



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 7 December 2012

17453/12

**ATO 169
SAN 321**

"I/A" ITEM NOTE

from : General Secretariat of the Council

to: Coreper/Council

Subject : Towards the Secure Supply of Radioisotopes for Medical Use in the
European Union
- Draft Council Conclusions
= Adoption

1. Following adoption of the Council Conclusions of 6 December 2010 and in view of continuing interest of some delegations to make progress on the conversion from HEU to LEU subject, the Presidency prepared draft Council conclusions, which were distributed to the delegations on 5 October 2012. Following several rounds of examination, the Working Party on Atomic Questions reached agreement on the text as set out in the attached Annex.
2. Coreper could therefore invite the Council to adopt Council Conclusions set out at the Annex of 17453/12, as an "A" item.

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 15 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 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 the commitment of the Community towards conversion from High Enriched Uranium (HEU) to Low Enriched Uranium (LEU) targets used for Mo-99 production,

STRESSING that the safety of nuclear reactors 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,

NOTING the existing and steadily 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 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, where appropriate, 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 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 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,
4. INVITES the Commission to present a proposal for a relevant instrument to provide Community support to the conversion from HEU to LEU targets, bearing in mind that any financial assistance by the Community through this instrument should be dedicated to support the installation's use for medical purposes, to contribute to the secure supply of medical radioisotopes in the European Union and to identify the necessary needs of research regarding the supply of medical radioisotopes 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 of 15 December 2009 on the Security of Supply of Radioisotopes for Medical Use and the Council Conclusions of 6 December 2010 Towards the Secure Supply of Radioisotopes for Medical Use in the European Union.