



**COUNCIL OF  
THE EUROPEAN UNION**

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**NOTE**

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from :	General Secretariat of the Council
to:	Delegations
Subject :	Towards the Secure Supply of Radioisotopes for Medical Use in the European Union - Draft Council Conclusions

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Delegations will find attached revised draft Council Conclusions, to be discussed at the WPAQ meeting on 28 November.

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**Council Conclusions**  
**"Towards the Secure Supply of Radioisotopes for Medical Use**  
**in the European Union"**

The Council of the European Union,

**RECALLING the outcome of the Informal Meeting of the Health Ministers on 8-9 September 2008 and 6-7 July 2009 and the Council Conclusions of December 2009 on the Security of Supply of Radioisotopes for Medical Use (doc. 17034/09).**

ACKNOWLEDGING that various initiatives have become available since the Council Conclusions of 6 December 2010 on the secure supply of radioisotopes for medical use in the European Union and in particular points 4 to 8 of these conclusions,

AGREEING that the European Observatory on the Supply of Medical Radioisotopes is a valuable instrument to support the secure Molybdenum-99 (Mo-99)/Technetium-99m (Tc-99m) supply for the medium and long term across the European Union, taking into account the worldwide need and supply,

CONSIDERING that production of Mo-99/Tc-99m ~~radioisotopes for medical use~~ in nuclear reactors is **currently** a robust and reliable method,

CONSIDERING that the facilities able to produce Mo-99 at the levels required for the medium-term needs of the European Union should remain located in the Union, with a view to ensuring self-sufficiency, as well as guaranteeing an appropriate price level,

NOTING ~~that~~ the commitment of **the Community** ~~some Member States~~ towards conversion from High Enriched Uranium (HEU) to Low Enriched Uranium (LEU) targets used for Mo-99 production is ~~based on nuclear security reasons~~,

STRESSING that the safety of nuclear reactors ~~involved in the production of radioisotopes~~ is and remains the first priority **and is covered by Directive 71/2009/Euratom of 25 June 2009 establishing a Community Framework for the nuclear safety of nuclear installations**, ~~which is also stipulated in the Code of Conduct on the Safety of Research Reactors, adopted by the International Atomic Energy Agency (IAEA) General Conference on 24 September 2004,~~

**NOTING** STRESSING the existing and **steadily** ~~vastly~~ increasing need of diagnostic and therapeutic patient treatment and the gradually decreasing availability of HEU,

STRESSING the need for national authorities, reactor operators and the radioisotopes processing facilities to work together cooperatively to enable and **preserve** ~~safeguard~~ the continuity of the present and future production facilities, including the future conversion from HEU to LEU targets in an efficient, timely, economically sound and sustainable way,

RECALLING that Member States involved in **the** supply chain of Mo-99 should take actions necessary to minimise any risks of disruption during the conversion process.

1. **Without prejudice to future guidance documents to be developed by its High Level Group** NOTES that the OECD/ NEA currently does not **mention the inclusion of** ~~include~~ the conversion from HEU to LEU **targets** in the full cost recovery model,
2. SHARES the Commission's analysis that the conversion from HEU to LEU targets in an efficient, timely and economically sound and sustainable way is a very important task and **that** a relevant risks analysis to the radioisotope supply chain needs to be undertaken by ~~the Commission in cooperation with~~ the Observatory,
3. STRESSES that given its importance for long-term security of supply of the key medical isotopes of Mo-99 and Tc-99m, the conversion from HEU to LEU targets should be supported by the **Community** ~~concerned Member States~~,

- ~~4. STRESSES that all activities must be accompanied by following the highest Standards of Nuclear Safety, e.g. the IAEA Safety Requirement No. 4 "Safety of Research Reactors", and that research reactors form part of nuclear installations as defined in Directive 71/2009/Euratom.~~
- ~~5. INVITES the Commission to prepare recommendations on the conversion issue.~~
46. INVITES the Commission to propose **to Member States** a relevant instrument to provide Community support to the conversion from HEU to LEU targets, and to prepare proposals contributing to the secure supply of medical radioisotopes in the European Union **and to identify the necessary needs of research that might be supported by the Euratom Framework Programme.**
5. INVITES the Commission to present to the Council a report on activities following-up the Council Conclusions Towards the Secure Supply of Radioisotopes for Medical Use in the European Union of 16 December 2009 and of 6 December 2010.
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