



Council of the
European Union

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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 revised draft of the Council conclusions on the "Justification of medical imaging involving exposure to ionising radiation". The revised draft is based on the discussions during the meeting of the Working Party on Atomic Questions on 9 September 2015 and on the subsequent comments received from delegations. Changes compared to doc. 11655/15 are marked in **bold** and ~~striketrough~~.

**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 ~~dangers~~ **potential undesirable effects** arising from **medical** exposure to ionising radiation,

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 outweighing the risks associated with the radiation exposure,

STRESSING that the principles of justification and optimisation, **which fully apply to** ~~of~~ medical exposure are ~~central~~ **crucial to the protection of patients, health care workers and the public protection**; and AWARE of the importance of implementing **these** 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~~ **the rules governing the justification of** individual medical radiological imaging acts, ~~by~~ **and** ensuring that their health **care** benefits outweigh the detriment that the exposure might cause, have been part of Euratom legislation since the 1980s¹, **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 ~~and individual health assessment~~, 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 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,

REAFFIRMING the commitment of the European Union, Euratom and their Member States to maintain a high level of ~~patient~~ 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,

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

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 **legal provisions related 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~~ **health care** professionals involved in the justification process,
4. INVITES Member States to **take appropriate steps to** raise awareness among ~~the medical profession~~ **health care professionals** and the patients by ~~preparing~~ **providing** 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. **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, 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 **explicit and** integral part of standard radiological practice,
7. BELIEVES that ~~the medical profession~~ **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 ~~medical~~ **these health care** professionals allowing them to meet their responsibilities for good medical care and **which integrate** 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. **TAKING INTO ACCOUNT the "Position Paper on Screening" published by HERCA (Heads of European Radiological Protection Competent Authorities) in May 2012²,** SUGGESTS that Member States **cooperate** ~~develop~~ **to issue** criteria and procedures for medical imaging of asymptomatic individuals, especially those ~~who do not participate in~~ **procedures that do not belong to** approved health screening programmes. ~~taking into account the "Position Paper on Screening" published by HERCA (Heads of European Radiological Protection Competent Authorities) in May 2012.~~
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² http://www.herca.org/herca_news.asp?newsID=22