

Five Questions for HERCA on the Euratom Basic Safety Standards Directive



The ESR and HERCA (Heads of the European Radiological Protection Competent Authorities) have organised the joint session 'EuroSafe Imaging Session 3: the new EU-BSS Directive – a step forward in patient safety'. *ECR Today* interviewed HERCA representatives Dr. Jürgen Griebel of the German Bundesamt für Strahlenschutz and Steve Ebdon-Jackson of Public Health England on this major piece of legislation.

ECR Today: From the regulators' perspective, what are the most important changes in the new Basic Safety Standards (BSS) Directive compared to the previous Euratom directive on medical exposures?

HERCA: For medical exposures, most of the changes are logical developments from Directive 97/43/ Euratom but these refinements are important. There are some significant additions however. Requirements for the early detection of diseases in asymptomatic individuals and non-medical imaging exposures will require new approaches and Article 63 introduces requirements for accidental and unintended exposures, and this will be new in some Member States. A new focus is justification of new types of practices at the generic level.

ECRT: What have been the main challenges in transposing the BSS Directive into national laws so far,

and what challenges do you foresee for the remainder of the transposition period until February 2018?

HERCA: The challenges will vary from Member State to Member State and will depend on the legislative frameworks in place for the wide range of issues addressed by the Directive and the healthcare system in the country. Some of the challenges for transposition of the aspects of the Directive relating to medical applications are not obvious to clinical staff and will be influenced by approaches for other types of practice that are within the Directive's remit. Examples would include the justification of medical practices at the generic level rather than for individual patients.

ECRT: Justification being perhaps the single most important aspect for radiologists in the Directive, can you provide some parameters for what regulators would regard as a 'best practice' implementation of BSS requirements in an imaging department?

HERCA: The Directive requires that Member States specify the involvement of the referrer and the practitioner in the justification process and requires that all individual medical exposures are justified prior to the procedure being undertaken. In addition, the Directive states that any medical exposure takes place under the clinical responsibility of a radiological practitioner. Regulators want to see that meaningful processes are in place within the imaging department to meet these requirements, with responsibilities clearly understood by and attributed to those involved. It is not possible to justify an examination without information about the clinical condition of the patient and a clear understanding of the clinical question that imaging may answer and every request must contain this. In addition, information about previous diagnostic studies should be available and the decision on the appropriate examination should be

clearly recorded. There will be occasions when on a case-by-case basis the radiologist may decide to deviate from published guidelines. The reasons for this should be clearly recorded for future audit purposes.

ECRT: Do you think that tools such as clinical audit and clinical decision support will affect (positively or negatively) the performance of imaging departments with regard to BSS requirements, particularly regarding justification of exposures?

HERCA: Clinical audit is now recognised as a major contributor to advancement in medicine and given the importance of imaging in almost all clinical pathways, it is important that clinical audit is built into the activities of imaging departments. Appropriate justification of procedures will benefit individual patients and make departments more efficient and effective, and clinical audit can provide useful data to ensure continuous improvement. Clinical decision support tools can take many forms and can certainly

improve the referral element of the complete justification process, but it is important to recognise these are tools and do not replace the skill and responsibility associated with experienced medical radiological practitioners.

ECRT: What can delegates expect from today's joint HERCA-ESR session on the BSS Directive?

HERCA: Today's session offers the opportunity for delegates to get a better understanding of the viewpoints of regulators and practitioners and to see how both parties are committed, through different methods, to improving patient safety in imaging departments.

Dr. Jürgen Griebel of the German Bundesamt für Strahlenschutz served as chair of the HERCA Working Group on Medical Applications (WPMED) from 2014–2015. Public Health England's Steve Ebdon-Jackson has now taken on this role for 2016–2017.

Joint Session

Friday, March 4, 16:00–17:30, Room M1

EuroSafe Imaging Session 3

Joint Session of the ESR and HERCA (Heads of the European Radiological protection Competent Authorities)

The new EU-BSS Directive – a step forward to patient safety

» **Chairmen's introduction**

G. Frija; Paris/FR
S. Ebdon-Jackson; Didcot/UK

» **Overview of EU radiation protection legislation**

J. Griebel; Neuherberg/DE

» **Regulators' expectations**

S. Ebdon-Jackson; Didcot/UK

» **Tools to support implementation of the BSS Directive: ESR perspective**

G. Frija; Paris/FR

» **Tools to support implementation of the BSS Directive: medical physicists' perspective**

J. Damilakis; Iraklion/GR

» **Tools to support implementation of the BSS Directive: radiographers' perspective**

S.J. Foley; Dublin/IE

» **Discussion: Regulators' vs practitioners' perspective: two sides of the same coin**

Chairs: G. Frija; Paris/FR (ESR)
S. Ebdon-Jackson; Didcot/UK (HERCA)

Panellists: J. Griebel; Neuherberg/DE (HERCA)

J. Damilakis; Iraklion/GR (EFOMP)

S.J. Foley; Dublin/IE (EFRS)

N. Denjoy; Belgium/BE (COCIR)

This session is part of the EuroSafe Imaging campaign.



THINKING OF WORKING IN THE UK?

Are you a radiologist thinking of working in the UK? The Royal College of Radiologists (RCR) will be running a workshop introducing the benefits of and requirements for working in the UK. The workshop will be held:

Friday 4 March 2016 16:00–18:00
Room 1.86, Austria Center Vienna

- Hear from radiologists who have already made the move to the UK
- Have your questions answered
- Network with UK recruiters and radiologists

To register to attend the workshop please visit the RCR stand at ECR 2016 in the Society Booths Area.

www.rcr.ac.uk/work-UK





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