

High Level Group on the Security of Supply of Medical Radioisotopes

Background

The OECD/NEA has become actively involved in global efforts to ensure a reliable supply of Molybdenum-99 (Mo-99) and its decay product, Technetium-99m (Tc-99m), the most widely used medical radioisotope. Mo-99 and Tc-99m have been in short supply a number of times over the last few years due to unexpected and/or extended shutdowns of those research reactors that produce world supply. These isotopes are used in medical diagnostic imaging techniques which enable precise and accurate, early detection and management of diseases such as heart conditions and cancer, all in a non-invasive manner. The imaging may significantly impact medical decisions, for example, by providing predictive information about the likely success of alternative therapy options or whether or not there is a need for surgical intervention.

Tc-99m medical imaging techniques account for over 80% of all nuclear medicine procedures, with an estimated 48 million doses used worldwide every year benefiting an estimated 30 million patients. Disruptions in the supply chain of these medical isotopes – which have half lives of 66 hours (Mo-99) and 6 hours (Tc-99m) and thus must be produced continually – can interrupt the availability of this important medical testing.

Currently five reactors commissioned between 43 and 53 years ago produce 90 to 95% of the total global supply of Mo-99. Given the age of these reactors, there are issues related to their reliability with unexpected shutdowns occurring more often. Most recently the Canadian National Research Universal Reactor (the NRU) was shutdown in May 2009 as a result of a leak in the reactor vessel and only expects to return to service at the end of July 2010.

The ages of these reactors also raise issues related to reactor availability given the need for extended shutdowns for planned maintenance work and possibly for unplanned maintenance. For example, in 2010 both the High Flux Reactor in the Netherlands and the OSIRIS reactor in France are scheduled to be down for extended maintenance periods.

There is also the fact that some of these reactors are expected to reach their end of life in the next six years. The OSIRIS reactor is planning to be retired from service in 2015 and Canada has indicated that it will only seek to extend the NRU reactor license to 2016.

In addition to issues related to the reactors, there are also potential limits to processing capacity. This capacity is needed to extract and purify the Mo-99 from the irradiated targets, making bulk Mo-99 which is used in Tc-99m generators for medical procedures. The limitation of processing capacity is especially evident in regards to the geographical location of these facilities; there would be difficult transport problems and loss of product from decay if irradiated targets were to be transported long distances.

OECD/NEA Involvement

At the request of the Government of Canada, the NEA hosted a workshop of international experts and stakeholders in January 2009 to identify the challenges faced in providing a reliable supply of Tc-99m and Mo-99 and measures that should be taken to ensure this supply. Over 90 participants were in attendance, with representatives from governments, universities, reactor operators,

processors, generator manufacturers and distributors, industry associations, the medical community, international organizations and regulators.

At the workshop, participants discussed a wide variety of issues including challenges to the management of existing capacities, regulatory impediments and demand side management. They identified the need to develop, deepen and share, as appropriate, contingency plans for future supply disruptions. They also focused on the longer term and on the need to engage health authorities to reduce uncertainties regarding long term demand and the means by which to encourage more investment in production and greater redundancy in the system.

In addition, there was unanimous support for the establishment of a working group to carry forward the conclusions of the workshop and to identify the practical measures that should be taken.

Formation of the High Level Group on Medical Radioisotopes

Following up on the workshop, the NEA Steering Committee established the High Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) in April 2009. This group is currently comprised of 19 experts from 11 countries, the European Commission and the International Atomic Energy Agency, and is being funded by its members through voluntary contributions. The group oversees and assists, where necessary, efforts of the international community to address the challenges of medical isotope supply reliability. The NEA secretariat supports the group and brings its expertise to the issue.

