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NEW INTERNATIONAL RECOMMEDATIONS AND REQUIREMENTS FOR NON-MEDICAL IMAGING EXPOSURE

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ABSTRACT

BSS Directive 2013/59 entered into force on the 6 February 2014 requiring the Member States to adopt legislation (laws, regulations and administrative provisions) in order to harmonise their national legislation with requirements of this Directive until 6 February 2018. This Directive explicitly defines „non-medical imaging exposure" as deliberate exposure of individuals for other than medical purposes. Those planned exposure situations, if justified need to be subject to the appropriate regulatory framework for optimization of protection, exemption, notification, authorisation, inspection and law enforcement in order to insure safety in operation. The most challenging part is a justification process of „non-medical imaging exposure" taking into account that regulatory radiation protection authorities have limited responsibility in decision making process. BSS Directive recommends regular periodical review of justified practices involving deliberate exposure of humans for non-medical imaging purposes taking into account new technologies available, magnitude of radiological exposure during screening and other screening objectives. Dose constrains for different categories of exposures (public exposure, occupational exposure) depending on particular application, should be established and used in the optimisation of protection. In addition, appropriate regulatory control should be established and enforced as well as the stakeholder dialoge and the provision of information responsive to stakeholders concerns.

1. INTRODUCTION

The aim of this paper is to provide overview of the various international standards and recommendations designed for application of non-medical imaging exposure in governmental regulatory and legal framework at the national level. The term "medico-legal" exposures introduced in Directive 97/43/Euratom have been clearly identified as the deliberate exposure of individuals for other than medical purposes, or "non-medical imaging exposures" by the new Council Directive 2013/59/Euratom [1]. In addition IAEA GSR 3 by requirement 18 in relation to human imaging for non-medical purposes strengthens the regulatory control over such practices stipulating that those exposures have to be subject to the system for protection and safety [2]. In order to provide recommendations and guidance on safety measures specific to meet the requirements on the use of X ray generators and radiation sources for inspection purposes and for other non-medical imaging IAEA is preparing the Safety Guide that will provide guidance on meeting the requirements of the IAEA GSR 3 and other relevant Safety Requirements publications in the Safety Standards Series in carrying out these practices. This will be a useful guidance for national authorities responsible for transposition and

implementation of Article 22 of Council Directive 2013/59 regarding the practices involving the deliberate exposure of humans for non-medical imaging purposes.

2. SYSTEM OF RADIATION PROTECTION

The main elements of the „system of radiation protection", covered by Chapter III of the Directive 2013/59/Euratom: justification of practices, optimization of protection and limitation of individual doses have to be applied in accordance with the graded approach to the regulatory control (Article 24 of Directive 2013/59/Euratom, Requirement 6 of IAEA GSR 3), of "non-medical imaging exposures." Radiation protection practices involving "non-medical imaging exposures" could be carried out in two different ways by:

1. procedures implemented by medical staff using medical radiological equipment and
2. procedures implemented by non-medical staff using non-medical radiological equipment

According to the Annex V of the Directive 2013/59/Euratom practices using medical radiological equipment incudes radiological health assessment for employment, immigration and insurance purposes, radiological evaluation of the physical development regarding career in sports, dancing, radiological age assessment as well as detection of concealed objects on or within the human body. Practices using non-medical equipment are those for detection of concealed objects on or attached to the human body, for detection of concealed humans as part of human screening as well as practices for legal or security purposes.

2.1. JUSTIFICATION

Article 4 of the Directive 2013/59 defines "non-medical imaging exposure" as deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed.

BSS Directive requires identification of practices involving non-medical imaging procedures including in Annex V and three-stage process of justification:

1. justification of practice before being generally accepted
2. justification of particular application of generally accepted type of practice and
3. justification of individual procedures taking into account specific objective of procedure as well as characteristics of the individual.

IAEA General Safety Guide, GSG-5 [3] recommends steps to be followed by different governmental bodies in the process of justification of type of practice (Figure 1).

Directive 2013/59 also require (Article 22.1.d) periodical review of generally and particularly justified practices taking into account new available screening technology, data from previous implementation of practice and evolution of potential threats (screening for security purposes). The same requirement for periodical review of justified practices is given in paragraph 3.63.of the requirement 18 of IAEA GSR 3 [2] as well as recommended by ICRP Publication 125 [4].

Recommendation 41 of ICRP Publication 125 considers process of justification and emphasizes needs for taking into account both the benefits and detriments to the individual, to groups of individuals and society as a whole while decision on justification of particular practice should be taken. In most cases especially when non-medical exposure procedures are used for security purposes, justification of use ionizing radiation

in security screening is almost always a governmental function. It is very important to mention that radiation protection authorities are only a part of decision process [4].

