Response to the ARSAC Report ‘A Review of the Supply of Molybdenum-99, the Impact of Recent Shortages and the Implications for Nuclear Medicine Services in the UK’

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Prepared by the National Imaging Clinical Advisory Group sub-group on radioisotope shortage

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Executive Summary

Nuclear medicine imaging is the final stage of a complex process which involves off site industrial production of radioactive substances and pharmaceuticals and, is therefore dependent on robust production, manufacturing and supply processes. In recent years, the reliance at the beginning of this chain on ageing research reactors to produce Molybdenum-99 (^{99}Mo), which is the base material used by UK sites to produce technetium-99m (^{99m}Tc) has resulted in interruption of nuclear medicine services during breakdowns and scheduled reactor maintenance periods.

During the latest interruption, the Department of Health asked their scientific advisory committee on nuclear medicine - the Administration of Radioactive Substances Advisory Committee (ARSAC) - to produce a report for the Department on the future requirements for Technetium-99m to inform discussions on longer term radioisotope supply options. The report drew on the expertise of the NHS, professional bodies and suppliers of imaging equipment and software currently in use in the UK.

This document sets out the NHS and Department of Health response to the 8 recommendations made in the ARSAC report. It has been prepared by a specially convened sub-group of the National Imaging Clinical Advisory Group (NICAG) to provide advice for commissioners and providers as well as inform the NHS of the actions the Department of Health is undertaking to mitigate impact due to any future shortages in supply of radioisotopes.

We accept all of the recommendations in the report. The Department of Health will continue to work towards finding a permanent long-term solution. The Department has made some progress in mitigating the effects of the forthcoming radioisotope shortfall by continuing to contribute towards a collective European Union solution, working with manufacturers to explore the possibilities of weekend production, continuing to explore technology and software solutions and supporting the NHS in organisational and workforce changes.

Background and Introduction

1. There are only a small number of reactors worldwide that produce the raw material Molybdenum-99 (^{99}Mo), of which Technetium-99m (^{99m}Tc) is a decay product. ^{99m}Tc is the most commonly used imaging radioisotope in the UK and the most widely used radioisotope for nuclear medicine procedures worldwide (being used in about 80% of all nuclear medicine diagnostics). Radioisotopes are used in medicine for the diagnosis and treatment of various diseases such as cancers, cardiovascular and brain diseases. As ^{99}Mo has a rapid rate of decay it is delivered on a weekly or more frequent basis to hospitals, which prevents stockpiling.

2. In 2009 the 'Chalk River' reactor in Canada was shut down for repair and did not return to normal operations until late 2010. The 'Chalk River' reactor is the biggest producer of ^{99}Mo for ^{99m}Tc worldwide and the only producer in North America, the region where the greatest volume of nuclear medicine procedures in the world is carried out. Meanwhile, during the same period the High Flux Reactor in Petten, Netherlands shutdown for maintenance. These reactors are over 40 years old and are therefore rapidly approaching the end of their lifespans. It is inevitable that problems with supplies will occur as the reactors need more breaks in operation for repairs and maintenance. The Department has already been notified that due to scheduled reactor maintenance periods planned in the summer of 2012, there may be another period of radioisotope shortage.

3. As a consequence of the shortages in 2009-10, the Department of Health monitored on a weekly basis the situation in the NHS in England. If supplies fell below 30% of radioisotope activity, NHS Hospitals were required to submit returns to their Strategic Health Authorities, who in turn submitted centrally. This allowed the Department of Health to gain an early indication of radioisotope shortages nationally and highlighted that some patients experienced a delay in being imaged. However, the NHS was able to minimise disruption by making effective adaptations including reducing wastage, maximising patient attendance to fit with the supply of radioisotopes, and undertaking alternative procedures where possible.

4. During this period, the Department of Health asked the scientific advisory committee on nuclear medicine - the Administration of Radioactive Substances Advisory Committee (ARSAC) - to produce a report on the future requirements for Technetium-99m to inform discussions on longer term radioisotope supply options. The report drew on the expertise of the NHS, professional bodies and suppliers of imaging equipment and software currently in use in the UK.

5. This document sets out our response to the 8 recommendations made in the ARSAC report 'A review of the supply of Molybdenum-99, the impact of recent shortages and

the implications for nuclear medicine services in the UK'. It is intended to provide advice for commissioners and providers as well as inform the NHS of the actions the Department of Health is undertaking to mitigate impact due to any future shortages in supply of radioisotopes.

