

EC Tender Contract N° ENER/16/NUCL/SI2.730592

**Evaluation of national actions
regarding the transposition of
Council Directive
2013/59/Euratom's requirements
in the medical sector**

(BSS Transposition in the Medical Sector)

Executive Summary

August 2017

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This project has received funding from the European Commission under Service Contract N° ENER/16/NUCL/SI2.730592. The information and views set out in this report are those of the authors and do not reflect the official opinion of the Commission.

Executive summary

This work results from a tender issued by the European Commission under ENER/D3/330-2-2015 *Evaluation of national actions regarding the transposition of Council Directive 2013/59/Euratom's requirements in the medical sector* (BSS MED). The contract was awarded to a consortium of three European umbrella organisations namely the European Federation of Organisations for Medical Physics (EFOMP), the European Society of Radiology (ESR) and the European Federation of Radiographer Societies (EFRS). The objective of the contract was to facilitate the detection of issues, an exchange of first experiences and resolutions, and the identification of good practices with the transposition of the new directive in the medical sector.

The specific objectives were to:

- Identify the competent authorities of the European Member States and EFTA States involved in the transposition of the requirements of the BSS MED;
- Prepare and perform a survey to collect information on Member States' strategies and plans for the transposition of the BSS MED;
- Prepare and organise a workshop to present and discuss the results of the survey. Evaluate the workshop, including the identification of issues and good practices, and prepare the workshop proceedings;
- Produce a final report that summarised and evaluated Member States' strategies and plans for the transposition of the BSS MED.

To enable scientific and professional input from experts or organisations outside the Consortium, an Expert Advisory Panel (EAP) was established consisting of: European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), Heads of the European Radiological Protection Competent Authorities (HERCA), European Association of Nuclear Medicine (EANM), European Society for Radiotherapy & Oncology (ESTRO), International Atomic Energy Agency (IAEA) and Riskaudit (co-ordinator of EC project for evaluation of national plans for the transposition of Council Directive 2013/59/Euratom).

Identification of Competent Authorities:

Members of the Working Party on Atomic Questions (WPAQ) were asked by the EC to identify the national points of contact for the transposition of the BSS MED. The list of contacts included contact persons for all 28 EU Member States as well as two EFTA States (Norway and Switzerland), who were approached to complete the survey.

Survey:

The survey asked questions relating to the BSS Chapter VII, 'Medical Exposures'. Associated articles found in other chapters were also included in the survey. The topics surveyed, which are based on the articles in the BSS relevant to the medical sector, are identified below. Questions regarding the requirements on the medical physics expert (Article 83) were interspersed throughout the survey and the results are provided at the end. The questions consisted mainly of multiple choice responses allowing a single response, although some allowed multiple answers. Most questions were compulsory, unless they were dependent on a previous question. To improve the response rate, text responses were not mandatory.

Workshop:

A two-day workshop was held in Brussels, Belgium on 24-25 January 2017. All EU Member States, as well as the EFTA States were invited to send two representatives to the workshop. The members of the EAP were also invited to the workshop to represent their organisations' views.

Each day began with presentations either from members of the EAP, other invited organisations or relevant national societies. Each session included a short introduction on

the concerned topic, followed by a presentation of key points identified in the survey. Survey respondents, as well as the organisations represented in the EAP and other relevant organisations were invited to contribute to sessions if they wished to present something on a specific topic. Each session concluded with a discussion period.

Final report:

Based on the results of the survey as well as on the discussions and feedback received at the workshop, the strategies and plans of the countries regarding the transposition of the BSS in the medical sector, as well as the identification of issues, experiences and good practices were documented in a final report to the EC.

Transposition of BSS MED requirements:

The perceived difficulty/effort in the transposition of the topics surveyed were indicated by the respondents as either: 'Low' - meaning the requirement is already in their existing legislation (or will require a very minor change to their existing legislation), 'Medium' - meaning additional requirements will need to be incorporated into their existing legislation, and, 'High' - meaning new legislation needs to be implemented. The respondents that indicated 'Medium' or 'High' were asked to identify how they would use to transpose the requirements (e.g. new legislation, regulation etc.). The relative proportion (%) of countries that indicated 'Low', 'Medium' or 'High' is provided below for each of the topics surveyed. All respondents were asked how they would verify the requirements. In addition, where relevant, specific questions relating to the requirements were asked of all respondents.

