

Terms of Reference and Outline Work Programme

High Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) Under the Auspices of the OECD Nuclear Energy Agency

Background

On January 29-30, the Nuclear Energy Agency of the OECD hosted a workshop *Security of Supply of Medical Radio-isotopes*. The purpose of the workshop was to discuss the challenges facing the reliable supply of Technetium-99m, a key medical isotope derived from Molybdenum-99 (Mo-99), and to identify measures that should be taken to ensure reliability of supply.

Workshop participants placed priority on challenges relating to the management of existing capacities and maximization of these capacities in times of shortages, on the economic validity of the current model, on flexibility and efficiency of the supply chain, on 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 the 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.

Participants identified the following measures to enhance short-term supply security:

- reactor owners and operators should continue to share information and to enhance co-ordination of reactor maintenance schedules, with a view to ensuring an uninterrupted global supply of isotopes;
- options for increasing production from existing reactors in times of global shortage should be further explored and encouraged;
- current economic conditions for irradiation services should be reviewed to provide better incentives to reactor operators, including where the main mission is research in support of national nuclear energy or scientific programmes;
- unnecessary impediments to the distribution of medical isotopes, such as restrictions in transport capabilities and denial of shipment by airline companies, should be removed;
- anticipative actions to avoid the dilemma between meeting nuclear safety requirements or meeting health care needs should be encouraged; in this regard, participants were pleased to be informed of the outcome of the nuclear regulators meeting held in Paris three weeks earlier;

- radio-pharmacies, hospitals, health product regulators and the medical community should explore options for more efficient patient scheduling and utilisation of Mo-99/Tc-99m generators to make best use of currently available supplies of Mo-99 and/or other potential alternatives.

There was unanimous support for the establishment of a working group to carry forward the agenda of the workshop, also involving the International Atomic Energy Agency (IAEA).

Establishment of the High Level Group

(A) Mandate from the Meeting of the NEA Steering Committee, April 28-29, 2009

On April 29th, the NEA Steering Committee held a policy debate on the isotopes issue, during which they reviewed the outcome of the workshop, heard presentations from four invited speakers and discussed the way forward. The Steering Committee endorsed the proposal for a high level group on the Security of Supply of Medical Isotopes under the auspices of the NEA to carry forward the agenda of the workshop and to identify the practical measures that should be taken.

The Steering Committee discussion covered the following points:

-in order to cover the supply side and demand side of the issue, a high level group consisting of 8 to 12 members would be established and that will consist of senior representatives nominated by interested member governments; several countries indicated at the Steering Committee meeting that they would nominate a representative to sit on the group;

-countries represented on this high level group should be ready to consider, subject to their agreement to the work programme, to share the burden of providing resources in order that the work can proceed.

The group will approve its terms of reference and action plan at its first meeting and to facilitate an early meeting, the NEA will send out letters to all member countries asking if they have a senior representative whom they wish to nominate to the group.

It is anticipated that the group will sustain engagement on this issue; it will ensure coordination of the above efforts and foster transparency and accountability; it will give due recognition to the fact that governments have the responsibility for establishing an environment conducive to the private and/or public sector investments that may be required; that the conversion to low enriched uranium is a common goal and the feasibility and timing of implementation should be weighed against impact on the vulnerability of the supply chain.

(B) Terms of Reference

To review the total Mo 99 supply chain from uranium procurement for targets through to patient delivery, indicating the areas of vulnerability and identifying issues to be addressed, and mechanisms to address them, to strengthen the reliability of supply. The group should consider the immediate issues, the medium term issues (2-5 years) and the longer term issues (greater than 5 years) in arriving at their conclusions and recommendations.

- The High Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) will report to the Steering Committee of the OECD Nuclear Energy Agency
- The NEA will provide the secretariat to the HLG-MR
- The NEA may also undertake specific studies within its area of expertise, as requested.
- HLG-MR members will identify necessary resources to enable this work to proceed.
- The HLG-MR will have a two year mandate. This will only be extendable by consent of the members and endorsement by the Steering Committee.
- The HLG-MR will establish an action plan at its first meeting, compatible with the available resources, to be approved by the Steering Committee. The action plan will contain specific deliverables, allocation of responsibilities and timing of deliverables.
- The NEA Steering Committee will be invited to approve the terms of reference and the action plan prior to its next meeting in October, 2009.
- The action plan will be developed in close cooperation with the IAEA and key international organizations and institutions that are well positioned to propose and implement the necessary changes.
- Specific HLG-MR members will be responsible for obtaining early and clear commitments from key international organizations and institutions to provide support in the development and implementation of the action plan and will report on progress at each subsequent HLG-MR meeting.

Roles and Responsibilities

The following provides a breakdown of roles and responsibilities to be further refined in consultation with key international organizations. As such, the roles and responsibilities listed below must be considered as indicative only. The HLG-MR will refine them as required.

Lead Organization

Roles and Responsibilities

OECD/NEA

Review the value chain for Technetium-99m with emphasis on the economics of the upstream segment of the market

Explore and advise on the role of government in the commercial market

Asses options to fund back up capacity to ensure security of supply; assessment of market or other mechanisms to fund back-up capacity

Assess and identify solutions to supply chain inadequacies; development of a mathematical model system reliability

AIPES/Isotope Industry

Coordinate existing reactor schedules used to produce medical radioisotopes to enhance supply response

Establish a mechanism to assess the production of Mo-99 over the coming short, medium and long term and the ability to meet demand.

Establish an arrangement whereby additional production capacity can be brought into action as needed in times of emergency

Establish communications protocols for early warning for unanticipated events

Reactor Owners/Operators

Assess and implement options for increasing production in times of shortages

Define their maximum output capacity and the time it would take to ramp up capacity

Assess the viability of existing reactors used to produce medical radioisotopes

Assess the options for expanding/introducing production in existing reactors used to produce medical radioisotopes

IAEA

Assess the possibilities of utilizing existing reactors, not currently being used to produce medical radioisotopes, for Mo-99 production, the timescale and the measures that would be needed to enable this to happen

Assess transport impediments and identify measures to remove impediments

Assess capability and requirements of smaller countries and the option of regional centres for irradiation and production

Assess the stage-wise needs, timelines and economics of large scale Mo-99 production using LEU and final waste management aspects

Assess the capabilities of alternative (non-reactor) technologies for the production of Mo-99 and the likely impact as well as the need for new reactor production capacity

INRA/ASN

Facilitate standardization/licensing of transport containers and other regulatory issues

Streamline inter-country agreements on approval processes for transport and certification of containers

Health Community (SNM, HC)

Develop options for efficient patient scheduling and utilization of available supplies

Assess potential alternatives to procedures using Mo-99, for employment in shortage situations

Assess long term demand for Tc-99m including the impact of alternative procedures and new technologies

Enhance contingency plans and information sharing on contingency plans; establish communication protocols for early warning for unanticipated events.

NEA Secretariat

The NEA will form a small secretariat, supported by voluntary contributions, to support the work of the HLG-MR; the Secretariat will arrange and host meetings/workshops, coordinate efforts with the organizations noted above, prepare necessary documentation (agendas, reports of meetings).

In addition, as noted above, the NEA may undertake specific studies as requested by the HLG-MR, subject to the resources being made available.