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High-level Group on the Security of Supply of Medical Radioisotopes

Second Mandate

This document contains the second mandate of the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). This mandate was approved by the OECD/NEA Committee for Technical and Economic Studies on Nuclear Energy Development and the Fuel Cycle (NDC).

Mr. Chad Westmacott
Nuclear Energy Analyst - Nuclear Development Division
Tel: +33 1 45 24 11 48 - EM: chad.westmacott@oecd.org

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HIGH-LEVEL GROUP ON THE SECURITY OF SUPPLY OF MEDICAL RADIOISOTOPES

SECOND MANDATE UNDER THE AUSPICES OF THE NUCLEAR DEVELOPMENT COMMITTEE

Background

In April 2009, the NEA Steering Committee for Nuclear Energy established the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). Under its first mandate, the group held its first meeting in June 2009 and its last in June 2011. During the two years of its original mandate, the HLG-MR examined the major issues that affect the short-, medium- and long-term reliability of $^{99}Mo/^{99m}Tc$ supply and then developed a policy approach to move the supply chain to a sustainable basis and ensure security of supply. The members of the HLG-MR and other key stakeholders have already implemented changes to address some of the immediate challenges affecting security of supply. For example, significant progress was achieved on improving the supply situation through increased communication, co-ordination of reactor schedules and a better understanding of demand-management opportunities. The policy approach recognises these actions and encourages their on-going action. Moreover, the policy approach seeks to address the fundamental problems that threaten reliable supply, cognisant that the underlying economic unsustainability will remain without the implementation of such a policy approach.

The work of the HLG-MR under its original mandate was completed in June 2011, with the release of its final report and its full policy approach.

Recognising that continued action is required on the part of all stakeholders to implement the HLG-MR policy approach in a context of international cooperation, HLG-MR members requested that the NEA involvement in the field of medical radioisotopes should continue, especially related to furthering action on issues that affect the implementation of the policy approach. The NEA Steering Committee agreed to the continued involvement of the NEA through the development of a new group focused more on implementation.

At the 5th and final meeting of the HLG-MR during its original mandate, the new group proposed the retention of the original name for the purposes of continuity and "brand recognition" among nuclear and health stakeholders.

Establishment of the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR): ***Implementation Mandate***

1. Mandate from the Meeting of the NEA Steering Committee, April 28-29, 2011

On 29th April, the NEA Steering Committee agreed to extend the work of the NEA in the field of security of supply of medical radioisotopes.

The Steering Committee agreed that the new group would report to the Committee for Technical and Economic Studies on Nuclear Energy Development and the Fuel Cycle (NDC). The group's activities would be included in the NDC programme of work.

2. Objectives of HLG-MR

The objectives of the HLG-MR during its implementation mandate are to work towards increasing the long-term security of supply of ^{99}Mo and ^{99m}Tc, especially through the implementation of the HLG-MR policy approach and its associated recommendations. This will entail actions to maintain transparency on global developments, continue communication with the supply chain and end users, evaluate progress toward implementation and provide additional information and analysis where necessary. The group will meet twice a year to share information and to discuss ongoing policy issues.

The broad deliverables of the group are:

- Sharing of information on the status of the ^{99}Mo/^{99m}Tc market and regular reports on technical developments within the market, to increase transparency and encourage consistency in approaches.
- Communicating the HLG-MR policy approach to governments and other supply chain participants, including working more closely with the health community.
- Providing guidance on specific aspects of implementing the HLG-MR policy approach. Suggested guidance could include developing a guidance document that defines the methodology for apportioning common costs within the full-cost recovery methodology, including further study on waste disposal processes and waste costs for ^{99}Mo production along the full supply chain, how to establish a level-playing field between old and new reactors and the issues related to implementation of full-cost recovery in the supply chain.
- Supporting the implementation of all aspects of the HLG-MR policy approach, where appropriate and feasible. Suggestions would be to: work with the health community to study the potential impacts of consistent ^{99m}Tc supply shortages; explore standardised approaches to separate reimbursement of ^{99m}Tc from the radiopharmaceutical and the diagnostic procedure; undertake further analysis of the impacts on health costs looking at different health care funding models, diagnostic procedures, and price elasticity of demand; further analysis on cost-saving actions at the radiopharmacies/hospitals to facilitate economic sustainability, such as better elution patterns, examining the role of centralised radiopharmacies, etc.
- Carrying out studies related to security of supply, e.g., analysing the market and economic impacts of converting to using low enriched uranium targets for ^{99}Mo production.
- Evaluating the progress towards the implementation of the HLG-MR policy approach, including through the periodic review of the supply chain. This periodic review could also provide an update

of the supply chain and its evolution, and an assessment of key issues affecting the supply chain, e.g. the growth of use of alternative technologies or changes in reimbursement rates.
- Re-evaluating the appropriateness of the policy principles once experience has been obtained.
- Regular reports to governments and other major stakeholders.

