BSS Directive, regulatory framework and inspections in an ideal world,

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Ritva Bly

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Article 55 Justification 1/3

1. Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

2. Member States shall ensure that the principle defined in paragraph 1 is applied and in particular that:

(a) new types of practices involving medical exposure are justified in advance before being generally adopted;

(b) all individual medical exposures are justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

Article 55 Justification 2/3

(c) if a type of practice involving medical exposure is not justified in general, a specific individual exposure of this type can be justified, where appropriate, in special circumstances, to be evaluated on a case-by-case basis and documented.

(d) the referrer and the practitioner, as specified by Member States, seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

(e) medical exposure for medical or biomedical research are examined by an ethics committee, set up in accordance with national procedures and/or by the competent authority;

Article 55 Justification 3/3

(f) specific justification for medical radiological procedures to be performed as part of a health screening programme are carried out by the competent authority in conjunction with appropriate medical scientific societies or relevant bodies.

(g) the exposure of carers and comforters show a sufficient net benefit, taking into account the direct health benefits to a patient, the possible benefits to the carer / comforter and the detriment that the exposure might cause.

(h) any medical radiological procedure on an asymptomatic individual, …

Article 56 Optimization 1/4

1. Member States shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

Article 56 Optimization 2/4

3. Member States shall ensure that for each medical or biomedical research project involving medical exposure:

(a) the individuals concerned participate voluntarily;

(b) these individuals are informed about the risks of exposure;

(c) a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;

(d) in the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer prior to the exposure taking place.

Article 56 Optimization 3/4

4. Member States shall ensure that the optimisation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.

5. Member States shall ensure that:

(a) dose constraints are established for the exposure of carers and comforters, where appropriate;

(b) appropriate guidance is established for the exposure of carers and comforters.

Article 56 Optimization 4/4

6. Member States shall ensure that in the case of a patient undergoing treatment or diagnosis with radionuclides, the practitioner or the undertaking, as specified by Member States, provides the patient or their representative with information on the risks of ionising radiation and appropriate instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable. For therapeutic procedures these shall be written instructions.

These instructions shall be handed out before leaving the hospital or clinic or a similar institution.

Article 58 Procedures 1/3

Member States shall ensure that:

(a) written protocols for every type of standard medical radiological procedure are established for each equipment for relevant categories of patients;

(b) information relating to patient exposure forms part of the report of the medical radiological procedure;

(c) referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers;

Article 58 Procedures 2/3

Member States shall ensure that:

(d) in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice. In particular:

(i) in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;

(ii) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in point (c) of Article 61(1), a medical physics expert shall be involved;

(iii) for other medical radiological practices not covered by points (a) and (b), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.

Article 58 Procedures 3/3

Member States shall ensure that:

(e) clinical audits are carried out in accordance with national procedures;

(f) appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that appropriate corrective action is taken without undue delay.

Article 61 Special practices

1. Member States shall ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment is used in medical exposure:

(a) of children;

(b) as part of a health screening programme;

(c) involving high doses to the patient, which may be the case in interventional radiology, nuclear medicine, computed tomography or radiotherapy.

Special attention shall be given to quality assurance programmes and the assessment of dose or verification of administered activity for these practices.

2. Member States shall ensure that practitioners and those individuals referred to in Article 57(2) who perform the exposures referred to in paragraph 1 obtain appropriate training on these medical radiological practices as required by Article 18.

Regulatory framework and inspections in an ideal world

Regulatory body / RP Authority

- BSS Directive transposed
  - One Act, few regulations
  - Easy to understand the content
- A single authority or well coordinated authorities
- Graded approach applied in the regulation and inspections
- Inspection programme executed
- Training and re-training of inspectors in place

Undertaking

- Roles and responsibilities assumed
- Training and re-training in place
- Justification and optimization carried out
- Reviews and clinical audits performed
- Good safety culture, continuous improvement