Strategies, plans and issues for the implementation of the topics relevant to the medical sector

1. Justification: Article 55 (incl. Justification of practices: Article 19)

The countries' efforts for the transposition: Low 62%, Medium 30%, High 8%.

Justification of existing classes or types of practices to be reviewed when there is new and important information about other techniques and technologies is a new challenging requirement. The need for additional justification of non-standard protocols and documentation in special circumstances is required, and also the need of a clear definition of 'new practice'. There is also a need for the justification for individual health assessment to be developed by the member states in the light of their screening policies. The greatest effort is foreseen for the new requirements involving justification of health screening and the exposures of asymptomatic patients to be documented. The explicit requirement to take into account the exposures of staff and members of the public is also seen as a significant challenge

Around half the countries (14) said the competent authorities will be responsible for judging whether practices are justified. In almost all countries (23) the practitioner together with the referrer in many cases (19) will be expected to obtain previous diagnostic information or medical records. Around a third of the countries (10) have specific guidance/procedures for seeking previous information for practitioners. Over half the countries (16) indicated it was mainly the responsibility of the practitioner to justify individual medical exposures and a few countries (4) noted it was mainly the responsibility of the referrer (8 countries identified a mixture of medical and other healthcare professionals were involved in justification). Only a couple of countries thought the change of terminology from 'prescriber' to 'referrer' has any impact. Not many countries (8) said they have national requirements and/or guidelines regarding medical radiological procedures on an asymptomatic individual.

In some general radiography procedures, where the clinical indications are clear, radiographers have responsibility to accept referrals which are not performed on children or pregnant women.

There is a need to develop specific referral guidance for paediatric examinations. Referral guidelines are an important tool to make the justification process more consistent and efficient. They are available for referrers in a few countries but their application in clinical practice is challenging. Embedding referral guidelines in an IT-driven physician workflow through Clinical Decision Support (CDS) systems is an effective way of making guidelines accessible and providing actionable information within the existing workflow to improve the appropriateness of requests.

Radiation protection should be integrated into the spectrum of the quality of care provided to the patients as a sign of good medical practice. Integration of the justification principle into a wider health policy is advocated. There should be regular inspections and clinical audits of the justification process and/or outcomes.

2. Optimisation: Article 56

The countries' efforts for the transposition: Low 71%, Medium 21%, High 8%.

There are a number of major changes: DRLs are mandatory and require regular review and use, and they need to be considered for interventional radiology; medical exposures for planning, guiding and verification purposes are to be kept as low as reasonable achievable; dose delivery to the tumour needs verification; and, written instructions are needed for restricting doses to persons in contact with a patient undergoing treatment with radionuclides. The establishment, regular review and use of DRLs is foreseen to require greatest effort.

The National Authority will be responsible for establishing and reviewing DRLs in most countries (22). The majority of countries (17) will review DRLs every 4 to 5 years with a few (3) every 2-3 years and the remaining countries indicating less frequent reviews. The majority of countries will use own national guidance for DRLs (17 countries) and a significant number of countries will rely upon European guidance reports (13 countries).

The majority of countries (18) have identified national paediatric DRLs for some examinations (9 countries have none). It will be difficult to produce paediatric DRLs for a wide range of paediatric examinations and efforts should be focussed on producing paediatric DRLs for the main ones.

Information and instructions after a nuclear medicine procedure will be given by the practitioner in around half the countries (14) and by the undertaking in just under a third of countries (8). These will mainly be given by the practitioner but in some countries also by the medical physicist.

3. Responsibilities: Article 57

The countries' efforts for the transposition: Low 76%, Medium 16%, High 8%.

Member States are now required to ensure that the practitioner, MPE and others involved in the practical aspects are involved in the optimisation process and they have to specify their involvement. The new requirement to provide information to patients is foreseen to require the greatest effort.

