number of outcomes that NDA would wish to see as a result of this strategic review:

- NDA would like its role in relation to this research topic re-aligned with its overall mission and specific needs in this area.
- NDA expect that national research assets should be protected for future use.
- NDA believe that a wider (national) strategic vision for this area may help to deliver longer term cost savings as well as research benefits and research efficiencies.

1.5 Scope and Boundaries

In keeping with our latest Strategy for R&D^[2], NDA must ensure that it conducts sufficient and appropriate research to support and technically underpin the delivery of its overall mission. The scope of this topic covers radiation epidemiology and radiobiology research in general and the specific research assets and associated research that now fall directly within the NDA estate. We aim to harmonise our research requirements in this area with those of other organisations to ensure a coherent and coordinated approach to enabling and supporting relevant research.

Our normal operating model of delivery through others means that we do not wish to directly manage either the research work or the research assets associated with this topic. We also do not consider ourselves best placed or equipped to directly manage either of these areas of work, as to do so effectively, we would need to recruit additional suitably qualified and experienced staff.

We consider that the current review, while not urgent, is important and is sufficiently well understood to anticipate acceptance of a preferred option by autumn 2013.

1.6 Constraints

Because of the nature of this topic there are legal and ethical constraints associated with it and any strategy for this area must ensure that these are addressed. All research must be conducted and all research assets must be managed in a legal and

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ethical manner. Beyond the legal and ethical constraints on this work, there are potentially less clearly definable moral issues that may need to be taken into account and addressing such issues is part of the remit of the Governance Group that oversees this work.

1.6.1 Legal

The epidemiological databases associated with this topic area contain personal information, therefore their operation is subject to the Data Protection Act (DPA).

The samples (taken from blood) and collected for specific radiobiological projects are regulated under the Human Tissues Act (HTA).

1.6.2 Ethical

The current projects were established with appropriate ethical approval but new research projects would need the approval of appropriate governance groups and/or ethics committees.

It is unethical to maintain research assets without a clear strategy to use them for productive research, so any research strategy that seeks to preserve these assets should have a research programme associated with it.

There is an ethical obligation to conclude research, if at all possible, once it has been initiated and this means that there is an onus to ensure that any strategy selected for the delivery of research must be robust.

1.7 Risks

The principal risk associated with failure to conduct adequate research in this topic area is the failure to adequately understand the risks from radiation exposure and hence to be able to provide reassurance to stakeholders that these risks are acceptable. Decommissioning relies on the availability of a suitably skilled and qualified workforce and such workers need reassurance that the specific risks from the activities associated with the NDA mission have been adequately addressed.

The knowledge acquired from previous epidemiological and radiobiological work has demonstrated the applicability of internationally agreed dose limits (derived largely from work involving Japanese bomb survivors and medically exposed patients) to the protection of a UK nuclear workforce.

Perception of radiation risk is a major factor in relation to workforce, stakeholder and public acceptability of all nuclear operations including decommissioning. Inadequate understanding of risk could lead to inappropriate restrictions and protection constraints which would impact on our ability to undertake our core decommissioning work.

Data collected for internally exposed workers in the UK nuclear populations will be key to better understanding - and it is expected reassurances - of the impacts of such

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exposures. This is an area of significant interest to a company and workforce primarily concerned with decommissioning and clean-up.

Epidemiological studies of workers at sites within the NDA estate can provide valuable information about risk as well as specific reassurance - to the workforce, SLCs, the public, NDA and government - that risks within these workforces are being appropriately assessed and controlled. We are mindful of a ethical obligation to employees of legacy companies (such as BNFL and UKAEA) to ensure that work begun under such management is fully followed through to completion.

There is significant interest in radiation epidemiology and radiobiology research (e.g. MELODI – www.melodi-online.eu; DoReMi – www.doremi-noe.net) and the NDA-owned databases are recognised as important research assets. Failure to appropriately protect the research assets developed by our legacy organisations could cause reputational damage to the NDA and UK, both at home and internationally.