Responses to Recommendations

6. The 8 recommendations from the ARSAC report have been divided into four broad categories and are not therefore responded to in numerical order:-

   - European Union and other Government departments work;
   - Work with manufacturers;
   - Technology and software
   - NHS organisation and workforce changes

European Union and Other Government Departments

Recommendation 1

Nuclear medicine services are an integral part of healthcare and, despite the increased use of PET CT, for the near future, diagnostic nuclear medicine will continue to be based on ^{99m}Tc -labelled products. Security therefore of ^{99}Mo supply is essential. This can be achieved in the long term at international level by investment to upgrade existing reactors and to build new research reactors, to ensure provision of ^{99}Mo at a sufficient level to meet current and expanding demand during all foreseeable events. We recommend that the Department of Health and other government departments should continue to support European Commission initiatives to ensure a stable supply of ^{99}Mo for Europe. In addition, the Commission and other international agencies should be supported in their efforts to amend European legislation to facilitate the transport of irradiated targets across national borders to ensure timely supply to generator manufacturers.

Response

7. The Department of Health agrees there should be continued support for European Commission initiatives to ensure a stable supply of ^{99}Mo for Europe, including the planned replacement of the Petten High Flux Reactor. UK reactors do not produce this raw material for ^{99m}Tc, so we have limited options available for local resolution of radioisotope shortage. The UK has contributed towards European Union Council Conclusions and has agreed with member states to look at the security of supply of radioisotopes. The Council Conclusions cover a range of cross government issues such as transportation of radioactive materials, production capacity, safety of nuclear installations and international commercial trade.

8. The Department of Health has registered with the Organisation for Economic Cooperation and Development/Nuclear Energy Agency (OECD/NEA) High-level Group

on the Security of Supply of Medical Radioisotopes (HLG-MR). The HLG-MR has recently completed its two year mandate and produced a report 'The Supply of Medical Radioisotopes – The Path to Reliability'. The HLG-MR will continue to sustain collaboration and to implement fully the changes needed in the supply chain for security of radioisotope supply in the long-term. The Department of Health will contribute from the UK health perspective as members of this group.

Recommendation 7

The UK has well-established regulatory frameworks designed to ensure the safe production, use and disposal of radioactive materials and radiopharmaceuticals. As a consequence of recent shortages, the Environment Agency in England and Wales has demonstrated a flexible approach regarding its own regulatory and enforcement policies to enable the most efficient use of available ^{99}Mo while maintaining overall safety strategies. We recommend that the Department of Health, with other government departments and agencies, addresses options regarding transfer of radioactivity, radiopharmaceuticals and generators between different hospitals, with a view to issuing clear guidance.

Response

9. The Department of Health agrees that to enable the most efficient use of available ^{99}Mo there needs to be clear guidance regarding transfer of radioactivity, radiopharmaceuticals and generators between different hospitals. The UK Radio-pharmacy Group has produced specific guidance to NHS trusts in relation to the emergency transfer of licensed ^{99m}Tc generators. This guidance clarifies issues and has been produced with input from the Medicines and Healthcare Products Regulatory Agency (MHRA). It can be found at http://www.bnms.org.uk/guidance-notes

Work with Manufacturers

Recommendation 3

Currently the three European companies that manufacture ^{99}Mo generators do so during the working week rather than during weekends. This is not the case in the USA. We recommend that the Department of Health should explore with generator suppliers the feasibility of weekend production and alternative delivery schedules to ensure that ^{99m}Tc availability matches the traditional, efficient service delivery model for healthcare.

Response

10. The Department agrees with the above recommendation and has written to the English 3 suppliers (GE Healthcare, Covidien, and IBA/CisBio) about the feasibility of weekend production and alternative delivery schedules to maximise available activity and cost

effectiveness. We will continue to liaise and work with manufacturers on finding solutions that provide the most efficient service delivery model for healthcare.

Technology and Software

Recommendation 2

While the existing model for ^{99}Mo production has proved effective for many years, the recent shortages have demonstrated that over-reliance on a few suppliers can prove problematic. We recommend that new technological solutions are monitored, including the potential long-term solution of UK-based production of ^{99m}Tc in medical cyclotrons.