In most countries practitioners (23 countries), MPEs (22 countries) and in around a third of countries (10) radiographers will be required to be involved in optimisation processes. A multi-disciplinary team approach to optimisation is advocated.

Most countries (20) will require referrers to be involved in the justification process of individual medical exposures. Only a few countries (7) require the referrer specifies the examination (not just requesting an opinion) on the appropriate modality. Nuclear medicine procedures have been considered intrinsically complex and the full process of justification is required.

Most countries (21) will have a national framework specifying who is responsible for providing the information to patients. Most countries will require practitioners (23 countries) and in some countries referrers (9 countries) to provide the patient or his/her representative with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure prior to the exposure taking place. Most countries (20) indicated they require the practitioner to provide the carers and comforters with information. Some form of delegation from the practitioner or the referrer for informing the patients and carers and comforters about the risks would introduce more flexibility in the legislation. The regulations should reflect the concept of interdisciplinary teamwork.

4. Procedures: Article 58

The countries' efforts for the transposition: Low 61%, Medium 26%, High 13%.

There is stronger emphasis on the need for written protocols for relevant categories of patients, on information related to patient exposure as a part of the report, on the stronger role of the MPE and on appropriate corrective actions to be taken without undue delay when DRLs are consistently exceeded. The requirement that information relating to patient exposure forms part of the report of the medical radiological procedure is foreseen to require greatest effort.

Written protocols are identified for children in the majority of countries (17), for obese patients in several countries (7) and for in just under a third of countries (9) for other categories (pregnant, high dose etc.). The dose metrics to be used in patient reports are identified nationally in over a third of countries (11). Referral guidelines are provided by the competent authority in only a few countries (6), with others mainly being supplied by other relevant authorities. Referral guidelines will be provided by the competent authority, professional societies, ministries, or undertakings.

Information regarding patient exposure provides a record for retrospective calculation of doses when needed. Patient exposure forming part of the report should be visible to referrers. The dose metrics to be used in the reports remain unclear. The transfer of the exposure parameters by electronic means would be of benefit.

Internal audit is a good starting point, but national/external audit is very important and should be centralised. Clinical audits are not implemented by many countries. The overlap with inspections should be minimised. There are financial issues blocking the implementation of external audits in nuclear medicine and radiology.

5. Training and recognition: Article 59 (incl. Definitions: Article 4; Recognition: Article 79; Education information and training in the field of medical exposure: Article 18 (incl. Article 14))

The countries' efforts for the transposition: Low 62%, Medium 26%, High 12%.

Member States are now required to establish legislative and administrative frameworks for education and training in radiation protection and need to make sure that arrangements are in place for the establishment of education, training and retraining and also in practical aspects. MPEs must be recognised, and continuity of their expertise must be ensured. The training requirements for practitioners and other staff involved in the medical exposure of patients is foreseen to require greatest effort.

The majority of countries (16) will require medical staff have formal qualifications in the practical aspects of medical radiological procedures to achieve state registration. Twelve countries identified that appropriate certificates/diplomas will be awarded by institutes of higher education for other healthcare workers. Most countries (22) will require undertakings to ensure continuing education and training is provided. Eight countries will

require professional scientific bodies to ensure this continuing training requirement is in place.

6. Equipment: Article 60 (incl. Information on equipment: Article 78)

The countries' efforts for the transposition: Low 67%, Medium 23%, High 10%.

There are a number of new requirements: a device to verify key treatment parameters, interventional radiology and CT equipment to display parameters for assessing the patient dose, interventional radiology and CT equipment to be able to record the parameters for assessing the patient dose, other imaging equipment to display and (when appropriate) record parameters for assessing the patient dose.

Furthermore, undertakings acquiring equipment are to be provided with adequate information on its proper use and on the risk assessment for patients, and on the clinical evaluation. The requirement for equipment to transfer the information relating to patient dose and also the requirement to provide risk assessments for patients was foreseen to require the greatest efforts.