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2 Development of the Credible Options

The objective of NDA's Radiation Epidemiology and Radiobiology Research Strategy is to ensure that our assets are appropriately managed and that research relevant to our mission is carried out. A key question to be addressed is that of the long-term strategic role of NDA with regard to radiation epidemiology and radiobiology. To address this question we have identified a number of credible options.

2.1 Credible Options

1. Close the programme and withdraw from these areas

This review provides an opportunity to consider whether there are still compelling reasons to continue with this activity into the future. If there are not, the strategy should obviously be to withdraw from the topic area.

2. Close the programme but maintain watching brief

This review provides an opportunity to consider whether there are sufficient research resources available or research being carried out by other parties, such that NDA does not need to maintain its assets and carry out new research. If there is, the strategy should be to withdraw from active involvement but maintain an interest on the outcome of research in this area.

3. Compete the programme through open tender with NDA maintaining overall management responsibility

Competition is central to our Strategy. We run competitions as part of our statutory duties to secure value for money, promote competition, promote best practice and meet our legal duties under the European Procurement Regulations and Energy Act 2004. NDA's preferred method of operating, where the option exists, is therefore to openly compete contracts for delivery of specific projects.

4. Devolve responsibility for management of the programme to one of our SLCs

Within larger packages of work, such as those to manage sites within the NDA estate, we can choose to devolve responsibility for the management and delivery of specific programmes. Responsibility for the oversight of radiation epidemiological and radiobiological research could be devolved back to the SLCs through our normal contractual arrangements with them.

5. Further develop a strategic relationship with PHE (formerly the HPA) with the long-term aim of restructuring the ownership and management of the assets

We recognise that other government bodies have an interest in this topic area and some have considerably more experience within it than NDA and so may be better placed to take a wider strategic view and to take this work forward. In particular PHE (Public Health England) has internationally recognised expertise in this area and already manages on behalf of the Department of Health national research assets

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including the UK-wide radiation worker epidemiology database, the National Registry for Radiation Workers (NRRW). PHE is currently managing the research and research assets associated with our current programme and has confirmed interest in doing so in the longer term. This strategic relationship could potentially result in combined governance (ex-BNFL, ex-UKAEA and NRRW) and the transfer of assets (e.g. databases) and funding from NDA to PHE to reflect the overall NDA strategic objectives.

2.2 Identification and Application of Screening Criteria

To confirm our preferred strategy for this topic we will evaluate the main credible strategic options against a range of criteria.

The criteria that we have arrived at have been derived from our strategic objective and aspirational outcomes for this strategy and also reflect the constraints that are placed on this topic area. They seek to answer the following questions:

- Does the strategy align with Government's overall nuclear industrial strategy?
- Does the strategy align with our overall strategy for delivery of R&D?
- Will the strategy achieve best value for money?
- Will the strategy protect the research assets currently within the NDA estate?
- Is the strategy deliverable and sustainable over the long term?
- Will the implementation of the strategy allow us to meet all legal and ethical requirements?
- How independent is the research from the nuclear industry?
- Will the strategy deliver the research we actually need?
- Will the strategy align with NDA's role as the strategic body responsible for decommissioning the UK's nuclear legacy?

Our initial evaluation of the options against these criteria, employing a 'Traffic light' approach, is presented in Table 1 and 2 (RED = Negative impact, AMBER = Neutral impact, GREEN = Positive impact).