Response

11. The Department of Health recognises the importance of new technological solutions and is continuously monitoring potential long-term solutions for UK-based production of ^{99m}Tc in medical cyclotrons. The National Imaging Clinical Advisory Group (NICAG) is chaired by Professor Erika Denton, National Clinical Director for Imaging. Its membership includes key stakeholder organisations such as the British Nuclear Medicine Society (BNMS), Institute of Physics and Engineering in Medicine (IPEM), Health Protection Agency (HPA), Society and College of Radiographers (SCoR), Royal College of Radiologists (RCR) and the Royal College of Physicians (RCP). The group meets quarterly and horizon scans new technologies and the latest developments in medical imaging, so as to assist in the development of good practice and to support the promotion and uptake of learning across imaging services. It is this group that has led on advising the Department on the response to ARSAC's recommendations.

12. Active engagement with suppliers includes Professor Denton's involvement in major service and vendor events including the UK Radiological Congress (UKRC) and the Radiological Society of North America (RSNA) conference and exhibition. RSNA is the largest gathering of members in the radiological specialty in the world. These showcases for the imaging industry offer an opportunity to have meetings and build professional working networks and relationships with manufacturers. As well as horizon scan manufacturer development, clinical practice, education and learning, technology and equipment, and to identify priorities for formal appraisal of new technologies and solutions.

Recommendation 6

Nuclear medicine imaging demonstrates functional information. It relies upon the administration of radiopharmaceuticals which in general are produced outside the UK. It has already been highlighted that ^{99}Mo production using traditional technology is not practicable at UK level. PET CT services, which can provide physiological information as an alternative to conventional nuclear medicine in some circumstances, rely upon local production of radiopharmaceuticals in cyclotrons. This is a robust supply chain; however, a large percentage of PET CT services in England are currently provided through time-limited independent sector contracts. We recommend that adequate PET CT services continue to be provided across the UK. Optimal coverage of these services should be ensured following the completion of the independent sector provision in England.

Response

13. The Department of Health agrees and is taking steps to ensure a coordinated commissioning approach for PET CT (Positron Emission Tomography – Computed Tomography). This responsibility could possibly transfer to the NHS Commissioning Board in the future but is part of the ongoing piece of work to consider future options and is subject to ministerial approval.. A detailed proposal for national commissioning arrangements has been submitted to the National Specialised Commissioning Team proposing future PET CT services to be under the auspices of the NHS Commissioning Board. The commissioning proposals including service specification and future development are derived from the PET CT sub group of the NICAG which has representation from the royal colleges, professional bodies, providers and service users. It is intended that:

    1) PET CT services should continue to be extended to provide activity levels comparable to European levels;

    2) The NHS and Research PET CT services provided outside the National Programme's contract should be formally commissioned with quality standards and performance parameters similar to the national contract;

    3) The original service designation criteria should be adopted and developed to provide a common benchmark across all PET CT services.

14. Any common specification for commissioning services will need to consider how best to take account of the following:

    - Commissioned activity examples by population, future demand, delivery sites, referral indications;

    - Current provision including referral casemix and time based parameters of the patients journey from referral to completed clinical report;

- Detailed activity profiles by site for all NHS, research and IS providers.

The above criteria will allow commissioners to set out common standards of access, service provision and integration across all referral pathways to meet present and future patient and service needs.

Recommendation 8

Technological developments in gamma camera hardware and software design have the potential for nuclear medicine investigations to be performed using less activity. This has benefits for the patient with regard to radiation dose but also for the nuclear medicine service in terms of costs and efficient use of available ^{99}Mo. We recommend that a multicentre, multivendor trial is undertaken in order that the viability of resolution recovery software with reduced activity is evaluated. If proved to be successful, we strongly recommend that nuclear medicine services purchase this software for new gamma camera systems and encouraged to apply this software to existing gamma cameras where applicable.

Response

15. The Department of Health has accepted the recommendation that a trial is needed to ascertain the viability of resolution recovery software with reduced activity and is currently considering how this might be carried out.

16. The project will need to be designed to validate manufacturers claims that by using their resolution recovery software the number of counts acquired can be halved without unduly affecting the quality of the final image. Because there are several different versions of commercially available resolution recovery software and different hospitals around the UK using a variety of different acquisition and processing protocols, it is necessary to use a multi-centre study in order to test as many different combinations of software and protocols as possible.

17. If proved to be successful, nuclear medicine services will be encouraged to purchase this software for new gamma camera systems and apply this software to existing gamma cameras where applicable.

