



Council of the
European Union

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ATO 42
SAN 265

NOTE

From: Presidency
To: Delegations

Subject: Justification of Medical Imaging Involving Exposure to Ionising Radiation
= Draft Council conclusions

Delegations will find in Annex a first draft of the Council conclusions on the "Justification of medical imaging involving exposure to ionising radiation". These draft conclusions will be examined by the Working Party on Atomic Questions on 9 September 2015.

**Draft Council conclusions on
Justification of medical imaging involving exposure to ionising radiation**

The Council of the European Union:

ACKNOWLEDGING the paramount importance of protecting patients effectively against the dangers arising from exposure to ionising radiation,

STRESSING that the principles of justification and optimisation of medical exposure are central to patient protection, and AWARE of the importance of implementing radiation protection principles in national health strategies,

AWARE that medical radiological imaging has proven to be an essential component of modern medical diagnosis and treatment which, if conducted appropriately, offers medical benefits far outweighing the risks associated with the radiation exposure,

RECALLING that legal obligations to justify individual medical radiological imaging acts, by ensuring that their health benefits outweigh the detriment that the exposure might cause, have been part of Euratom legislation since the 1980s¹,

AWARE of the challenge of generic justification of new classes or types of practices, particularly in the areas of screening programmes and individual health assessment, due to the constant progress in medical radiological imaging techniques,

¹ 1) Council Directive 80/836/Euratom of 15 July 1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation
2) Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment

RECALLING that guidance and practical advice on justification of medical radiological imaging have been available throughout Europe for many years,

CONCERNED about the fact that a significant share of the medical radiological imaging taking place in the European Union may not be necessary, entailing an increased and unjustified level of patient radiation exposure,

REAFFIRMING the commitment of the European Union, Euratom and their Member States to maintain a high level of patient protection, including through enhanced implementation of the principle of justification,

RECALLING Council Directive 2013/59/Euratom, which contains several provisions applicable to the justification of medical radiological imaging, as well as Communication COM(2010) 423 from the Commission to the European Parliament and the Council on medical applications of ionizing radiation and security of supply of radioisotopes for nuclear medicine,

1. STRESSES that, while based on previously existing principles and requirements for justification, optimisation and dose limitation, Council Directive 2013/59/Euratom contains important changes requiring revision of existing national arrangements by 6 February 2018,
2. INVITES the Commission, when reviewing the implementation of Council Directive 2013/59/Euratom, to pay particular attention to the proper justification of medical radiological imaging and the related legal provisions,
3. URGES Member States to define the roles and responsibilities of all medical professionals involved in the justification process,
4. INVITES Member States to raise awareness among the medical profession and the patients by preparing information and publicity/awareness raising campaigns in cooperation with national health authorities, in order to facilitate and enhance individual justification of medical imaging and foster an improved radiation benefit-risk dialogue,

5. URGES Member States to issue referral guidelines for medical imaging ensuring regular updating, sustainability and availability of these guidelines, and to promote their implementation,
6. HIGHLIGHTS the importance of clinical audits to improve justification and URGES Member States to strengthen the application of clinical audits in relation to justification, ensuring that justification becomes an integral part of standard radiological practice,
7. BELIEVES that the medical profession must receive adequate theoretical and practical training for the purpose of the medical radiological practice and URGES Member States to establish appropriate arrangements for initial and continuous training of medical professionals allowing them to meet their responsibilities for good medical care and adequate radiation protection,
8. SUGGESTS that Member States cooperate in the generic justification of new classes or types of practices involving medical radiological exposure,
9. SUGGESTS that Member States develop criteria and procedures for medical imaging of asymptomatic individuals, especially those who do not participate in approved health screening programmes, taking into account the "Position Paper on Screening" published by HERCA (Heads of European Radiological Protection Competent Authorities) in May 2012².

² http://www.herca.org/herca_news.asp?newsID=22