	Epidemiology and Radiobiology Options				
	Option 1	Option 2	Option 3	Option 4	Option 5
	<i>Withdraw from this area</i>	<i>Maintain watching brief</i>	<i>Compete programme</i>	<i>Devolve responsibility to the SLCs</i>	<i>Further our strategic relationship with PHE</i>
Aligns with nuclear industrial strategy	NDA estate has a significant workforce of radiation workers and will need to engage at some level	NDA will need to coordinate its involvement through the Nuclear Industry Council	NDA will need to coordinate its involvement through the Nuclear Industry Council	SLC will need to coordinate its involvement through the NDA and Nuclear Industry Council	Government with the PHE and the Nuclear Industry Council will work with universities, research institutes and others on programmes that improve understanding of radiation and how it is used in society and managed within the nuclear industry.
Aligns with R&D strategy	NDA estate has a significant workforce of radiation workers and will need to engage at some level	Yes	Yes	Yes	Yes
Value for money	Limited costs to close out.	Limited costs to close out and for continuing surveillance.	No cost saving.	No cost saving.	Potential cost saving (to government) through integrated national strategy.
Protection of research assets	Assets would have to be destroyed.	Assets would have to be destroyed.	Unknown, previous experience has cast doubt on the robustness of small research groups.	Unknown, previous experience has cast doubt on the robustness of small research groups.	Extensive experience in managing and protecting such research assets.

Table 1: Initial Assessment of Credible Options

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	Epidemiology and Radiobiology Options				
	Option 1 <i>Withdraw from this area</i>	Option 2 <i>Maintain watching brief</i>	Option 3 <i>Compete programme</i>	Option 4 <i>Devolve responsibility to the SLCs</i>	Option 5 <i>Further our strategic relationship with PHE</i>
Deliverable and sustainable	Closure relatively straightforward.	Closure relatively straightforward.	Limited competition available.	Limited alignment with existing SLC programmes.	Need to further develop strategic relationship
Meets legal and ethical requirements	Failure to finalise partially completed research could be considered unethical.	Failure to finalise partially completed research could be considered unethical.	Unknown, there are a limited number of qualified research groups.	Unknown, there are a limited number of qualified research groups.	PHE already operates within these legal and ethical frameworks.
Independence of research from nuclear industry	NDA not involved in directing research	NDA not involved in directing research	NDA involved in research via contractor	NDA involved in research via SLC	Greater independence as PHE take larger role
Ability to deliver relevant research	No research possible. The NDA-PHE Epidemiology Governance Group strongly believes that research will be required.	No research possible. The NDA-PHE Epidemiology Governance Group strongly believes that research will be required.	Unknown, there are a limited number of qualified research groups.	Unknown, there are a limited number of qualified research groups and there may be difficulties associated with site based interests.	Internationally recognised experience and ability in this area.
Aligns with NDA role as a strategic body	NDA estate has a significant workforce of radiation workers and will need to engage at some level.	NDA would have limited ability to align future research with its needs	NDA would still need to retain overall responsibility	NDA likely to have to retain a responsibility to hold together the NDA-wide interest over the specific SLC interest	Yes

Table 2: Initial Assessment of Credible Options - Continued

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2.3 Strategic Options Diagram (SOD)

A Strategic Options Diagram for radiation epidemiology and radiobiology has been produced and is presented in Appendix A.

2.4 Stakeholder Engagement Plan

In identifying the credible options and selection criteria, we have engaged with PHE, Data Custodians, union representatives and internal NDA stakeholders.

The importance of external stakeholder support, particularly for key stakeholder groups such as the workforce and their representatives, has been identified as being critical to the success of any proposed strategy.

2.5 Communications Plan

We will present our Radiation Epidemiology and Radiobiology Research Credible Options paper at the NDA-PHE Epidemiology Governance Group, NDA Strategy Delivery and Implementation Group (SDIG) and publish it via our website for comment.

The final strategy document will be published on the NDA's website.

3 Summary

3.1 Summary of Our Assessment

Our review has identified a number of credible options and criteria for selecting between them. We have carried out an initial assessment of the credible options using these criteria but recognise that other stakeholders may identify additional options, additional criteria and/or disagree with our initial assessment. We are therefore engaging with more stakeholders before determining our Preferred Option.

3.2 Way Forward

We will continue our work to evaluate and underpin our strategic position on radiation epidemiology and radiobiology research. A key part of this will be to understand the views of stakeholders.