The majority of countries (17) will provide specific criteria for acceptability of equipment. Just under half the countries (13) do not plan on using the allowed exemption for radiotherapy equipment installed before 6 February 2018. The majority of countries (16) do not plan to use the exemption for interventional radiology and CT equipment installed before 6 February 2018. Just under half the countries (13) were not yet decided whether equipment will be exempted from the requirement to transfer information to the record of examination, around a third of countries (8) will not use this exemption.

Vendors/manufacturers will be expected to provide undertakings with information on risk assessment. A harmonised approach on common standards for equipment commissioning and acceptance would be beneficial for manufacturers.

7. Special practices: Article 61

The countries' efforts for the transposition: Low 75%, Medium 16%, High 9%.

There are no major changes compared to the previous directive. However, some significant challenge is foreseen in the employment of MPEs in special circumstances.

The appropriateness of using a graded approach to equipment/practical technique inspection and the MPE involvement in equipment selection, quality assurance and dose assessment according to modality or risk should be considered. Whether internal quality assurance would suffice for verification of equipment or the appropriateness of practical techniques and whether this has to be centrally reported or verified also needs to be considered.

It was noted that paediatric age definition variations between countries exists.

8. Special protection during pregnancy and breastfeeding: Article 62

The countries' efforts for the transposition: Low 71%, Medium 21%, High 8%.

There is a stronger emphasis on the requirement to display public notices. The identification of the pregnancy status of young individuals was foreseen to remain challenging and requires further considerations.

Thorough investigation of the reproductive status of adolescents and young women is needed to avoid accidental exposures. Variations exist in the practice for questioning patients about the status of their pregnancy. The age for questioning typically ranges from 12 years (or younger) to 55 years (or older).

Most countries (23) will require practitioners to enquire if the patient is pregnant or breastfeeding and over half of the countries (15) will require the referrer to also ask the

question. Although practitioners and referrers are required to enquire the pregnancy status of the patient in most cases, it was noted that radiographers are the final point of patient contact prior to the examination taking place and they are therefore in the best position to enquire about the pregnancy status. There should be flexibility allowed for the enquiry of the pregnancy status to be delegated to radiographers.

There is a sensitive issue regarding the inquiry of pregnancy amongst very young children and healthcare professionals should be trained to enquire if patients are pregnant or breastfeeding. Imaging departments must define their policy regarding screening of pregnant patients prospectively; clear guidelines are needed on what constitutes childbearing age and how the patient's pregnancy status is determined. Posters should be displayed in appropriate places of the imaging and radiation therapy departments asking patients to inform staff before their examination if they think they might be pregnant or if they are breastfeeding. The majority of countries will require the undertakings to raise awareness of individuals of the issues around pregnancy and breastfeeding (18 countries) and place public notices (19 countries). Around a third of countries (10) will centrally develop and distribute public notices to raise awareness.

There is both a misunderstanding of the radiological need for abortion (i.e. there is very seldom such a need) and also that the exposure of the foetus may be used in some cases as an excuse to perform an abortion. It is of vital importance that countries increase awareness of the issues around pregnancy and breast feeding to avoid cases of accidental exposures.

9. Accidental and unintended exposures: Article 63 (incl. Significant events: Article 96)

The countries' efforts for the transposition: Low 46%, Medium 34%, High 20%.

There are multiple new additional requirements related to accidental or unintended exposures which bring additional responsibilities on individual personnel, undertakings and competent authorities. These new requirements are foreseen to be particularly challenging.

Around a third of countries (9) reported having guidance/methodology on the risk of accidental/ unintended exposures for radiotherapy (13 countries reported they had not yet decided).

A few countries (4) have a national electronic reporting system in place for accidents or unintended medical exposures. Only a couple of countries have defined "clinically significant" nationally, although a few countries (3) have partially defined it (in radiotherapy).

The specified reporting time period in which undertakings must notify the competent authority of the results of investigations and corrective actions to be taken, varied with a third of countries (9) each indicating ≤ 5 days, >5 days or have not yet decided.

The timely dissemination of information was typically reported as being the responsibility of the competent authority, although a few countries (4) indicated it was the responsibility of undertakings and several countries (6) indicated another national body, such as professional bodies or radiation protection unit. Countries indicated a variety of mechanisms for dissemination, which included dissemination on a case by case basis to other undertakings, to institutions with similar practices, via annual reports, via websites or via lectures and presentations at annual meetings of scientific bodies.