The HLG-MR will establish an action plan at its first meeting under the new mandate that would clearly address the objectives identified above, compatible with the available resources. The action plan will contain specific deliverables, allocation of responsibilities and timing of deliverables. This action plan will be evaluated at each meeting of the HLG-MR with the intent to ensure delivery of agreed outcomes.

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.

3. Organisation of the HLG-MR

The HLG-MR will report to the Committee for Technical and Economic Studies on Nuclear Energy Development and the Fuel Cycle (NDC) of the OECD Nuclear Energy Agency.

Membership of the HLG-MR for the implementation mandate will be determined by a call for nominations from the NDC. For those key nations that are not members of the NEA but would be welcome as members of the HLG-MR (e.g., Argentina, Brazil, the Russian Federation and South Africa) nominations will be sought through other official channels.

Members should represent the producer and user communities (health).

Members will be expected to make a commitment to implement the HLG-MR policy approach and agree to undergo self-assessments as part of the periodic reviews of the supply chain.

The NEA may also undertake specific studies within its area of expertise, as requested by the HLG-MR or its member countries.

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 NDC.

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	Communicate the HLG-MR policy approach to governments and other supply chain participants, including the health community

	Provide guidance on the implementation of the HLG-MR policy approach
	Work with the health community to assess in greater detail the impacts of the implementation of the HLG-MR policy approach, including impacts on health care costs
	Work with the OECD Health Committee, the International Agency for Research on Cancer (IARC) and others to study the potential impacts of consistent ^{99m}Tc supply shortfalls
	Work with the industry to assess the market and economic impacts of LEU conversion and identify measures to address market or economic impediments to conversion
	Undertake periodic reviews of the progress of the supply chain in implementing the HLG-MR policy approach
AIPES/Isotope Industry	Work to ensure the implementation and ongoing application of the HLG-MR policy approach
	Continue the efforts to coordinate existing reactor schedules, considering the need for outage reserve capacity
	Participate in efforts to assess the market and economic impacts of LEU conversion and identify measures to address market or economic impediments to conversion
Reactor Operators/Processors	Work to ensure the implementation and ongoing application of the HLG-MR policy approach especially in the areas of cost recovery and reserve capacity
	Contribute to efforts to optimize reactor scheduling
	Continue efforts to ensure adequate production, including through new infrastructure
	Participate in self assessment and the periodic review of supply chain progress to implementing the HLG-MR policy approach

IAEA	Continue work to address transport impediments
	Continue work to address the technical challenges of large scale ^{99}Mo production using LEU and final waste management aspects
	Continue to assess the capabilities of alternative (non-reactor) technologies for the production of ^{99}Mo and the likely impact as well as the need for new reactor production capacity
	Continue to work with their member states on promoting long-term sustainable supply of ^{99}Mo, including explaining the HLG-MR policy approach
European Commission	Contribute to efforts to communicate and support the implementation of the HLG-MR policy approach within the European Union member states
	Continue efforts to further explore and examine the solutions to support a sustainable supply of ^{99}Mo and ^{99m}Tc
HLG-MR Member Country Governments	Contribute to efforts to communicate and support the implementation of the HLG-MR policy approach
	Continue efforts to further explore and examine the solutions to support a sustainable supply of ^{99}Mo and ^{99m}Tc
Health Community	Work to ensure the implementation and ongoing application of the HLG-MR policy approach
	Participate in efforts to assess in greater detail the impacts of the implementation of the HLG-MR policy approach, including impacts on health care costs and potential impacts of consistent ^{99m}Tc supply shortages.
	Recognise the need for long-term economic sustainability for security of supply and work to minimise the impacts of cost increases necessary for upstream economic sustainability, for example through developing and implementing better utilisation of available supplies
	Examine reimbursement rate structures that would better support economic sustainability of the product supply chain