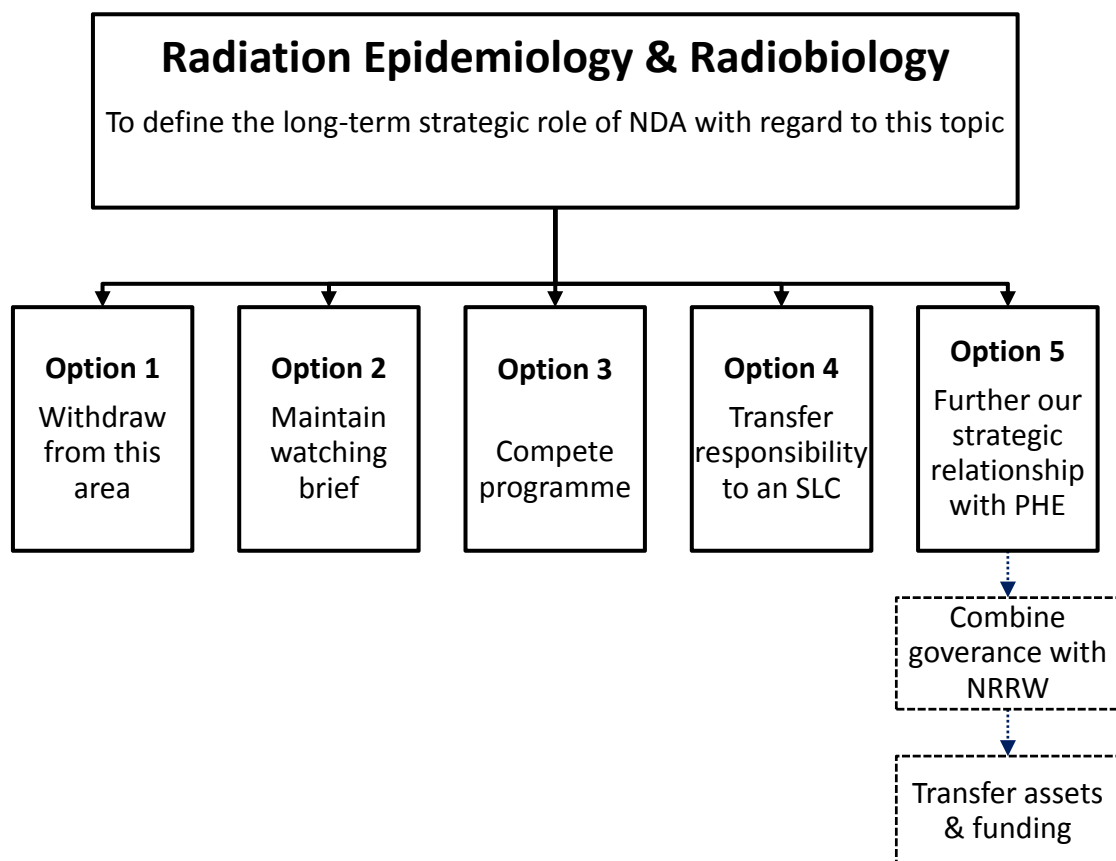
We expect to have underpinned our strategic position on radiation epidemiology and radiobiology research by the end of 2013 when our Preferred Option will then be confirmed as our strategy. We are therefore interested in receiving views on the identified options, the criteria for selecting between them and the results of our initial assessment. Please email your comments to strategy@nda.gov.uk by 15/11/2013.

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References

- 1 NDA Strategy (2006)
http://www.nda.gov.uk/documents/upload/NDA_Final_Strategy_published_7_April_2006.pdf
- 2 NDA Strategy (2011) <http://www.nda.gov.uk/documents/upload/Research-and-Development-Strategy-March-2011.pdf>

Appendix A – Radiation Epidemiology & Radiobiology
Strategic Options Diagram



The Strategic Option Diagram will be updated following engagement with stakeholders. No Preferred Option is therefore indicated at this time.

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