10. Estimation of population doses: Article 64

The countries' efforts for the transposition: Low 43%, Medium 39%, High 18%.

The need for the age and gender to be taken into account in the distribution of individual dose estimates from medical exposures is foreseen to be challenging.

Around half the countries (15) will take into account the age and gender of radiodiagnostic and interventional radiology exposures (10 countries have not yet decided). National authorities will be responsible for adopting/developing individual dose estimates from medical exposures for radiodiagnostic and interventional radiology purposes in most countries (24). Most countries (19) will update their national dose estimates reviews every five years or less and several countries (7) will update more than every five years.

UNSCEAR has an online platform to improve the assessment of global medical exposure based on the network of national contact persons and on cooperation with international organisations (WHO, IAEA, EC, and others).

11. Dose limits for occupational exposure: Article 9

The countries' efforts for the transposition: Low 39%, Medium 50%, High 11%.

The reduction in the eye dose level to 20 mSv per annum (with the option for competent authorities to allow 100 mSv in 5 consecutive years, with a maximum limit of 50 mSv in any year) is foreseen to be challenging.

Around a third of countries (10) will allow the equivalent dose for the eye lens to be 100 mSv in any five consecutive years (limit 50 mSv in any year) instead of 20 mSv per year, several countries (6) will not allow this measure and just over a third of countries (11) have not decided.

Around a third of countries (10) reported that there will be changes to the eye dose measuring programs and over a third of countries (12) identified that fast-track protective measures have been identified or undertaken. It was noted that the wearing of monitors outside the apron at shoulder level would normally provide a conservative estimate of eye dose (especially if some form of protective shield to protect the eye is in use). If the dose on the shoulder badge was found to be much less than 15 mSv, there was no need for further monitoring of eye dose. In cases where direct monitoring of eye dose was required, protective glasses should be considered. It was noted that glasses do not provide an assured dose reduction as the glasses may not be the correct size (too large/small) allowing radiation to reach the eyes.

The number and complexity of fluoroscopy-guided interventions have increased and have led to an increased radiation exposure for interventional radiologists, surgeons, and supporting medical staff. Around a third of countries (10) have identified medical staff likely to exceed the 20 mSv dose limit to the eyes. A third of countries (9) have not identified staff likely to exceed this limit and several countries (8) remain undecided.

Attention needs to be given to the dose to the lens of the eye for staff working in nuclear medicine using beta emitting radionuclides (at therapeutic levels).

12. Practices involving the deliberate exposure of humans for non-medical imaging purposes: Article 22

The countries' efforts for the transposition: Low 25%, Medium 50%, High 25%.

The new requirements for non-medical imaging exposures are foreseen to be challenging.

This is a new topic, which will need to be monitored and may require further follow-up by Competent Authorities. No DRLs currently exist for non-medical imaging purposes. Relevant requirements (dose constraints, dose limits, equipment, optimisation, authorisation, specific protocols, criteria for individual implementation, pregnancy, involvement of MPEs), and specific DRLs will need to be implemented for justified

practices. Specific DRLs for non-medical imaging are foreseen in only a few countries (5), while nearly half the countries (13) have not yet decided. There are a variety of non-medical imaging exposures that are clearly defined; employment, immigration, insurance, career in sports, age assessment etc. Ethical implications are of major importance since there may be no direct benefit to the individuals concerned. This is of particular importance in cases where there is no informed consent (e.g. personal security checks at airports). IAEA safety guidelines on non-medical imaging exposures are currently being drafted.

Strategies, plans and issues for the Medical Physics Expert

There are many significant changes to the requirements under the new directive that both directly and indirectly have an impact on the need to involve MPEs. The MPE must take responsibility for dosimetry, including the measurement and evaluation of patient dose and others subject to medical exposures and give advice on medical radiological equipment. The MPE has specific responsibilities for; optimisation, quality assurance, acceptance testing, technical specifications, surveillance, analysis of accidents and unintended exposures, selection of equipment, and, training of practitioners and other staff.

