



Council of the  
European Union

Brussels, 19 October 2015  
(OR. en)

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REV 2

ATO 42  
SAN 265

**NOTE**

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From: Presidency  
To: Delegations

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

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Delegations will find in Annex a second revised draft of the Council conclusions on the "Justification of medical imaging involving exposure to ionising radiation". This revised draft is based on the discussions during the meeting of the Working Party on Atomic Questions of 5 October 2015 and on the subsequent comments received from delegations. Changes compared to doc. 11655/1/15 REV 1 are marked in **bold** and ~~striketrough~~.

This draft will be examined by the Working Party on Atomic Questions on 4 November 2015. In preparation for the meeting, the Presidency invites delegations to send any written comments by **30 October 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, ~~health care workers and members of the public~~ effectively against the potential undesirable effects arising from medical exposure to ionising radiation, **and protecting workers and members of the public against dangers arising from associated occupational and public exposures,**

ACKNOWLEDGING 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~~ **that** outweighing the risks associated with the radiation exposure,

STRESSING that the principles of justification and optimisation, which fully apply to medical exposure are crucial to the protection of patients, ~~health care workers and the public~~; and AWARE of the importance of implementing these radiation protection principles in national health strategies,

**STRESSING that the principles of justification, optimisation and dose limitation of associated occupational and public exposures arising from practices involving medical imaging are crucial to the protection of workers and members of the public,**

RECALLING that the rules governing the justification of individual medical radiological imaging acts, ~~and ensuring that their health care benefits outweigh the detriment that the exposure might cause,~~ have been part of Euratom legislation since the 1980s<sup>1</sup>, and AWARE of the need to continue strengthening their application,

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

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

CONCERNED about the **possibility** ~~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, ~~health care worker and public radiation~~ exposure **and associated exposures of workers and members of the public,**

REAFFIRMING the commitment of the European Union, Euratom and their Member States to maintain a high level of protection of patients, health care workers and members of the public, 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,

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<sup>1</sup> 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

1. STRESSES that, while based on previously **established** ~~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 legal provisions related to the proper justification of medical radiological imaging,
3. URGES Member States to define the roles and responsibilities of all health care professionals involved in the justification process,
4. INVITES Member States, **if necessary**, to take appropriate steps to raise awareness among health care professionals and patients by providing information and ~~publicity~~ **public** 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. STRESSES the importance of properly established, regularly updated and widely available referral guidelines for medical imaging and URGES Member States to ensure their proper implementation,
6. HIGHLIGHTS the importance of clinical audits to improve justification, **STRESSES the importance of properly established rules for conducting clinical audits** and URGES Member States to strengthen the application of clinical audits in relation to justification, ensuring that justification becomes an explicit and integral part of standard radiological practice,
7. ~~BELIEVES~~ **STRESSES** that all health care professionals concerned 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 these health care professionals allowing them to meet their responsibilities for good medical care and which integrate adequate radiation protection,

8. ~~SUGGESTS~~ **INSISTS** that Member States cooperate in the generic justification of new classes or types of practices involving medical radiological exposure,
9. ~~TAKING INTO ACCOUNT~~ the "~~Position Paper on Screening~~" published by ~~HERCA (Heads of European Radiological Protection Competent Authorities) in May 2012~~<sup>2</sup>; **TAKING into account advice from relevant medical societies and the competent authorities**, ~~SUGGESTS~~ that Member States cooperate to issue criteria and procedures for medical imaging of asymptomatic individuals, especially those ~~procedures~~ that do not belong to ~~approved~~ health screening programmes.
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<sup>2</sup> ~~http://www.herca.org/herca\_news.asp?newsID=22~~