NHS Organisational and Workforce Changes

Recommendation 4

During periods of ^{99}Mo shortages many hospitals have adapted traditional working practices, e.g. changing the radiopharmaceutical production model to provide a second elution and production run per day or working at weekends to make more efficient use of the available ^{99}Mo. We recommend that where practicable hospitals should consider adopting some of these strategies on a permanent basis, and that traditional employment contracts should be amended to introduce flexible working patterns, to include weekends and extended days within the current pay constraints.

Response

18. This recommendation is for consideration by NHS providers, but the Department of Health recognises the importance of flexible working practices and agrees that weekend access to diagnostic imaging improves patient safety and experience and can reduce costs and length of stay. 7 day working can aid workflow within Nuclear Medicine departments; for example, on Monday mornings it is possible to see in-patient workload left over from Friday and the weekend that cannot be delivered on the same day due to the volume of work. This impacts not only on the Monday but also on the rest of the week as departments struggle to “play catch up”.

19. The National Imaging Clinical Advisory Group (NICAG) has recently published good practice guidance to encourage NHS Trusts to help facilitate the move from traditional working to 7 day working in imaging departments. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_132018. This guidance describes the reasons to move away from traditional 9-5 working and the benefits of seven day working with case study examples to help NHS providers move towards 7 day working. Although Nuclear Medicine services have been excluded from the guide because there are complex issues around shortages of particular technical staff groups, the principles within the document can be applied to nuclear medicine departments in the future if the specific staffing issues are resolved.

20. On wider seven-day working in healthcare the Department of Health is in the early stages of gathering the evidence base including workforce issues and a full cost benefit analysis.

Recommendation 5

Compared with Wales, Scotland and Northern Ireland, radiopharmaceutical production and supply within England is essentially local and is undertaken on a small scale. This is for historical rather than logistical reasons. While some larger central radiopharmacies exist, these are very much in the minority. The introduction of PET CT services in the UK using 18F-FDG has demonstrated that for routine diagnostic nuclear medicine services, a production and supply service based on fewer centralised facilities is viable. We recommend that the Department of Health undertakes a review of radiopharmacy services to explore whether the number of large central radiopharmacies, which are more resilient during shortages, should be increased to provide the majority of ^{99m}Tc based radiopharmaceuticals for safe and patient-focussed nuclear medicine services within England.

Response

21. The Department of Health agrees that the proposal to conserve ^{99m}Tc by consolidating preparation of radiopharmaceuticals on fewer sites is worth exploring. Undertaking a review to address this issue will require robust planning and co-ordination across a wide range of organisations. The Department of Health has written to the President of BNMS asking whether it would be prepared to undertake the above review. The BNMS are proposing to set up a working group and are currently in discussion with the Department of Health with regards resources for this working group. The Department of Health will consider what action is needed when the group comes to its conclusions. .

Summary / Conclusion

22. This response document outlines the various steps that will be undertaken to address the ARSAC report 'A review of the supply of Molybdenum-99, the impact of recent shortages and the implications for nuclear medicine services in the UK'. Although the current supply situation of ^{99m}Tc has stabilised with the return to service of 'Chalk River' and the High Flux Reactor at Petten, which are two of the world's five main supplying research reactors, further shortages are likely to occur due to scheduled reactor maintenance periods planned in the summer of 2012.

23. The underlying problem – that of an unsustainable market structure – remains to be adequately addressed and the Department will continue to work towards finding a permanent long-term solution. Otherwise, the long-term supply situation will be no more stable or secure than it is during the shortage periods. In the longer term, the Dutch Nuclear Research & Consultancy Group (NRG) have announced plans for PALLAS, a new nuclear reactor to replace the High Flux Reactor in Petten. It is expected that the High Flux Reactor will stay on line until PALLAS is fully operational around 2022 and the new reactor will have increased capacity to meet the future demand for radioisotopes in Europe.

24. The Department has made some progress in mitigating the affects of the forthcoming 2012 radioisotope shortfall by continuing to contribute towards a collective European solution developed by the European Commission. The Department also continues to work with manufacturers to explore the possibilities of weekend production of ^{99m}Tc, to explore technology and software solutions and to support the NHS in organisational and workforce changes. If all these initiatives bear fruit, we are confident that NHS capacity will continue to be able to meet the demands of effective patient care until increased capacity is available from the new PALLAS reactor.

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