Most countries (19) have a formal process for the recognition of MPEs. The validity of recognition/certification of an MPE will be time limited in just over a third of countries (11), whilst others (9) will have no limit. Around half the countries (14) identified the academic qualification of the MPE to be at European Qualifications Framework (EQF) level 7 with additional clinical training and with further supervision between 2 and 5 years and with requirements for continuous professional development. It is unclear, however, whether the tasks associated with the MPE and less experienced medical physicists are clearly distinguished by the competent authorities.

Specific regulatory requirements or guidance regarding the level of the involvement of the MPE is found in around half the countries (14). Most countries (20) specify the requirements/guidance of the MPE in terms of tasks. The majority of countries will involve MPEs; in the selection of equipment (15 countries), regular performance testing (15 countries), in the development of practical techniques (21 countries), in quality assurance programmes (21 countries), in establishing the parameters for assessing patient dose (15 countries), in acceptance testing of new equipment (18 countries) and after any maintenance procedures liable to affect equipment performance (16 countries). Around a third of countries (9) specify the onsite presence of MPEs in standardised therapeutical nuclear medicine practice and with off-site contact (8 countries). A few countries (5) specify the onsite presence of MPEs in radiodiagnostic practices involving high doses and around a third (11) with off-site contact. Several countries (6) specify the onsite presence of MPEs in interventional radiology practices involving high doses and around a third (10) with off-site contact. Only one country specified the onsite presence of MPEs in other radiology practices and around a half (15 countries) with off-site contact. Those countries that did not specify the presence of MPEs were largely either undecided or the presence was not defined. Around a third of countries (10) will involve the MPE in the assessment of dose or verification of administered activity and in the establishment of the reports of the medical radiological exposure procedures. More than half of the countries will involve the MPE in the corrective actions required (16 countries) and in the comparison of local doses with DRLs and local reviews (15 countries) when DRLs are consistently exceeded. Most countries (19) will not involve MPEs in the management of equipment inventory.

During the project workshop it was noted that there is a lack of medical physicists employed in diagnostic x-ray imaging in many European countries. There are also few

medical physicists employed in nuclear medicine, especially in radionuclide therapy. The lack of medical physicists across Europe was highlighted as an obstacle for the recognition of sufficient numbers of MPEs. Some tasks of the MPE may be delegated, under supervision, to junior or trainee medical physicists, to medical physics assistants/technicians, or to suitably trained radiographers. There is also the possibility that some employers may make use of "a group of individuals" that includes the above staff groups although only 1 country indicated they would make use of this option and around a third of countries (9) were not yet decided.

Around half of the countries (15) foresee the roles of the MPE and radiation protection expert to be combined in the medical sector (depending upon areas of specialities). Around half the countries (13) will also establish arrangements for the recognition of radiation protection officers.

Conclusions

The strategies and plans of the countries regarding the transposition of the BSS MED, as well as the identification of issues, experiences and good practices were documented in a final report to the European Commission. The strength of this study is based on the high level of responses by the countries surveyed and the positive contributions received during the workshop.

The majority of countries perceived the difficulty/effort in the transposition of the majority of the topics surveyed to be predominantly low. However, some sub-topics/articles were rated mainly Medium/High and raised some specific concerns.

For the respondents that indicated the effort required for the transposition of the requirements of the BSS MED to be 'Medium' or 'High' the survey showed that the requirements will largely be transposed through changes to regulations with a small proportion requiring new legislation. The survey also showed that the requirements will be verified mainly through inspection, although many countries will use a combination of approaches including licencing and audit as well as inspection.

The most challenging areas involved the new requirements – e.g. justification of exposure of asymptomatic individuals, dose recording and reporting, information to patients, stronger DRLs, stronger involvement of MPE in CT, IR and NM, reduction of eye dose limit and stronger requirements involving accidental and unintended exposures. However, in many areas, where there is no significant change from 97/43/Euratom, their implementation continues to pose a challenge – e.g. generic justification, referral guidelines, clinical audit and training.

The overall results indicate that a successful transposition of the BSS MED is expected, although specific challenges exist in some areas as noted above.