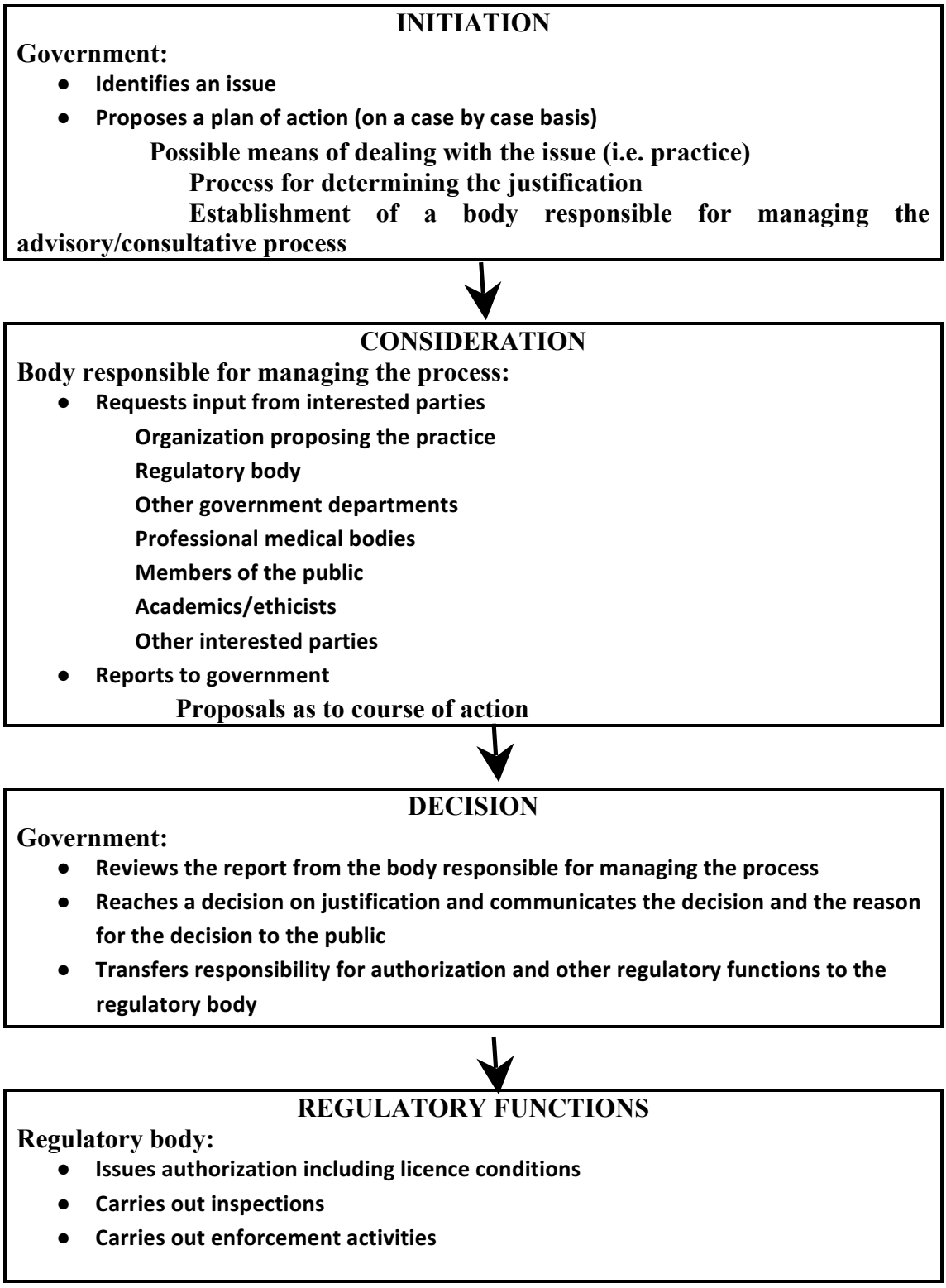

Figure 1. Steps to be followed by different governmental bodies in the process of justification of type of practice

ICRP publication 103 recommending considering all benefits, detriments and impacts of a proposed activity that are in the case of security screening numerous taking into account that justification is out of scope of radiation protection [5].
Another issue that should be taken into account according to the recommendation 44 of ICRP Publication 125 is a justification for security screening of individuals without health benefit to the individual being exposed like in medical exposures. Benefit of individual could be for example living in the environment secured from certain threats. Because of various risks and benefits that are considering in the process of justification, the role of radiation protection authorities is limited to the providing adequate information on radiation risks while using ionizing radiation for these purposes [4]. The main task of radiation protection authorities is connected with assessment of radiation risk while other authorities and professional bodies have to assess and consider other types of associated risks connected with a proposed activity.