The main objective of the HLG-MR is to strengthen the reliability of Mo-99/Tc-99m supply in the short, medium and long term. In order to reach this objective the group has been reviewing the Mo-99 supply chain, working to identify the key areas of vulnerability, the issues that need to be addressed and the mechanisms that could be used to address those issues. The HLG-MR recognises that governments have the ultimate responsibility for establishing an environment conducive to investment and also for regulations related to the Mo-99 supply chain. In the process of its work, the group acknowledges the common goal of converting to low enriched uranium (LEU) targets and fuel; however, the security of supply considerations may result in the use of more highly enriched uranium (HEU) in the short to medium term.

The HLG-MR is aware that there are a number of other on-going forums related to medical isotope supply reliability and is ensuring that efforts are not duplicated. The NEA's goal in getting involved in this issue is to add value to the ongoing work and to support member countries. Bringing the international community together to discuss, share and learn, and applying NEA expertise on nuclear issues and economic studies, represent important contributions to the current global effort.

Meetings of the HLG-MR

Since its formation, the HLG-MR has had four conference calls and two face to face meetings. At the face to face meetings, supply chain stakeholders were invited to share their views and knowledge.

At the first meeting on 17-18 June 2009, the Terms of Reference for the group and the first instalment of a rolling action plan were agreed upon. The plan included undertaking an economic analysis of the supply chain, increasing useful and regular communications to users about Mo-99 and Tc-99m supply availability, developing protocols to inform stakeholders of unanticipated events, and

coordinating reactor schedules. The action plan also included assessing options to increase short-, medium- and long-term production. These options include demand side management (e.g., promoting efficient patient scheduling, using alternative procedures) and producing Mo-99 from alternative reactors or technologies. In terms of bringing new supply to market, the action plan included work to identify regulatory issues, especially those related to the transportation of Mo-99 and Tc-99m, and measures to address these issues.

On 14-15 December 2009, the second meeting of the HLG-MR occurred with invited representatives of the nuclear regulation community, the medical isotope industry and the nuclear medicine community. Participants welcomed the positive actions that have been taken to date, such as the progress on the economic study, the development of communication protocols and the coordination and communication of reactor schedules. The presentations and ensuing discussions at the meeting highlighted the complexity of the issues affecting the reliable supply of medical radioisotopes, especially those related to the economics of the supply chain.

Participants agreed to a list of actions to further improve the management of the current shortage and to work to increasing reliable supply – the second instalment of the rolling action plan. This list included developing and implementing communication protocols; sharing guidelines with the global health community on the efficient use of available supplies of Mo-99 and Tc-99m; and examining opportunities for securing longer-term medical radioisotope supply.

In addition, the HLG-MR will continue its work on examining the economics of the Mo-99 supply chain, regulatory impacts, transport difficulties and opportunities for securing Mo-99 production. The Group will start work to assess issues related to processing capacity and future Tc-99m demand.

Economic Study

As part of the workplan, the NEA Secretariat is undertaking a study on the economics of the upstream Mo-99 and Tc-99m supply chain, given the possibility of a market failure in the supply chain whereby the economic structure does not provide sufficient incentive for current reactors to produce Mo-99 or for additional production reactors to be constructed.

The study, expected to be completed in mid-2010, will develop a solid factual basis of the economics of the supply chain with the goal of providing recommendations to governments on how to create a sustainable economic environment that would encourage the investments needed to ensure reliable medical isotope supplies. The study will also aim to provide a better understanding of the costs of supplying Mo-99 amongst end users in order to support a better functioning market.

Future Work

The work of the HLG is being progressed through the rolling action plan. Two reports are being prepared: the economic study and a mid-term diagnostic report. The latter will summarise the actions of the HLG-MR and Mo-99 stakeholders and will include information about the Mo-99 situation, the issues affecting its reliable supply, and actions needed to address these issues.

The HLG-MR will hold its next meeting in June 2010, again inviting supply chain stakeholders to share their perspectives. The HLG-MR will continue with its efforts to address the issues that negatively affect security of Mo-99 supply and will produce a final report in mid-2011.