2.2. OPTIMISATION OF PROTECTION

Consistent with the requirements of the Directive 2013/59 and IAEA GSR 3 justified practices including non-medical imaging exposure, managed as planned exposure situations, have to be under appropriate regulatory control (exemption, notification, authorisation) and further optimisiation.
Application of tools for optimisation such as dose limits, dose constrains (for procedures including occupational and public exposures) and diagnostic reference levels (for procedures using medical radiological equipment) have to be established and implemented as a part of process of regulatory control of these practices by different parties such as regulatory body, licensee and registrants.
During the process of optimization two types of exposure have to be considered: public exposures and occupational exposures.
Public exposure should include individuals who may be working in the screening area as well as individuals, members of public in the vicinity of screening area. Article 22.4.d of Directive 2013/59 requires for justified practices not using medical radiological equipment, that are not exempted, establishment and implementation of dose constraints that are significantly below the dose limit for members of the public. For procedures using inspection imaging devices in security purposes, requirement 18, paragraph 3.65 of IAEA GSR 3 requires application of dose constrains (by registrants and licenses) for public exposure set by the government or the regulatory body.
In line with recommendation 72 and 73 of ICRP Publication 125, occupational exposures as a consequence of human screening for security purposes potentially should be taken into account for individuals operating security systems and technicians including in servicing, calibrating or maintaining of equipment if it is necessary. Although those occupational exposures are usually at low levels they should be as low as reasonable achievable under given social and economic circumstances (ALARA principle). Because of that dose constrains should be set at very low level. It is expected that level of protection of those potential occupationally exposed individuals are of the same level of magnitude as for the members of the public as a result of adequate equipment design, shielding, training of individuals operating security systems, QC/QA system, etc.

2.3. LIMITATION OF INDIVIDUAL DOSES

If optimization for protection during operation and maintenance of equipment is appropriate it is expected that all public and occupational exposures are under dose limits established in Section 2 of BSS Directive.

3. CONCLUSION

BSS Directive 2013/59 concerning practices involving the deliberate exposure of humans for non-medical imaging purposes obliges Member States to identify practices involving non-medical imaging procedures, to establish and implement national system of justification of such practices as well as to further apply appropriate regulatory control. The most challenging part of this process is justification of exposures of individuals for security purposes because it includes balancing between the welfares and detriments whereby benefits are usually to society while determents are individual. It opens discussion about ethical issues that could be taken into account in decision making process of justification of "non-medical imaging exposure."

4. REFERENCES

[1] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, Official Journal of the European Union, L 0133, 2014.

[2] International Atomic Energy Agency, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, Safety Standard Series No. GSR Part 3, 2014.

[3] International Atomic Energy Agency, Justification of Practices, Including Non-Medical Human Imaging, General Safety Guide, GSG-5, 2014.

[4] ICRP Publication 125, Radiological Protection in Security Screening, Annals of the ICRP **43**, 2, 2014.

[5] ICRP Publication 103, The 2007 Recommendations of the International Commission on Radiological Protection, Annals of the ICRP **37** (2-4), 2007.

NOVE MEĐUNARODNE PREPORUKE I ZAHTEVI U VEZI IZLAGANJA U NEMEDICINSKE SVRHE

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SADRŽAJ

BSS direktiva 2013/59 stupila je na snagu 6. februara 2014. godine. To znači da su države članice u obavezi da usvoje legislativu (zakone, uredbe i upravne odredbe) kako bi uskladile svoje nacionalno zakonodavstvo sa zahtevima ove Direktive do 6. februara 2018. godine. Ova Direktiva jasno definiše „nemediciska izlaganja" kao namerna izlaganja pojedinaca u svrhe koje nisu medicinske. Ukoliko su ove situacije planiranog izlaganja opravdane potrebno je da budu deo regulatornog okvira tj. da se na njih primenjuju zahtevi za: optimizaciju zaštite, izuzimanje, prijavljivanje, odobrenje delatnosti kao i inspekciju i sprovođenje propisa a u cilju obezbeđivanja sigurnosti tokom rada. Najzahtevniji deo je proces opravdavanja nemediciskih izlaganja imajući u vidu da regulatorna tela za zaštitu od zračenja imaju ograničenu odgovornost u procesu donošenja odluke o opravdanosti delatnosti. Preporuka BSS direktive je da se periodično vrši revizija opravdanih delatnosti koje uključuju namerna izlaganja ljudi u nemedicinske svrhe uzimajući u obzir nove dostupne tehnologije, stepen izlaganja zračenju tokom skrininga i druge ciljeve skrininga. U procesu optimizacije zaštite potrebno je uspostaviti i primenjivati ograničenja doza za različite kategorije izlaganja (izlaganje stanovništva, profesionalno izlaganje) u zavisnosti od pojedinačne primene. Takođe, potrebno je uspostaviti i primenjivati odgovarajuću regulatornu kontrolu kao i sprovoditi dijalog i obezbediti odgovarajuće informacije u vezi sa pitanjima svih zainteresovanih strana.